

Information obtained during the consultation on potential candidates for substitution from 25/02/2025 until 30/04/2025.

Substance name: Ethanol

Product type: 1,2,4

Intended use:

- PT 01 – Human hygiene biocidal products Hygienic and surgical hand disinfection by hand rubbing without rinsing: Ethanol based disinfectants are ready for use products for hygienic hand disinfection. Additionally, they are used as skin antiseptics (medical products). Ethanol based disinfectants for human hygiene applied in all areas where hygiene is important, e.g. intensive care units, infection departments, sanitation areas, in laboratories, in medical practices, in the home-care of patients, in home dialysis and in pharmaceutical, cosmetic, and food processing industry. The ready-to-use solution is poured into the palms of one hand out of an automatic dispenser and the complete surface of both hands is moistened with the ready for use solution and let to dry.
- PT 02 – Private area and public health area disinfectant Small surface disinfection by low distance spraying, pouring and wiping in hospitals and other health care institutions, private areas, veterinary practices and laboratories: Ethanol based disinfectants are ready for use product for small surface disinfection by short distance spraying, pouring and wiping. Ethanol based disinfectants are applied in all areas where hygiene is important, e.g. healthcare institutions, hospitals, in sanitation areas, in laboratories, in pharmaceutical, cosmetic, in home dialysis and in the home-care of patients.
- PT 04 – Food and feed area disinfectant Ethanol based disinfectants are ready for use product for small surface disinfection by short distance spraying, pouring and wiping. Ethanol based disinfectants are applied in food processing industry.

EC number: 200-578-6

CAS number: 64-17-5

eCA: Greece

Comment 1	2025/02/26 12:47
Country	Ireland
Name of organization/institution	
I do not wish the name of my organisation/institution to be	

published on the ECHA website.	
General information	
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	I would wish to support and reiterate the conclusion from the Analysis of Alternatives: "In conclusion, Ethanol is irreplaceable for PT1 hand-rub disinfectants. Its unmatched combination of efficacy, rapid action, and skin tolerability makes it the gold standard for hand hygiene in healthcare and other settings requiring frequent disinfection. Based on this AoA, no viable alternative exists that meets the

	technical and practical requirements for PT1 uses, reaffirming the necessity of Ethanol's continued availability in this critical application." I would also wish to question the position of the eCA on including assessment of the hazardous nature of the material via alternative routes (ie oral v dermal) without critical consideration of the situation.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 2	2025/02/26 12:49
Country	Ireland
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	
Product Type	1,2,4
Alternative Identity and Properties	

Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	I would wish to support and reiterate the conclusion from the Analysis of Alternatives: "In conclusion, Ethanol remains indispensable for PT2 uses, particularly in healthcare environments where its effectiveness, safety profile, and rapid disinfection capabilities are unmatched. Based on the findings of this AoA, there is no viable alternative to Ethanol for surface disinfection in PT2 applications. Ensuring its continued availability is essential to maintaining infection control standards and protecting public health." I would also wish to question the position of the eCA on including assessment of the hazardous nature of the material via alternative routes (ie oral v dermal) without critical consideration of the situation.
Information above is confidential	

Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 3	2025/02/26 12:50
Country	Ireland
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	

Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	I would wish to support and reiterate the conclusion from the Analysis of Alternatives: "In conclusion, Ethanol is irreplaceable for PT4 food and feed disinfectants. Its unmatched combination of efficacy, rapid action, and food-contact safety makes it the gold standard for disinfection in this sector. Based on this AoA, no viable alternative exists that meets the technical, regulatory, and practical requirements for PT4 uses, reaffirming the necessity of Ethanol's continued availability in this critical application." I would also wish to question the position of the eCA on including assessment of the hazardous nature of the material via alternative routes (ie oral v dermal) without critical consideration of the situation.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	

Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 4	2025/02/27 16:53
Country	Germany
Name of organization/institution	Dr. Brill + Partner GmbH Institut für Hygiene und Mikrobiologie
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	The classification of ethanol as carcinogenic or toxic to reproduction could mean that many biocidal products could lose their authorisation in the future. Some critical use cases are described below. We therefore see the need to keep ethanol-based disinfectants on the market. Ethanol is used as active substance in many Biocidal PT as Desinfectants for the use within the production of Pharmaceuticals, Cosmetics, Medical Products, Food- and Feedstuff, ... in order to provide safe products. Additionally Ethanol containing Biocidal PT are used as Handdesinfectants by staff in processing facilities to prevent contamination of Pharmaceuticals, Cosmetics, Medical Products, Food- and Feedstuff, ... and ensure corporate hygiene. Good hygiene at the workplace is essential, especially during pandemics, to protect critical infrastructure employees from non-enveloped viruses. The case of the Covid-19 pandemic has demonstrated the necessity of ethanol-based disinfectants for the survival of critical infrastructure. Ethanol is not only used as an active substance in biocidal products, but also as a solvent in other biocidal products, e.g. in repellents. As a result, a large number of biocidal products could be affected by a classification and consequently lose their authorisation. A classification as CMR will probably lead to customer concern and thus a lack of acceptance of ethanol-based biocidal products and a switch to alternative products. We fear the

	following shortages in the availability of alternative biocidal products on the market.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	The workers health and safety Directives, including the Pregnant Workers Directive, prescribe that employers shall assess all risks linked to the safety and health of workers (pregnant, breastfeeding, teenagers) and decide what preventive and protective measures should be taken. One measure could be a ban on the use for workers (pregnant, breastfeeding, teenagers) with Ethanol classified as cancerogenic or reprotoxic. The evaluation on the CMR endpoints and a subsequent decision on this endpoints by the European Commission would result in official statement on the CMR properties of Ethanol for Biocidal Uses. This available information would have to be taken into account by all users of Ethanol during their self-classification. Thus a classification within the Biocide sector would transfer into all Sectors. Additionally, this official position on the CMR properties could influence the opinion-forming process of other CLP committees and thus affect the currently ongoing harmonised classification process.
Information above is confidential	
Justification for confidentiality	

Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Please do not classify Ethanol as CRM and substance for substitution as will will costs the life of patients and people in case of the next pandemic maybe of millions, also outside a pandemic of hundrets of thousand people. It is not CRM outside the oral application which is excluded for biocidal products. So please do not take this risk for a theoretical risk.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	• Kramer A, Pittet D, Exner M, Wendt C. Medical associations and expert committees urge that ethanol be approved as a virucidal active substance for use in hand antiseptics under the European Biocidal Products Regulation, without a CMR classification. <i>GMS Hyg Infect Control</i>. 2024 Aug 21;19:Doc40. doi: 10.3205/dgkh000495. PMID: 39224501; PMCID: PMC11367556. • Kramer A, Benkhail H, Jäkel C, Zwicker P. Ethanol is indispensable for virucidal hand antisepsis and without toxic risks in daily use. <i>GMS Hyg Infect Control</i> 2023;18:Doc02. DOI: 10.3205/dgkh000428 • Kramer A, Borg Dahl M, Bengtsson MM, Boyce JM, Heckmann M, Meister M, Papke R, Pittet D, Reinhard A, Slevogt H, Wang H, Zwicker P, Ulrich T, Seifert U. No detrimental effect on the hand microbiome of health care staff by frequent alcohol-based antisepsis. <i>Am J Infect Control</i>. 2024 Nov 15:S0196-6553(24)00846-0. doi: 10.1016/j.ajic.2024.11.006. Epub ahead of print. PMID: 39551096. • Tartari E, Bellissimo-Rodrigues F, Pires D, Fankhauser C, Lotfinejad N, Saito H, Suchomel M, Kramer A, Allegranzi B, Boyce J, Sax H, Stewardson AJ, Pittet D; ICPIIC Alcohol-Based Handrub Task Force. Updates and future directions regarding hand hygiene in the healthcare setting: insights from the 3rd ICPIIC alcohol-based handrub

	(ABHR) task force. Antimicrob Resist Infect Control. 2024 Feb;13(1):26. DOI: 10.1186/s13756-024-01374-9 • Eggers M, Exner M, Müller D, Mutters NT, Schwebke I, Pittet D. Ethanol is indispensable for virucidal hand antisepsis: memorandum from the alcohol-based hand rub (ABHR) Task Force, WHO Collaborating Centre on Patient Safety, and the Commission for Hospital Hygiene and Infection Prevention (KRINKO), Robert Koch Institute, Berlin, Germany. Antimicrob Resist Infect Control. 2022 Jul 6;11(1):93. doi: 10.1186/s13756-022-01134-7. PMID: 35794648; PMCID: PMC9257567. •Verbund für Angewandte Hygiene (VAH). VAH: Ethanol ist als biozider Wirkstoff zur hygienischen Händedesinfektion unverzichtbar [As a biocidal active substance, ethanol is indispensable for hygienic hand disinfection]. HygMed. 2020;45(11):194–200. Available from: https://vah-online.de/files/download/vah-mitteilungen/VAH_Ethanol_ZT_6_20_354_359_en.pdf • DGKH. Ethanol darf nicht als CMR eingestuft werden. HygMed 2024;49(9):177-178. https://www.krankenhaushygiene.de/pdffdata/177_178_DGKH_Stellungnahme_Ethanol_HM_9_24.pdf • Pires D, Bellissimo-Rodrigues F, Pittet D. Ethanol-based handrubs: Safe for patients and health care workers. Am J Infect Control. 2016 Aug 1;44(8):858-9. doi: 10.1016/j.ajic.2016.02.016. Epub 2016 Apr 15. PMID: 27091229. https://www.ajicjournal.org/article/S0196-6553(16)00167-X/fulltext
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 5	2025/02/28 07:11
Country	Austria
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	

General information	TEST
Product Type	1,2,4
Alternative Identity and Properties	TEST
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	TEST
Information above is confidential	on
Justification for confidentiality	TEST
Economic Feasibility	TEST
Information above is confidential	on
Justification for confidentiality	TEST
Hazards and Risks of the Alternative	TEST
Information above is confidential	
Justification for confidentiality	
Availability	TEST
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	TEST
Information above is confidential	
Justification for confidentiality	
Other comments	TEST

Information above is confidential	on
Justification for confidentiality	TEST
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 6	2025/03/03 09:03
Country	Sweden
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Alcohol has been used by humans for thousands and thousands of years, animals too seek out and consume alcohol when they can find it in nature in the form of fruits. One of humanity's defining traits is our ability to control the fermentation process to enjoy a spiritually nourishing drink. This discussion however, isn't about the consumption of alcohol as a beverage as it only regards its topical application of ethanol where the CMR effects do not apply. It's worth noting that the ethanol in question is denatured, meaning its consumption isn't even possible. Only in the EU can such an oversight be allowed to continue for this many years, wasting tax payer funds and time which could be spent on serious issues. Instead we're now at the point where our healthcare professionals are about to lose one of their most important tools along with patients whom are benefiting from ethanol due to the lower costs of a highly effective sanitizer. As an EU citizen and as a professional working in the field I am ashamed and quite frankly infuriated to hear of these ongoing decisions to keep such a ludicrous on the table for this many years. There must be

	no sense of responsibility and care for your fellow EU citizens to contemplate putting all of our health in jeopardy whilst increasing healthcare costs multifold. Please stop wasting time, please remain realistic in your decision making process and please invite professionals to way in on topics beyond your comprehension.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Denatured ethanol is a perfectly viable option, not to be confused with ethanol consumed as a beverage.

Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 7	2025/03/05 15:25
Country	Germany
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	Ethanol is part of cleaning products for our medical devices.
Product Type	1,2,4
Alternative Identity and Properties	Cleaning and disinfection products based on different alcohols, e.g. isopropyl alcohol.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Change of cleaning products necessary. Change needs to be confirmed with testing.

Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Additional costs for new cleaning products, additional costs for change of manufacturing steps und costs for testing.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Risk of poorer cleaning results.
Information above is confidential	
Justification for confidentiality	
Availability	Alternative cleaining products are already on the market.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Substitution possible, but increaes costs of production.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	

Justification for confidential attachment	

Comment 8	2025/03/06 13:55
Country	Germany
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Ethanol for disinfection of surfaces used for cosmetic production
Product Type	1,2,4
Alternative Identity and Properties	There is no alternative
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Disinfectant Ethanol denatured with Isopropanol is sprayed onto the surfaces, where it disinfects and evaporates completely free of residue.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	There is no alternative to Ethanol
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	No alternative
Information above is confidential	

Justification for confidentiality	
Availability	Denatured Ethanol is readily available. There is no alternative.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	There is no alternative to Ethanol as disinfectant
Information above is confidential	
Justification for confidentiality	
Other comments	Most basic chemicals are nowadays produced in India and China. If there were an alternative to Ethanol (which is for us not), at least some parts would come from one of these countries.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 9	2025/03/06 14:42
Country	Germany
Name of organization/institution	RYSSEN S.A.S
I do not wish the name of my organisation/institution to be	

published on the ECHA website.	
General information	As a candidate for substitution Ethanol will no longer be available for use by the general public. The consequences of a ban of Ethanol will be extremely severe. Particularly in the event of outbreaks and pandemics with non-enveloped viruses, the lack of disinfectant hand rubs based on this potent and well-tolerated core active substance will put the safety of patients, nursing home residents, staff and the general public at stake. There is no substitute biocidal active substance with equal efficacy against non-enveloped viruses. In case of non approval shortage of sufficient equivalent alternatives. In case of a outbreak of a non-enveloped virus disease, it is not possible to fight against these without ethanol. Increase of production capacities associated with tremendous costs (New facilities, new technologies, new production permits and hurdles form authorities and NGO's.
Product Type	1,2,4
Alternative Identity and Properties	Propan-1-ol Propan-2-ol Iodine (I2) Peracetic acid Sodium hypochlorite (NaOCl) Chlorhexidine gluconate Quaternary ammonium compounds (QAC) Monochloramine Chlorocresol hydrogen peroxide (H2O2) Lactic Acid Phenoxyethanol soap
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	The alcoholic alternatives Propan-1-ol and Propan-2-ol are lacking of full virucidal activity. They are not sufficient available in EU. Other disinfectant active substances are not skin friendly or act not fast enough within seconds, or do not evaporate, or do stick on the skin.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Due to the limited number of manufacturers and synthesis routes, all alternative substances are significantly more expensive than ethanol.
Information above is confidential	

Justification for confidentiality	
Hazards and Risks of the Alternative	Propan-1-ol & Propan-2-ol: not fully virucidally efficient, not readily available in sufficient quantities. No sustainable production possible, Higher risk of accidental poisoning. Iodine: Endocrine Disruptor for human and environment, not readily available in sufficient quantities, not fast enough for efficacy, residue formation, DBP. Peracetic acid: corrosive, longevity not sufficient, reactivity with other chemicals in product formulations. Higher safety standards for workers and higher storage standards. Higher risk of accidental poisoning. NaOCl: DBP-formation, no evaporation, longevity not sufficient, corrosive, reactivity with other chemicals in product formulations. Higher risk of accidental poisoning. CHDG & QAC: no full virucidal activity, residues, not fast efficacy action. Monochlor-amine: DBP formation, only in situ generation, not storable. Chlorocresol: skin sensitizer, Phenol as degradation product: Higher risk of accidental poisoning. H2O2: micro lesions on skin, not fast efficacy action, no evaporation, longevity not sufficient, corrosive, not efficacious at low concentrations and ambient temperatures. Higher safety standards for workers and higher storage standards. Higher risk of accidental poisoning. Lactic Acid: not full virucidal, odor formation. Phenoxyethanol: not full virucidal, Higher risk of accidental poisoning. Soap: not full virucidal
Information above is confidential	
Justification for confidentiality	
Availability	Limited amount of producers on the European Market. Continuous supply of sufficient quantities not as certain as with ethanol, especially in the event of a complete ban on ethanol in the biocide sector (as an active agent or as a solvent) or another pandemic.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	As a candidate for substitution Ethanol will no longer be available for use by the general public. The consequences of a ban of Ethanol will be extremely severe. Particularly in the event of outbreaks and pandemics with non-enveloped viruses, the lack of disinfectant hand rubs based on this potent and well-tolerated core active substance will put the safety of patients, nursing home residents, staff and the

	general public at stake. There is no substitute biocidal active substance with equal efficacy against non-enveloped viruses. In case of non approval shortage of sufficient equivalent alternatives. In case of a outbreak of a non-enveloped virus disease, it is not possible to fight against these without ethanol.
Information above is confidential	
Justification for confidentiality	
Other comments	The combination of all substance inherent properties is only given by Ethanol: fast acting, full virucidal, no residues, fast evaporation, long storage time, no transfer to or tainting of food, odorless, no disinfection by products or (eco-) toxicologically relevant degradation products. Most important is the lack of efficacy for not enveloped virus of all possible alternatives of Ethanol. This means, it is not possible to prevent the spreading of diseases by non-enveloped virus's like Polio, Noro, etc. See hospital paper: "Ethanol is indispensable for virucidal hand antisepsis: memorandum from the alcohol-based hand rub (ABHR) Task Force, WHO Collaborating Centre on Patient Safety, and the Commission for Hospital Hygiene and Infection Prevention (KRINKO), Robert Koch Institute, Berlin, Germany, Kramer et al, 2022. Ethanol is indispensable for virucidal hand antisepsis: memorandum from the alcohol-based hand rub (ABHR) Task Force, WHO Collaborating Centre on Patient Safety, and the Commission for Hospital Hygiene and Infection Prevention (KRINKO), Robert Koch Institute, Berlin, Germany - PubMed & GMS GMS Hygiene and Infection Control Medical associations and expert committees urge that ethanol be approved as a virucidal active substance for use in hand antiseptics under the European Biocidal Products Regulation, without a CMR classification. Ethanol is comparatively cheap to other active substances, generally available, easy and fast to produce ensuring a constant supply, green and sustainable. As a candidate for substitution Ethanol will no longer be available for use by the general public. This is particularly critical for pandemic situations.
Information above is confidential	
Justification for confidentiality	
References	

Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 10	2025/03/06 14:58
Country	Germany
Name of organization/institution	CropEnergies Bioethanol GmbH
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	As a candidate for substitution Ethanol will no longer be available for use by the general public. The consequences of a ban of Ethanol will be extremely severe. Particularly in the event of outbreaks and pandemics with non-enveloped viruses, the lack of disinfectant hand rubs based on this potent and well-tolerated core active substance will put the safety of patients, nursing home residents, staff and the general public at stake. There is no substitute biocidal active substance with equal efficacy against non-enveloped viruses. In case of non approval shortage of sufficient equivalent alternatives. In case of a outbreak of a non-enveloped virus disease, it is not possible to fight against these without ethanol.
Product Type	1,2,4
Alternative Identity and Properties	Chlorocresol. Iodine. Monochloramine. Hydrogen Peroxide. Lactic Acid. Phenoxyethanol. Propan-1-ol. Propan-2-ol. Peracetic acid. Quaternary ammonium compounds. Sodium Hypochlorite.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	The alcoholic alternatives Propan-1-ol and Propan-2-ol are lacking of full virucidal activity. They are not sufficient

	available in EU. Other disinfectant active substances are not skin friendly or act not fast enough within seconds, or do not evaporate, or do stick on the skin.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Due to the limited number of manufacturers and synthesis routes, all alternative substances are significantly more expensive than ethanol.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Iodine: Endocrine Disruptor for human and environment, not readily available in sufficient quantities, not fast enough for efficacy, residue formation, DBP. QAC: no full virucidal activity, residues, not fast efficacy action. Monochlor-amine: DBP formation, only in situ generation, not storable. Chlorocresol: skin sensitizer, Phenol as degradation product: Higher risk of accidental poisoning. H2O2: micro lesions on skin, not fast efficacy action, no evaporation, longevity not sufficient, corrosive, not efficacious at low concentrations and ambient temperatures. Higher safety standards for workers and higher storage standards. Higher risk of accidental poisoning. Lactic Acid: not full virucidal, odor formation. Phenoxyethanol: not full virucidal: Higher risk of accidental poisoning. Propan-1-ol & Propan-2-ol: not fully virucidally efficient, not readily available in sufficient quantities. No sustainable production possible, Higher risk of accidental poisoning. Peracetic acid: corrosive, longevity not sufficient, reactivity with other chemicals in product formulations. Higher safety standards for workers and higher storage standards. Higher risk of accidental poisoning. Sodium Hypochlorite: DBP-formation, no evaporation, longevity not sufficient, corrosive, reactivity with other chemicals in product formulations. Higher risk of accidental poisoning.
Information above is confidential	
Justification for confidentiality	
Availability	There are only a few manufacturers and few production plants for alternatives to the active ingredient ethanol. The

	production facilities can not garanty high quality as needed for biocidal products (Pharmacopea). This means that the supply of sufficient biocidal products is not guaranteed. This will lead to a price increase for alternative products.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	As a candidate for substitution Ethanol will no longer be available for use by the general public. The consequences of a ban of Ethanol will be extremely severe. Particularly in the event of outbreaks and pandemics with non-enveloped viruses, the lack of disinfectant hand rubs based on this potent and well-tolerated core active substance will put the safety of patients, nursing home residents, staff and the general public at stake. There is no substitute biocidal active substance with equal efficacy against non-enveloped viruses. In case of non approval shortage of sufficient equivalent alternatives. In case of a outbreak of a non-enveloped virus disease, it is not possible to fight against these without ethanol.
Information above is confidential	
Justification for confidentiality	
Other comments	Exposure to Ethanol via application to the skin (dermal exposure) or by breathing in Ethanol in the air (inhalation), being the two potential routes of exposure from the production or use of biocidal products, does not result in levels of Ethanol in the human body that have been shown to cause cancer and/or have adverse reproductive effects. Ethanol evaporates rapidly from the skin. Intake via the dermal route is low. Occupational inhalation does not lead to a significant increase in the concentration of Ethanol in the blood. ¹³ Atmospheric concentrations of Ethanol in workplaces where it is used are generally well below (6 to 20 times) national occupational exposure limits over an eight-hour period. The combination of all substance inherent properties is only given by Ethanol: fast acting, full virucidal, no residues, fast evaporation, long storage time, no transfer to or tainting of food, odorless, no disinfection by products or (eco-) toxicologically relevant degradation products. Most important is the lack of efficacy for not enveloped virus of all possible alternatives of Ethanol. This means, it is not possible to prevent the spreading of diseases by non-enveloped virus's like Polio, Noro, etc. See

	hospital paper: "Ethanol is indispensable for virucidal hand antisepsis: memorandum from the alcohol-based hand rub (ABHR) Task Force, WHO Collaborating Centre on Patient Safety, and the Commission for Hospital Hygiene and Infection Prevention (KRINKO), Robert Koch Institute, Berlin, Germany, Kramer et al, 2022. Ethanol is indispensable for virucidal hand antisepsis: memorandum from the alcohol-based hand rub (ABHR) Task Force, WHO Collaborating Centre on Patient Safety, and the Commission for Hospital Hygiene and Infection Prevention (KRINKO), Robert Koch Institute, Berlin, Germany - PubMed & GMS GMS Hygiene and Infection Control Medical associations and expert committees urge that ethanol be approved as a virucidal active substance for use in hand antiseptics under the European Biocidal Products Regulation, without a CMR classification. Ethanol is comparatively cheap to other active substances, generally available, easy and fast to produce ensuring a constant supply, green and sustainable. As a candidate for substitution Ethanol will no longer be available for use by the general public. This is particularly critical for pandemic situations. Ethanol based hand sanitisers are often commonly used in the food industry. The loss of ethanol will increase the risk of food outbreaks involving non-enveloped viruses such as norovirus.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 11	2025/03/10 16:00
Country	Sweden
Name of organization/institution	Essity Hygiene & Health AB

I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Please have a look at our consultation response letter. We believe the search for an alternative should be put on hold and the main question in the letter should be addressed to the EU-Commission. Justification is, that this whole activity affects much more than just biocidal product usage of Ethanol and need to be solved on a political level.
Product Type	1,2,4
Alternative Identity and Properties	No suitable alternative identified by us, see attached letter as well
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	No suitable alternative identified by us, see attached letter as well
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Economically the CMR classification of Ethanol in the proposed way may lead to an EU-wide disaster from our perspective, because it cannot be limited to biocidal product usages. About 98% are used outside the BPR regulated areas! It will generate a lot of bureaucratic burden without any good reasoning and without improving the safety at all. Justification can be found in the attached document.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	No suitable alternative identified by us, see attached letter as well
Information above is confidential	
Justification for confidentiality	

Availability	No suitable alternative identified by us, see attached letter as well
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	If Ethanol would be replaced by any other substance (combination) it will for sure be less environmental friendly, less skin friendly and it may contribute to antimicrobial resistance.
Information above is confidential	
Justification for confidentiality	
Other comments	Known mixtures, which could deliver similar efficacy values will most likely come with a corrosive warning. This would exclude them from being made available to broad public. As a result the whole structure of hand disinfection in hospitals would collapse.
Information above is confidential	
Justification for confidentiality	
References	See attached letter as well
Attachments (non-confidential information)	CMR Ethanol - Consultation.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 12	2025/03/11 13:50
Country	Germany
Name of organization/institution	
I do not wish the name of my organisation/institution to be	

published on the ECHA website.	
General information	Regarding hand disinfection the planned CMR1 classification for ethanol is based on wrong scientific data. While oral uptake of ethanol can lead to cancer, there is no scientific evidence that hygienical handrub can lead to skin cancer. According to a risk assessment one should conclude that saving millions of lives by applying hand disinfection is much more important than not existing skin cancer followed hygienic handrub.
Product Type	1,2,4
Alternative Identity and Properties	Ethanol can be evaluated as an CMR1 by oral uptake but not as a skin disinfectant.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Ethanol is used as a skin disinfectant because of its virucidal properties. There is no scientific evidence of developing skin cancer after applying ethanol on skin for disinfection purposes.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	The costs of infection will explode if ethanol is banned from hand disinfection. Viral pandemic situations will rise extremely.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	There is no alternative considering the virucidal impact of ethanol. Isopropanol does work against bacteria and yeasts but not against important viruses. And just because isopropanol is not used as a beverage it is not CMR1.
Information above is confidential	
Justification for confidentiality	

Availability	Ethanol is cheap and effective in hand hygiene. In pandemic situations it can be produced in all needed amounts.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	If ethanol will be classified as CMR1 for hand disinfection and therefore banned as a hand disinfectant, Europe will run into a disaster and the Trumps of this world will get oil for their fire. We should not ignore a healthy understanding and scientifically based evidences. Please distinguish between oral uptake of ethanol and applying it on skin surfaces!
Information above is confidential	
Justification for confidentiality	
Other comments	Nobody drinks hand disinfectants!
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 13	2025/03/13 15:39
Country	Germany
Name of organization/institution	██████████
I do not wish the name of my organisation/institution to be published on the ECHA website.	1

General information	Our company is part of a group which is the world leader in Freeze Dry. The use of ethanol in disinfectants within in our facilities is crucial for maintaining high standards of hygiene and safety. Ethanol is effective in killing a wide range of pathogens, including bacteria and viruses, which are significant concerns in food processing environments. Its application helps prevent contamination that could lead to foodborne illnesses, thereby protecting consumer health.
Product Type	1,2,4
Alternative Identity and Properties	According to our information, Ethanol based disinfectants have no adequate substitutes for use as disinfectants in food and feed facilities. It has a well-documented safety profile with minimal risks provided that it is used in the appropriate manner. Its efficacy is crucial to prevent foodborne illnesses thus protecting consumer health. In this regard, Ethanol is only one of a few substances which are fully virucidal. This includes its effectiveness against non-enveloped viruses such as noroviruses which is one virus of substantial concern in food businesses. Adding to this, ethanol based formulations - due to their efficiency in disinfection - are highly beneficial in terms of economic and ecologic sustainability compared to weaker substitutes. Formulations with ethanol also have long shelf lifes which additionally ensures its easy and sustainable use.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	-
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	-
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	

Justification for confidentiality	
Availability	-
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	The risks of substitutions are in sum: -Lack of equally effectiveness potentially resulting in higher residues of such substitutes -Lack in availability of such alternatives which may result in higher prices and shortages when consumer health and economical and ecological sustainability is at stake. -Potential health risks through the use of weaker alternatives which may result from raising numbers of foodbourne illnesses and higher microbial resistances of microorganisms
Information above is confidential	
Justification for confidentiality	
Other comments	-
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 14	2025/03/15 11:15
Country	Hungary
Name of organization/institution	Innoway R&D Kft.

I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	"General Information on Far-UVC and Initus-V in Continuous Air and Surface Disinfection Far-UVC Technology Far-UVC (typically 222 nm wavelength) is an advanced disinfection technology that effectively inactivates airborne and surface pathogens, including bacteria and viruses, while being safe for human exposure. Unlike traditional germicidal UV (254 nm), which poses risks to human health (such as skin burns and eye damage), Far-UVC operates within a range that does not penetrate human skin or eyes deeply, making it suitable for occupied spaces. Key Benefits of Far-UVC: • Effective Against Pathogens: Destroys bacteria, viruses (including coronaviruses), and fungi in the air and on surfaces. • Safe for Humans: Unlike traditional UV-C, Far-UVC does not cause harm to human skin or eyes when properly filtered. • Continuous Disinfection: Provides ongoing protection in real-time without requiring manual intervention. • No Chemical Residue: Unlike ethanol-based disinfectants, Far-UVC does not leave residues or produce harmful fumes. • Energy-Efficient & Cost-Effective: Reduces reliance on consumables such as chemical disinfectants. Far-UVC is gaining attention as a powerful alternative to traditional biocidal disinfectants, especially in healthcare, public transportation, food production, and other high-risk environments. Initus-V Product: A Paradigm Shift in Continuous Disinfection Initus-V is a novel continuous air and surface disinfection system that integrates Far-UVC technology and textile combination to make thi technology applicable in all parts of the world under all regulatory environments. Designed to be a safe and effective alternative to ethanol-based biocidal disinfectants, Initus-V ensures real-time, non-stop microbial control in both healthcare and public environments. Core Features of Initus-V: • Uses Safe 222 nm Far-UVC Technology, Intermittant use option for regulatory compliance and textile protection for continuous use: Ensures high-level disinfection without harming humans.

	• Continuous Air & Surface Protection: Unlike manual disinfection with chemicals, Initus-V provides ongoing decontamination. • Eliminates the Need for Ethanol-Based Biocides: Reduces chemical exposure, preventing potential health risks and environmental harm. • Low Maintenance & Cost-Effective: Requires minimal upkeep compared to frequent chemical applications. • Preliminary trials are performed in Healthcare: Suitable for hospitals, clinics, offices, schools, and transportation hubs. Why Initus-V Over Ethanol-Based Biocides? • No Chemical Residue: Safe for sensitive environments like ICUs, labs, and food processing areas. • Eco-Friendly: Reduces the environmental footprint associated with chemical disinfectants. • Eliminates Resistance Issues: Unlike chemicals, which may lead to microbial resistance, Far-UVC remains effective over time. • Safe in Occupied Spaces: Can be used without evacuating rooms, unlike fogging or chemical spray disinfection. Conclusion Far-UVC technology and the Initus-V system present a revolutionary shift in disinfection, offering a safe, effective, and continuous solution for air and surface hygiene. Initus-V stands as a viable alternative to ethanol-based disinfectants, providing a non-toxic, sustainable, and efficient method for pathogen control in high-risk and public environments. "
Product Type	1,2,4
Alternative Identity and Properties	"Alternative Identity and Properties of Far-UVC and Initus-V Alternative Identity: Far-UVC and Initus-V can be positioned not just as disinfection tools but as next-generation biosecurity solutions that redefine hygiene standards across various industries. Their identity can be framed in different ways based on their unique properties and applications: • A Non-Chemical, Non-Touch, Continuous Disinfection System - o Unlike traditional disinfectants that rely on manual application, Far-UVC and Initus-V operate passively, ensuring seamless and constant protection. • A Paradigm Shift in Infection Control

	- o Moving beyond surface cleaning to real-time pathogen elimination in the air, preventing airborne and fomite-based disease transmission. • Smart Hygiene Technology - o Integrated into modern buildings, hospitals, and public spaces, providing an automated and intelligent layer of microbial protection. • The Future of Disinfection Without Human Intervention - o Eliminating reliance on chemical consumables, manual labor, and safety risks associated with traditional disinfectants. Properties of Far-UVC and Initus-V: 1. Antimicrobial Efficacy • Broad-spectrum Disinfection: Kills bacteria, viruses (including SARS-CoV-2, influenza, MRSA, and tuberculosis), and fungi. • Airborne & Surface Protection: Unlike conventional disinfection methods that focus only on surfaces, Far-UVC in Initus-V decontaminates the air as well. • Continuous Action: Functions 24/7, reducing pathogen load in real time without requiring downtime or manual reapplication. 2. Safety & Human Compatibility • Wavelength-Specific Protection: Uses 222 nm, a wavelength that does not penetrate human skin or eyes, unlike traditional 254 nm UV-C. • Non-Toxic & Non-Irritating: Unlike ethanol-based disinfectants, it does not cause respiratory irritation, allergic reactions, or surface damage. • Safe for Occupied Spaces: Can be deployed in hospitals, schools, offices, and public areas without risk to people. • Combination of intermittent mode and wearable textile in Initus-V system: Makes technology compatible with all regulatory standards and makes usable as of today until further long term data accumulates. 3. Environmental & Sustainability Benefits • Chemical-Free Disinfection: Eliminates the need for ethanol-based and other chemical biocides that contribute to volatile organic compound (VOC) emissions. • No Waste Generation: Unlike disposable chemical wipes and disinfectant sprays, Initus-V does not produce packaging waste. • Energy Efficient: Operates with low power consumption compared to HVAC-based filtration or chemical-based fogging systems. 4. Operational & Cost Efficiency

	• Low Maintenance: Requires minimal servicing compared to frequent replenishment of chemical disinfectants. • Reduces Labor Costs: Removes the need for manual cleaning interventions and periodic disinfection routines. • Long-Term Investment: Provides sustained protection with a one-time installation and periodic maintenance, making it cost-effective over time. 5. Resistance Prevention & Microbial Control • Prevents Resistance Development: Unlike antibiotics or chemical disinfectants, UV radiation does not induce microbial resistance. • Prevents Biofilm Formation: Regular exposure to Far-UVC disrupts microbial colonies before they establish biofilms, a major issue in hospital-acquired infections (HAIs). Conclusion: A Superior Alternative to Ethanol-Based Disinfectants Far-UVC and Initus-V redefine hygiene and infection prevention by offering a continuous, safe, and sustainable alternative to conventional biocidal solutions. With safety, high efficacy, and cost efficiency, this technology is set to become a core component of modern infection control strategies, making chemical-based disinfection obsolete in many settings. "
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	"Technical Feasibility of Far-UVC and Initus-V for Continuous Air and Surface Disinfection The feasibility of Far-UVC and Initus-V depends on several technical factors, including its ability to provide continuous disinfection, safety in occupied environments, energy efficiency, and regulatory compliance. Below is a breakdown of the key technical considerations and feasibility assessment: 1. Far-UVC Efficacy in Air and Surface Disinfection • Mechanism of Action: - o Far-UVC (typically 222 nm) disrupts microbial DNA/RNA by breaking molecular bonds, rendering viruses and bacteria inactive. - o At this wavelength, photons do not penetrate deeper than the outermost dead skin layer (stratum corneum) or

the tear layer in the eye, ensuring human safety while still effectively eliminating airborne and surface pathogens.

- Proven Disinfection Performance:
 - o Multiple peer-reviewed studies confirm that Far-UVC at 222 nm can achieve 99.9% reduction in bacteria and viruses, including SARS-CoV-2, influenza, and MRSA.
 - o Unlike traditional UV-C at 254 nm, Far-UVC does not require high doses for effectiveness and can be used continuously in occupied spaces.
- Efficacy Range:
 - o Airborne Pathogens: Effective within 3-5 meters of deployment.
 - o Surface Pathogens: Best suited for high-touch surfaces within a direct line-of-sight range.
 - o Reduction of Aerosol Transmission: Can significantly lower airborne virus transmission in enclosed spaces such as hospitals, offices, and public transportation.

2. Engineering and Integration of Initus-V

- Customizable Design:
 - o Initus-V can be implemented as standalone units, ceiling-mounted fixtures, for seamless operation.
 - o Its scalable design makes it adaptable to different environments such as hospitals, laboratories, schools, airports, and public transport.
- Automated and Passive Operation:
 - o Unlike chemical disinfectants, Initus-V operates continuously without human intervention, making it ideal for high-traffic and high-risk environments.
 - o Multimode wireless operation allows different use scenarios in multiple settings
 - o Can be combined with wearable textiles in the system to make it compatible with all regulatory standards all over the world for adaptive disinfection in occupied spaces.
- Energy Consumption:
 - o Low-power UV-C lamps consume less energy than HVAC HEPA filters or chemical fogging systems.
 - o Typical power consumption per unit is below 20W, making it sustainable for 24/7 operation.

3. Safety and Regulatory Considerations

- Photobiological Safety:
 - o Studies confirm that 222 nm Far-UVC does not cause DNA damage in human skin or eyes, making it safe for occupied spaces.
 - o Compliance with ICNIRP (International Commission on Non-Ionizing Radiation Protection) and ANSI RP-27 safety standards.

	With its ability to inactivate pathogens in real-time, ensure safety in occupied environments, and eliminate the need for chemical disinfectants, Initus-V presents a scalable and cost-efficient solution for hospitals, public spaces, and commercial environments. While line-of-sight limitations and upfront costs exist, its low operational costs, long-term sustainability, and automation capabilities make it a game-changing alternative to traditional disinfection methods. "																					
Information above is confidential																						
Justification for confidentiality																						
Economic Feasibility	"Economic Feasibility of Far-UVC and Initus-V for Continuous Air and Surface Disinfection The economic feasibility of Far-UVC and Initus-V depends on initial investment, operational expenses, long-term savings, and return on investment (ROI) compared to traditional disinfection methods. Below is a detailed cost-benefit analysis based on updated calculations. 1. Cost Breakdown A. Initial Investment Costs • Device Acquisition Cost: - o Standalone units: €3,000 - €8,000 per unit - o Ceiling-mounted fixtures: €3,500 - €9,000 per unit • Installation Cost: - o Plug-and-play units: Minimal setup (~€100) - o Ceiling-mounted: €500 - €1,000 B. Operational Costs • Electricity Consumption: - o Average power usage: 10-30W per unit - o Monthly electricity cost per unit: €4 - €6 - o Annual electricity cost: €50 per unit • Maintenance Costs: - o Annual system check-up: €100 per unit - o Lamp replacement every 2 years: €1,000 per unit C. Total 5-Year Cost Estimate <table><tr><td>Cost Factor</td><td>Min Price Case (€3,000 Unit)</td><td>Max Price Case (€8,000 Unit)</td></tr><tr><td>Device Cost</td><td>€3,000</td><td>€8,000</td></tr><tr><td>Installation</td><td>€100</td><td>€1,000</td></tr><tr><td>Annual Electricity (5 Years)</td><td>€250</td><td>€250</td></tr><tr><td>Annual Maintenance (5 Years)</td><td>€500</td><td>€500</td></tr><tr><td>Lamp Replacements (2x over 5 years)</td><td></td><td>€2,000</td></tr><tr><td>Total 5-Year Cost</td><td>€6,350</td><td>€12,250</td></tr></table>	Cost Factor	Min Price Case (€3,000 Unit)	Max Price Case (€8,000 Unit)	Device Cost	€3,000	€8,000	Installation	€100	€1,000	Annual Electricity (5 Years)	€250	€250	Annual Maintenance (5 Years)	€500	€500	Lamp Replacements (2x over 5 years)		€2,000	Total 5-Year Cost	€6,350	€12,250
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	2. Return on Investment (ROI) A. Cost Savings from Replacing Traditional Disinfection Methods <table><tr><th>Disinfection Method</th><th>Annual Cost (Labor + Materials)</th><th>5-Year Cost</th></tr><tr><td>Ethanol-Based Chemical Disinfectants</td><td>€3,000 - €10,000</td><td>€15,000 - €50,000</td></tr><tr><td>Hydrogen Peroxide Fogging</td><td>€4,000 - €12,000</td><td>€20,000 - €60,000</td></tr><tr><td>HVAC HEPA Filtration</td><td>€3,000 - €8,000</td><td>€15,000 - €40,000</td></tr></table> Cost Savings with Initus-V Over 5 Years: • Compared to chemical disinfectants: €8,650 - €37,750 saved per unit • Compared to hydrogen peroxide fogging: €13,650 - €47,750 saved per unit • Compared to HVAC upgrades: €8,650 - €27,750 saved per unit B. Break-Even Period • Best-Case Scenario (High Annual Savings of €10,000): 0.64 years (~7.5 months) • Worst-Case Scenario (Low Annual Savings of €3,000): 4.08 years (~4 years, 1 month) Conclusion: • In high-traffic environments (hospitals, offices, transport hubs), the break-even point is under a year. • For smaller-scale users, cost recovery takes 3-4 years, but savings continue for a decade. 3. Productivity Gains and Indirect Benefits • Reduction in Sick Leave & Infections: - o Up to 80-90% reduction in airborne disease transmission. - o Fewer employee absences → €1,000 - €10,000 in productivity gains annually. • No Business Downtime: - o Unlike chemical disinfectants, Initus-V operates continuously without requiring room evacuations. - o Prevents disruptions in hospitals, manufacturing, hospitality, and retail sectors. • Eliminates Chemical Costs & Waste Management Fees: - o Reduces expenses related to disinfectant storage, handling, and disposal. - o Supports green business initiatives and sustainability compliance.	Disinfection Method	Annual Cost (Labor + Materials)	5-Year Cost	Ethanol-Based Chemical Disinfectants	€3,000 - €10,000	€15,000 - €50,000	Hydrogen Peroxide Fogging	€4,000 - €12,000	€20,000 - €60,000	HVAC HEPA Filtration	€3,000 - €8,000	€15,000 - €40,000
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	4. Scalability and Market Potential Industries Where Far-UVC and Initus-V Provide Economic Value: • Hospitals & Healthcare Facilities - o Saves €20,000 - €200,000 annually on infection control and regulatory compliance. • Airports & Public Transport - o Prevents disease spread, reducing quarantine & sanitation costs. • Food Processing & Hospitality - o Eliminates chemical contamination risks and regulatory burdens. • Corporate Offices & Commercial Spaces - o Reduces employee sick leave, increasing productivity. Future Cost Reduction Potential: • As Far-UVC technology scales, device prices will decrease (like LED lighting). • Government incentives & tax credits for sustainable disinfection can reduce upfront costs. • Potential leasing models allow businesses to spread out costs. 5. Risk Analysis <table><tr><th>Risk Factor</th><th>Impact</th><th>Mitigation Strategy</th></tr><tr><td>High Initial Cost</td><td>Medium</td><td>Offer financing options, government grants, leasing models.</td></tr><tr><td>Consumer Awareness</td><td>High</td><td>Conduct educational campaigns, showcase cost savings with real-world case studies.</td></tr><tr><td>Regulatory Barriers</td><td>Low</td><td>Ensure compliance with ICNIRP, FDA, ISO, and ANSI standards.</td></tr><tr><td>Technological Advances</td><td>Low</td><td>Continuous R&D investment for next-gen Far-UVC technology.</td></tr></table> Conclusion: Is Initus-V Economically Feasible? ■ YES! Initus-V is economically feasible, offering a high ROI, lower long-term costs, and significant operational savings compared to traditional disinfectants. Key Takeaways: • Break-even period: 7.5 months to 4 years, making it a sustainable investment. • Long-term cost savings: Up to 75% cheaper than ethanol-based disinfectants over 5 years. • Productivity & efficiency gains: Fewer sick days, reduced downtime, and improved business efficiency. • Scalability: Suitable for hospitals, public transport, food processing, and corporate offices.	Risk Factor	Impact	Mitigation Strategy	High Initial Cost	Medium	Offer financing options, government grants, leasing models.	Consumer Awareness	High	Conduct educational campaigns, showcase cost savings with real-world case studies.	Regulatory Barriers	Low	Ensure compliance with ICNIRP, FDA, ISO, and ANSI standards.	Technological Advances	Low	Continuous R&D investment for next-gen Far-UVC technology.
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Technological Advances	Low	Continuous R&D investment for next-gen Far-UVC technology.														

	👉 Final Verdict: Initus-V is a cost-effective, sustainable, and future-proof alternative to chemical disinfection. "
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	"Hazards and Risks of Far-UVC and Initus-V as an Alternative Disinfection Method While Far-UVC (222 nm) and Initus-V present a highly effective, chemical-free disinfection alternative, they still come with potential hazards and risks that must be evaluated. Below is a comprehensive risk assessment for their use in continuous air and surface disinfection. 1. Potential Biological and Health Risks Risk Factor Description Mitigation Strategy Eye Exposure Risks While Far-UVC (222 nm) does not penetrate deeply into human tissues, prolonged direct exposure may cause photokeratitis (temporary eye irritation). Use intermittent wireless setup mode, occupancy limits, or protective textile in Initus-V in high-exposure areas. Ensure compliance with ICNIRP safety limits. Skin Sensitivity Risks Though Far-UVC does not penetrate the live skin layers, some individuals with pre-existing skin conditions (e.g., photosensitivity disorders) may experience mild irritation. Use remote controlled intermittent mode operation, textile combination of Initus-V ensure proper device calibration to maintain safe exposure levels. Potential DNA/RNA Impact Studies show that 222 nm does not penetrate live cells, but long-term exposure data is still limited. There is minimal concern, but further studies are needed. Use only filtered Far-UVC lamps that eliminate wavelengths higher than 230 nm, as unfiltered UV may cause harm. Use intermittent mode and protective textiles like in Initus-V system Ozone Generation Concerns Traditional UV-C (254 nm) can generate ozone, which is harmful to respiratory health. Far-UVC (222 nm) does not produce ozone when properly filtered. Ensure high-quality excimer lamps that do not emit secondary wavelengths. Conduct air quality monitoring in enclosed spaces. ■ Overall Risk Level: Low to Moderate Proper safety measures, compliance with exposure guidelines, and the use of filtered Far-UVC lamps eliminate most biological risks.

	2. Technical and Operational Risks <table><tr><th>Risk Factor</th><th>Description</th><th>Mitigation Strategy</th></tr><tr><td>Line-of-Sight Dependency</td><td>Far-UVC is effective only on exposed surfaces and air within direct range. Pathogens in shadows or behind objects may not be disinfected.</td><td>Use multiple devices for uniform coverage or combine with airflow systems.</td></tr><tr><td>Lamp Degradation Over Time</td><td>UV lamps lose efficiency with prolonged use, reducing disinfection effectiveness.</td><td>Implement scheduled maintenance & lamp replacement every 2 years to maintain consistent performance.</td></tr><tr><td>Device Calibration Requirements</td><td>Improperly calibrated UV devices may exceed safe exposure limits or underperform.</td><td>Use automated control systems to monitor output and ensure proper dosing.</td></tr><tr><td>Compatibility with Materials</td><td>Long-term exposure may degrade certain plastics, fabrics, or painted surfaces.</td><td>Use Far-UVC-safe materials for furniture, equipment, and facility surfaces.</td></tr><tr><td>Energy Consumption</td><td>Although relatively low, continuous operation adds to facility power costs.</td><td>Optimize with smart automation and motion-sensing activation to reduce unnecessary use.</td></tr></table> ■ Overall Risk Level: Low to Moderate Proper calibration, regular maintenance, and strategic placement mitigate most technical risks. 3. Economic and Regulatory Risks <table><tr><th>Risk Factor</th><th>Description</th><th>Mitigation Strategy</th></tr><tr><td>High Initial Cost</td><td>Initus-V requires an upfront investment (€3,000 - €8,000 per unit), which may be a barrier for adoption.</td><td>Offer leasing models, financing options, and government incentive programs for buyers.</td></tr><tr><td>Market Adoption Challenges</td><td>Many businesses still rely on chemical-based disinfection, and adoption may be slow due to lack of awareness.</td><td>Conduct educational campaigns, pilot studies, and regulatory endorsements to demonstrate benefits.</td></tr><tr><td>Regulatory Uncertainty</td><td>Far-UVC (222 nm) is relatively new, and some countries may not have clear regulations for its use.</td><td>Work with FDA, ICNIRP, and ISO standards to ensure compliance and advocate for updated guidelines.</td></tr><tr><td>Risk of Counterfeit or Low-Quality UV Products</td><td>The market has many unverified UV-C products that do not meet safety standards.</td><td>Source only certified, high-quality Far-UVC devices from reputable manufacturers.</td></tr></table> ■ Overall Risk Level: Moderate	Risk Factor	Description	Mitigation Strategy	Line-of-Sight Dependency	Far-UVC is effective only on exposed surfaces and air within direct range. Pathogens in shadows or behind objects may not be disinfected.	Use multiple devices for uniform coverage or combine with airflow systems.	Lamp Degradation Over Time	UV lamps lose efficiency with prolonged use, reducing disinfection effectiveness.	Implement scheduled maintenance & lamp replacement every 2 years to maintain consistent performance.	Device Calibration Requirements	Improperly calibrated UV devices may exceed safe exposure limits or underperform.	Use automated control systems to monitor output and ensure proper dosing.	Compatibility with Materials	Long-term exposure may degrade certain plastics, fabrics, or painted surfaces.	Use Far-UVC-safe materials for furniture, equipment, and facility surfaces.	Energy Consumption	Although relatively low, continuous operation adds to facility power costs.	Optimize with smart automation and motion-sensing activation to reduce unnecessary use.	Risk Factor	Description	Mitigation Strategy	High Initial Cost	Initus-V requires an upfront investment (€3,000 - €8,000 per unit), which may be a barrier for adoption.	Offer leasing models, financing options, and government incentive programs for buyers.	Market Adoption Challenges	Many businesses still rely on chemical-based disinfection, and adoption may be slow due to lack of awareness.	Conduct educational campaigns, pilot studies, and regulatory endorsements to demonstrate benefits.	Regulatory Uncertainty	Far-UVC (222 nm) is relatively new, and some countries may not have clear regulations for its use.	Work with FDA, ICNIRP, and ISO standards to ensure compliance and advocate for updated guidelines.	Risk of Counterfeit or Low-Quality UV Products	The market has many unverified UV-C products that do not meet safety standards.	Source only certified, high-quality Far-UVC devices from reputable manufacturers.
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Regulatory Uncertainty	Far-UVC (222 nm) is relatively new, and some countries may not have clear regulations for its use.	Work with FDA, ICNIRP, and ISO standards to ensure compliance and advocate for updated guidelines.																																
Risk of Counterfeit or Low-Quality UV Products	The market has many unverified UV-C products that do not meet safety standards.	Source only certified, high-quality Far-UVC devices from reputable manufacturers.																																

	High initial costs and regulatory uncertainties can be managed through financing options and industry-standard compliance efforts. 4. Environmental and Sustainability Risks <table><tr><th>Risk Factor</th><th>Description</th><th>Mitigation Strategy</th></tr><tr><td>Lamp Disposal and Mercury Content</td><td>Some UV lamps contain mercury, which is hazardous to the environment.</td><td>Use mercury-free excimer lamps or follow proper recycling protocols for UV lamps.</td></tr><tr><td>Energy Consumption vs. Sustainability</td><td>Though low-energy, Far-UVC systems still consume power continuously, affecting sustainability.</td><td>Use motion-sensing activation to minimize unnecessary energy use. Consider integrating solar power where feasible.</td></tr><tr><td>Impact on Indoor Air Quality</td><td>Unfiltered UV-C can produce ozone and other harmful byproducts, though Far-UVC (222 nm) does not produce ozone if properly filtered.</td><td>Ensure proper lamp selection and air monitoring to prevent potential emissions.</td></tr></table> ■ Overall Risk Level: Low Choosing mercury-free lamps, optimizing energy use, and ensuring proper disposal minimize environmental concerns. 5. Comparison with Alternative Disinfection Methods <table><tr><th>Disinfection Method</th><th>Health Risks</th><th>Technical Risks</th><th>Economic Risks</th><th>Environmental Risks</th></tr><tr><td>Far-UVC (Initus-V, 222 nm)</td><td>◆ Low (if properly filtered)</td><td>◆ Moderate (line-of-sight limits)</td><td>◆ Low (energy use, lamp disposal)</td><td>◆ Moderate (high initial cost)</td></tr><tr><td>Traditional UV-C (254 nm)</td><td>● High (harmful to skin/eyes)</td><td>◆ Moderate (material degradation)</td><td>◆ Moderate</td><td>● High (ozone & mercury risks)</td></tr><tr><td>Ethanol-Based Chemical Disinfectants</td><td>◆ Moderate (respiratory irritation, chemical exposure)</td><td>◆ Moderate (frequent reapplication needed)</td><td>● High (recurring costs, labor-intensive)</td><td>● High (VOC emissions, chemical waste)</td></tr><tr><td>Hydrogen Peroxide Fogging</td><td>● High (respiratory hazard, requires PPE)</td><td>● High (room evacuation required)</td><td>● High (setup & consumable costs)</td><td>● High (chemical residue, environmental impact)</td></tr></table> ■ Far-UVC (Initus-V) presents the lowest overall risk profile when compared to other methods. Conclusion: Is Initus-V a Safe and Feasible Alternative?	Risk Factor	Description	Mitigation Strategy	Lamp Disposal and Mercury Content	Some UV lamps contain mercury, which is hazardous to the environment.	Use mercury-free excimer lamps or follow proper recycling protocols for UV lamps.	Energy Consumption vs. Sustainability	Though low-energy, Far-UVC systems still consume power continuously, affecting sustainability.	Use motion-sensing activation to minimize unnecessary energy use. Consider integrating solar power where feasible.	Impact on Indoor Air Quality	Unfiltered UV-C can produce ozone and other harmful byproducts, though Far-UVC (222 nm) does not produce ozone if properly filtered.	Ensure proper lamp selection and air monitoring to prevent potential emissions.	Disinfection Method	Health Risks	Technical Risks	Economic Risks	Environmental Risks	Far-UVC (Initus-V, 222 nm)	◆ Low (if properly filtered)	◆ Moderate (line-of-sight limits)	◆ Low (energy use, lamp disposal)	◆ Moderate (high initial cost)	Traditional UV-C (254 nm)	● High (harmful to skin/eyes)	◆ Moderate (material degradation)	◆ Moderate	● High (ozone & mercury risks)	Ethanol-Based Chemical Disinfectants	◆ Moderate (respiratory irritation, chemical exposure)	◆ Moderate (frequent reapplication needed)	● High (recurring costs, labor-intensive)	● High (VOC emissions, chemical waste)	Hydrogen Peroxide Fogging	● High (respiratory hazard, requires PPE)	● High (room evacuation required)	● High (setup & consumable costs)	● High (chemical residue, environmental impact)
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Hydrogen Peroxide Fogging	● High (respiratory hazard, requires PPE)	● High (room evacuation required)	● High (setup & consumable costs)	● High (chemical residue, environmental impact)																																		

	■ YES! While Far-UVC (222 nm) and Initus-V have some potential risks, they are significantly lower compared to chemical-based disinfection methods or traditional UV-C. Key Takeaways: • Health risks are minimal if proper safety measures are followed. • Technical risks (e.g., line-of-sight limitations, lamp degradation) are manageable with good system design. • Economic feasibility improves over time due to lower operational costs and long-term savings. • Environmental impact is significantly lower than chemical disinfectants. • Initus-V provides a scalable, future-proof disinfection solution for healthcare, public spaces, and industries. 👉 Final Verdict: With the right safety precautions and compliance standards, Initus-V is a low-risk, high-reward alternative for continuous disinfection. "
Information above is confidential	
Justification for confidentiality	
Availability	"Availability of Far-UVC and Initus-V Disinfection Systems Far-UVC technology, particularly the Initus-V system, is accessible in Hungary, offering advanced solutions for continuous air and surface disinfection. Initus-V System: • Manufactured in Turkey: • The Initus-V system utilizes a 222 nm Far-UVC light source produced collaboratively by Vestel Inc. (Manisa, Turkey) and Innoway R&D Kft. (Budapest, Hungary) www.initusv.com • CE Certification: uvsolutionsmag.com - o The Initus-V 222 system is CE marked, indicating compliance with European health, safety, and environmental protection standards. innowayrd.hu In summary, Initus-V and other Far-UVC disinfection systems are available in Hungary. Prospective buyers should ensure product compliance with national standards and consult with authorized distributors for procurement. "
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Justification for confidentiality	

Conclusion on suitability and availability of the alternative	Initus-V and Far-UVC (222 nm) technology offer a highly suitable, cost-effective, and future-proof alternative to traditional ethanol-based disinfection methods. 1. Suitability of Initus-V and Far-UVC ☒ Effective Disinfection: Real-time inactivation of bacteria, viruses, and fungi in air and surfaces. ☒ Safe for Occupied Spaces: Unlike UV-C (254 nm), filtered 222 nm light does not harm skin or eyes. ☒ Cost-Effective: Lower long-term costs than ethanol-based disinfectants; break-even in 7.5 months - 4 years. ☒ Eco-Friendly: No chemical residues or VOC emissions; eliminates antimicrobial resistance risks. ☒ Regulatory Compliance: CE-marked, meets ICNIRP, ISO 15858, ANSI RP-27 standards, and Turkish Ministry of Health approval. 2. Availability in Hungary & Globally ☒ Initus-V is CE-certified, produced by Vestel & Innoway R&D Kft. Available through local distributors & healthcare procurement. ☒ Global Far-UVC Adoption: Certified solutions from Ushio (Care222®), Lumenizer™ 222, widely used in hospitals & public spaces. ☒ Growing Market: Increasing demand for contactless, chemical-free disinfection post-pandemic. 3. Why Initus-V & Far-UVC Are the Best Alternatives Factor Initus-V & Far-UVC Ethanol-Based Disinfectants Disinfection ☒ Continuous ☒ Manual application Safety ☒ Safe ☐ Skin/eye irritation Cost (5 Years) ☒ €6,350 - €12,250 ☒ €15,000 - €50,000 Scalability ☒ Hospitals, offices, transport ☐ Limited A safe, cost-efficient, and sustainable disinfection alternative. 🚀 Future-Proof: Ideal for hospitals, offices, public transport, and food processing.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	

References	"References: 1. A new Far-UVC based method for germ free hospitals and travel: Initus-V Ayhan Olcay, Serdar Baki Albayrak, İbrahim Faruk Aktürk, Mehmet Cengiz Akbülbul, Onur Yolay, Hande İkitimur, Mehmet Çetin Bayer medRxiv 2021.04.23.21255969; doi:https://doi.org/10.1101/2021.04.23.21255969 2. A new Far-UVC based systemfor germ free cathlabs: Initus-V Ayhan Olcay, Serdar Baki Albayrak, İbrahim Faruk Aktürk, Mehmet Cengiz Akbülbul, Onur Yolay, Handeİkitimur, SinemYetim,Mustafa Mazlum, Mehmet Çetin Bayer. https://www.pcronline.com/Courses/PCR-Valves-e-Course/Programme 3. Results of Far-UVC and Protective Textile Based System For Germ Free Angiography Units, Ayhan Olcay, https://www.iuva.org/2021-WC-Program-1 https://www.researchgate.net/publication/352367462_Results_of_Far-UVC_and_Protective_Textile_Based_System_For_Germ_Free_Angiography_Units 4. Buonanno, M., Welch, D., Shuryak, I., & Brenner, D. J. (2020). Far-UVC light (222 nm) efficiently and safely inactivates airborne human coronaviruses. Scientific Reports, 10(1), 10285. https://doi.org/10.1038/s41598-020-67211-2 5. Kaidzu, S., Sugihara, K., Sasaki, M., Nishiaki, A., Igarashi, T., & Tanito, M. (2019). Evaluation of acute corneal damage induced by 222-nm and 254-nm ultraviolet light in Sprague–Dawley rats. PLoS ONE, 14(4), e0215904. https://doi.org/10.1371/journal.pone.0215904 6. Welch, D., Buonanno, M., Grilj, V., Shuryak, I., Randers-Pehrson, G., Spotnitz, H. M., ... & Brenner, D. J.(2018). Germicidal Efficacy and Mammalian Skin Safety of 222-nm UV Light. Radiation Research, 187(4), 483-491. https://doi.org/10.1667/RR0010CC.1 7. Kowalski, W. J. (2009). Ultraviolet Germicidal Irradiation Handbook: UVGI for Air and Surface Disinfection. Springer Science & Business Media. https://doi.org/10.1007/978-3-642-01999-9 8. Hessling, M., Haag, R., Sieber, N., & Vatter, P. (2020). The impact of far-UVC radiation (200–230 nm) on pathogens, cells, skin, and eyes – A collection and analysis of a hundred years of data. GMS Hygiene and Infection Control, 15, Doc08. https://doi.org/10.3205/dgkh000346

	9. Narita, K., Asano, K., Morimoto, Y., Igarashi, T., Nakane, A., & Tanito, M. (2020). Disinfection and healing effects of 222-nm UVC light on methicillin-resistant <i>Staphylococcus aureus</i> infection in mouse wounds. <i>PLOS ONE</i>, 15(2), e0229992. https://doi.org/10.1371/journal.pone.0229992 10. Cutler, T. D., & Zimmerman, J. J. (2011). Ultraviolet irradiation and the mechanisms underlying its inactivation of infectious agents. <i>Animal Health Research Reviews</i>, 12(1), 15-23. https://doi.org/10.1017/S1466252311000016 11. Raeiszadeh, M., & Adeli, B. (2020). A critical review on ultraviolet disinfection systems against COVID-19 outbreak: Applicability, validation, and safety considerations. <i>ACS Photonics</i>, 7(11), 2941–2951. https://doi.org/10.1021/acsphotonics.0c01245 12. Columbia University Irving Medical Center. (2022). Far-UVC Light Can Virtually Eliminate Airborne Virus in an Occupied Room. Retrieved from https://www.cuimc.columbia.edu/news/far-uv-light-can-virtually-eliminate-airborne-virus-occupied-room 13. ISO 15858:2016. (2016). UV-C Devices - Safety Information - Permissible human exposure. International Organization for Standardization. https://www.iso.org/standard/68417.html "
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 15	2025/03/20 10:48
Country	Germany
Name of organization/institution	Berufsverband der Ärzte für Mikrobiologie, Virologie und Infektionsepidemiologie e.V.
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	

Product Type	1,2,4
Alternative Identity and Properties	Alkoholbasierte Desinfektionsmittel spielen eine entscheidende Rolle in der Hygiene. Sie wirken rasch und umfassend gegen die meisten Erreger und sind für Menschen gut verträglich. Aus diesen Gründen werden sie weltweit eingesetzt und sind in Deutschland Standard seit den 1950er Jahren. Ethanol hebt sich im Vergleich zu anderen Alkoholen durch seine überlegene Effektivität gegen unbehüllte Viren, z. B. Adeno-, Noro-, Rota- und Enteroviren, hervor (VAH 2020, Kramer et al. 2022). Aufgrund seiner breiten Wirksamkeit, der sicheren Handhabung und der hohen Verfügbarkeit ist Ethanol der am häufigsten eingesetzter Wirkstoff in Desinfektionsmitteln und ist ein unverzichtbarer Bestandteil der Infektionsprävention.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Ethanol wird von der WHO als essenzieller Wirkstoff eingestuft, was ihn zur Grundversorgung zählt. Die durch Händedesinfektion aufgenommenen Mengen Ethanol liegen unterhalb toxikologisch relevanter Konzentrationen. Innerhalb weniger Sekunden verdunstet die Hälfte des Ethanols und nur 1–2 % des auf die Haut aufgetragenen Ethanols werden aufgenommen. Dagegen wird Ethanol nicht nur endogen gebildet, sondern kann auch über Lebensmittel – z. B. Fruchtsäfte – aufgenommen werden (VAH 2020). Die Einstufung von Ethanol als reproduktionstoxisch oder gar kanzerogen (außerhalb der oralen Aufnahme) nicht gerechtfertigt, da diese Überlegungen ausschließlich auf den Effekten nach oraler Aufnahme beruhen. Andere Aufnahmewege (inhalativ, dermal) resultieren unter realen Bedingungen im Gesundheitswesen in Blutspiegeln, die im Hintergrundlevel (endogene Bildung, Aufnahme über Lebensmittel) liegen.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	

Justification for confidentiality	
Hazards and Risks of the Alternative	Um sicherzustellen, dass ethanolhaltige Produkte zur Desinfektion von Händen und Flächen weiterhin effektiv zur Vermeidung und Bekämpfung von Infektionen eingesetzt werden können, ist es wichtig, dass Ethanol nicht als CMR-Substanz klassifiziert wird. Ein Verbot von Ethanol in der Verwendung als Desinfektionsmittel würde einen effektiven und schnellen Infektionsschutz und somit die Patientenversorgung erheblich gefährden.
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol hebt sich im Vergleich zu anderen Alkoholen durch seine überlegene Effektivität gegen unbehüllte Viren, z. B. Adeno-, Noro-, Rota- und Enteroviren, hervor. Ein Verbot von Ethanol in der Verwendung als Desinfektionsmittel würde einen effektiven und schnellen Infektionsschutz und somit die Patientenversorgung erheblich gefährden.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	Kramer, A. et al: Ethanol is indispensable for virucidal hand antisepsis: memorandum from the alcohol-based hand rub (ABHR) Task Force, WHO VAH: Ethanol ist als biozider Wirkstoff zur hygienischen Händedesinfektion unverzichtbar. Hyg Med 2020, 45, 194-200
Attachments (non-confidential information)	BÄMI_Stellungnahme_Ethanolverbot durch EU_final.pdf

Attachments (confidential information)	
Justification for confidential attachment	

Comment 16	2025/03/21 12:07
Country	Belgium
Name of organization/institution	Fecc
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Fecc emphasised that the proposed classification of ethanol as a CMR (Carcinogenic, Mutagenic and/or toxic to Reproduction) would have catastrophic consequences on infection control in hospitals, as it would prevent its use. Society is at risk of losing access to the crucial ingredient that could help us survive another pandemic like Covid-19.
Product Type	1,2,4
Alternative Identity and Properties	The combination of all substance inherent properties is only given by Ethanol: fast acting, full virucidal, no residues, fast evaporation, long storage time, no transfer to or tainting of food, odorless, no disinfection by products or (eco-) toxicologically relevant degradation products. Most important is the lack of efficacy for not enveloped virus of all possible alternatives of Ethanol.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	

Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	A classification as CMR will probably lead to customer concern and thus a lack of acceptance of ethanol-based biocidal products and a switch to alternative products. We fear the following shortages in the availability of alternative biocidal products on the market.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	Fecc - Et-OH - Consultation.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 17	2025/03/24 12:44
Country	Germany
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	
Product Type	1,2,4
Alternative Identity and Properties	While there are other disinfectants available, none have the same balance of efficacy, safety, and accessibility as ethanol. Alternatives may not offer the same broad-spectrum effectiveness, or they may come with additional risks such as higher toxicity, longer drying times, less user acceptance, or less environmental compatibility. For example, while isopropyl alcohol is an alternative, it is not as effective in all cases as ethanol. Moreover, there are currently no alternatives that can provide the same combination of effectiveness, availability, user acceptance and safety in all applications where ethanol is used.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Substituting ethanol with an alternative substance could lead to significant environmental and economic consequences. Manufacturing processes for alternative substances may involve more energy-intensive production methods, resulting in higher carbon emissions and a larger environmental footprint. Additionally, the production and disposal of alternative substances could present new environmental hazards. From an economic perspective, replacing ethanol could increase costs for industries that rely on it, which would in turn affect consumers. Ethanol, on the other hand, is produced from renewable resources,

	making it a more sustainable option compared to many other chemicals that might replace it. Furthermore, the cost of replacing ethanol on a large scale could increase prices, placing economic strain on industries, especially during a time when many sectors are still recovering from the economic impact of the pandemic. Ethanol, being renewable and relatively inexpensive, provided an accessible solution during the pandemic, and any disruption to its availability could hamper recovery efforts.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Ethanol has been extensively studied and used safely in a wide range of applications for many years. Regulatory agencies such as the European Medicines Agency (EMA), U.S. Food and Drug Administration (FDA), and the World Health Organization (WHO) have all approved ethanol for use in medical and consumer products. The safety data available supports its use in applications where direct human contact is involved, such as hand sanitizers and disinfectants. Additionally, ethanol's regulatory history ensures it is well-understood and monitored for safety, reducing the likelihood of unforeseen adverse effects.
Information above is confidential	
Justification for confidentiality	
Availability	The immediate availability and cost-effectiveness of ethanol made it indispensable during the pandemic, and alternatives may not be as versatile or accessible, especially in emergency situations.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol plays a vital role in public health, particularly highlighted during the COVID-19 pandemic. It is a highly effective, broad-spectrum disinfectant, essential for controlling the spread of viruses like SARS-CoV-2. Alternatives to ethanol are limited in their effectiveness, safety, and accessibility, making ethanol indispensable, especially in emergencies. Its safety profile is well-established through extensive regulatory approvals from

	global health organizations, ensuring its continued safe use. Moreover, ethanol is produced from renewable resources, making it an environmentally and economically viable option. Substituting ethanol could have significant environmental, economic, and public health consequences, particularly in the aftermath of the pandemic.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 18	2025/03/25 11:12
Country	Germany
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	The simplified BPR gives the EU many possibilities of alternative products for all PT classes. Not only is the speed similar to ethanol also the broad spectrum of bacteria and yeast is identical. In some cases even AMR bacteria are eliminated where ethanol has its limitations. The information concerns PT 1, PT 2 and PT 4

Product Type	1,2,4
Alternative Identity and Properties	in the simplified BPR lactic acid, tartaric acid and citric acid in combination with and without benzoic acid show similar results to ethanol.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	There are several fomulations that are already approved in France and Holland and new ones are prepared for approval that can be brought to market very quickly. The approval time of the simplified process is the rate limiting step.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	The raw materials can be sourced in the EU and the manufacturing is very simple, some are already sold in the EU.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	none as it falls under the simplified BPR
Information above is confidential	
Justification for confidentiality	
Availability	Some are already apporved for sale others are in the pipeline for registration
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Easy to source the raw materials in the EU and easy to produce. The products are non hazardous and non flammable. MADE in the EU

Information above is confidential	
Justification for confidentiality	
Other comments	If the simplified BPR were really streamlined and simple, more alternative products could be on the market very fast. Some of these formulations show a wider spectrum bacterial kill (AMR bacteria) than ethanol versions
Information above is confidential	
Justification for confidentiality	
References	Salveco France, Hygienix Holland
Attachments (non-confidential information)	Dlversey PT 1 PT 2 survey C Auris.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 19	2025/03/26 11:14
Country	Germany
Name of organization/institution	Food Federation Germany (Lebensmittelverband Deutschland e.V.
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	In the food sector, ethanol is a natural compound of various foodstuffs, it is deliberately added to certain foods, it is used as a functional compound in food and food production - and it is used for disinfection purposes. With regard to disinfection, ethanol is used for the disinfection of surfaces and equipment (PT 4) and for personal hygiene (hand rubs; PT 1). Disinfection with ethanol is not only used by the food processing industry, but in the whole food chain. This also comprises the restaurant and catering sector, retails and shops where food is marketed, craft production and primary producers of food. Ethanol as an ingredient, food additive,

	food flavouring (aromes) or functional substance in food and food production is covered by the European (and national) food legislation, its horizontal and specific regulations and its general and specific provisions. So far, there are no restrictions for the use of ethanol in food and food production. For oral consumption, ethanol always must be undenatured. When ethanol is used for disinfection purposes, it is always denatured. This is also true for disinfectants of PT 4. Although the denaturation is originally done for customs reasons, it prevents humans to drink denatured ethanol. Oral consumption of disinfectants with ethanol is not feasible therefore.
Product Type	1,2,4
Alternative Identity and Properties	Mainly other alcohols, esp. iso-propanol (2-propanol) (and 1-propanol). Also mentioned were: sodium hypochlorite solutions, hydrogen peroxide solutions, peracetic acid, quarternary ammonium compounds (QAV). Chlorine generating agents (e.g. sodium hypochlorite) and QAV may lead to residues in food which is not desirable in the food sector. Hydrogen peroxide and peracetic acid are aggressive chemicals which are not suitable for surfaces with food contact. Peracetic acid has corrosive properties, hydrogen peroxide is an irritant and not suitable for use with plastic materials. Therefore, the only “realistic” alternatives for ethanol in the food sector to be discussed further, are other alcohols, esp. iso-propanol. In contrast to ethanol, iso-propanol is less volatile. The use of iso-propanol may lead to residues which spoil food due to the bad taste and odour of iso-propanol. Ethanol, however, evaporates quickly and even if traces would remain on the surfaces, they were not considered relevant given that ethanol is also naturally occurring in food.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	The use of other alcohols, esp. iso-propanol instead of ethanol, is feasible from a technical point of view. However, in situations where residues might occur or where the use of alternatives requires rinsing with water afterwards, other alcohols are no suitable alternative. Ethanol is especially suitable in concepts to combat moulds because it does not require rinsing. The same is for the disinfection of tubes and tanks where other alcohols would contaminate the goods transferred or stored within.

Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Disinfectants with ethanol are widely used in the food sector. A main application throughout the whole food chain is spraying and/or wiping surfaces with disinfectants containing ethanol. But e.g. also for the disinfection of dispensing systems in food production and restaurants/pubs, for cleaning and disinfection of cutting and slicing machines and equipment and for the disinfection of filling lines, disinfectants with ethanol are used. Disinfectants with other alcohols than ethanol are more expensive. Ethanol can be produced in high amounts which lowers its price. "Alcoholic beverages without ethanol/alcohol" (e.g. alcohol-free beer and wine) have become trend products and the released ethanol is mainly sold to manufacturers of disinfectants with ethanol. This is also true for ethanol that is formed in some production processes in the food industry as a by-product.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Ethanol is the only active substance in disinfectants that is effective against non-enveloped viruses. That is, in contrast to ethanol, iso-propanol/other alcohols are not/less effective against e.g. noroviruses which are known pathogens in certain foodstuffs. In case that rinsing steps (with water) are required after the use of iso-propanol/other alcohols, this may introduce new microbiological risks in the food produced. This is especially true for the formation of mould (and mycotoxins) and will often also lead to a reduced shelf-life of the product. So far, ethanol is perceived as active substance in disinfectants having the lowest risks for all kind of users. In general, the main risks with ethanol are associated with the misuse of drinking too much alcohol/alcoholic beverages. However, when it comes to disinfectants of PT 4, ethanol is denatured. That is, oral consumption is not possible. The relevant routes of exposure for ethanol as disinfectant are dermal uptake and inhalation only.
Information above is confidential	
Justification for confidentiality	

Availability	Other alcohols like iso-propanol can only be produced in smaller amounts than ethanol. Ethanol is mainly produced from agricultural crops, other alcohols are produced by chemical industry. As the Corona pandemic has shown, production of ethanol can easily be raised at short time. This is unique for active substances in disinfectants.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Disinfectants with ethanol are widely used in the whole food sector/food chain. Main applications are the (quick) disinfection of surfaces by wiping or spraying and the cleaning and disinfection of machines, tubes, tanks and equipment. Disinfectants are not only used by professionals in the food sector, but also by staff working in pubs, shops etc. Possible alternatives for ethanol in disinfectants are other alcohols, esp. iso-propanol. So far, iso-propanol is considered to be more toxic than ethanol, it is not/less effective against non-enveloped viruses (e.g. noroviruses as known pathogens in food) and it is less volatile which leads to residues on surfaces and machines that spoil food due to bad taste and odour of iso-propanol. Risks with ethanol are mainly associated with drinking too much alcohol/alcoholic beverages. In disinfectants, the ethanol used is denatured. That is, oral consumption is not feasible. It is proposed therefore to do the evaluation under the BPR resp. the chemical legislation for "ethanol, denatured" instead of "ethanol". This would lead to a more realistic scenario and evaluation for "ethanol" used as active substance in disinfectants.
Information above is confidential	
Justification for confidentiality	
Other comments	In disinfectants, only denatured ethanol is used. Undenatured and denatured ethanol are traded separately due to customs reasons. It is proposed to do the evaluation for "ethanol, denatured" instead of "ethanol", when ethanol is evaluated under the chemical legislation, here the Biocidal Products Regulation. This would lead to a more realistic scenario and evaluation of ethanol used as active substance in disinfectants.
Information above is confidential	

Justification for confidentiality	
References	
Attachments (non-confidential information)	Ethanol_BLL statement 2015_Food Federation Germany_english_2024.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 20	2025/03/26 14:22
Country	Austria
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	Ethanol (60-95%) demonstrates exceptional efficacy against a broad pathogen spectrum, with 80% ethanol effectively eliminating 21 types of enveloped viruses within 30 seconds. Primary alternatives include benzalkonium chloride (BZK), chlorhexidine gluconate (CHG), and quaternary ammonium compounds (QACs). These alternatives show fundamentally different antimicrobial properties with significantly reduced efficacy compared to ethanol. Most critically, ethanol remains the only active ingredient in hand disinfectants effective against non-enveloped viruses, creating an irreplaceable role in comprehensive infection control.
Product Type	1,2,4
Alternative Identity and Properties	Ethanol (60-95%) demonstrates exceptional efficacy against a broad pathogen spectrum, with 80% ethanol effectively eliminating 21 types of viruses within 30 seconds. Primary alternatives include benzalkonium chloride (BZK), chlorhexidine gluconate (CHG), and quaternary ammonium compounds (QACs). These alternatives show fundamentally different antimicrobial properties with significantly reduced efficacy compared to ethanol. Most critically, ethanol remains the only active ingredient in hand disinfectants

	effective against non-enveloped viruses, creating an irreplaceable role in comprehensive infection control.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Ethanol's mechanism of action involves protein denaturation and lipid membrane dissolution, disrupting microbial cell structures. This dual action provides broad-spectrum antimicrobial activity that alternatives cannot match. The CDC recommends alcohol-based hand rubs over soap and water in most clinical scenarios due to superior efficacy and better compliance. Studies consistently show BZK and other alternatives have "less reliable activity against certain bacteria and viruses than alcohols". Most significantly, ethanol is uniquely effective against non-enveloped viruses, creating an irreplaceable technical role that no current alternative fulfills.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Ethanol's economic advantages stem from established global production infrastructure and relative affordability, costing about € 1 per litre and representing approximately 40% of hand sanitizer production costs. During the COVID-19 pandemic, when isopropyl alcohol prices increased 2-4 times, ethanol emerged as the more economical and readily available alternative. While some alternatives claim cost advantages through on-site production, they require significant initial investment and often necessitate complementary disinfection products due to their narrower antimicrobial spectrum, increasing total economic burden. Ethanol provides reliability and cost predictability that alternatives cannot match.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	A comprehensive risk assessment of alternatives reveals significant concerns: QACs demonstrate concerning toxicological profiles, including "dermal and respiratory effects, developmental and reproductive toxicity, disruption of metabolic function, and impairment of mitochondrial

	function". Additionally, QACs' role in promoting antimicrobial resistance creates potential long-term public health risks. Chlorhexidine can cause "serious allergic reactions" including anaphylaxis, particularly when used on open wounds or during surgery. Higher concentrations (2-4%) show increased skin irritation, potentially increasing sensitization risks. Ethanol's safety profile for topical application is well-established through decades of use, presenting a more favorable safety profile for hand disinfection applications compared to the documented risks of alternatives.
Information above is confidential	
Justification for confidentiality	
Availability	Ethanol is produced worldwide for healthcare, food and beverage, and fuel industries, ensuring consistent availability even during demand surges. The global hand sanitizer market is projected to reach more than \$2 billion by 2027, requiring reliable supply chains. In contrast, alternatives face significant availability challenges. Quaternary ammonium compounds depend on key ingredients like ethylbenzyl chloride. During the COVID-19 pandemic, ethanol emerged as the most readily available disinfectant solution, with some countries repurposing fuel ethanol for sanitizers, demonstrating its superior supply reliability.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	After thorough analysis, no current substitute demonstrates the necessary combination of antimicrobial efficacy, safety profile, economic feasibility, and reliable availability required to replace ethanol in hand disinfection. Ethanol remains uniquely valuable for its proven efficacy against both enveloped and non-enveloped viruses, established safety record in topical application, global production infrastructure, and cost-effectiveness. Alternatives present significant limitations including narrower antimicrobial spectrum, concerning toxicological profiles, and supply chain vulnerabilities. The classification of ethanol as a CMR substance would eliminate the only active ingredient effective against non-enveloped viruses in hand disinfection, creating substantial public health risks that far outweigh the theoretical concerns behind the proposed classification.

	Effective infection control, particularly in healthcare settings, depends on continued access to ethanol-based hand disinfectants.
Information above is confidential	
Justification for confidentiality	
Other comments	The WHO and CDC consistently recommend alcohol-based hand sanitizers containing 60-95% ethanol as the gold standard for hand hygiene, particularly in healthcare settings. This recommendation is based on decades of research demonstrating ethanol's superior efficacy, safety profile, and user acceptance compared to alternatives.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 21	2025/03/26 18:34
Country	Italy
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	
Product Type	1,2,4

Alternative Identity and Properties	Ethanol (CAS 64-17-5) is widely used in PT1 products for human hygiene due to its proven virucidal efficacy against a broad spectrum of viruses, including non-enveloped ones. Alternatives such as isopropanol, n-propanol, hydrogen peroxide, benzalkonium chloride, and chlorhexidine do not guarantee the same level of efficacy, safety, and user acceptability. Scientific data supporting these alternatives remain fragmented or incomplete. The World Health Organization (WHO) recommends ethanol as the active ingredient in hand disinfectant formulations (WHO hand rubs), due to its validated efficacy and safety. Medical and scientific associations worldwide (EU, USA, Canada, Asia-Pacific, World Society for Virology) strongly recommend that ethanol should be approved as a PT1 biocidal active substance, not be classified as a category 2 CMR, and be recognized for its favorable toxicological profile. Toxicological studies demonstrate that: Transdermal absorption during the use of ethanol-based hand rubs (EBHRs) is minimal. A study assessing ethanol absorption during hygienic and surgical hand disinfection found that the overall dermal and pulmonary absorption of ethanol was below toxic levels in humans, concluding that the use of evaluated ethanol-based hand rubs is safe. Blood alcohol levels remain within the physiological range of a normal diet. Sources: Kramer et al., 2024 – GMS Hygiene and Infection Control (PMC11367556); WHO Guidelines on Hand Hygiene; Miller et al., 2006 – BMC Infectious Diseases (PMC2089071).
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Alternatives to ethanol pose significant technical limitations: hydrogen peroxide is unstable and irritating; benzalkonium chloride is less effective against certain viruses and bacteria; IPA and NPA require complex reformulations and offer lower user acceptability; quaternary ammonium compounds show limited efficacy; propanols require complete reformulation and are less volatile. Ethanol offers fast evaporation, high dermal compatibility and good sensory properties—key factors in PT1 applications. In sectors such as printing, cosmetics and food disinfection, ethanol remains technically irreplaceable. Sources: WHO; Wilkinson et al., 2018; Annex I–II ePure.
Information above is confidential	

Justification for confidentiality	
Economic Feasibility	Replacing ethanol would lead to substantial costs related to the development of new formulations, modification of production lines, staff retraining and new regulatory approvals—especially impacting microenterprises and PMI. Alternatives such as IPA and NPA are generally more expensive and less available at scale. Ethanol is often derived from renewable sources, contributing to EU sustainability targets, while many alternatives are derived from petrochemical processes, are more expensive, and less accessible. Sources: Annex II, ePure; Kramer et al., 2024.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Scientific evidence confirms the safety of ethanol in hand hygiene products. A study assessing ethanol absorption during hygienic and surgical hand disinfection concluded that the overall dermal and pulmonary absorption of ethanol was below toxic levels in humans, supporting the safety of ethanol-based hand rubs. Kramer et al. (2024) found no epidemiological evidence that the use of ethanol-based disinfectants poses significant risks to workers or patients. Transdermal absorption is minimal, and systemic exposure remains within physiological levels, confirming its favorable toxicological profile. In contrast, alternatives such as isopropanol and n-propanol show greater systemic toxicity, may cause skin irritation, have a more unpleasant odor, and lower efficacy against non-enveloped viruses. Benzalkonium chloride is less effective against some pathogens, may contribute to antimicrobial resistance, and is a known sensitizer; hydrogen peroxide is irritating and unstable. Sources: Kramer et al., 2024; Wilkinson et al., 2018; Annex II ePure; Miller et al., 2006 – BMC Infectious Diseases (PMC2089071).
Information above is confidential	
Justification for confidentiality	
Availability	Ethanol is widely available across the European Union, with a well-established production and supply chain. Alternatives such as IPA and NPA are produced in smaller quantities and may not meet the necessary demand to fully replace ethanol in PT1 products. Increased demand for these alternatives may cause significant price hikes and supply

	issues. These alternatives do not offer the same level of availability, cost-efficiency or environmental sustainability. In many sectors, there are no sufficient alternative volumes to meet EU-wide needs. Sources: Annex I–II, ePure.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol is currently the only active substance in PT1 with: A well-established favorable toxicological profile; Broad-spectrum microbiological efficacy; Wide-scale industrial availability; Global acceptance by health authorities (e.g., WHO, ECDC). The proposed alternatives do not present sufficient scientific evidence to guarantee comparable efficacy and safety, especially against non-enveloped viruses. Replacing ethanol with IPA or NPA would require entirely new regulatory evaluations, involve significant costs for industry, and could result in a decrease in the effectiveness of hand hygiene products, with potential consequences for public health, hospital infection control, and consumer safety. The document “Analysis of Alternatives for the use of Ethanol in Human Hygiene Products (PT1)” prepared by the Alcohol Task Force (February 2025) provides a comprehensive technical and regulatory assessment, in line with ECHA Guidance (2023). It confirms the absence of realistic alternatives to ethanol in PT1 in terms of efficacy, toxicological profile, availability and cost. Therefore, ethanol should remain an approved active substance in PT1 without classification as a CMR, in order to safeguard public health, hospital hygiene, and supply chain resilience. Sources: Kramer et al., 2024; WHO; Annex I–II ePure; Wilkinson et al., 2018; Miller et al., 2006 (PMC2089071); WHO Task Force on Hand Hygiene, 2022 (PubMed ID: 35794648).
Information above is confidential	
Justification for confidentiality	
Other comments	Ethanol represents the global benchmark for hand hygiene products, as recommended by WHO. Its virucidal and bactericidal efficacy is supported by decades of scientific data and clinical experience. It is widely used in hospital, industrial, and domestic settings. A study published in 2022 concluded that there is no risk of carcinogenicity, mutagenicity, or reprotoxicity from repeated use of ethanol-based hand rubs and strongly recommended retaining

	ethanol as an essential constituent in hand rubs for healthcare. Systemic exposure via skin is lower than that from common food sources containing trace ethanol. Classifying ethanol as a CMR substance, even as Category 2, would lead to disproportionate regulatory consequences, market uncertainty, reduced consumer trust, and hygiene risks due to the lack of viable alternatives. The alternatives (isopropanol, n-propanol, quaternary ammonium compounds, hydrogen peroxide) pose specific concerns and are less studied regarding long-term systemic risks. Sources: WHO; Kramer et al., 2024; Annex I–II; ePure communications to ECHA; WHO Task Force on Hand Hygiene, 2022 – Journal of Hospital Infection (PubMed ID: 35794648)
Information above is confidential	
Justification for confidentiality	
References	Kramer, A. et al. (2024) – Ethanol-based hand rubs: no toxicologically relevant systemic exposure via dermal or inhalation routes GMS Hygiene and Infection Control, PMC11367556 Miller, M.A. et al. (2006) – Systemic ethanol absorption from alcohol-based hand rubs during hygienic and surgical hand disinfection BMC Infectious Diseases, PMC2089071 WHO Guidelines on Hand Hygiene in Health Care (2009, update 2020) World Health Organization – who.int Wilkinson, M. et al. (2018) – Toxicological and functional assessment of alcohol-based disinfectants Cited in alcohol task force documentation and WHO references WHO Task Force on Hand Hygiene (2022) – Retain ethanol in WHO hand rubs: summary of toxicological and regulatory review Journal of Hospital Infection, PubMed ID: 35794648 Alcohol Task Force – Analysis of Alternatives (AoA) for PT1 Version 3.0, February 2025 – Submitted to ECHA and included in consultation appendix Annex I – Legislative impact of CMR Cat. 1&2 by sector ePURE (2024), attached in consultation Annex II – Legislative impact of CMR Cat. 2 by sector ePURE (2024), attached in consultation ePURE communications to ECHA (2024–2025) Industry position papers and regulatory feedback submitted to ECHA regarding ethanol ECHA – Article 95 List (updated 2024) List of approved biocidal active substance suppliers – echa.europa.eu
Attachments (non-confidential information)	

Attachments (confidential information)	
Justification for confidential attachment	

Comment 22	2025/03/26 19:13
Country	Italy
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	
Product Type	1,2,4
Alternative Identity and Properties	Ethanol (CAS 64-17-5) is a reference active substance for disinfectants and algacides not intended for direct application to humans or animals (PT2). Its broad-spectrum antimicrobial action, rapid evaporation, compatibility with various surfaces and materials, and biodegradability make it unique compared to the identified alternatives. Substances such as propan-1-ol, propan-2-ol, peracetic acid, biphenyl-2-ol, or lactic acid show significant limitations in terms of virucidal efficacy, corrosiveness, or toxicity. Kampf (2018) demonstrated that ethanol has superior virucidal efficacy compared to other alcohols, even at lower concentrations, and is one of the few active substances effective within 30 seconds. McDonnell (2007) confirmed that ethanol has broad-spectrum antimicrobial activity, high efficacy against viruses and bacteria, and no cumulative toxic effects. Sources: Alcohol Task Force AoA PT2 (2025); Kampf et al., Journal of Hospital Infection (2018); WHO Guidelines; McDonnell (2007), Journal of Applied Microbiology.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Ethanol meets the key technical requirements for PT2 disinfectants: effectiveness against non-enveloped viruses, rapid action (-1 minute), compatibility with common

	surfaces (stainless steel, plastic, glass), and safety for non-professional users. Alternatives require higher concentrations, longer contact times, or specific PPE. Some, such as peracetic acid, are incompatible with sensitive surfaces or release irritating vapours. Standard EN 14476:2013+A2:2019 requires a disinfectant to demonstrate virucidal activity within 60 seconds against non-enveloped viruses: ethanol is one of the few substances that meets this criterion. Kramer et al. (2024) emphasize that ethanol does not require PPE for environmental use, unlike many alternatives, and is also compatible with delicate materials. Sources: Alcohol Task Force AoA PT2; EN 14476; ECHA Article 95 List; Kramer et al., GMS Hygiene and Infection Control (2024).
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Ethanol is produced on a large scale from a wide range of sources, including non-food renewable biomass (e.g. molasses, agricultural residues) and fermentable agricultural commodities (e.g. maize, wheat, sugar beet). Its average industrial cost for technical and biocidal uses is considered highly competitive. Replacing ethanol in PT2 would require significant investments in R&D (to validate new active substances), plant modifications (compatibility with materials and processes), new regulatory authorisations (Biocidal Product Authorisation, CLP labelling), and supply chain adaptation (suppliers, transport, storage, operator training). The currently identified alternatives are more expensive per kg/litre of active substance, less available at industrial scale in Europe, and less sustainable, as they often rely on petrochemical processes or have a higher environmental impact (e.g. residues, energy consumption, specialised transport). According to Petersen et al. (2021), ethanol is the most economically efficient disinfectant for environmental use, due to decentralised production in Europe and the use of non-food feedstocks. The ePURE (2024) analysis highlights that European SMEs would suffer disproportionate economic impacts from the removal of ethanol, with consequences throughout the industrial and distribution chain. Sources: AoA PT2 (2025); Petersen et al., Energy Conversion and Management (2021); Annex II – Legislative impact of CMR Cat. 2 by sector (2024, ePURE).

Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Ethanol has a well-known toxicological profile, with dermal and inhalation exposure at negligible levels. CMR classification proposals are based on oral exposure at high doses, which are not representative of biocidal uses. Alternatives such as peracetic acid, IPA, or QACs pose higher risks: corrosiveness, systemic toxicity, sensitisation, or potential bacterial resistance. Kramer et al. (2024) clarify that environmental or dermal exposure to ethanol in PT2 products is not associated with carcinogenic or mutagenic effects and that ethanol does not cause sensitisation or bioaccumulation. The World Health Organization (WHO) has repeatedly stated that the use of ethanol in disinfectants does not pose significant toxicological risks, even with frequent applications. Sources: Kramer et al., GMS Hygiene and Infection Control (2024); Alcohol Task Force AoA PT2; WHO.
Information above is confidential	
Justification for confidentiality	
Availability	Ethanol is widely available across Europe, with over 700 suppliers registered in the ECHA Article 95 List. Its supply chain is resilient, with production facilities in Germany, France, Italy and Poland. It is also one of the few disinfectants whose production can be rapidly increased thanks to multifunctional bioethanol plants. Alternatives (IPA, NPA, QACs, peroxide) do not ensure the same distribution coverage or continuity of supply. Many are imported from non-EU countries, lacking sustainability certifications comparable to the European ethanol supply chain. Moreover, many are not fully registered under the BPR and REACH, complicating compliance with EU regulatory requirements for safety, labelling, and environmental liability. According to ECHA (2024), ethanol is the most represented substance among registered biocides, ensuring regulatory coverage and traceability across the European supply chain. SEAC Guidance (2023) identifies ethanol as a positive example of a locally available, sustainable substance that meets EU standards, unlike alternatives dependent on critical raw materials or external supply chains. Sources: AoA PT2; ECHA Article 95 List (2024); SEAC Guidance (ECHA, 2023), Annex I & II; ePURE (2024); REACH Regulation (EC) No. 1907/2006.

Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol is irreplaceable in PT2 products due to its unique combination of rapid efficacy, broad-spectrum antimicrobial action, safety, environmental compatibility, industrial availability, and low cost. No technically, economically, or regulatory equivalent alternatives currently exist. Its exclusion would jeopardise public health, industrial sustainability, and regulatory coherence. WHO Guidelines on Hand Hygiene (2009, updated 2022) recognise ethanol as the global reference active substance for disinfection, highlighting its proven efficacy, rapid action and safety in both clinical and environmental contexts. The BfR (2020) confirms in its opinion that ethanol cannot be classified as CMR 1A/1B in the absence of systemic oral exposure, a condition not applicable to PT2 uses. According to SEAC Guidance (ECHA, 2023), excluding substances with proven functional value, sustainability, and widespread availability (such as ethanol) would cause disproportionate socio-economic damage, particularly for SMEs. Sources: Analysis of Alternatives for the use of Ethanol in disinfectants and algaecides not intended for direct application to humans or animals (PT2), Alcohol Task Force (v3.0, Feb. 2025); WHO Guidelines; BfR (2020); SEAC Guidance (2023).
Information above is confidential	
Justification for confidentiality	
Other comments	Eliminating ethanol from PT2 would cause critical hygienic, economic and logistical impacts. No alternative simultaneously satisfies all requirements of efficacy, safety, material compatibility, stability and cost. Ethanol is a key element in the EU's response to pandemics and environmental disinfection strategies. The BfR (German Federal Institute for Risk Assessment) published a scientific opinion concluding that dermal or inhalation exposure to ethanol does not justify a CMR 1A/1B classification. WHO Guidelines on Hand Hygiene (2009, updated 2022) recommend ethanol for frequent and prolonged use, even in sensitive environments, without toxicological contraindications. SEAC recognises that removing ethanol would have disproportionate impacts on SMEs, employment, and the availability of hygiene products. Sources: Alcohol Task Force AoA PT2 (2025); WHO Guidelines; SEAC Guidance; Kramer et al. (2024); BfR (2020).

Information above is confidential	
Justification for confidentiality	
References	Alcohol Task Force AoA PT2 (2025); Kampf et al., Journal of Hospital Infection (2018); WHO Guidelines; McDonnell (2007), Journal of Applied Microbiology; EN 14476; ECHA Article 95 List; Kramer et al., GMS Hygiene and Infection Control (2024); Petersen et al., Energy Conversion and Management (2021); Annex II – Legislative impact of CMR Cat. 2 by sector (2024, ePURE);); SEAC Guidance (ECHA, 2023), Annex I & II; ePURE (2024); REACH Regulation (EC) No. 1907/2006; BfR (2020).
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 23	2025/03/26 19:27
Country	Italy
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	
Product Type	1,2,4
Alternative Identity and Properties	Ethanol (CAS 64-17-5) is an active substance used for the disinfection of surfaces, equipment, and containers in the food and feed sector (PT4). It has broad-spectrum antimicrobial activity, fast action, good compatibility with sensitive materials, and complete evaporation without residues. Among the identified alternatives, lactic acid, propanol, and isopropanol show limited efficacy against non-enveloped viruses, longer contact times, or classifications that restrict their use in food-related settings.

	Chlorine-based substances and QACs are often corrosive, with compatibility limitations and the risk of hazardous residues on food-contact surfaces. References: AoA PT4 (Alcohol Task Force, 2025); Kramer et al., Antimicrobial Resistance & Infection Control (2022); Kampf (2018), Journal of Hospital Infection.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Ethanol acts quickly (30–60 seconds), is effective against viruses, bacteria, and fungi, and is safe for food-contact surfaces without requiring rinsing. Alternatives generally require longer contact times, may leave residues, or require personal protective equipment (PPE) for safe use. Non-chemical methods such as UV-C or steam are costly and have limitations when applied to porous surfaces. References: AoA PT4; WHO; EN Standards (EN 1276, EN 14476).
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Ethanol is produced on a large scale, often from renewable sources such as molasses and non-food biomass, or from fermentable agricultural crops (e.g., maize, wheat, sugar beet). Its average industrial cost for technical and biocidal applications is competitive. Replacing ethanol in PT4 would require significant investment in R&D, plant modifications, additional regulatory authorisations, and a full reorganisation of the supply chain. The evaluated alternatives are more expensive, less available at industrial scale in Europe, and less sustainable from an environmental and climate standpoint. References: AoA PT2 (Alcohol Task Force, 2025); Petersen et al., Energy Conversion and Management, 2021.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Ethanol has a well-established toxicological profile, with negligible dermal absorption and very low systemic risk in PT4 applications. Alternatives (e.g., IPA, QACs, peracetic acids) pose higher risks: sensitisation, corrosiveness,

	formation of toxic by-products (e.g., chlorates), and environmental impact. Furthermore, many are classified for professional use only, limiting their applicability in the food industry. References: Kramer et al. (2024); ECHA; EFSA; AoA PT4
Information above is confidential	
Justification for confidentiality	
Availability	Ethanol is listed by over 735 suppliers on the ECHA Article 95 List. Its production is widespread in Europe (Germany, France, Poland, Italy). Alternatives are available in smaller quantities, with more fragile and often centralised supply chains. References: ECHA Art. 95; AoA PT4 (2025).
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol is irreplaceable in PT4: no alternative matches its combination of efficacy, safety, compatibility, cost-effectiveness, and availability. It is one of the few disinfectants authorised for use in food environments where rinsing and residue are not acceptable (ethanol is used at controlled concentrations, evaporates fully before consumption, and does not result in ingestible or systemically absorbable residues), as in the sanitisation of surfaces and packaging of ready-to-eat food. Some products, such as panettone and baked goods, use ethanol vapours to prevent mould growth without compromising edibility. Leading agencies (WHO, EFSA, EMA) agree that the risk is zero or negligible in the absence of systemic ingestion. None of the proposed alternatives (IPA, QACs, peracetic acids) are edible or approved for such applications: they leave toxic residues or by-products, require rinsing, and raise toxicological concerns in food contexts. Overall, alternatives present technical limitations, health risks, or disproportionate economic impacts. Ethanol's exclusion would harm the entire European food chain. References: Kramer et al. (2024) – PMC11367556; EFSA (2005, 2010) – opinions on ethanol as a food residue; WHO – Guidelines on Hand Hygiene; Analysis of Alternatives for the use of Ethanol in the Food and Feed Area (PT4), Alcohol Task Force (version 3.0, 2025), confirming the lack of technically and economically sustainable alternatives.

Information above is confidential	
Justification for confidentiality	
Other comments	Ethanol supports circular economy objectives, is biodegradable, and is also produced from renewable sources. Its efficacy against non-enveloped viruses is supported by standardised tests (EN 14476) and peer-reviewed publications. Removing ethanol from PT4 would undermine food safety and hygienic resilience in the agri-food sector. References: AoA PT4; WHO; Kampf et al. (2018); Kramer et al. (2022).
Information above is confidential	
Justification for confidentiality	
References	AoA PT4 (Alcohol Task Force, 2025); Kramer et al., Antimicrobial Resistance & Infection Control (2022); Kampf (2018), Journal of Hospital Infection; WHO; EN Standards (EN 1276, EN 14476); Petersen et al., Energy Conversion and Management, 2021; ECHA; EFSA; PMC11367556; EFSA (2005, 2010) – opinions on ethanol as a food residue; WHO – Guidelines on Hand Hygiene; Analysis of Alternatives for the use of Ethanol in the Food and Feed Area (PT4), Alcohol Task Force (version 3.0, 2025), confirming the lack of technically and economically sustainable alternatives.
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 24	2025/03/27 22:16
Country	Finland
Name of organization/institution	
I do not wish the name of my organisation/institution to be	

published on the ECHA website.	
General information	If ethanol were reclassified, it could encourage the use of alternative disinfectants with zero reprotoxic profiles (e.g., hypochlorous acid (HOCl)). In addition to ethanol's potential reprotoxic effects via dermal absorption and inhalation, its efficacy as a disinfectant is compromised by emerging bacterial tolerance and its inability to kill spores.
Product Type	1,2,4
Alternative Identity and Properties	Ethanol's identity as a small, volatile, and lipophilic molecule enables it to penetrate human skin, particularly during frequent hand disinfection. A study by Kramer et al. (2004) in Journal of Hospital Infection demonstrated that repeated application of ethanol-based hand rubs (e.g., 62-85% concentration) results in detectable blood ethanol levels, peaking around 1.2-3.8 mg/L after 30 minutes in worst-case scenarios (e.g., 20 applications over 10 minutes). An alternative is HOCl: HOCl's identity as a strong oxidizer enables it to kill bacteria, viruses, fungi, and spores effectively. A study by Block et al. (2010) in American Journal of Infection Control demonstrated that HOCl at 200 ppm achieves a smaller than 5-log reduction in Clostridium difficile spores within 10 minutes, a capability ethanol lacks (Kampf & Hollingsworth, 2003). This property makes HOCl highly suitable for PT1 use in high-risk settings like healthcare, where spore-forming pathogens threaten hygiene.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Ethanol's technical feasibility for PT1 applications is well-established due to its straightforward production and application, yet it faces emerging challenges. Industrially, ethanol is produced via fermentation of sugars or hydration of ethylene, yielding high-purity solutions (60-95%). Its volatility ensures rapid drying on skin, a practical advantage, and its compatibility with existing manufacturing and dispensing systems supports widespread use. However, technical drawbacks include its inability to kill spores. Ethanol's flammability (flash point ~13°C) also demands stringent storage and transport controls, adding logistical burdens that challenge its long-term practicality. HOCl can be produced via electrolysis of saline solutions or chemical neutralization of chlorine with water, yielding concentrations

	(50-500 ppm) suitable for skin use, as described by Wang et al. (2007) in Journal of Hospital Infection. Its broad-spectrum efficacy, including sporicidal activity (Block et al., 2010), reduces the need for co-formulants, simplifying aspects of use compared to ethanol.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Ethanol's economic feasibility for PT1 applications benefits from its mature, large-scale production infrastructure and low raw material costs, though certain factors erode its cost-effectiveness. However, economic drawbacks include flammability-related transport and storage costs (e.g., hazmat compliance), and the need for supplementary disinfectants due to inefficacy against spores (Kampf & Hollingsworth, 2003) or rising bacterial tolerance (Pidot et al., 2018). HOCl's lack of reprotoxic concerns and lower environmental disposal costs will yield long-term savings when ethanol hopefully faces stricter regulation, making it economically competitive with innovation and scale.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	HOCl's strong oxidizing nature, which underpins its antimicrobial efficacy (Block et al., 2010), poses none hazard to human tissues at lower concentrations and 500 ppm are generally well-tolerated (Rossi-Fedele et al., 2011). Compared to ethanol, HOCl presents very few reprotoxic hazards (no acetaldehyde formation) and lower systemic absorption risks. Ethanol's hazards—skin barrier disruption (Löffler et al., 2007), inhalation of volatile ethanol (Arndt et al., 2012), and potential reproductive harm—stem from chronic exposure and metabolic byproducts, while HOCl's risks are more immediate if any (light irritation, or decomposition) and tied to formulation control. Ethanol's flammability contrasts with HOCl's corrosivity, and both carry environmental considerations, though HOCl's are less persistent. For PT1 use, HOCl's hazards are close to zero, offering a safer toxicological profile if hopefully ethanol's reprotoxic classification escalates.
Information above is confidential	

Justification for confidentiality	
Availability	No problem.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Hypochlorous acid (HOCl) emerges as a highly suitable alternative to ethanol for PT1 human hygiene applications, offering superior antimicrobial efficacy, including sporicidal activity, and a safer toxicological profile with no clear reprotoxic concerns. Its broad-spectrum performance (Block et al., 2010) and low resistance potential (McKenna & Davies, 1988) address ethanol's limitations—inefficacy against spores (Kampf & Hollingsworth, 2003) and emerging bacterial tolerance (Pidot et al., 2018)—making it ideal for critical hygiene settings like healthcare. HOCl's skin compatibility (Rossi-Fedele et al., 2011) further enhances its suitability over ethanol's barrier-disrupting effects (Löffler et al., 2007). Availability is promising, with production via electrolysis or chemical synthesis scalable through existing technologies (e.g., on-site generators). While ethanol benefits from entrenched supply chains, HOCl's commercial presence is growing, and its availability could expand rapidly if regulatory pressures on ethanol increase. Despite formulation and cost challenges, HOCl's overall profile supports its adoption as a viable, safer substitute under the BPR, contingent on technical and economic optimization.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	

Justification for confidential attachment	

Comment 25	2025/03/28 10:20
Country	Germany
Name of organization/institution	Südzucker AG
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Die Einstufung von Ethanol als krebserregend oder fortpflanzungsgefährdend könnte dazu führen, dass viele Biozidprodukte in Zukunft ihre Zulassung verlieren. Einige kritische Anwendungsfälle werden im Folgenden beschrieben. Wir sehen daher die Notwendigkeit, ethanolbasierte Desinfektionsmittel auf dem Markt zu halten. Ethanol wird als Wirkstoff in vielen Desinfektionsmitteln für die Verwendung in unserer Produktion von Lebens- und Futtermitteln verwendet, um sichere Produkte zu gewährleisten (PT2 und PT4). Darüber hinaus werden ethanolhaltige Biozidprodukte von Mitarbeitern in Verarbeitungsbetrieben als Händedesinfektionsmittel verwendet, um eine Kontamination von Lebens- und Futtermitteln zu verhindern und die Betriebshygiene zu gewährleisten (PT 1). Eine gute Hygiene am Arbeitsplatz ist unerlässlich, insbesondere während Pandemien, um Mitarbeiter kritischer Infrastrukturen vor unbehüllten Viren zu schützen. Der Fall der Covid-19-Pandemie hat gezeigt, dass ethanolbasierte Desinfektionsmittel für das Überleben kritischer Infrastrukturen notwendig sind. Ethanol wird nicht nur als Wirkstoff in Biozidprodukten verwendet, sondern auch als Lösungsmittel in anderen Biozidprodukten, z. B. in Repellentien. Diese sind für unsere Lebensmittelsicherheit wichtig, um sichere Produkte zu gewährleisten. Infolgedessen könnte eine große Anzahl von Biozidprodukten von einer Einstufung betroffen sein und infolgedessen ihre Zulassung verlieren.
Product Type	1,2,4
Alternative Identity and Properties	Iso-Propanol, n-Propanol, Wasserstoffperoxid, Peressigsäure

Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Die meisten Alternativen können nicht verwendet werden, da sie keine Zulassungen für den Herstellungsprozess von Lebens-/Futtermitteln haben (siehe europäische und nationale Vorschriften und Bestimmungen für Lebens-/Futtermittel). In den meisten Fällen werden nicht entfernbare Rückstände durch die Verwendung alternativer Desinfektionsmittel verursacht was die Herstellung sicherer Lebensmittel nicht ermöglicht.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Um alternative Biozidprodukte (ohne Ethanol) verwenden zu können, müssten die Produktionsprozesse neu organisiert und die Anlagen umgerüstet werden. Eine Einstufung als CMR wird wahrscheinlich entweder zu einem vollständigen Verbot von Biozidprodukten mit Ethanol führen. Da es weniger Unternehmen gibt, die Desinfektionsmittel mit Alternativen zu Ethanol anbieten, befürchten wir eine anschließende Verknappung der Verfügbarkeit und folgende eine Preiserhöhung auf dem Markt für Desinfektionsmittel. Ethanol ist im Vergleich zu anderen Wirkstoffen vergleichsweise günstig, allgemein verfügbar, einfach und schnell herzustellen, was eine konstante Versorgung gewährleistet, umweltfreundlich und nachhaltig ist.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	In den meisten Fällen werden nicht entfernbare Rückstände durch die Verwendung alternativer Desinfektionsmittel verursacht. Die alkoholischen Alternativen Propan-1-ol und Propan-2-ol weisen keine vollständige viruzide Wirkung auf. Andere desinfizierende Wirkstoffe (Wasserstoffperoxid, Peressigsäure) sind nicht hautfreundlich oder wirken nicht schnell genug innerhalb von Sekunden, oder sie verdunsten nicht, oder sie kleben auf der Haut oder geben einen Geruch ab (nicht in Lebensmitteln möglich).
Information above is confidential	

Justification for confidentiality	
Availability	Eine Einstufung als CMR wird wahrscheinlich entweder zu einem vollständigen Verbot von Biozidprodukten mit Ethanol führen. Außerdem wird die Diskussion zu Bedenken bei den Kunden und damit zu einer mangelnden Akzeptanz von Biozidprodukten auf Ethanolbasis führen was die Hertseller zu einer Umstellung auf alternative Produkte veranlassen wird. Die Erhöhung der Produktionskapazitäten für alternative Desinfektionsmitteln ist mit enormen Aufwänden und damit Kosten verbunden: Neue Anlagen, neue Technologien, neue Produktionsgenehmigungen und Hürden durch Behörden und Nichtregierungsorganisationen. Diese Aufwände werden vermutlich zu Engpässen auf dem Markt für Desinfektionsmitteln führen und ggf. auch zu Kostenerhöhungen. Da es immer weniger Unternehmen gibt, die sichere und nachhaltige Desinfektionsmittel mit Alternativen zu Ethanol anbieten, befürchten wir eine daraus resultierende Verknappung der Verfügbarkeit auf dem Markt.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Als Substitutionskandidat wird Ethanol nicht mehr für die Allgemeinheit verfügbar sein. Die Folgen eines Verbots von Ethanol wären äußerst schwerwiegend. Insbesondere im Falle von Ausbrüchen und Pandemien mit unbehüllten Viren würde das Fehlen von Desinfektionsmitteln auf der Basis dieses potenten und gut verträglichen Kernwirkstoffs die Sicherheit der Lebensmittelproduktion, der Arbeitnehmer und der Allgemeinheit gefährden. Es gibt keinen bioziden Wirkstoff, der einen gleichwertigen Ersatz für Ethanol darstellt und eine ebenso hohe Wirksamkeit gegen unbehüllte Viren und in der Lebens-/Futtermittelproduktion aufweist. Im Falle eines Ausbruchs einer Krankheit, die durch ein unbehülltes Virus verursacht wird (siehe Covid-19), ist es nicht möglich, diese ohne Ethanol zu bekämpfen.
Information above is confidential	
Justification for confidentiality	
Other comments	Studien zur Verwendung von Ethanol zeigen, dass Ethanol schnell von der Haut verdunstet. Die Aufnahme über die Haut ist gering. Das Einatmen am Arbeitsplatz führt nicht zu einem signifikanten Anstieg der Ethanolkonzentration im

	Blut. Die atmosphärische Ethanolkonzentration an Arbeitsplätzen, an denen es verwendet wird, liegt in der Regel weit unter (6- bis 20-mal) den nationalen Arbeitsplatzgrenzwerten über einen Zeitraum von acht Stunden. Siehe Bessonneau V, Clement M, Thomas O. Kann die intensive Verwendung von alkoholbasierten Handdesinfektionsmitteln zu einer passiven Alkoholisierung führen? Internationale Zeitschrift für Umweltforschung und öffentliche Gesundheit 2010; 7: 3038-50. Die Kombination aller substanzinhärenten Eigenschaften ist nur bei Ethanol gegeben: schnell wirkend, vollständig viruzid, keine Rückstände, schnelle Verdunstung, lange Haltbarkeit, keine Übertragung auf oder Verunreinigung von Lebensmitteln, geruchlos, keine Desinfektionsnebenprodukte oder (öko-)toxikologisch relevante Abbauprodukte. Am wichtigsten ist, dass Ethanol im Vergleich zu allen anderen möglichen Alternativen nicht gegen unbehüllte Viren wirkt. Das bedeutet, dass es nicht möglich ist, die Ausbreitung von Krankheiten durch unbehüllte Viren wie Polio, Noro usw. zu verhindern. Siehe WHO-Kernliste 15.1 und 15.2: Web-Anhang A. Modellliste der unentbehrlichen Arzneimittel der Weltgesundheitsorganisation – 23. Liste, 2023. In: Die Auswahl und Verwendung von unentbehrlichen Arzneimitteln 2023: Zusammenfassung des Berichts des 24. WHO-Sachverständigenausschusses für die Auswahl und Verwendung von unentbehrlichen Arzneimitteln, 24. bis 28. April 2023. Genf: Weltgesundheitsorganisation; 2023 (WHO/MHP/HPS/EML/2023.02). Zusammenhang zwischen dem Biozidverfahren und anderen Sektoren: Die Bewertung der CMR-Endpunkte und eine anschließende Entscheidung der Europäischen Kommission über diese Endpunkte würden zu einer offiziellen Erklärung über die CMR-Eigenschaften von Ethanol für biozide Verwendungszwecke führen. Diese verfügbaren Informationen müssten von allen Anwendern von Ethanol bei ihrer Selbsteinstufung berücksichtigt werden. Somit würde eine Einstufung innerhalb des Biozidsektors auf alle Sektoren übertragen werden. Darüber hinaus könnte diese offizielle Position zu den CMR-Eigenschaften den Meinungsbildungsprozess anderer CLP-Ausschüsse beeinflussen und sich somit auf den derzeit laufenden harmonisierten Klassifizierungsprozess auswirken. Ein Beispiel: Die Richtlinien zum Schutz der Gesundheit und Sicherheit von Arbeitnehmern, einschließlich der Richtlinie über schwangere Arbeitnehmerinnen, schreiben vor, dass Arbeitgeber alle Risiken im Zusammenhang mit der Sicherheit und Gesundheit von Arbeitnehmern (Schwangere, Stillende, Jugendliche) bewerten und entscheiden müssen, welche Präventiv- und Schutzmaßnahmen ergriffen werden sollten. Eine Maßnahme könnte ein Verbot der Verwendung

	von Ethanol, das als krebserzeugend oder fortpflanzungsgefährdend eingestuft ist, für schwangere, stillende oder jugendliche Arbeitnehmer sein.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 26	2025/03/28 10:35
Country	Poland
Name of organization/institution	Südzucker Polska
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Klasyfikacja etanolu jako substancji rakotwórczej lub działającej szkodliwie na rozrodczość może oznaczać, że wiele produktów biobójczych może w przyszłości utracić pozwolenie na dopuszczenie do obrotu. Poniżej opisano niektóre krytyczne przypadki użycia. Dlatego widzimy potrzebę utrzymania na rynku środków dezynfekujących na bazie etanolu. Etanol jest stosowany jako substancja czynna w wielu środkach dezynfekujących do stosowania w naszej produkcji żywności i pasz w celu zapewnienia bezpiecznych produktów (PT4). Ponadto produkty biobójcze zawierające etanol są stosowane jako środek do dezynfekcji rąk przez personel w zakładach przetwórczych, aby zapobiec zanieczyszczeniu żywności i pasz oraz zapewnić higienę korporacyjną (PT 1). Właściwa higiena w miejscu pracy jest niezbędna, zwłaszcza podczas pandemii, aby chronić pracowników infrastruktury krytycznej przed nierozwiniętymi wirusami. Przypadek pandemii Covid-19

	wykazał konieczność stosowania środków dezynfekujących na bazie etanolu w celu przetrwania infrastruktury krytycznej. Etanol jest stosowany nie tylko jako substancja czynna w produktach biobójczych, ale także jako rozpuszczalnik w innych produktach biobójczych, np. w repelentach. Są one ważne dla naszego bezpieczeństwa żywności w celu zapewnienia bezpiecznych produktów. W rezultacie klasyfikacja może mieć wpływ na dużą liczbę produktów biobójczych i w konsekwencji utracić pozwolenie.
Product Type	1,2,4
Alternative Identity and Properties	Izopropanol, n-propanol, nadtlenuk wodoru, kwas nadoctowy
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Większość środków alternatywnych nie może być stosowana, ponieważ nie posiadają one zatwierdzeń dla procesu produkcji żywności/paszy (patrz europejskie i krajowe przepisy i regulacje dotyczące żywności/paszy). W większości przypadków nieusuwalne pozostałości są spowodowane użyciem alternatywnych środków dezynfekujących.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	W celu stosowania alternatywnych produktów biobójczych (bez etanolu), procesy produkcyjne musiałyby zostać zreorganizowane, a zakłady musiałyby zostać zmodernizowane. Klasyfikacja jako CMR prawdopodobnie doprowadzi do całkowitego zakazu stosowania produktów biobójczych zawierających etanol. Ponieważ istnieje mniej firm dostarczających środki dezynfekujące alternatywne dla etanolu, obawiamy się kolejnych niedoborów i wzrostu cen na rynku. Etanol jest stosunkowo tani w porównaniu z innymi substancjami czynnymi, ogólnie dostępny, łatwy i szybki w produkcji, zapewniający stałe dostawy, ekologiczny i zrównoważony.
Information above is confidential	
Justification for confidentiality	

Hazards and Risks of the Alternative	W większości przypadków stosowanie alternatywnych środków dezynfekujących powoduje powstawanie nieusuwalnych pozostałości. Alternatywy alkoholowe 1-Propan-ol i 2-Propan-ol nie mają pełnej aktywności wirusobójczej. Inne aktywne substancje dezynfekujące (nadtlenek wodoru, kwas nadoctowy) nie są przyjazne dla skóry lub nie działają wystarczająco szybko w ciągu kilku sekund, lub nie odparowują, lub przyklejają się do skóry lub wydzielają dziwny zapach (żywność).
Information above is confidential	
Justification for confidentiality	
Availability	Klasyfikacja jako CMR prawdopodobnie doprowadzi do całkowitego zakazu stosowania produktów biobójczych zawierających etanol. Zwiększenie alternatywnych zdolności produkcyjnych wiąże się z ogromnymi kosztami: Nowe obiekty, nowe technologie, nowe pozwolenia na produkcję i przeszkody ze strony władz i organizacji pozarządowych. Ponieważ istnieje mniej firm dostarczających bezpieczne i zrównoważone środki dezynfekujące alternatywne do etanolu, obawiamy się następujących niedoborów w dostępności na rynku.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Etanol jako kandydat do zastąpienia nie będzie już dostępny do powszechnego użytku. Konsekwencje zakazu stosowania etanolu będą niezwykle poważne. Szczególnie w przypadku wybuchów epidemii i pandemii z nierozwiniętymi wirusami, brak środków dezynfekujących do rąk opartych na tej silnej i dobrze tolerowanej podstawowej substancji czynnej zagrazi bezpieczeństwu produkcji żywności, pracowników i ogółu społeczeństwa. Nie istnieje zastępcza biobójcza substancja czynna o takiej samej skuteczności przeciwko nierozwiniętym wirusom w produkcji żywności/pasz. W przypadku wybuchu choroby wywołanej przez wirusy bezotoczkowe (patrz Covid-19), nie jest możliwe zwalczanie ich bez etanolu.
Information above is confidential	
Justification for confidentiality	

Other comments	Badania dotyczące stosowania etanolu pokazują, że etanol szybko odparowuje ze skóry. Wchłanianie przez skórę jest niskie. Wdychanie w miejscu pracy nie prowadzi do znaczącego wzrostu stężenia etanolu we krwi. Stężenia etanolu w atmosferze w miejscach pracy, w których jest on stosowany, są na ogół znacznie niższe (od 6 do 20 razy) od krajowych limitów narażenia zawodowego w okresie ośmiu godzin. Zob. Bessonneau V, Clement M, Thomas O. Czy intensywne stosowanie środków do pocierania rąk na bazie alkoholu może prowadzić do biernej alkoholizacji? International Journal of Environmental Research and Public Health 2010; 7: 3038-50. Połączenie wszystkich nieodłącznych właściwości substancji zapewnia tylko etanol: szybkie działanie, pełna wirusobójczość, brak pozostałości, szybkie odparowanie, długi czas przechowywania, brak przenoszenia na żywność lub jej skażenia, bezwonny, brak produktów ubocznych dezynfekcji lub (eko-) toksykologicznie istotnych produktów degradacji. Najważniejszy jest brak skuteczności wszystkich możliwych alternatyw etanolu wobec wirusów bez otoczki. Oznacza to, że nie jest możliwe zapobieganie rozprzestrzenianiu się chorób wywoływanych przez wirusy bezotoczkowe, takie jak Polio, Noro itp. Patrz lista podstawowa WHO 15.1 i 15.2: Załącznik internetowy A. Wzorcowy wykaz podstawowych leków Światowej Organizacji Zdrowia - lista 23, 2023. W: Wybór i stosowanie podstawowych leków 2023: Streszczenie raportu 24. Komitetu Ekspertów WHO ds. Wyboru i Stosowania Podstawowych Leków, 24-28 kwietnia 2023 r. Genewa: Światowa Organizacja Zdrowia; 2023 (WHO/MHP/HPS/EML/2023.02). Związek między procesem biobójczym a innymi sektorami: Ocena punktów końcowych CMR i późniejsza decyzja Komisji Europejskiej w sprawie tych punktów końcowych skutkowałaby oficjalnym oświadczeniem w sprawie właściwości CMR etanolu do zastosowań biobójczych. Te dostępne informacje będą musiały zostać uwzględnione przez wszystkich użytkowników etanolu podczas ich samodzielnej klasyfikacji. W ten sposób klasyfikacja w sektorze produktów biobójczych zostałaby przeniesiona na wszystkie sektory. Ponadto to oficjalne stanowisko w sprawie właściwości CMR mogłoby wpłynąć na proces kształtowania opinii innych komitetów CLP, a tym samym wpłynąć na trwający obecnie zharmonizowany proces klasyfikacji. Na przykład dyrektywy dotyczące zdrowia i bezpieczeństwa pracowników, w tym dyrektywa w sprawie pracownic w ciąży, stanowią, że pracodawcy powinni oceniać wszystkie zagrożenia związane z bezpieczeństwem i zdrowiem pracowników (w ciąży, karmiących piersią, nastolatków) i decydować, jakie środki zapobiegawcze i ochronne należy podjąć. Jednym ze

	środków może być zakaz stosowania przez pracownice (w ciąży, karmiące piersią, nastolatki) etanolu sklasyfikowanego jako rakotwórczy lub działający szkodliwie na rozrodczość.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 27	2025/03/28 11:54
Country	Germany
Name of organization/institution	Food Federation Germany (Lebensmittelverband Deutschland e.V.
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	In the food sector, ethanol is a natural compound of various foodstuffs, it is deliberately added to certain foods, it is used as a functional compound in food and food production - and it is used for disinfection purposes. With regard to disinfection, ethanol is used for the disinfection of surfaces and equipment (PT 4) and for personal hygiene (hand rubs; PT 1). Hand rubs with ethanol are not only used by the food processing industry, but in the whole food chain. This comprises the restaurant and catering sector, retails and shops where food is marketed, craft production and primary producers of food. Ethanol as an ingredient, food additive, food flavouring (aromes) or functional substance in food and food production is covered by the European (and national) food legislation, its horizontal and specific regulations and its general and specific provisions. So far, there are no restrictions for the use of ethanol in food and food

	production. For oral consumption, ethanol always must be undenatured. In case that ethanol is used for disinfection purposes, it is always denatured. This is also true for hand rubs/disinfectants PT 1. Although the denaturation is originally done for customs reasons, it prevents humans to drink denatured ethanol. Oral consumption of disinfectants with ethanol is not feasible therefore.
Product Type	1,2,4
Alternative Identity and Properties	Iso-propanol (2-propanol) and 1-propanol Also mentioned were: quarternary ammonium compounds (QAV) Active substances in hand rubs can also be a mixture of ethanol with propanols. As hand rubs resp. hands after application of a hand rub can contaminate food during its production or preparation, the question of residues of disinfectants in food is also relevant for hand rubs. This is especially true for QAVs (and propanols). For this reason, hand rubs with ethanol are the preferred option in the food sector. Ethanol evaporates quickly and even if traces remain on hands or are transferred to the food, they were not considered relevant given that ethanol is also naturally occurring in food.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	The use of hand rubs with active substances other than ethanol is feasible from a technical point of view. However, in situations where a contamination of food via hand rubs might occur, other active substances than ethanol are no suitable alternative. In case that hand rubs with ethanol are used, it is deemed not necessary to use protective gloves in food production.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Hand rubs with ethanol are widely used in the food sector. Disinfectants with other alcohols than ethanol are more expensive. Ethanol can be produced in big amounts which lowers its price. In food production processes where ethanol is removed from the product (e.g. production of alcohol-free beer and wine) or is formed as a by-product, the released ethanol can be sold by the FBO, mainly to manufacturers of disinfectants with ethanol.

Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Personal hygiene is of utmost importance in food production as well as in food preparation, like e.g. in the restaurants and catering sector. Hand rubs are essential tools to guarantee personal hygiene and to avoid that pathogens and other microorganisms contaminate food. Ethanol is the only active substance in hand rubs that is fully effective against non-enveloped viruses. Propanols are not/less effective against several important human pathogens like norovirus, hepatitis viruses and rhinoviruses. So far, ethanol is perceived as active substance in hand rubs having the lowest risks for all kind of users. In general, the main risks with ethanol are associated with the misuse of drinking too much alcohol/alcoholic beverages. However, when it comes to disinfectants of PT 1, ethanol is denatured. That is, oral consumption is not possible. The relevant routes of exposure for ethanol as disinfectant are dermal uptake and inhalation only.
Information above is confidential	
Justification for confidentiality	
Availability	Propanols and QAVs can only be produced in smaller amounts than ethanol. Ethanol is mainly produced from agricultural crops, propanols and QAVs are produced by chemical industry. As the Corona pandemic has shown, production of ethanol can easily be raised at short time. This is unique for active substances in disinfectants.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Hand rubs with ethanol are widely used in the whole food sector/food chain. Hand rubs are not only used by professionals in the food sector, but also by staff working in pubs, shops etc. Personal hygiene is of utmost importance in food production and in the preparation of food. Hand rubs are essential tools to guarantee personal hygiene in the whole food chain and avoid that pathogens and other microorganisms contaminate food. Possible alternatives for ethanol in hand rubs are propanols and QAVs. However, hand rubs resp. hands after application of a hand rub can

	contaminate food during the production or preparation which is undesirable in the food sector. Hand rubs with ethanol are the preferred option in the food sector therefore. Also, ethanol is the only active substance in hand rubs that is fully effective against non-enveloped viruses. Risks with ethanol are mainly associated with drinking too much alcohol/alcoholic beverages. In disinfectants, the ethanol used is denatured. That is, oral consumption is not feasible. It is proposed therefore to do the evaluation under the BPR resp. the chemical legislation for “ethanol, denatured” instead of “ethanol”. This would lead to a more realistic scenario and evaluation for “ethanol” used as active substance in disinfectants.
Information above is confidential	
Justification for confidentiality	
Other comments	In disinfectants, only denatured ethanol is used. Undenatured and denatured ethanol are traded separately due to customs reasons. It is proposed to do the evaluation for “ethanol, denatured” instead of “ethanol”, when ethanol is evaluated under the chemical legislation, here the Biocidal Products Regulation. This would lead to a more realistic scenario and evaluation of ethanol used as active substance in disinfectants.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	Ethanol_BLL statement 2015_Food Federation Germany_english_2024.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 28	2025/03/28 12:40
Country	Germany

Name of organization/institution	[REDACTED]
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	As a Medical device manufacturer we have a registration for a medicines with Ethanol as ingredient. We also have drug approvals in which we use plant-based active ingredients whose extracting agent is ethanol.
Product Type	1,2,4
Alternative Identity and Properties	As the recepies are fixed within the registration by the competent authority there is no alternative.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	[REDACTED]
Information above is confidential	[REDACTED]
Justification for confidentiality	[REDACTED]
Economic Feasibility	[REDACTED]
Information above is confidential	[REDACTED]
Justification for confidentiality	[REDACTED]
Hazards and Risks of the Alternative	None, there is no alternative

Information above is confidential	
Justification for confidentiality	
Availability	n/a
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	There is no alternative to ethanol, as traditional medicines/traditionell registrations can not be changed by law.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 29	2025/03/28 14:29
Country	Spain
Name of organization/institution	
I do not wish the name of my organisation/institution to be	

published on the ECHA website.	
General information	
Product Type	1,2,4
Alternative Identity and Properties	Riesgos de las alternativas
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Técnicamente no hay sustituto tan eficaz, medioambientalmente es el más sostenible.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Desde el punto de vista económico, es el más económico frente a acción y espectro desinfectante que cubre. Como disolvente en perfumería es el más idóneo, en cuanto a su inocuidad y eficacia.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Las alternativas son más tóxicas, se dispone de menos accesibilidad de suministro.
Information above is confidential	
Justification for confidentiality	
Availability	El alcohol etílico tiene más disponibilidad que el resto de las alternativas, menos eficaces.
Information above is confidential	
Justification for confidentiality	

Conclusion on suitability and availability of the alternative	Es una materia prima ampliamente usada desde hace muchos años en la industria, muy segura, eficaz en situaciones de pandemia, de fácil accesibilidad y con gran disponibilidad.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 30	2025/03/31 12:40
Country	Germany
Name of organization/institution	CG Chemikaliengesellschaft mbH & Co. KG
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	We sell denatured Ethanol as a disinfection product. High demand during pandemic situations. Denatured Ethanol is also used for technical applications e.g. windshield washer fluid in Automotive industry worldwide.
Product Type	1,2,4
Alternative Identity and Properties	

Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Disinfection with high performance. Misuse is avoided by denaturation.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Ethanol is available from renewable sources.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	For specific species other alcoholic disinfections are not as effective as ethanol.
Information above is confidential	
Justification for confidentiality	
Availability	In case of high demand (pandemic) all sources must be available
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	No alternative with comparative efficacy
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	

References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 31	2025/03/31 19:24
Country	France
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	

Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Laissez les modélistes utiliser de l'éthanol
Information above is confidential	
Justification for confidentiality	
Other comments	Avez vous pensé aux "aéromodélistes" qui ne pourront plus faire fonctionner les petits moteurs qui deviennent, comme des voitures anciennes, des "Classics" depuis l'arrivée des moteurs électriques. Personne n'est DCD à cause de ces moteurs qui ne pollueront jamais vraiment la planète compte tenu de leur très faible consommation. Ce serait dommage de ne plus voir ces bijoux de technologie et de miniaturisme fonctionner.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 32	2025/04/01 16:48
Country	Spain
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	

Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Nearly all fine fragrances use ethanol. There have been shifts to water based products but they are not easy to make and can throw up lots of issues with clarity and drop out. We are not aware of any other alternative to ethanol - the only one we can think of is IPA but this has a strong note and has its own limitations Ethanol is used in a lot of room sprays - aerosols and pump sprays, hand gels, reed diffusers, car Air Fresheners, metered Air Fresheners etc It is a very cheap easy solvent which fragrances are easily diluted in. It also has antibacterial properties, which once you remove this you are going to add in preservatives
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 33	2025/04/02 12:01
Country	Germany
Name of organization/institution	Industrieverband Körperpflege- und Waschmittel e.V. (IKW)
I do not wish the name of my organisation/institution to be published on the ECHA website.	

General information	The department for detergents of the German Cosmetic, Toiletry, Perfumery and Detergent Association, supports, advises and represents its more than 174 member companies, which are manufacturers or contract manufacturers of household care products, including vis-à-vis ministries, authorities and the media. The value of beauty and household care products sold in Germany totaled 22.6 billion euros in 2024, plus 12 billion euros from the export of these products.
Product Type	1,2,4
Alternative Identity and Properties	Ethanol is one of the most important industrial solvents due to its ability to dissolve both hydrophilic (water-soluble) and lipophilic (fat-soluble) substances. Further advantages of ethanol over other alcohols (e.g. 1- or 2-propanol) are - Established starting material for many applications: Ethanol has been used safely and effectively for decades in various technical applications with no evidence of risk to humans or the environment. The dermal or inhalative uptake (e.g. in the context of hand disinfection) is far below the toxicologically relevant concentrations. - Highly biodegradable: Ethanol is highly biodegradable and therefore does not accumulate in the environment in the long term. - Effective in disinfectants: In disinfectants, ethanol (e.g. for hand disinfection) is extremely important for effective antimicrobial, antifungal and antiviral use. The highest effectiveness is achieved with a mixture of 70 percent ethanol with water. The Robert Koch Institute classifies a mixture with 70 percent isopropanol used for hand disinfection as limited virucidal, i.e. it is only effective against enveloped viruses. Propanol is optimally effective against non-enveloped viruses, such as murine noroviruses, at a concentration of 80 percent, whereas 90 percent mixtures are no longer effective. - Low inherent odour. - Manufactured from renewable raw materials.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	- Fast volatility without residue: Due to its low molecular weight, ethanol volatilizes very quickly and dries without leaving any residue - an advantage, for example, in the rapid disinfection of surfaces. Isopropanol is similarly volatile. - Unrivalled virus effectiveness among alcohols: A unique selling point of ethanol is its effectiveness against non-enveloped viruses, which cannot be deactivated by other alcohols such as 1-propanol and 2-propanol, e.g.

	polioviruses, Coxsackieviruses, Echoviruses and Enterovirus A71. - Flexibility in application: Ethanol is very well suited for combination with other active ingredients such as acids and with excipients like glycerine. This means that appropriate formulations can increase the effectiveness and skin compatibility of hand sanitizers, for example. - High safety and tolerability: Inhalation or dermal absorption, e.g. during hand disinfection, is far below toxicologically relevant concentrations. Ethanol does not accumulate in the environment in the long term. - International relevance: Ethanol is used worldwide as an active ingredient in hand sanitizers. The WHO lists ethanol as an indispensable active ingredient for antiseptic applications.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	We demand: A sense of proportion in categorization - consideration of the actual risk. The harmful effects of ethanol when ingested (excessively) orally are undisputed. It has also been proven that ethanol has a teratogenic (fertility-damaging) effect on pregnant women and is carcinogenic when ingested orally above a certain threshold dose. It is therefore very likely that the CMR Cat. 1 (respectively Cat. 2) classification discussed in the biocide process will also have an impact on the update of the harmonized classification initiated in the CLH process. A CMR classification according to the CLP Regulation would be made irrespective of the actual exposure (dermal, inhalation), i.e. without considering the actual risk according to the intended use. Furthermore, denaturing of ethanol efficiently prevents unintentional oral intake. According to Dr Thorsten Reinecke, Head of the Department of Hazardous Substances and Biological Agents at the German Social Accident Insurance Institution for the construction industry (BG Bau), dermal exposure is also irrelevant. Ethanol is not a skin-resorptive substance, i.e. it cannot be absorbed through intact skin and cause damage to health: 'Ethanol is not a skin-resorptive substance. If substances have skin-resorptive properties, they can also be absorbed through intact skin due to their physico-chemical properties

	and cause damage to health. Skin-resorptive substances are labelled with 'H' in TRGS 900. This is not the case for ethanol. When handling ethanol, compliance with the OEL [occupational exposure limit value] is therefore sufficient to protect the health of employees.' The BG BAU has carried out numerous workplace measurements for activities involving cleaning agents containing ethanol, such as glass cleaners, in some cases under worst-case conditions. The OEL for ethanol was complied with in all measurements.'
Information above is confidential	
Justification for confidentiality	
Availability	Classification under the CLP Regulation would result in successive restrictions under the REACH Regulation for consumer products such as detergents and cleaning agents and would therefore result in a practical ban on such products. Manufacturers would be forced to change proven and efficient formulations. On the one hand, such recipe changes are associated with a disproportionately cost-intensive amount of work. On the other hand, there are very often no suitable substitutes for ethanol. Due to the aforementioned properties and good availability (e.g. compared to propanol), ethanol cannot be easily and broadly substituted. In view of this, ethanol would be subject to a ban on use in detergents and cleaning agents despite its excellent material properties (hydrophilic, lipophilic, highly biodegradable, can be obtained sustainably from renewable raw materials), regardless of its many years of safe use. It is therefore questionable what benefit the proposed categorization would have for human health or the environment. On the contrary, the use for hygienic aspects, especially as a disinfectant such as a biocidal product for hand disinfection, has long proven itself and would now be under threat. There would be negative consequences for human health, especially in the event of an emergency such as a pandemic caused, for example, by pathogens against which ethanol is effective, but not 1- or 2-propanol.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Active substances classified as candidates for substitution are authorized for a maximum of seven years, even in the event of an extension. If the active substance fulfills one or more exclusion criteria, it is only authorized for five years. If

	ethanol were to be classified as a candidate for substitution, a comparative assessment would have to be carried out at the time of authorization for biocidal products containing ethanol as an active substance. Authorization would only be granted for such biocidal products if no better alternatives were available. There are no alternatives available that fulfill comparable safety, efficacy and technical properties to ethanol.
Information above is confidential	
Justification for confidentiality	
Other comments	Due to the particular importance of ethanol as a substance for household care and as a biocidal active ingredient, a special sense of proportion and pragmatism is required in regulation. Before a CMR classification of ethanol, it must be checked - whether a harmonized classification of ethanol is necessary at all (based on Art. 36, 37(1) of the CLP Regulation), - what effort and costs would be involved, - what benefits such a classification would bring and what harm it would cause (i.e. holistic impact assessment). The actual routes of exposure (oral vs. inhalation) should be considered. The toxicological data mentioned are based on alcohol abuse, i.e. exclusively on oral intake. Thus, the available human data are not suitable for an adequate assessment, as the inhalation and dermal routes of exposure are not included. In the case of applications as detergents, cleaning agents or disinfectants, this route of exposure is irrelevant, and no risk results from these applications. The consequence would be a blanket ban on all cleaning agents containing ethanol. In addition, the socio-economic effects should be considered in the ongoing process. It is also evident that the automated linking of the classification according to the CLP Regulation and the associated regulations of the chemicals legislation (e.g., Biocidal Products Regulation, Detergents Regulation) does not serve the intended protection of human health and the environment.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	2025_04_02-Konsultation EtOH Attachment.pdf

Attachments (confidential information)	
Justification for confidential attachment	

Comment 34	2025/04/02 12:14
Country	Germany
Name of organization/institution	Industrieverband Körperpflege- und Waschmittel e. V.
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	The department for detergents of the German Cosmetic, Toiletry, Perfumery and Detergent Association, supports, advises and represents its more than 174 member companies, which are manufacturers or contract manufacturers of household care products, including vis-à-vis ministries, authorities and the media. The value of beauty and household care products sold in Germany totaled 22.6 billion euros in 2024, plus 12 billion euros from the export of these products.
Product Type	1,2,4
Alternative Identity and Properties	Ethanol is one of the most important industrial solvents due to its ability to dissolve both hydrophilic (water-soluble) and lipophilic (fat-soluble) substances. Further advantages of ethanol over other alcohols (e.g. 1- or 2-propanol) are - Established starting material for many applications: Ethanol has been used safely and effectively for decades in various technical applications with no evidence of risk to humans or the environment. The dermal or inhalative uptake (e.g. in the context of hand disinfection) is far below the toxicologically relevant concentrations. - Highly biodegradable: Ethanol is highly biodegradable and therefore does not accumulate in the environment in the long term. - Effective in disinfectants: In disinfectants, ethanol (e.g. for hand disinfection) is extremely important for effective antimicrobial, antifungal and antiviral use. The highest effectiveness is achieved with a mixture of 70 percent ethanol with water. The Robert Koch Institute classifies a mixture with 70 percent isopropanol used for

	hand disinfection as limited virucidal, i.e. it is only effective against enveloped viruses. Propanol is optimally effective against non-enveloped viruses, such as murine noroviruses, at a concentration of 80 percent, whereas 90 percent mixtures are no longer effective. - Low inherent odour. - Manufactured from renewable raw materials.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	- Fast volatility without residue: Due to its low molecular weight, ethanol volatilizes very quickly and dries without leaving any residue - an advantage, for example, in the rapid disinfection of surfaces. Isopropanol is similarly volatile. - Unrivalled virus effectiveness among alcohols: A unique selling point of ethanol is its effectiveness against non-enveloped viruses, which cannot be deactivated by other alcohols such as 1-propanol and 2-propanol, e.g. polioviruses, Coxsackieviruses, Echoviruses and Enterovirus A71. - Flexibility in application: Ethanol is very well suited for combination with other active ingredients such as acids and with excipients like glycerine. This means that appropriate formulations can increase the effectiveness and skin compatibility of hand sanitizers, for example. - High safety and tolerability: Inhalation or dermal absorption, e.g. during hand disinfection, is far below toxicologically relevant concentrations. Ethanol does not accumulate in the environment in the long term. - International relevance: Ethanol is used worldwide as an active ingredient in hand sanitizers. The WHO lists ethanol as an indispensable active ingredient for antiseptic applications.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	The harmful effects of ethanol when ingested (excessively) orally are undisputed. It has also been proven that ethanol has a teratogenic (fertility-damaging) effect on pregnant women and is carcinogenic when ingested orally above a

	certain threshold dose. It is therefore very likely that the CMR Cat. 1 (respectively Cat. 2) classification discussed in the biocide process will also have an impact on the update of the harmonized classification initiated in the CLH process. A CMR classification according to the CLP Regulation would be made irrespective of the actual exposure (dermal, inhalation), i.e. without considering the actual risk according to the intended use. Furthermore, denaturing of ethanol efficiently prevents unintentional oral intake. According to Dr Thorsten Reinecke, Head of the Department of Hazardous Substances and Biological Agents at the German Social Accident Insurance Institution for the construction industry (BG Bau), dermal exposure is also irrelevant. Ethanol is not a skin-resorptive substance, i.e. it cannot be absorbed through intact skin and cause damage to health: 'Ethanol is not a skin-resorptive substance. If substances have skin-resorptive properties, they can also be absorbed through intact skin due to their physico-chemical properties and cause damage to health. Skin-resorptive substances are labelled with 'H' in TRGS 900. This is not the case for ethanol. When handling ethanol, compliance with the OEL [occupational exposure limit value] is therefore sufficient to protect the health of employees.' The BG BAU has carried out numerous workplace measurements for activities involving cleaning agents containing ethanol, such as glass cleaners, in some cases under worst-case conditions. The OEL for ethanol was complied with in all measurements.'
Information above is confidential	
Justification for confidentiality	
Availability	Classification under the CLP Regulation would result in successive restrictions under the REACH Regulation for consumer products such as detergents and cleaning agents and would therefore result in a practical ban on such products. Manufacturers would be forced to change proven and efficient formulations. On the one hand, such recipe changes are associated with a disproportionately cost-intensive amount of work. On the other hand, there are very often no suitable substitutes for ethanol. Due to the aforementioned properties and good availability (e.g. compared to propanol), ethanol cannot be easily and broadly substituted. In view of this, ethanol would be subject to a ban on use in detergents and cleaning agents despite its excellent material properties (hydrophilic, lipophilic, highly biodegradable, can be obtained sustainably from renewable raw materials), regardless of its many years

	of safe use. It is therefore questionable what benefit the proposed categorization would have for human health or the environment. On the contrary, the use for hygienic aspects, especially as a disinfectant such as a biocidal product for hand disinfection, has long proven itself and would now be under threat. There would be negative consequences for human health, especially in the event of an emergency such as a pandemic caused, for example, by pathogens against which ethanol is effective, but not 1- or 2-propanol.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Active substances classified as candidates for substitution are authorized for a maximum of seven years, even in the event of an extension. If the active substance fulfills one or more exclusion criteria, it is only authorized for five years. If ethanol were to be classified as a candidate for substitution, a comparative assessment would have to be carried out at the time of authorization for biocidal products containing ethanol as an active substance. Authorization would only be granted for such biocidal products if no better alternatives were available. There are no alternatives available that fulfill comparable safety, efficacy and technical properties to ethanol.
Information above is confidential	
Justification for confidentiality	
Other comments	Due to the particular importance of ethanol as a substance for household care and as a biocidal active ingredient, a special sense of proportion and pragmatism is required in regulation. Before a CMR classification of ethanol, it must be checked - whether a harmonized classification of ethanol is necessary at all (based on Art. 36, 37(1) of the CLP Regulation), - what effort and costs would be involved, - what benefits such a classification would bring and what harm it would cause (i.e. holistic impact assessment). The actual routes of exposure (oral vs. inhalation) should be considered. The toxicological data mentioned are based on alcohol abuse, i.e. exclusively on oral intake. Thus, the available human data are not suitable for an adequate assessment, as the inhalation and dermal routes of exposure are not included. In the case of applications as detergents, cleaning agents or disinfectants, this route of exposure is irrelevant, and no risk results from these

	applications. The consequence would be a blanket ban on all cleaning agents containing ethanol. In addition, the socio-economic effects should be considered in the ongoing process. It is also evident that the automated linking of the classification according to the CLP Regulation and the associated regulations of the chemicals legislation (e.g., Biocidal Products Regulation, Detergents Regulation) does not serve the intended protection of human health and the environment.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	2025_04_02-Konsultation EtOH Attachment.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 35	2025/04/02 12:16
Country	Germany
Name of organization/institution	Industrieverband Körperpflege- und Waschmittel e. V.
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	The department for detergents of the German Cosmetic, Toiletry, Perfumery and Detergent Association, supports, advises and represents its more than 174 member companies, which are manufacturers or contract manufacturers of household care products, including vis-à-vis ministries, authorities and the media. The value of beauty and household care products sold in Germany totaled 22.6 billion euros in 2024, plus 12 billion euros from the export of these products. Ethanol is currently being evaluated as a biocidal active substance under the review program for existing active substances of the Biocidal

	Products Regulation (EU) No. 528/2012, led by the competent Greek authority. The Biocidal Products Committee (BPC) of the European Chemicals Agency (ECHA) is currently discussing a tightening of the classification of ethanol proposed by the Greek authority: carcinogenic, mutagenic, and toxic to reproduction, each in hazard category 1 (CMR Cat. 1). CMR substances in Cat. 1 are considered candidates for substitution and are subject to exclusion criteria according to Article 5 of the Biocidal Products Regulation. Active substances classified as candidates for substitution are authorized for a maximum of seven years, even in the event of an extension. If the active substance fulfills one or more exclusion criteria, it is only authorized for five years. The results of the evaluation for the approval of ethanol as a biocidal active substance will also impact the planned update of the harmonized classifications of ethanol according to the CLP Regulation (EC) No. 1272/2008. A harmonized classification as CMR Cat. 1 would have even more far-reaching consequences in chemical law: a practical ban on its use as an ingredient in detergents and many other products would be the consequence.
Product Type	1,2,4
Alternative Identity and Properties	Ethanol is one of the most important industrial solvents due to its ability to dissolve both hydrophilic (water-soluble) and lipophilic (fat-soluble) substances. Further advantages of ethanol over other alcohols (e.g. 1- or 2-propanol) are - - Established starting material for many applications: Ethanol has been used safely and effectively for decades in various technical applications with no evidence of risk to humans or the environment. The dermal or inhalative uptake (e.g. in the context of hand disinfection) is far below the toxicologically relevant concentrations. - Highly biodegradable: Ethanol is highly biodegradable and therefore does not accumulate in the environment in the long term. - Effective in disinfectants: In disinfectants, ethanol (e.g. for hand disinfection) is extremely important for effective antimicrobial, antifungal and antiviral use. The highest effectiveness is achieved with a mixture of 70 percent ethanol with water. The Robert Koch Institute classifies a mixture with 70 percent isopropanol used for hand disinfection as limited virucidal, i.e. it is only effective against enveloped viruses. Propanol is optimally effective against non-enveloped viruses, such as murine noroviruses, at a concentration of 80 percent, whereas 90 percent mixtures are no longer effective. - Low inherent odour. - Manufactured from renewable raw materials.

Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Fast volatility without residue: Due to its low molecular weight, ethanol volatilizes very quickly and dries without leaving any residue - an advantage, for example, in the rapid disinfection of surfaces. Isopropanol is similarly volatile. - Unrivalled virus effectiveness among alcohols: A unique selling point of ethanol is its effectiveness against non-enveloped viruses, which cannot be deactivated by other alcohols such as 1-propanol and 2-propanol, e.g. polioviruses, Coxsackieviruses, Echoviruses and Enterovirus A71. - Flexibility in application: Ethanol is very well suited for combination with other active ingredients such as acids and with excipients like glycerine. This means that appropriate formulations can increase the effectiveness and skin compatibility of hand sanitizers, for example. - High safety and tolerability: Inhalation or dermal absorption, e.g. during hand disinfection, is far below toxicologically relevant concentrations. Ethanol does not accumulate in the environment in the long term. - International relevance: Ethanol is used worldwide as an active ingredient in hand sanitizers. The WHO lists ethanol as an indispensable active ingredient for antiseptic applications.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	The harmful effects of ethanol when ingested (excessively) orally are undisputed. It has also been proven that ethanol has a teratogenic (fertility-damaging) effect on pregnant women and is carcinogenic when ingested orally above a certain threshold dose. It is therefore very likely that the CMR Cat. 1 (respectively Cat. 2) classification discussed in the biocide process will also have an impact on the update of the harmonized classification initiated in the CLH process. A CMR classification according to the CLP Regulation would be made irrespective of the actual exposure (dermal, inhalation), i.e. without considering the actual risk according

	to the intended use. Furthermore, denaturing of ethanol efficiently prevents unintentional oral intake. According to Dr Thorsten Reinecke, Head of the Department of Hazardous Substances and Biological Agents at the German Social Accident Insurance Institution for the construction industry (BG Bau), dermal exposure is also irrelevant. Ethanol is not a skin-resorptive substance, i.e. it cannot be absorbed through intact skin and cause damage to health: 'Ethanol is not a skin-resorptive substance. If substances have skin-resorptive properties, they can also be absorbed through intact skin due to their physico-chemical properties and cause damage to health. Skin-resorptive substances are labelled with 'H' in TRGS 900. This is not the case for ethanol. When handling ethanol, compliance with the OEL [occupational exposure limit value] is therefore sufficient to protect the health of employees.' The BG BAU has carried out numerous workplace measurements for activities involving cleaning agents containing ethanol, such as glass cleaners, in some cases under worst-case conditions. The OEL for ethanol was complied with in all measurements.'
Information above is confidential	
Justification for confidentiality	
Availability	Classification under the CLP Regulation would result in successive restrictions under the REACH Regulation for consumer products such as detergents and cleaning agents and would therefore result in a practical ban on such products. Manufacturers would be forced to change proven and efficient formulations. On the one hand, such recipe changes are associated with a disproportionately cost-intensive amount of work. On the other hand, there are very often no suitable substitutes for ethanol. Due to the aforementioned properties and good availability (e.g. compared to propanol), ethanol cannot be easily and broadly substituted. In view of this, ethanol would be subject to a ban on use in detergents and cleaning agents despite its excellent material properties (hydrophilic, lipophilic, highly biodegradable, can be obtained sustainably from renewable raw materials), regardless of its many years of safe use. It is therefore questionable what benefit the proposed categorization would have for human health or the environment. On the contrary, the use for hygienic aspects, especially as a disinfectant such as a biocidal product for hand disinfection, has long proven itself and would now be under threat. There would be negative consequences for human health, especially in the event of an emergency such

	as a pandemic caused, for example, by pathogens against which ethanol is effective, but not 1- or 2-propanol.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Active substances classified as candidates for substitution are authorized for a maximum of seven years, even in the event of an extension. If the active substance fulfills one or more exclusion criteria, it is only authorized for five years. If ethanol were to be classified as a candidate for substitution, a comparative assessment would have to be carried out at the time of authorization for biocidal products containing ethanol as an active substance. Authorization would only be granted for such biocidal products if no better alternatives were available. There are no alternatives available that fulfill comparable safety, efficacy and technical properties to ethanol.
Information above is confidential	
Justification for confidentiality	
Other comments	Due to the particular importance of ethanol as a substance for household care and as a biocidal active ingredient, a special sense of proportion and pragmatism is required in regulation. Before a CMR classification of ethanol, it must be checked - whether a harmonized classification of ethanol is necessary at all (based on Art. 36, 37(1) of the CLP Regulation), - what effort and costs would be involved, - what benefits such a classification would bring and what harm it would cause (i.e. holistic impact assessment). The actual routes of exposure (oral vs. inhalation) should be considered. The toxicological data mentioned are based on alcohol abuse, i.e. exclusively on oral intake. Thus, the available human data are not suitable for an adequate assessment, as the inhalation and dermal routes of exposure are not included. In the case of applications as detergents, cleaning agents or disinfectants, this route of exposure is irrelevant, and no risk results from these applications. The consequence would be a blanket ban on all cleaning agents containing ethanol. In addition, the socio-economic effects should be considered in the ongoing process. It is also evident that the automated linking of the classification according to the CLP Regulation and the associated regulations of the chemicals legislation (e.g., Biocidal Products Regulation, Detergents Regulation) does

	not serve the intended protection of human health and the environment.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	2025_04_02-Konsultation EtOH Attachment.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 36	2025/04/02 13:00
Country	Germany
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	

Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	keep classification of Ethanol as it is
Information above is confidential	
Justification for confidentiality	
Other comments	Ethanol is not only used in food industry but also in pharmaceutical industry - no substitution possible. It would have a big impact for workforce if Ethanol is classified as toxic for reproduction category 1A or 1B and as carcinogen category 1A or 1B
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	

Justification for confidential attachment	

Comment 37	2025/04/03 08:21
Country	Germany
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Ethanol ist ein bewährtes Desinfektions- und Genussmittel, was bei bestimmungsgemäßen Gebrauch auch wenig Risiken und Komplikationen hat.
Product Type	1,2,4
Alternative Identity and Properties	Ethanol wirkt zuverlässig gegen eine große Anzahl von Keimen und ist oberflächenverträglich, baut keine Biofilme auf und löst ebensolche von Oberflächen. Darüber hinaus ist es ein Genussmittel in der menschlichen Ernährung. Wenn Krebsrisiken beschrieben sind, dann sind diese am Ehesten durch den innerlichen Genuss hervorgerufen, als durch eine geringe Aufnahme über die Haut.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Bei Einhaltung einer maximalen Konzentration von Ethanol in Flächendesinfektionsmitteln kann das Risiko einer Explosionsgefahr drastisch gesenkt werden.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	

Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	Ethanol ist sehr günstig industriell herstellbar bez. fällt als Abfallstoff bei industriellen Produktionen an
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Keine Verschärfung der Anwendung von Ethanol als Biozid!
Information above is confidential	
Justification for confidentiality	
Other comments	Ethanol sollte unbedingt zur hygienischen Hände- und Flächendesinfektion erhalten bleiben, da es gut Haut- und Oberflächenverträglich ist, ohne Filmbildung verdunstet und zuverlässig gegen eine große Zahl von Mikroorganismen wirkt. Der Stoff ist im menschlichen Körper gut abbaubar und hat bei bestimmungsgemäßen Gebrauch wenig Risiken.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 38	2025/04/03 11:18

Country	Germany
Name of organization/institution	Deutscher Bauernverband e.V. (German Farmers Association)
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	

Conclusion on suitability and availability of the alternative	See attachment.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	SN DBV Statement on the public consultation regarding the biocide classification of ethanol.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 39	2025/04/03 14:14
Country	United Kingdom
Name of organization/institution	A.F. Suter
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	The substitution of ethanol for the production of shellac is not possible.
Product Type	1,2,4
Alternative Identity and Properties	Shellac is not soluble in any water. Ethanol is the solvent used for its application.
Information above is confidential	

Justification for confidentiality	
Technical Feasibility	It is not feasible to replace ethanol as a solvent in the manufacturing process
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	The production and the whole shellac industry will cease to exist
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	NA
Information above is confidential	
Justification for confidentiality	
Availability	Not available
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Replacement of ethanol is not feasible for shellac and many other products
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	

Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 40	2025/04/04 13:14
Country	United Kingdom
Name of organization/institution	National Alcohol Producers Association UK (NAPA)
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	NAPA is a UK trade association that exists to support and represent its members within the UK alcohol (ethanol) production and associated industries. NAPA members cover the production, distribution and sale of ethanol across the major end-use sectors of beverages, industrial applications, and biofuels. They are also involved in the use of ethanol in human hygiene disinfectants. Ethanol is supplied into many important and essential downstream use sectors, including biocidal applications such as liquid hand disinfectants and surface cleaning disinfectants. Ethanol is very effective against target organisms, and any exposure to ethanol is not harmful. There are no suitable alternatives to ethanol. The only possibility would be isopropanol, but this is less effective, more expensive, and in limited supply. Attached is the NAPA position paper on the potential harmonised classification of ethanol as a CMR Category 1. It is directed at the widespread impacts across the entire ethanol industry that would be triggered by such classification under the biocides authorisation process.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	

Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	There are no suitable alternatives to ethanol.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	NAPA position on Ethanol classification as CMR Category 1 - April 2025.pdf

Attachments (confidential information)	
Justification for confidential attachment	

Comment 41	2025/04/04 17:31
Country	France
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	Our company is a distributor of the substance ethanol Many of our customers are using ethanol as ethanol based liquid hand disinfectant. Due to its alcoholic components the product has a wide sphere of action and is bactericidal, fungicidal and full virucidal efficient. The product has been tested by an independent institute as particularly skin friendly. Ethanol (64 g/100 g), n-Propanol (8 g/100 g): Evidence of efficacy according to EN 1500, 13624, 13727, 14476: full virucidal activity against Noro, Adeno, Polio, and all kind of enveloped viruses. This product is liquid, ready to use, fast and residue-free drying surface disinfectant. The product is for the effective disinfection of sensitive, alcohol-resistant surfaces. Compatibility with most common surface materials. The product is used wherever quick and effective disinfection is required, e.g. in health facilities, medical practices, nursing homes, nursing services, fitness facilities, restaurants, food and beverage plants and other facilities in the public and industrial sector. 1-propanol (35 g/100 g), ethanol (25 g/100 g): has a broad spectrum of antimicrobial activity and shows the following exposure times according to the tests carried out in line with EN standards at 20°C: Bacteria Yeast Fungi Viruses Time 15 sec 15 sec 180 sec Corona virus Limited virucidal activity (Noro virus, adeno virus) 30 sec 120 sec For use in health care areas a contact time of 1 minute for bacteria and yeasts must be observed. The contained alcohols react mainly by denaturing cell membranes and proteins and other cellular components. Due to the unspecific mode of action of the alcohols, there is no risk of resistance phenomena. Fast and efficient killing effect, fast evaporation from surfaces during

	action, no residues on surfaces, longevity of formulated products. Low degree of deterioration for open packages. No formation of disinfection by products or other toxicologically relevant chemical species for human health and environment. Exposure to Ethanol via application to the skin (dermal exposure) or by breathing in Ethanol in the air (inhalation), being the two potential routes of exposure from the production or use of biocidal products, does not result in levels of Ethanol in the human body that have been shown to cause cancer and/or have adverse reproductive effects. Ethanol evaporates rapidly from the skin. Intake via the dermal route is low. Occupational inhalation does not lead to a significant increase in the concentration of Ethanol in the blood.¹³ Atmospheric concentrations of Ethanol in workplaces where it is used are generally well below (6 to 20 times) national occupational exposure limits over an eight-hour period. The available data from oral route do not represent a 'reasonably expected use' for ethanol as chemical in related uses and exposure according to Art. 5 of the CLP. The 'reasonably expected use' is defined in the CLP Guidance: • Any process, including production, handling, maintenance, storage, transport or disposal. • All technical operations/manufacturing activities like e.g. spraying, filing, and sawing. • Any putative consumer contact through e.g. do-it-yourself or household chemicals. All professional and non-professional uses include reasonably foreseeable accidental exposure, but not abuse such as criminal or suicidal uses. Therefore, human data on adverse effects should obviously be related to the sector of chemical substances (e.g. occupational data and data from accident databases). Other human data, e.g. from oral intake except accidental intake does not fit for purpose with the CLP Regulation and the definition of 'reasonably expected use'. For occupational and consumer exposure to biocidal products, it has to be taken into account that oral intake is prevented by denaturant and should be considered as misuse. In their conclusion on the harmonised classification and labelling of acetaldehyde, the Risk Assessment Committee (RAC101) also followed this approach and did not consider effects of oral intake in humans of ethanol from consumption of alcoholic beverages. Regarding the classification of Ethanol, the WHO and IARC evaluated and classified alcoholic beverages as carcinogenic to humans. The classification of alcoholic beverages takes into account the route of consumption (oral) and the specific dosage or amount that is voluntarily consumed in the noted amounts (e.g. up to 70 g for heavy drinking or abuse situation). It has to be noted, that alcoholic beverages are complex mixtures containing

	ethanol and other substances, such as acetaldehyde, aflatoxins, and ethyl carbamate (see Lachenmeier et al. 2012⁹⁷) that are known to be carcinogenic compounds and may contribute to increase the risk of cancer due to alcohol consumption reported in observational studies (Rehm et al. 2014⁹⁸). The combination of all substance inherent properties is only given by Ethanol: fast acting, full virucidal, no residues, fast evaporation, long storage time, no transfer to or tainting of food, odorless, no disinfection by products or (eco-) toxicologically relevant degradation products. Most important is the lack of efficacy for not enveloped virus of all possible alternatives of Ethanol. This means, it is not possible to prevent the spreading of diseases by non-enveloped virus's like Polio, Noro, etc. See hospital paper: "Ethanol is indispensable for virucidal hand antisepsis: memorandum from the alcohol-based hand rub (ABHR) Task Force, WHO Collaborating Centre on Patient Safety, and the Commission for Hospital Hygiene and Infection Prevention (KRINKO), Robert Koch Institute, Berlin, Germany, Kramer et al, 2022. Ethanol is indispensable for virucidal hand antisepsis: memorandum from the alcohol-based hand rub (ABHR) Task Force, WHO Collaborating Centre on Patient Safety, and the Commission for Hospital Hygiene and Infection Prevention (KRINKO), Robert Koch Institute, Berlin, Germany - PubMed & GMS GMS Hygiene and Infection Control Medical associations and expert committees urge that ethanol be approved as a virucidal active substance for use in hand antiseptics under the European Biocidal Products Regulation, without a CMR classification. Ethanol is comparatively cheap to other active substances, generally available, easy and fast to produce ensuring a constant supply, green and sustainable. As a candidate for substitution Ethanol will no longer be available for use by the general public. This is particularly critical for pandemic situations. Ethanol based hand sanitisers are often commonly used in the food industry. The loss of ethanol will increase the risk of food outbreaks involving non-enveloped viruses such as norovirus. As a candidate for substitution Ethanol will no longer be available for use by the general public. The consequences of a ban of Ethanol will be extremely severe. Particularly in the event of outbreaks and pandemics with non-enveloped viruses, the lack of disinfectant hand rubs based on this potent and well-tolerated core active substance will put the safety of patients, nursing home residents, staff and the general public at stake. There is no substitute biocidal active substance with equal efficacy against non-enveloped viruses. In case of non approval shortage of sufficient equivalent alternatives. In case of a outbreak of a non-

	enveloped virus disease, it is not possible to fight against these without ethanol. Increase of production capacities associated with tremendous costs (New facilities, new technologies, new production permits and hurdles form authorities and NGO's. The alcoholic alternatives Propan-1-ol and Propan-2-ol are lacking of full virucidal activity. They are not sufficient available in EU. Other disinfectant active substances are not skin friendly or act not fast enough within seconds, or do not evaporate, or do stick on the skin. All alternative substances are more expensive; continuous supply and quantities not as certain as for ethanol. Propan-1-ol & Propan-2-ol: not fully virucidally efficient, not readily available in sufficient quantities. No sustainable production possible, Higher risk of accidental poisoning. Iodine: Endocrine Disruptor for human and environment, not readily available in sufficient quantities, not fast enough for efficacy, residue formation, DBP. Peracetic acid: corrosive, longevity not sufficient, reactivity with other chemicals in product formulations. Higher safety standards for workers and higher storage standards. Higher risk of accidental poisoning. NaOCl: DBP-formation, no evaporation, longevity not sufficient, corrosive, reactivity with other chemicals in product formulations. Higher risk of accidental poisoning. CHDG & QAC: no full virucidal activity, residues, not fast efficacy action. Monochlor-amine: DBP formation, only in situ generation, not storable. Chlorocresol: skin sensitizer, Phenol as degradation product: Higher risk of accidental poisoning. H₂O₂: micro lesions on skin, not fast efficacy action, no evaporation, longevity not sufficient, corrosive, not efficacious at low concentrations and ambient temperatures. Higher safety standards for workers and higher storage standards. Higher risk of accidental poisoning. Lactic Acid: not full virucidal, odor formation. Phenoxyethanol: not full virucidal: Higher risk of accidental poisoning. Some of our customers also use ethanol in Biocidal Product Sector: The classification of ethanol as carcinogenic or toxic to reproduction could mean that many biocidal products could lose their authorisation in the future. Some critical use cases are described below. We therefore see the need to keep ethanol-based disinfectants on the market. Ethanol is used as active substance in many Biocidal PT as Desinfectants for the use within the production of Pharmaceuticals, Cosmetics, Medical Products, Food- and Feedstuff, and ensure corporate hygiene. Good hygiene at the workplace is essential, especially during pandemics, to protect critical infrastructure employees from non-enveloped viruses. The case of the Covid-19 pandemic has demonstrated the necessity of ethanol-based disinfectants for the survival of critical infrastructure.

	Ethanol is not only used as an active substance in biocidal products, but also as a solvent in other biocidal products, e.g. in repellents. As a result, a large number of biocidal products could be affected by a classification and consequently lose their authorisation. A classification as CMR will probably lead to customer concern and thus a lack of acceptance of ethanol-based biocidal products and a switch to alternative products. We fear the following shortages in the availability of alternative biocidal products on the market. To finish, many of our customers are using ethanol in other sectors than biocides The workers' health and safety Directives, including the Pregnant Workers Directive, prescribe that employer shall assess all risks linked to the safety and health of workers (pregnant, breastfeeding, teenagers) and decide what preventive and protective measures should be taken. One measure could be a ban on the use for workers (pregnant, breastfeeding, teenagers) with Ethanol classified as cancerogenic or reprotoxic. The evaluation on the CMR endpoints and a subsequent decision on this endpoint by the European Commission would result in official statement on the CMR properties of Ethanol for Biocidal Uses. This available information would have to be taken into account by all users of Ethanol during their self-classification. Thus, a classification within the Biocide sector would transfer into all Sectors. Additionally, this official position on the CMR properties could influence the opinion-forming process of other CLP committees and thus affect the currently ongoing harmonised classification process.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	

Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol is a widely used biocidal active substance with broad-spectrum efficacy, particularly in disinfectants and antiseptics. Its advantages include: Proven virucidal, bactericidal, fungicidal, and tuberculocidal activity. High efficacy against non-enveloped viruses, No residues on surfaces. Rapid evaporation Well-documented safety profile with minimal risks when used appropriately. Ethanol is one of the few substances fully virucidal and efficient against non-enveloped viruses, supported by WHO recommendations and studies that highlight its superior disinfection properties and ensure a long shelf life of formulated products. Concerning safety, ethanol has no toxicologically relevant residues or persistent environmental contamination, no reported cases of skin sensitization under normal use. Compared to alternatives, ethanol has lower risk of accidental poisoning due to rapid evaporation and is suitable for food-related applications. There is no conclusive evidence of carcinogenicity from real-world exposure levels. Toxicological evaluations should differentiate ingestion vs. topical and inhalation exposure. Classification must consider risk assessment rather than hazard classification. If ethanol is substituted or restricted, the following risks must be considered: No substitute offers equal virucidal efficacy. Other active substances have higher toxicity profiles or leave residues. Alternative substances are significantly more expensive and less available. Scaling up production for substitutes would require massive investments in new facilities, technologies, and regulatory approvals, facing resistance from authorities and NGOs. Reduced availability of effective disinfectants

	could increase infection rates in healthcare, food processing, and public hygiene. Increased use of weaker disinfectants may lead to higher microbial resistance. Alternative biocides face higher production costs, lower availability, and logistical challenges.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 42	2025/04/07 15:19
Country	France
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	Ethanol is known as biocidal active substance for its key advantages : virucidal, bactericidal, fungicidal activity in short time No residues and rapid evaporation
Product Type	1,2,4
Alternative Identity and Properties	we doesnt know alternative active substance which give the same properties. Comparative to alternatives ethanol is :

	no toxicologically relevant residues or persistent environmental contamination No reported cases of skin sensitization under normal use lower risk of accidental poisoning due to rapid evaporation
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	If ethanol is restricted, the following risks must be considered Lack of equally effective alternatives Supply chain vulnerabilities Potential public health risks
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol is indispensable in public health. Scientific evidence supporting that ethanol is safe and efficacious. Alternative biocides face higher production costs, lower availability and present a potential public health risk.
Information above is confidential	
Justification for confidentiality	

Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 43	2025/04/08 14:41
Country	Germany
Name of organization/institution	Bombastus-Werke AG
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Bombastus Werke AG is a medium sized manufacturer of pharmaceutical, cosmetic and food products in Freital, Germany. In these three sectors ethanol is used as extraction solvent (recycled to large percentage) or product solvent (integral part of the product) respectively. The amount of ethanol used per year is about 5 tons.
Product Type	1,2,4
Alternative Identity and Properties	Bombastus Werke AG uses ethanol-based disinfectants in pharmaceutical production processes. These disinfectants are applied on the skin of production workers or on surfaces of the production equipment, respectively. Both for skin and for equipment disinfection there are application cases without suitable alternatives to ethanol. Especially for the application on the skin the hypothetical alternatives are mostly more toxic or more irritant than ethanol or they are less effective. Our main problems are others; they are described in point 6.

Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Not applicable
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Not applicable
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Not applicable
Information above is confidential	
Justification for confidentiality	
Availability	Not applicable
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol is in several areas of its use (biocide, extraction solvent) without alternative. The natural baseline caused by normal nutrition is in the range 1 – 3 g ethanol per day, without alcoholic beverages. It is not reasonable to set additional limitations in fractional amounts of this ubiquitous baseline. The conclusion from misuse in oral consumption must not be extended „automatically“ to other exposition pathways e.g. inhalation.
Information above is confidential	
Justification for confidentiality	
Other comments	Classification of ethanol as a CMR- substance would cause strong challenges in the highly regulated sector of pharmaceutical products. In the European Pharmacopoeia

	are defined a lot of ethanolic solutions for - Manufacturing processes, e.g. use as extraction solvent - Solution of chemicals (reagents) for test purposes In addition to requirements of pharmacopoeias, Bombastus Werke AG has individually approved respectively registered pharmaceutical products, for which ethanol is essential as extraction solvent and ingredient. For many types of pharmaceutical active natural substances there is no alternative to ethanol. It is in the middle of the polar range and the extraction yield with ethanol is achieved neither by water nor by other organic solvents. The requested justification for the change of solvent (demanded by the pharmaceutical authorities BfArM or EMA) would therefore be impossible. This would result in the loss of phytotherapeutic and homoeopathic products not only for Bombastus Werke AG but also for many other manufacturers working with ethanol. A lot of established pharmaceutical products would vanish from the market. In the cosmetic sector ethanol is without alternatives as well. The odour of the products depends on the purity of the ethanol used. Other solvents would generate a not acceptable odour e.g. of ethanol-based perfumes. A similar situation exists in the food sector. It is impossible to replace ethanol by other solvents. The main problem for manufacturers is the limit of ethanol in the air at the workplace. This limit would be considerably lowered in case of the CMR-classification of ethanol. The calculation below demonstrates that no tightening of the current ethanol limits is necessary: <table><tr><td>Estimation of ethanol intake by inhalation on 1 working day:</td><td>-</td><td>Breathing volume in 8 h working phase</td></tr><tr><td></td><td>4,80 m³</td><td>- Actual limit for ethanol in the air</td></tr><tr><td></td><td>380 mg/ m³</td><td>- Ethanol, amount in the</td></tr><tr><td>Breathing volume</td><td>1,82 g</td><td>- Transition rate (Gestis database)</td></tr><tr><td></td><td>60%</td><td>- Uptake ethanol in</td></tr><tr><td>8 h working phase</td><td>1,09 g</td><td></td></tr></table> This estimated uptake is comparable to the amount of ethanol in 220 ml apple juice, which may contain up to 0,5 % ethanol. This quantity in the range 1 - 3 g is quickly degradable by the human organism and represents the baseline for ethanol caused by normal food without alcoholic beverages. (Also bread, fresh fruits and others may contribute small amounts of ethanol.) Therefore is no need to exacerbate the limit for inhalation of ethanol. The problem is that in the current regulatory framework, misuse in oral consumption is extended „automatically“ to other exposition pathways e.g. inhalation. This automatism has to be interrupted, to get an appropriate solution for the problem.	Estimation of ethanol intake by inhalation on 1 working day:	-	Breathing volume in 8 h working phase		4,80 m ³	- Actual limit for ethanol in the air		380 mg/ m ³	- Ethanol, amount in the	Breathing volume	1,82 g	- Transition rate (Gestis database)		60%	- Uptake ethanol in	8 h working phase	1,09 g	
Estimation of ethanol intake by inhalation on 1 working day:	-	Breathing volume in 8 h working phase																	
	4,80 m ³	- Actual limit for ethanol in the air																	
	380 mg/ m ³	- Ethanol, amount in the																	
Breathing volume	1,82 g	- Transition rate (Gestis database)																	
	60%	- Uptake ethanol in																	
8 h working phase	1,09 g																		

Information above is confidential	
Justification for confidentiality	
References	None
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 44	2025/04/08 15:28
Country	France
Name of organization/institution	██████
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	Ethanol is widely used as biocidal substance with a real efficiency. Ethanol has real virucidal, bactericidal and fungicidal activities. Moreover, there is no residu on surfaces due to speed evaporation. The safety profile is well documented.
Product Type	1,2,4
Alternative Identity and Properties	There are only few substances including ethanol with fully virucidal and efficient activity against virus. Ethanol complies with WHO recommendations.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	There is no toxicologically residu. Human skin is not sensitive to ethanol. Compared to others substances, there is a few risk of accidental poisoning. Finally, ethanol is

	odorless. This ethanol is adapted to food industry applications.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	There is no evidence that ethanol is carcinogenic ou toxic for reproduction.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	There is not enough efficient alternatives. The supply chain of alternative substances is not mature. There is a risk of reducing avaibility of effective disinfectants which increase infection rates in healthcare, food processing and hygiene.
Information above is confidential	
Justification for confidentiality	
Availability	Ethanol has a real mature supply chain. Others alternative substances have higher production costs, lower avaibility and logistical challenges.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	We request that ethanol shall not be classified as CMR and can be used as a biocide in view of the benefits provided by this molecule.
Information above is confidential	
Justification for confidentiality	
Other comments	Scientific community is supporting its safety and efficiency. Indeed ethanol plays a crucial role in public health
Information above is confidential	
Justification for confidentiality	

References	
Attachments (non-confidential information)	Answer to the consultation.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 45	2025/04/10 17:41
Country	Sweden
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Proposal for substitution to Sanify
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	

Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Attached PDF
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	SANIFY AS A POTENTIAL SUBSTITUTION TO ETHANOL-BASED DISINFECTION PT 1 v.1.1.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 46	2025/04/11 09:39
Country	Austria
Name of organization/institution	AGRANA Zucker GmbH

I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Die Einstufung von Ethanol als krebserregend oder fortpflanzungsgefährdend könnte bedeuten, dass viele Biozid-Produkte in Zukunft ihre Zulassung verlieren könnten. Einige kritische Anwendungsfälle werden im Folgenden beschrieben. Wir sehen daher die Notwendigkeit, Desinfektionsmittel auf Ethanolbasis auf dem Markt zu halten. In unserem Fall wird Ethanol hauptsächlich als Wirkstoff in vielen Desinfektionsmitteln verwendet, die in unseren Produktionsstätten für Lebens- und Futtermittel eingesetzt werden, um sichere Produkte zu liefern (PT4). Darüber hinaus werden ethanolhaltige Biozidprodukte als Händedesinfektionsmittel vom Personal in Verarbeitungsbetrieben verwendet, um eine Kontamination von Lebens- und Futtermitteln zu verhindern und die Betriebshygiene zu gewährleisten (PT 1). Darüber hinaus wird Ethanol nicht nur als Wirkstoff in Biozidprodukten verwendet, sondern auch als Lösungsmittel in anderen Biozidprodukten, z. B. in Repellentien, Insektiziden usw. Diese sind für unsere Anlagen wichtig, um hygienische Bedingungen zu schaffen und sichere Produkte für unsere Kunden zu gewährleisten. Infolgedessen könnte eine große Anzahl von Biozidprodukten von einer Einstufung betroffen sein und folglich ihre Zulassung verlieren.
Product Type	1,2,4
Alternative Identity and Properties	Chlorkresol Wasserstoffsuperoxyd Jod Milchsäure Monochloramin Phenoxyethanol Propan-1-ol und Propan-2-ol Peressigsäure Quaternäre Ammonium-Verbindungen Natriumhypochlorit
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Jod, quartäre Ammoniumverbindungen und Natriumhypochlorit können nicht verwendet werden, da sie zur Bildung von nicht entfernbaren Rückständen im fertigen Lebensmittel führen. Wasserstoffsuperoxyd und Peressigsäure sind korrosiv und für viele verwendete Materialien nicht geeignet Chlorocresol, Phenoxyethanol und Monochloramin können nicht verwendet werden, da sie zur Geruchsbildung im fertigen Lebensmittel führen. Die

	alkoholischen Alternativen Propan-1-ol und Propan-2-ol sowie Milchsäure haben keine volle viruzide Wirkung.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Eine Einstufung als CMR wird wahrscheinlich entweder zu einem vollständigen Verbot von Biozidprodukten, die Ethanol enthalten, oder zu einer Besorgnis der Kunden und damit zu einer mangelnden Akzeptanz von Biozidprodukten auf Ethanolbasis und einem Wechsel zu alternativen Produkten führen. Da es immer weniger Firmen gibt, die technisch oder rechtlich brauchbare Desinfektionsmittel mit Alternativen zu Ethanol auf dem Markt anbieten, z.B. die Alkohole Propan-1-ol und Propan-2-ol, befürchten wir eine folgende Verknappung und damit eine Preissteigerung auf dem Markt. Um an unseren Standorten alternative Biozidprodukte ohne Ethanol zu verwenden, müssten die Produktionsprozesse umgestellt und die Anlagen umgerüstet werden. Ethanol ist vergleichsweise günstig im Vergleich zu anderen Wirkstoffen, allgemein verfügbar, einfach und schnell zu produzieren, was eine konstante Versorgung gewährleistet, und wenn es aus erneuerbaren Quellen stammt, auch nachhaltig (siehe RED III).
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Die alkoholischen Alternativen Propan-1-ol und Propan-2-ol haben keine volle viruzide Wirkung. Chlorocresol, Wasserstoffperoxid, Jod, Milchsäure, Monochloramin, Phenoxyethanol, Peressigsäure und Natriumhypochlorit sind ätzend, einige haben auch toxische Eigenschaften.
Information above is confidential	
Justification for confidentiality	
Availability	Kurz- und mittelfristige Verfügbarkeit von technisch machbaren Alternativen ist nicht gegeben, da weniger Unternehmen Alternativen anbieten und die Steigerung der Produktion von Alternativen zu Ethanol mit neuen Anlagen, neuen Technologien, neuen Produktionsgenehmigungen etc. verbunden ist. Dies wird sich zusätzlich negativ auf die wirtschaftliche Machbarkeit auswirken, da es zu einer

	Verknappung der Verfügbarkeit auf dem Markt kommt. Aufgrund zusätzlicher (gesetzlicher) Anforderungen an die Produktsicherheit (Lebens- und Futtermittel) sind die oben aufgeführten Alternativen nicht verfügbar - Quaternäre Ammoniumverbindungen und Natriumhypochlorit können nicht verwendet werden, da sie zur Bildung von nicht entfernbaren Rückständen im fertigen Lebensmittel führen. - Chlorocresol, Phenoxyethanol, Monochloramin können nicht verwendet werden, da sie zur Bildung von Gerüchen im fertigen Lebensmittel führen. Dies widerspricht der Herstellung sicherer Produkte, wie sie in den europäischen und nationalen Lebens- und Futtermittelgesetzen und -verordnungen beschrieben sind. besondere Anforderungen für die Herstellung von Babynahrung, die in einigen unserer Werke hergestellt wird. Alternativen zu Ethanol für die Verwendung bei der Herstellung von ökologischen Lebens- und Futtermitteln sind gesetzlich nicht zugelassen.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Die Folgen eines Verbots von Ethanol werden äußerst schwerwiegend sein. Gute Hygiene am Arbeitsplatz ist vor allem bei Pandemien wichtig, um Mitarbeiter kritischer Infrastrukturen vor nicht entwickelten Viren zu schützen. Der Fall der Covid-19-Pandemie hat gezeigt, wie notwendig Desinfektionsmittel auf Ethanolbasis für das Überleben kritischer Infrastrukturen sind. Das Fehlen von Desinfektionsmitteln mit diesem potenten und gut verträglichen Wirkstoff gefährdet die Sicherheit der Lebensmittelproduktion, der Beschäftigten und der Öffentlichkeit. Es gibt keinen bioziden Ersatzwirkstoff mit gleicher Wirksamkeit in der Produktionsstätte von Lebens- und Futtermittel-Ausgangserzeugnissen (PT4 und PT1).
Information above is confidential	
Justification for confidentiality	
Other comments	Studien über die Verwendung von Ethanol zeigen, dass Ethanol schnell verdunstet. Das Einatmen am Arbeitsplatz führt nicht zu einem signifikanten Anstieg der Ethanolkonzentration im Blut. Die atmosphärischen Ethanolkonzentrationen an Arbeitsplätzen, an denen Ethanol verwendet wird, liegen im Allgemeinen weit unter den nationalen Grenzwerten für die berufsbedingte Exposition

	(das 6- bis 20-fache) für einen Zeitraum von acht Stunden. Siehe Bessonneau V, Clement M, Thomas O. Can intensive use of alcohol-based hand rubs lead to passive alcoholization? Internationale Zeitschrift für Umweltforschung und öffentliche Gesundheit 2010; 7: 3038-50. Die Kombination aller stoffeigenen Eigenschaften ist nur bei Ethanol gegeben: schnell wirkend, voll viruzid, keine Rückstände, schnelle Verdunstung, lange Lagerzeit, keine Übertragung auf oder Verfärbung von Lebensmitteln, geruchlos, keine Desinfektionsnebenprodukte oder (öko-) toxikologisch relevante Abbauprodukte. Eine weitere wichtige Tatsache ist die fehlende Wirksamkeit aller möglichen Ethanol-Alternativen für nicht umhüllte Viren. Dies bedeutet, dass es nicht möglich ist, die Ausbreitung von Krankheiten durch unbehüllte Viren wie Polio, Noro, etc. zu verhindern. Siehe WHO-Kernliste 15.1 und 15.2: Web Annex A. World Health Organization Model List of Essential Medicines - 23rd List, 2023. In: The selection and use of essential medicines 2023: Zusammenfassung des Berichts des 24. WHO-Sachverständigenausschusses für die Auswahl und Anwendung unentbehrlicher Arzneimittel, 24. bis 28. April 2023. Genf: Weltgesundheitsorganisation; 2023 (WHO/MHP/HPS/EML/2023.02). Verbindung zwischen Biozidverfahren und anderen Sektoren: Die Bewertung der CMR-Endpunkte und eine anschließende Entscheidung der Europäischen Kommission über diese Endpunkte würden zu einer offiziellen Erklärung über die CMR-Eigenschaften von Ethanol für biozide Anwendungen führen. Diese verfügbaren Informationen müssten von allen Anwendern von Ethanol bei ihrer Selbsteinstufung berücksichtigt werden. Somit würde eine Einstufung innerhalb des Biozidsektors auf alle Sektoren übertragen werden. Darüber hinaus könnte dieser offizielle Standpunkt zu den CMR-Eigenschaften den Meinungsbildungsprozess anderer CLP-Ausschüsse beeinflussen und sich somit auf den derzeit laufenden harmonisierten Einstufungsprozess auswirken. So schreiben beispielsweise die Richtlinien über Sicherheit und Gesundheitsschutz am Arbeitsplatz, einschließlich der Richtlinie über schwangere Arbeitnehmerinnen, vor, dass Arbeitgeber alle Risiken im Zusammenhang mit der Sicherheit und Gesundheit von Arbeitnehmerinnen (schwangeren, stillenden und jugendlichen Arbeitnehmerinnen) bewerten und entscheiden müssen, welche Präventiv- und Schutzmaßnahmen ergriffen werden sollten. Eine Maßnahme könnte ein Verbot der Verwendung von Ethanol, das als krebserregend oder fortpflanzungsgefährdend eingestuft ist, für (schwangere, stillende und jugendliche) Arbeitnehmerinnen sein.

Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 47	2025/04/11 09:47
Country	Austria
Name of organization/institution	AGRANA Fruit Austria GmbH
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Die Einstufung von Ethanol als krebserzeugend oder fortpflanzungsgefährdend könnte bedeuten, dass viele Biozid-Produkte in Zukunft ihre Zulassung verlieren könnten. Einige kritische Anwendungsfälle werden im Folgenden beschrieben. Wir sehen daher die Notwendigkeit, Desinfektionsmittel auf Ethanolbasis auf dem Markt zu halten. In unserem Fall wird Ethanol hauptsächlich als Wirkstoff in vielen Desinfektionsmitteln verwendet, die in unseren Produktionsstätten für Lebensmittel eingesetzt werden, um sichere Produkte zu liefern (PT4). Darüber hinaus werden ethanolhaltige Biozidprodukte als Händedesinfektionsmittel vom Personal in Verarbeitungsbetrieben verwendet, um eine Kontamination von Lebensmitteln zu verhindern und die Betriebshygiene zu gewährleisten (PT 1). Darüber hinaus wird Ethanol nicht nur als Wirkstoff in Biozidprodukten verwendet, sondern auch als Lösungsmittel in anderen Biozidprodukten, z. B. in Repellentien, Insektiziden usw. Diese sind für unsere Anlagen wichtig, um hygienische Bedingungen zu schaffen und sichere Produkte für unsere Kunden zu gewährleisten.

	Infolgedessen könnte eine große Anzahl von Biozidprodukten von einer Einstufung betroffen sein und folglich ihre Zulassung verlieren.
Product Type	1,2,4
Alternative Identity and Properties	Chlorkresol Wasserstoffperoxid Monochloramin Phenoxyethanol n-Propanol und iso-Propanol Peressigsäure Quaternäre Ammonium-Verbindungen Natriumhypochlorit
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Quartäre Ammoniumverbindungen und Natriumhypochlorit können nicht verwendet werden, da sie zur Bildung von nicht entfernbaren Rückständen im fertigen Lebensmittel führen. Wasserstoffperoxid und Peressigsäure sind korrosiv und für viele verwendete Materialien nicht geeignet Chlorocresol, Phenoxyethanol und Monochloramin können nicht verwendet werden, da sie zur Geruchsbildung im fertigen Lebensmittel führen. Die alkoholischen Alternativen n-Propanol und iso-Propanol haben keine volle viruzide Wirkung.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Eine Einstufung als CMR wird wahrscheinlich entweder zu einem vollständigen Verbot von Biozidprodukten, die Ethanol enthalten, oder zu einer Besorgnis der Kunden und damit zu einer mangelnden Akzeptanz von Biozidprodukten auf Ethanolbasis und einem Wechsel zu alternativen Produkten führen. Da es immer weniger Firmen gibt, die technisch oder rechtlich brauchbare Desinfektionsmittel mit Alternativen zu Ethanol auf dem Markt anbieten, z.B. die Alkohole n-Propanol und iso-Propanol, befürchten wir eine folgende Verknappung und damit eine Preissteigerung auf dem Markt. Um an unseren Standorten alternative Biozidprodukte ohne Ethanol zu verwenden, müssten die Produktionsprozesse umgestellt und die Anlagen umgerüstet werden. Ethanol ist vergleichsweise günstig im Vergleich zu anderen Wirkstoffen, allgemein verfügbar, einfach und schnell zu produzieren, was eine konstante Versorgung gewährleistet, und wenn es aus erneuerbaren Quellen stammt, auch nachhaltig (siehe Nachhaltigkeits-RED III).

Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Die alkoholischen Alternativen n-Propanol und iso-Propanol haben keine volle viruzide Wirkung. Chlorocresol, Wasserstoffperoxid, Monochloramin, Phenoxyethanol, Peressigsäure und Natriumhypochlorit sind ätzend, einige haben auch toxische Eigenschaften.
Information above is confidential	
Justification for confidentiality	
Availability	Die Verfügbarkeit von technisch machbaren Alternativen ist kurz- und mittelfristig nicht gegeben, da weniger Unternehmen Alternativen anbieten und die Steigerung der Produktion von Alternativen zu Ethanol mit neuen Anlagen, neuen Technologien, etc. verbunden ist. Dies wird sich zusätzlich negativ auf die wirtschaftliche Machbarkeit auswirken, da es zu einer Verknappung der Verfügbarkeit auf dem Markt kommt. Aufgrund zusätzlicher (gesetzlicher) Anforderungen an die Produktsicherheit (Lebensmittel) sind die oben aufgeführten Alternativen nicht verfügbar - Quaternäre Ammoniumverbindungen und Natriumhypochlorit können nicht verwendet werden, da sie zur Bildung von nicht entfernbaren Rückständen im fertigen Lebensmittel führen. - Chlorocresol, Phenoxyethanol, Monochloramin können nicht verwendet werden, da sie zur Bildung von Gerüchen im fertigen Lebensmittel führen. Dies widerspricht der Herstellung sicherer Produkte, wie sie in den europäischen und nationalen Lebensmittelgesetzen und -verordnungen beschrieben sind. Besondere Anforderungen für die Herstellung von Baby- oder Kleinkindnahrung, die in einigen unserer Werke hergestellt wird. Alternativen zu Ethanol für die Verwendung bei der Herstellung von ökologischen Lebensmitteln sind gesetzlich nicht zugelassen.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Die Folgen eines Verbots von Ethanol werden äußerst schwerwiegend sein. Gute Hygiene am Arbeitsplatz ist vor allem bei Pandemien wichtig, um Mitarbeiter kritischer Infrastrukturen vor nicht entwickelten Viren zu schützen.

	Der Fall der Covid-19-Pandemie hat gezeigt, wie notwendig Desinfektionsmittel auf Ethanolbasis für das Überleben kritischer Infrastrukturen sind. Das Fehlen von Desinfektionsmitteln mit diesem potenten und gut verträglichen Wirkstoff gefährdet die Sicherheit der Lebensmittelproduktion, der Beschäftigten und der Öffentlichkeit. Es gibt keinen bioziden Ersatzwirkstoff mit gleicher Wirksamkeit in der Produktionsstätte von Lebens- und Futtermittel-Ausgangserzeugnissen (PT4 und PT1).
Information above is confidential	
Justification for confidentiality	
Other comments	Studien über die Verwendung von Ethanol zeigen, dass Ethanol schnell verdunstet. Das Einatmen am Arbeitsplatz führt nicht zu einem signifikanten Anstieg der Ethanolkonzentration im Blut. Die atmosphärischen Ethanolkonzentrationen an Arbeitsplätzen, an denen Ethanol verwendet wird, liegen im Allgemeinen weit unter den nationalen Grenzwerten für die berufsbedingte Exposition (das 6- bis 20-fache) für einen Zeitraum von acht Stunden. Siehe Bessonneau V, Clement M, Thomas O. Can intensive use of alcohol-based hand rubs lead to passive alcoholization? Internationale Zeitschrift für Umweltforschung und öffentliche Gesundheit 2010; 7: 3038-50. Die Kombination aller stoffeigenen Eigenschaften ist nur bei Ethanol gegeben: schnell wirkend, voll viruzid, keine Rückstände, schnelle Verdunstung, lange Lagerzeit, keine Übertragung auf oder Verfärbung von Lebensmitteln, geruchlos, keine Desinfektionsnebenprodukte oder (öko-) toxikologisch relevante Abbauprodukte. Eine weitere wichtige Tatsache ist die fehlende Wirksamkeit aller möglichen Ethanol-Alternativen für nicht umhüllte Viren. Dies bedeutet, dass es nicht möglich ist, die Ausbreitung von Krankheiten durch unbehüllte Viren wie Polio, Noro, etc. zu verhindern. Siehe WHO-Kernliste 15.1 und 15.2: Web Annex A. World Health Organization Model List of Essential Medicines - 23rd List, 2023. In: The selection and use of essential medicines 2023: Zusammenfassung des Berichts des 24. WHO-Sachverständigenausschusses für die Auswahl und Anwendung unentbehrlicher Arzneimittel, 24. bis 28. April 2023. Genf: Weltgesundheitsorganisation; 2023 (WHO/MHP/HPS/EML/2023.02). Verbindung zwischen Biozidverfahren und anderen Sektoren: Die Bewertung der CMR-Endpunkte und eine anschließende Entscheidung der Europäischen Kommission über diese Endpunkte würden zu einer offiziellen Erklärung über die CMR-Eigenschaften von

	Ethanol für biozide Anwendungen führen. Diese verfügbaren Informationen müssten von allen Anwendern von Ethanol bei ihrer Selbsteinstufung berücksichtigt werden. Somit würde eine Einstufung innerhalb des Biozidsektors auf alle Sektoren übertragen werden. Darüber hinaus könnte dieser offizielle Standpunkt zu den CMR-Eigenschaften den Meinungsbildungsprozess anderer CLP-Ausschüsse beeinflussen und sich somit auf den derzeit laufenden harmonisierten Einstufungsprozess auswirken. So schreiben beispielsweise die Richtlinien über Sicherheit und Gesundheitsschutz am Arbeitsplatz, einschließlich der Richtlinie über schwangere Arbeitnehmerinnen, vor, dass Arbeitgeber alle Risiken im Zusammenhang mit der Sicherheit und Gesundheit von Arbeitnehmerinnen (schwangeren, stillenden und jugendlichen Arbeitnehmerinnen) bewerten und entscheiden müssen, welche Präventiv- und Schutzmaßnahmen ergriffen werden sollten. Eine Maßnahme könnte ein Verbot der Verwendung von Ethanol, das als krebserregend oder fortpflanzungsgefährdend eingestuft ist, für (schwangere, stillende und jugendliche) Arbeitnehmerinnen sein.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 48	2025/04/11 09:51
Country	Austria
Name of organization/institution	Moravskoslezské Cukrovary s.r.o.
I do not wish the name of my organisation/institution to be	

published on the ECHA website.	
General information	Klasifikace etanolu jako karcinogenního nebo toxického pro reprodukci by mohla znamenat, že mnoho biocidních přípravků by mohlo v budoucnu ztratit povolení. Některé kritické případy použití jsou popsány níže. Proto vidíme potřebu zachovat dezinfekční prostředky na bázi etanolu na trhu. V našem případě se etanol používá hlavně jako účinná látka v mnoha dezinfekčních prostředcích pro použití v našich výrobních závodech potravin a krmiv, aby se zajistila bezpečnost výrobků (PT4). Kromě toho se etanol obsahující biocidní přípravky používá jako dezinfekční prostředek na ruce pro zaměstnance ve zpracovatelských závodech, aby se zabránilo kontaminaci potravin a krmiv a zajistila se firemní hygiena (PT 1). Etanol se navíc používá nejen jako účinná látka v biocidních přípravcích, ale také jako rozpouštědlo v jiných biocidních přípravcích, např. v repelentech, insekticidech atd. Ty jsou pro naše závody důležité vytvoření hygienických podmínek a zajištění bezpečných výrobků pro naše zákazníky. V důsledku toho by klasifikace mohla postihnout velké množství biocidních přípravků, které by následně ztratily povolení.
Product Type	1,2,4
Alternative Identity and Properties	Chlorkrezol Peroxid vodíku Jód Kyselina mléčná Monochloramin Fenoxxyethanol Propan-1-ol a propan-2-ol Kyselina peroctová Kvartérní amonné sloučeniny Chlornan sodný
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Jód, kvartérní amonné sloučeniny a chlornan sodný nelze použít, protože vedou k tvorbě neodstranitelných zbytků v konečné potravíně. Peroxid vodíku a kyselina peroctová jsou korozivní a nejsou vhodné pro mnoho používaných materiálů Chlorkrezol, fenoxxyethanol a monochloramin nelze použít, protože vedou k tvorbě zápachu v konečné potravíně. Alkoholové alternativy Propan-1-ol a Propan-2-ol a kyselina mléčná nemají plnou virucidní aktivitu.
Information above is confidential	
Justification for confidentiality	

Economic Feasibility	Klasifikace jako CMR pravděpodobně povede buď k úplnému zákazu biocidních přípravků obsahujících etanol, nebo k obavám zákazníků, a tedy k nepřijetí biocidních přípravků na bázi etanolu a k přechodu na alternativní přípravky. Vzhledem k tomu, že na trhu je méně společností, které poskytují technicky nebo legálně použitelné dezinfekční prostředky s alternativami k etanolu, např. alkoholy Propan-1-ol a Propan-2-ol, obáváme se následujícího nedostatku, a tedy zvýšení cen na trhu. Aby bylo možné v našich závodech používat alternativní biocidní přípravky bez etanolu, musely by se reorganizovat výrobní procesy a přestavět zařízení. Etanol je ve srovnání s jinými účinnými látkami poměrně levný, všeobecně dostupný, snadno a rychle se vyrábí, což zajišťuje stálé zásobování, a pokud pochází z obnovitelných zdrojů, je také udržitelný (viz RED III).
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Alkoholové alternativy Propan-1-ol a Propan-2-ol nemají plnou virucidní aktivitu. Chlorkrezol, peroxid vodíku, jód, kyselina mléčná, monochloramin, fenoxxyethanol, kyselina peroctová a chlornan sodný jsou žíravé, některé mají i toxické vlastnosti.
Information above is confidential	
Justification for confidentiality	
Availability	Krátkodobá/střednědobá dostupnost technicky proveditelných alternativ není dána, protože alternativy poskytuje méně společností a zvýšení výroby alternativ k etanolu je spojeno s novými zařízeními, novými technologiemi, novými výrobními povoleními atd. To bude mít navíc negativní dopad na ekonomickou proveditelnost, protože na trhu je nedostatečná dostupnost. Vzhledem k dalším (zákonným) požadavkům bezpečnost výrobků (potravin a krmiv) nejsou výše uvedené alternativy k dispozici. - Kvartérní amonné sloučeniny a chlornan sodný nelze použít, protože vedou k tvorbě neodstranitelných zbytků v konečné potravíně. - Chlorkrezol, fenoxxyethanol a monochloramin nelze použít, protože vedou k tvorbě zápachu v konečné potravíně. To je v rozporu s výrobou bezpečných produktů, jak je popsáno v evropských a národních zákonech a předpisech o potravinách a krmivech. alternativy etanolu

	pro použití při výrobě biopotravin a krmiv nejsou právně schváleny.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Důsledky zákazu etanolu budou velmi závažné. Dobrá hygiena na pracovišti je nezbytná, zejména během pandemií, aby byli zaměstnanci kritické infrastruktury chráněni před nevyvinutými viry. Případ pandemie Covid-19 ukázal nezbytnost dezinfekčních prostředků na bázi etanolu pro přežití kritické infrastruktury. Nedostatek dezinfekčních prostředků na tuto silnou a dobře tolerovanou účinnou látku ohrozí bezpečnost výroby potravin, pracovníků i široké veřejnosti. Neexistuje žádná náhradní biocidní účinná látka se stejnou účinností v místě výroby potravin a krmiv (PT4 a PT1).
Information above is confidential	
Justification for confidentiality	
Other comments	Studie o používání etanolu ukazují, že se etanol rychle odpařuje. Vdechování při práci nevede k významnému zvýšení koncentrace etanolu v krvi. Atmosférické koncentrace Ethanolu na pracovištích, kde se používá, jsou obecně výrazně nižší (6 až 20krát) než národní limity expozice na pracovišti po dobu osmi hodin. Viz Bessonneau V, Clement M, Thomas O. Can intensive use of alcohol-based hand rubs lead to passive alcoholization? International journal of environmental research and public health 2010; 7: 3038-50. Kombinace všech vlastností, které jsou látky vlastní, je dána pouze etanolem: rychlý účinek, plná virucidnost, žádná rezidua, rychlé odpařování, dlouhá doba skladování, žádný přenos do potravin nebo jejich poskvrnění, bez zápachu, žádné vedlejší produkty dezinfekce nebo (eko)toxikologicky významné produkty rozkladu. Další důležitou skutečností je nedostatečná účinnost všech možných alternativ etanolu na neobalené viry. To znamená, že není možné zabránit šíření nemocí způsobených neobalenými viry, jako je poliomyelitida, noro atd. Viz základní seznam WHO 15.1 a 15.2: Webová příloha A. Modelový seznam základních léčiv Světové zdravotnické organizace - 23. seznam, 2023. In: Lékařská literatura a zdravotnictví: Výběr a používání základních léčiv 2023: Souhrn zprávy 24. zasedání Výboru odborníků WHO pro výběr a používání základních léčiv, 24. - 28. dubna 2023.

	Ženeva: Světová zdravotnická organizace; 2023 (WHO/MHP/HPS/EML/2023.02). Propojení biocidních procesů s ostatními odvětvími: Výsledkem hodnocení koncových bodů CMR a následného rozhodnutí Evropské komise o těchto koncových bodech bude oficiální prohlášení o vlastnostech CMR etanolu pro biocidní použití. Tyto dostupné informace by museli vzít v úvahu všichni uživatelé etanolu při své vlastní klasifikaci. Klasifikace v rámci odvětví biocidů by se tak přenesla do všech odvětví. Kromě toho by toto oficiální stanovisko k vlastnostem CMR mohlo ovlivnit proces tvorby stanovisek ostatních výborů CLP a ovlivnit tak v současné době probíhající harmonizovaný proces klasifikace. Směrnice o bezpečnosti a ochraně zdraví pracovníků, včetně směrnice o těhotných zaměstnankyních, například předepisují, že zaměstnavatelé musí posoudit všechna rizika spojená s bezpečností a ochranou zdraví zaměstnankyň (těhotných, kojících, mladistvých) a rozhodnout, jaká preventivní a ochranná opatření by měla být přijata. Jedním z opatření by mohl být zákaz používání pro pracovníky (těhotné, kojící, dospívající) s etanolem klasifikovaným jako rakovinotvorný nebo reprotoxický.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 49	2025/04/11 09:58
Country	Austria
Name of organization/institution	Magyar Cukor Zrt.
I do not wish the name of my organisation/institution to be	

published on the ECHA website.	
General information	Az etanol rákkeltőnek vagy reprodukciót károsítónak minősítése azt jelentheti, hogy számos biocid termék elveszítheti az engedélyét a jövőben. Az alábbiakban néhány kritikus felhasználási esetet ismertetünk. Ezért szükségesnek látjuk, hogy az etanol alapú fertőtlenítőszeresek továbbra is a piacon maradjanak. Esetünkben az etanolt főként hatóanyagként használjuk számos fertőtlenítőszerben, amelyeket élelmiszer- és takarmánygyártó telephelyeinken használunk a biztonságos termékek előállítása érdekében (PT4). Ezen túlmenően a feldolgozóüzemek személyzete etanol tartalmú biocid termékeket használ kézfertőtlenítőként az élelmiszer- és takarmányszennyeződés megelőzése és a vállalati higiénia biztosítása érdekében (PT 1). Ezenkívül az etanolt nemcsak biocid termékekben használják hatóanyagként, hanem más biocid termékekben, pl. repellensekben, rovarölő szerekben stb. oldószerként is. Ezek fontosak üzemünk számára, hogy higiénikus körülményeket teremtsenek és biztonságos termékeket biztosítsanak ügyfeleink számára. Ennek eredményeképpen számos biocid terméket érinthet a besorolás, és következésképpen elveszíthetik engedélyüket.
Product Type	1,2,4
Alternative Identity and Properties	Klorokrezol Hidrogén-peroxid Monoklóramin Fenoxietanol Propan-1-ol és Propan-2-ol Per ecetsav Kvaterner ammóniumvegyületek Nátrium-hipoklorit
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	A, kvaterner ammóniumvegyületek és a nátrium-hipoklorit nem használható, mivel ezek nem eltávolítható maradványok képződéséhez vezetnek a kész élelmiszerben. A hidrogén-peroxid és a per ecetsav maró hatásúak, és sok használt anyaghoz nem alkalmasak A klór-krezol, fenoxietanol, monoklóramin nem használható, mert a kész élelmiszerben szagok kialakulásához vezetnek. Az alkoholos alternatívák, a n-propánol és a iso-propánol nem rendelkeznek teljes vírusölő hatással.
Information above is confidential	
Justification for confidentiality	

Economic Feasibility	A CMR besorolás valószínűleg vagy az etanolt tartalmazó biocid termékek teljes betiltásához, vagy a fogyasztók aggodalmához és ezáltal az etanol alapú biocid termékek elfogadásának hiányához, valamint az alternatív termékekre való áttéréshez vezet. Mivel kevesebb olyan vállalat van a piacon, amely technikailag vagy jogilag használható fertőtlenítőszereket kínál az etanol alternatíváival, például a propán-1-ol és a propán-2-ol alkoholokkal, félünk a következő hiánytól és így a piaci áremelkedéstől. Ahhoz, hogy telephelyeinken etanol nélküli alternatív biocid termékeket használhassunk, a gyártási folyamatokat át kellene szervezni, és a létesítményeket át kellene alakítani. Az etanol más hatóanyagokhoz képest viszonylag olcsó, általában rendelkezésre áll, könnyen és gyorsan előállítható, ami biztosítja a folyamatos ellátást, és ha megújuló forrásokból származik, fenntartható is.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Az alkoholos alternatívák, a Propanol nem rendelkeznek teljes vírusölő hatással. A klórkrezol, a hidrogén-peroxid, a monoklóramin, a fenoxietanol, a peracetsav és a nátrium-hipoklorit maró hatásúak, némelyikük mérgező tulajdonságokkal is rendelkezik.
Information above is confidential	
Justification for confidentiality	
Availability	Rövid/középtávon nem állnak rendelkezésre technikailag megvalósítható alternatívák, mivel kevesebb vállalat kínál alternatívákat, és az etanol alternatíváinak termelésének növekedése új létesítményekhez, új technológiákhoz. Ez ráadásul negatívan befolyásolja a gazdasági megvalósíthatóságot, mivel a piacon nem áll rendelkezésre elegendő mennyiség. A termékbiztonságra (élelmiszer- és takarmánybiztonság) további (jogi) követelmények miatt a fent felsorolt alternatívák nem állnak rendelkezésre. - A kvaterner ammóniumvegyületek és a nátrium-hipoklorit nem használható, mert nem eltávolítható maradványok képződéséhez vezetnek a kész élelmiszerben. - A klórkrezol, fenoxietanol, monoklóramin nem használható, mert a kész élelmiszerben szagok kialakulásához vezetnek. Ez ellentétes a biztonságos termékek előállításával, ahogyan azt az európai és nemzeti élelmiszer- és takarmánytörvények és -rendelkezések leírják. az etanol

	alternatívái a bioélelmiszerek és takarmányok előállításához jogilag nem engedélyezettek.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Az etanol betiltásának rendkívül súlyos következményei lesznek. A jó munkahelyi higiénia alapvető fontosságú, különösen a világjárványok idején, hogy megvédjük a kritikus infrastruktúrában dolgozókat a nem kifejlett vírusoktól. A Covid-19 világjárvány esete bebizonyította, hogy a kritikus infrastruktúrák túlélése érdekében szükség van etanol alapú fertőtlenítőszerekre. Az ilyen erős és jól tolerálható hatóanyagú fertőtlenítőszerek hiánya az élelmiszertermelés, a munkavállalók és a lakosság biztonságát veszélyezteti. Az élelmiszer- és takarmány-alapanyagok (PT4 és PT1) előállítási helyén nincs helyettesítő biocid hatóanyag, amely azonos hatékonyságú lenne.
Information above is confidential	
Justification for confidentiality	
Other comments	Az etanol használatával kapcsolatos tanulmányok azt mutatják, hogy az etanol gyorsan elpárolog. A munkahelyi belégzés nem vezet a vérben lévő etanol koncentrációjának jelentős növekedéséhez. Az etanol légköri koncentrációja azokon a munkahelyeken, ahol használják, általában jóval a nemzeti munkahelyi expozíciós határértékek alatt van (6-20-szoros) egy nyolcórás időszak alatt. Lásd Bessonneau V, Clement M, Thomas O. Az alkoholalapú kézradírok intenzív használata vezethet passzív alkoholizálódáshoz? International journal of environmental research and public health 2010; 7: 3038-50. Az összes, az anyagban rejlő tulajdonság kombinációja csak az etanol esetében adott: gyors hatású, teljes mértékben vírusölő, nem hagy maradványokat, gyors elpárolgás, hosszú tárolási idő, nem kerül át az élelmiszerekre és nem szennyezi azokat, szagtalan, nincsenek fertőtlenítő melléktermékek vagy (öko-) toxikológiailag releváns bomlástermékek. Egy másik fontos tény, hogy az etanol minden lehetséges alternatívája nem hatékony a nem burkolt vírusokra. Ez azt jelenti, hogy nem lehet megakadályozni a nem burkolt vírusok, mint a Polio, Noro stb. által okozott betegségek terjedését. Lásd a WHO 15.1. és 15.2. alaplístáját: Web Annex A. World Health Organization Model List of Essential Medicines - 23. lista,

	2023. In: Az alapvető gyógyszerek kiválasztása és alkalmazása 2023: Az alapvető gyógyszerek kiválasztásával és alkalmazásával foglalkozó 24. WHO Szakértői Bizottság jelentésének összefoglalója, 2023. április 24-28. Genf: Egészségügyi Világszervezet; 2023 (WHO/MHP/HPS/EML/2023.02). Kapcsolat a biocid folyamat és más ágazatok között: A CMR végpontok értékelése és az Európai Bizottság ezt követő döntése a biocid felhasználásra szánt etanol CMR tulajdonságairól szóló hivatalos nyilatkozatot eredményezne. Ezt a rendelkezésre álló információt az etanol valamennyi felhasználójának figyelembe kell vennie az önbesorolás során. Így a biocid ágazaton belüli besorolás minden ágazatra átkerülne. Ezenkívül a CMR-tulajdonságokra vonatkozó hivatalos álláspont befolyásolhatja más CLP-bizottságok véleményalkotási folyamatát, és így hatással lehet a jelenleg folyamatban lévő harmonizált osztályozási folyamatra. Például a munkavállalók egészségéről és biztonságáról szóló irányelvek, köztük a várandós munkavállalókról szóló irányelv előírja, hogy a munkáltatóknak fel kell mérniük a munkavállalók (várandós, szoptató, tizenéves) biztonságával és egészségével kapcsolatos valamennyi kockázatot, és el kell dönteniük, hogy milyen megelőző és védőintézkedéseket kell tenniük. Az egyik intézkedés lehet a munkavállalók (terhesek, szoptatók, tizenévesek) számára a rákkeltőnek vagy reprotoxikusnak minősített etanol használatának tilalma.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 50	2025/04/11 10:03
Name of organization/institution	AGRANA Romania S.A.

I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Clasificarea etanolului ca fiind cancerigen sau toxic pentru reproducere ar putea însemna că multe produse biocide și-ar putea pierde autorizația în viitor. Unele cazuri critice de utilizare sunt descrise mai jos. Prin urmare, considerăm necesară menținerea pe piață a dezinfectanților pe bază de etanol. În cazul nostru, etanolul este utilizat în principal ca substanță activă în multe dezinfectante utilizate în cadrul unităților noastre de producție de produse alimentare și furajere pentru a furniza produse sigure (PT4). În plus, produsele biocide care conțin etanol sunt utilizate ca dezinfectant pentru mâini de către personalul din instalațiile de prelucrare pentru a preveni contaminarea alimentelor și a furajelor și pentru a asigura igiena întreprinderii (PT 1). În plus, etanolul nu este utilizat doar ca substanță activă în produsele biocide, ci și ca solvent în alte produse biocide, de exemplu în repelenți, insecticide etc. Acestea sunt importante pentru ca fabricile noastre creeze condiții de igienă și să asigure produse sigure pentru clienții noștri. Ca urmare, un număr mare de produse biocide ar putea fi afectate de o clasificare și, în consecință, și-ar putea pierde autorizația.
Product Type	1,2,4
Alternative Identity and Properties	Acid peracetic Clorocresol Compuși cuaternari de amoniu Hipoclorit de sodiu Fenoxietanol Monocloramină nPropanol și isoPropanol Peroxid de hidrogen
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Compușii cuaternari de amoniu și hipocloritul de sodiu nu pot fi utilizați deoarece duc la formarea de reziduuri nedetașabile în produsul alimentar final. Peroxidul de hidrogen și acidul peractic sunt corozive și nu sunt potrivite pentru multe materiale utilizate Clorocresol, fenoxietanol, monocloramină nu pot fi utilizate deoarece duc la formarea de mirosuri în alimentul final. Alternativele alcoolice nPropanol și isoPropanol sunt lipsite de activitate virucidă completă.
Information above is confidential	

Justification for confidentiality	
Economic Feasibility	O clasificare ca CMR va duce probabil fie la interzicerea completă a produselor biocide care conțin etanol, fie la îngrijorarea clienților și, prin urmare, a produselor biocide pe bază de etanol și la trecerea la produse alternative. Deoarece există mai puține companii care furnizează pe piață dezinfectanți utilizabili din punct de vedere tehnic sau legal cu alternative la etanol, de exemplu alcoolii Propanol, ne temem de o penurie și, prin urmare, de o creștere a prețurilor pe piață. Pentru a utiliza produse biocide alternative fără etanol în fabricile noastre, procesele de producție ar trebui reorganizate și instalațiile ar trebui reamenajate. Etanolul este relativ ieftin în comparație cu alte substanțe active, disponibil în general, ușor și rapid de produs, asigurând o aprovizionare constantă și, dacă provine din surse regenerabile, este și durabil.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Alternativele alcoolice Propanol sunt lipsite de activitate virucidă completă. Clorocresolul, peroxidul de hidrogen, monocloramina, fenoxietanolul, acidul peractic și hipocloritul de sodiu sunt corozive, unele având și proprietăți toxice.
Information above is confidential	
Justification for confidentiality	
Availability	Disponibilitatea pe termen scurt/mediu a alternativelor fezabile din punct de vedere tehnic nu este indicată, deoarece există mai puține întreprinderi care oferă alternative și creșterea producției de alternative la etanol este asociată cu noi instalații, noi tehnologii, noi autorizații de producție etc. Acest lucru va avea în plus un impact negativ asupra fezabilității economice din cauza lipsei de disponibilitate pe piață. Din cauza cerințelor (legale) suplimentare pentru siguranța produselor (alimente și furaje), alternativele enumerate mai sus nu sunt disponibile - Compușii cuaternari de amoniu și hipocloritul de sodiu nu pot fi utilizați deoarece duc la formarea de reziduuri nedetașabile în produsul alimentar final. - Chlorocresol, Phenoxyethanol, Monochloramine nu pot fi utilizate deoarece conduc la formarea de mirosuri în alimentul final. Acest lucru este contrar producției de produse sigure, așa cum este descris în legile și

	reglementările europene și naționale privind alimentele și furajele. alternative la etanol pentru utilizarea în producția de alimente și furaje ecologice nu sunt aprobate legal.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Consecințele unei interdicții privind etanolul vor fi extrem de grave. O bună igienă la locul de muncă este esențială, în special în timpul pandemiilor, pentru a proteja angajații din infrastructurile critice de virușii nedezvoltați. Cazul pandemiei Covid-19 a demonstrat necesitatea dezinfectanților pe bază de etanol pentru supraviețuirea infrastructurilor critice. Lipsa dezinfectanților pe această substanță activă puternică și bine tolerată va pune în pericol siguranța producției alimentare, a lucrătorilor și a publicului larg. Nu există nicio substanță activă biocidă de înlocuire cu eficacitate egală în cadrul locului de producție a produselor alimentare și a materiilor prime pentru hrana animalelor (PT4 și PT1).
Information above is confidential	
Justification for confidentiality	
Other comments	Studiile privind utilizarea etanolului arată că acesta se evaporă rapid. Inhalarea profesională nu duce la o creștere semnificativă a concentrației de etanol în sânge. Concentrațiile atmosferice de etanol la locurile de muncă în care acesta este utilizat sunt, în general, cu mult sub (de 6 până la 20 de ori) limitele naționale de expunere profesională pe o perioadă de opt ore. A se vedea Bessonneau V, Clement M, Thomas O. Can intensive use of alcohol-based hand rubs lead to passive alcoholization? International journal of environmental research and public health 2010; 7: 3038-50. Combinația tuturor proprietăților inerente ale substanței este dată doar de etanol: acțiune rapidă, virucid total, fără reziduuri, evaporare rapidă, timp lung de depozitare, fără transfer sau contaminare a alimentelor, inodor, fără produse secundare de dezinfecție sau produse de degradare relevante din punct de vedere (eco)toxicologic. Un alt fapt important este lipsa de eficacitate a tuturor alternativelor posibile ale etanolului pentru virusurile care nu sunt învelite. Aceasta înseamnă că nu este posibil să se prevină răspândirea bolilor cauzate de virusuri neînvelite, cum ar fi poliomielita, Noro etc. A se vedea lista de bază a OMS 15.1 și 15.2: Web Annex A.

	World Health Organization Model List of Essential Medicines - 23rd List, 2023. În: Selectarea și utilizarea medicamentelor esențiale 2023: Rezumat executiv al raportului celui de-al 24-lea Comitet de experți al OMS privind selectarea și utilizarea medicamentelor esențiale, 24 - 28 aprilie 2023. Geneva: Organizația Mondială a Sănătății; 2023 (WHO/MHP/HPS/EML/2023.02). Legătura dintre procesul biocid și alte sectoare: Evaluarea punctelor finale CMR și o decizie ulterioară a Comisiei Europene cu privire la aceste puncte finale ar duce la o declarație oficială privind proprietățile CMR ale etanolului pentru utilizări biocide. Aceste informații disponibile ar trebui să fie luate în considerare de toți utilizatorii de etanol în timpul autoclasificării lor. Astfel, o clasificare în cadrul sectorului biocid s-ar transfera în toate sectoarele. În plus, această poziție oficială privind proprietățile CMR ar putea influența procesul de formare a opiniei altor comitete CLP și, astfel, ar putea afecta procesul de clasificare armonizată aflat în desfășurare. De exemplu, directivele privind sănătatea și securitatea lucrătorilor, inclusiv directiva privind lucrătoarele gravide, prevăd că angajatorii trebuie să evalueze toate riscurile legate de securitatea și sănătatea lucrătoarelor (gravide, care alăptează, adolescente) și să decidă ce măsuri preventive și de protecție trebuie luate. O măsură ar putea fi interzicerea utilizării pentru lucrătoare (gravide, care alăptează, adolescente) a etanolului clasificat drept cancerigen sau reprotoxic.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 51	2025/04/11 12:08
Country	Germany

Name of organization/institution	Dalli Werke GmbH & Co KG
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Die dalli-group ist ein Familienunternehmen in sechster Generation mit klarer Fokussierung auf das europäische Handelsmarken- und Markengeschäft. Entsprechend unserem Qualitätsversprechen verbinden wir als mittelständisches Unternehmen Tradition, Werte und soziale Verantwortung in unserer mehr als 175-jährigen Firmengeschichte mit den Ansprüchen einer leistungsstarken und zukunftsorientierten Unternehmensgruppe. Unser Portfolio umfasst ein breites Produktspektrum in den Märkten Schönheits- und Haushaltspflege.
Product Type	1,2,4
Alternative Identity and Properties	Als Wirkstoff in Desinfektionsmitteln ist Ethanol vielseitig einsetzbar, da es sowohl eine antimikrobielle, antifungizide als auch antivirale Wirkung hat. Außerdem ist Ethanol eines der wichtigsten industriellen Lösemittel, da es sowohl lipophile als auch hydrophile Stoffe lösen kann. Darüber hinaus kommt Ethanol in vielen technischen Anwendungen zum Einsatz. Trotz der Jahrzehnte langen Verwendung, zum Teil auch in Anwendungen mit direktem Hautkontakt (z.B. Handdesinfektion), gibt es keine epidemiologischen Hinweise auf eine toxikologisch relevante Wirkung durch dermale oder inhalative Aufnahme.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Einige seiner positiven Eigenschaften teilt Ethanol mit anderen Stoffen. So ist zum Beispiel Propanol ähnlich flüchtig, was zum Beispiel vorteilhaft für die Schnelldesinfektion von Oberflächen ist. Trotzdem ist

	Propanol kein gleichwertiger Ersatz für Ethanol, da es – anders als Ethanol – nicht wirksam gegen behüllte Viren ist.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Dass sich aus den epidemiologischen Daten für Ethanol eine gesundheitsschädliche Wirkung ableiten lässt, ist unumstritten. Allerdings liegt all diesen Daten eine orale Aufnahme zu Grunde. Die Exposition des Menschen mit Ethanol erfolgt aber nicht nur oral beim Konsum alkoholhaltiger Speisen und Getränke. Auch auf anderen Wegen kommen Menschen mit Ethanol in Kontakt, z.B. dermal bei der Handdesinfektion oder inhalativ beim Umgang mit Gemischen, die Ethanol als Lösemittel enthalten. Trotzdem gibt es keine epidemiologischen Daten, die auf eine toxikologische Wirkung bei diesen Expositionen hinweisen. Eine CMR-Einstufung im Biozidprozess, die mit hoher Wahrscheinlichkeit eine CMR-Einstufung im CLH-Prozess zur Folge hätte, käme in der Praxis einem Verbot für viele Anwendungen gleich und das obwohl kein tatsächliches Risiko bei diesen Anwendungen vorliegt. Das würde zum Beispiel auch Wasch- und Reinigungsmittel betreffen. Bewährte und effiziente Rezepturen müssten geändert werden. Damit wäre nicht nur ein großer Kosten- und Arbeitsaufwand für die Hersteller verbunden. Da es keinen gleichwertigen, gleich gut verfügbaren Ersatz für Ethanol gibt, könnten Produkte weniger wirksam sein oder gar ganz wegfallen. Unter hygienischen Aspekten würde eine CMR-Einstufung von Ethanol der menschlichen Gesundheit also am Ende schaden statt nutzen.
Information above is confidential	
Justification for confidentiality	
Availability	Ethanol lässt sich aus nachwachsenden Rohstoffen herstellen, was auch im großen Maßstab geschieht. Ein Wegfall von Ethanol und Ersatz durch andere Stoffe wäre also auch unter Umweltaspekten nicht wünschenswert.
Information above is confidential	
Justification for confidentiality	

Conclusion on suitability and availability of the alternative	Es sind keine Alternativen verfügbar, die eine vergleichbare Sicherheit, Wirksamkeit und technische Eigenschaften wie Ethanol erfüllen.
Information above is confidential	
Justification for confidentiality	
Other comments	Die CLP-Verordnung verfolgt einen gefahrenbasierten Ansatz. Trotzdem müssen in diesem Fall die tatsächlichen Expositionswege in Betracht gezogen werden. Desinfektionsmittel aber auch Wasch- und Reinigungsmittel, um die es indirekt auch geht, werden nicht oral aufgenommen. Es besteht also kein Risiko bei diesen Anwendungen von Ethanol.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 52	2025/04/11 13:38
Country	Germany
Name of organization/institution	██████████
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	██████ uses Ethanol for cleaning purposes and as solvent.
Product Type	1,2,4

Alternative Identity and Properties	not applicable
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	not applicable
Information above is confidential	
Justification for confidentiality	
Other comments	Ethanol is used industrially as a solvent and in numerous mixtures intended for the general public. If the respective use or scope of application is not outside the scope of the CLP Regulation (e.g. in pharmaceuticals, food, feed), a restriction under Annex XVII of the REACH Regulation could

	apply in the event of a classification as carcinogenic and toxic for reproduction. With the exception of ethanol-containing foods, the supply of ethanol-containing mixtures and products to the end consumer would then no longer be permitted and ethanol would have to be substituted in the products, regardless of whether substitutes with the same benefit are available (e.g. for surface disinfection). Advantages of Ethanol: - No toxicologically relevant residues or permanent pollution. • No cases of skin sensitization have been reported during normal use. • Lower risk of accidental poisoning due to rapid evaporation compared to alternatives. • No discoloration of food and odorless, making it suitable for food-related applications Ethanol is assessed with a view to a possible classification as carcinogenic and/or toxic to reproduction, however: - o There is no conclusive evidence for carcinogenicity at real exposure levels. - o The toxicological assessment should distinguish between ingestion, topical and inhaled exposure. - Each classification must be a risk-based assessment and not a pure hazard classification. Important: According to point 3.6.2.1 of Annex 1 to the CLP Regulation, it may be justified to classify as carcinogenic according to one route of exposure only, if it is demonstrated that there is no risk from the other routes of exposure. According to this, ethanol would only have to be classified as carcinogenic via the oral exposure pathway. As already explained, there is no intended oral exposure to ethanol within the scope of substance law.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 53	2025/04/12 19:51
Country	Switzerland

Name of organization/institution	B. Braun Medical AG
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	B. Braun Medical AG is a manufacturer of the Biocidal Active Substance acc BPR as well as a manufacture of several biocidal preparations based on ethanol. Therefore, we like to give a feedback in the current consultation procedure.
Product Type	1,2,4
Alternative Identity and Properties	see attached file
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	see attached file
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	see attached file
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	see attached file
Information above is confidential	
Justification for confidentiality	
Availability	see attached file
Information above is confidential	
Justification for confidentiality	

Conclusion on suitability and availability of the alternative	see attached file
Information above is confidential	
Justification for confidentiality	
Other comments	see attached file
Information above is confidential	
Justification for confidentiality	
References	see attached file
Attachments (non-confidential information)	Statement of BBraun on public Ethanol Consultation_final.zip
Attachments (confidential information)	
Justification for confidential attachment	

Comment 54	2025/04/12 19:53
Country	Switzerland
Name of organization/institution	B. Braun Medical AG
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	B. Braun Medical AG is a manufacturer of the Biocidal Active Substance acc BPR as well as a manufacture of several biocidal preparations based on ethanol. Therefore, we like to give a feedback in the current consultation procedure.
Product Type	1,2,4
Alternative Identity and Properties	see attached file

Information above is confidential	
Justification for confidentiality	
Technical Feasibility	see attached file
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	see attached file
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	see attached file
Information above is confidential	
Justification for confidentiality	
Availability	see attached file
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	see attached file
Information above is confidential	
Justification for confidentiality	
Other comments	see attached file
Information above is confidential	
Justification for confidentiality	
References	see attached file

Attachments (non-confidential information)	Statement of BBraun on public Ethanol Consultation_final.zip
Attachments (confidential information)	
Justification for confidential attachment	

Comment 55	2025/04/12 19:55
Country	Switzerland
Name of organization/institution	B. Braun Medical AG
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	B. Braun Medical AG is a manufacturer of the Biocidal Active Substance acc BPR as well as a manufacture of several biocidal preparations based on ethanol. Therefore, we like to give a feedback in the current consultation procedure.
Product Type	1,2,4
Alternative Identity and Properties	see attached file
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	see attached file
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	see attached file
Information above is confidential	
Justification for confidentiality	

Hazards and Risks of the Alternative	see attached file
Information above is confidential	
Justification for confidentiality	
Availability	see attached file
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	see attached file
Information above is confidential	
Justification for confidentiality	
Other comments	see attached file
Information above is confidential	
Justification for confidentiality	
References	see attached file
Attachments (non-confidential information)	Statement of BBraun on public Ethanol Consultation_final.zip
Attachments (confidential information)	
Justification for confidential attachment	

Comment 56	2025/04/14 09:20
Country	Germany
Name of organization/institution	

I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	Ethanol ist ein weit verbreiteter biozider Wirkstoff mit breitem Wirkungsspektrum, insbesondere in Desinfektionsmitteln und Antiseptika. Von besonderer Bedeutung sind hier die Mittel für die hygienische Händedesinfektion in medizinischen Einrichtungen, die ein wesentlicher Faktor in der Verhinderung der Übertragung von Erregern (inkl. multiresistenter Erreger) sind. Die zunehmende Verbreitung von Erregern mit Resistenzen wird seitens der WHO als eine der Top Ten Bedrohung für die weltweiten Gesundheitssysteme gesehen. Die wichtigsten Eigenschaften sind: . Nachgewiesene viruzide, bakterizide, fungizide und tuberkulozide Wirkung. . Hohe Wirksamkeit gegen unbehüllte Viren, was für die Infektionskontrolle entscheidend ist. . Keine Rückstände auf Oberflächen, wodurch es sicher für Anwendungen mit Lebensmittelkontakt ist. . Gut dokumentiertes Sicherheitsprofil mit minimalen Risiken bei sachgemäßer Anwendung.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Gerade bei der Viruzidie gibt es im Grunde keine Alternative: Ethanol ist der einzige Alkohol, der vollständig viruzid und umfassend wirksam gegen unbehüllte Viren

	einschl. Enteroviren (z.B. Polioviren) ist und eine der wenigen alkoholischen Substanzen, die gegen Noroviren wirksam ist. Ethanol verursacht keine toxikologisch relevanten Rückstände oder dauerhafte Umweltverschmutzung. . Es gibt keine gemeldeten Fälle von Hautsensibilisierung bei normalem Gebrauch. Ethanol wird im Hinblick auf eine mögliche Einstufung als krebserregend und/oder reproduktionstoxisch bewertet. Jedoch: . Es gibt keine schlüssige Evidenz für die Karzinogenität von realen Expositionswegen/-werten. . Bei der toxikologischen Bewertung sollte zwischen der Aufnahme über die Nahrung und der Exposition durch Einatmen unterschieden werden.
Information above is confidential	
Justification for confidentiality	
Availability	stabile Lieferketten, günstig und breit verfügbar
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Aufgrund der Wirksamkeit und guten Verträglichkeit gibt es keine sinnvollen Alternativen. Eine Toxizität bei der Anwendung als Händedesinfektionsmittel ist nicht anzunehmen, da es nicht zu einer relevanten Aufnahme über die Haut kommt.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	Unterstützt durch WHO-Empfehlungen und Studien (z. B. Kramer et al., 2022), die seine hervorragenden Desinfektionseigenschaften hervorheben. Empfehlung der KRINKO zur Hygienischen Händedesinfektion
Attachments (non-confidential information)	

Attachments (confidential information)	
Justification for confidential attachment	

Comment 57	2025/04/14 11:22
Country	Germany
Name of organization/institution	Lipoid GmbH
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	The assessment of the reproductive toxicity of ethanol is based on experience from the misuse of alcoholic beverages, i.e. exclusively on oral intake. When used as a chemical, this is not relevant and does not play a role in occupational hazards, so these data are not suitable for classification as an industrial chemical or in consumer products. Typically, ethanol is used in the chemical industry in denatured form to prevent oral uptake.
Product Type	1,2,4
Alternative Identity and Properties	We are a group of companies manufacturing pharmaceutical excipients and active substances as well as cosmetic raw materials and food in GMP compliant facilities. In our manufacturing facilities ethanol is used for hand disinfection, cleaning/disinfection of manufacturing equipment and as manufacturing solvent. In some of our formulation products ethanol is used as integral part of the formulation, relevant to obtain physicochemical properties necessary for further processing steps. The possible exposure routes for all three applications might be dermal exposure and inhalative exposure. As the ethanol used for disinfection, cleaning and manufacturing is denatured exposure by the oral route is not likely. For ethanol that is not denatured the use for manufacturing is strictly controlled by the customs authorities. Manufacturing solvent: The amounts of ethanol needed for hand disinfection are rather small in comparison to the amounts used for cleaning of manufacturing equipment and especially as solvent for manufacturing. We, among others,

are purifying natural raw materials for the use as pharmaceutical active or excipient as well as cosmetic raw materials and food in our company. For these manufacturing processes there are no alternatives available for ethanol as safe and especially environmentally friendly solvent. Residual ethanol from production processes in our products is always within the limits of ICH Q3C Impurities: Guideline for Residual Solvents (limit for class 3 solvents n.m.t 0.5 %). In comparison, this is far below the naturally occurring amounts of ethanol in foodstuffs like e.g. fruits, fruit juices (might contain up to 3 % of ethanol, VAH 2020), baking goods, etc. Therefore, the ethanol residue from production processes and disinfection does not significantly increase the existing daily exposure to ethanol. Thus, this would be a regulation with a huge economic impact without significant impact on exposure. With many other disinfectants, these would be introduced to the body solely through their use in the process or disinfection and would mainly cause exposure to them. Hand disinfection, cleaning/disinfection of manufacturing equipment: Hand disinfection as well as disinfection/cleaning of manufacturing equipment is an integral part of pharmaceutical manufacturing to prevent contamination of the products and ensures hygiene during manufacturing also in our company. For disinfection alternatives for ethanol are 2-propanol or n-propanol, which are also used together with ethanol. The following data are taken from the MSDS (according to regulation 1907/2006/EG) of the three substances:

Substance / Exposure route / LD50/LC50 Ethanol		
Oral	LD50: 10470 mg/kg (rat)	Dermal
	LD50: 15800 mg/kg (rabbit)	Inhalation
	LC50: 51 mg/l (rat; 4h, vapour)	2-Propanol
Oral	LD50: 5840 mg/kg (rat)	Dermal
	LD50: 12800 mg/kg (rabbit)	Inhalation
	LC50: 37.5 mg/l (rat; 4h, vapour)	n-Propanol
Oral	LD50: approx. 8000 mg/kg (rat)	
Dermal	LD50: 4032 mg/kg (rabbit)	Inhalation
	LC50: more than 33.8 mg/l (rat; 4h, vapour)	

As can be seen from the data ethanol is less toxic than the possible alternatives (for all three exposure routes) that may be used for disinfection. Human data for the alternative products are not available for obvious reasons. Therefore, there is evidence that ethanol is the least toxic and best tolerated solvent, with a well-studied effect on the human body, compared to alternatives. Ethanol as disinfectant is more effective than the alternative products against healthcare-associated infections (HAIs) [VAH 2020]. Ethanol is one of the few substances fully virucidal and efficient against non-enveloped viruses such as noroviruses and

	polioviruses. During hand disinfection only 1-2 % of the ethanol is taken up. A large part of the ethanol evaporates within seconds. Therefore, the amounts of ethanol taken up during hand disinfection are below toxicological relevant concentrations. The World Health Organisation (WHO) recommends ethanol-based hand sanitisers as 'the gold standard for hand hygiene in healthcare' and in March 2020 WHO launched the "Safe Hands Challenge" widely promoting the use of alcohol-based hand sanitisers to fight COVID-19. VAH 2020: Verbund für Angewandte Hygiene e.V. et al. (Hrsg.). Ethanol ist als biozider Wirkstoff zur hygienischen Händedesinfektion unverzichtbar. Vorabveröffentlichung online www.vah-online.de, 20. Oktober 2020. HygMed 2020;45(11)
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Manufacturing solvent: We, among others, are purifying natural raw materials for the use as pharmaceutical active or excipient as well as cosmetic raw materials and food in our company. For these manufacturing processes there are no alternatives available for ethanol as safe and environmentally friendly solvent. Ethanol is also used for manufacturing of many plant extracts all over the world without having alternative solvents available.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Manufacturing solvent: We, among others, are purifying natural raw materials for the use as pharmaceutical active or excipient as well as cosmetic materials and food in our company. For these manufacturing processes there are no alternatives available for ethanol as safe and environmental friendly solvent. Ethanol is also used for manufacturing of many plant extracts all over the world without having alternative solvents available. A classification of ethanol therefore would aggravate the use of ethanol as solvent for extraction of natural raw materials. Ethanol is the only safe solvent that is reliably available worldwide in large quantities from renewable raw materials. The production of ethanol is easy and cost effective. The use of alternatives would lead to rising costs for the industry and therefore also for consumers. To obtain sustainable production processes the substitution of petrochemical solvents is essential. A

	classification of ethanol will largely diminish the use scenarios for ethanol obtained from renewable sources. This would lead to a rise in the use of petrochemical solvents which will be in contrast to the strategy to get sustainable production processes. This will lead to higher production costs as well as to less sustainable processes and in many cases to more critical residues in pharmaceutical products. Due to its polarity, mixability with water and its further physico-chemical properties there is no replacement for ethanol in many industrial production processes. A classification of ethanol would aggravate the use of ethanol as solvent for extraction of natural raw materials. A restriction of the use of ethanol might lead to shortage of important pharmaceutical excipients and active substances. This would influence also the availability of important pharmaceutical products needed for patient care, putting the live of thousands of patients at risk. A general classification of ethanol as a CMR substance might cause a shortening of disinfectants, cleaners, medicines and medicinal products leading to a deterioration of human healthcare and hygiene. This will be in contrast to the aim to “ensure a high level of protection of human health and the environment” of the CLP regulation and regulations of biocides and pharmaceuticals. For the pharmaceutical production in Europe European industry a general classification of ethanol as CMR substance would be a locational handicap due to massive restrictions and the resulting additional expenses. This is in contrast to the “Pharmaceutical Strategy for Europe” (COM(2020) 761 final).
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Manufacturing solvent: We among others are purifying natural raw materials for the use as pharmaceutical active or excipient as well as cosmetic raw materials and food in our company. For these manufacturing processes there are no alternatives available for ethanol as safe and environmental friendly solvent. Ethanol is also used for manufacturing of many plant extracts all over the world without having alternative solvents. Hand disinfection, cleaning/disinfection of manufacturing equipment: Hand disinfection as well as disinfection/cleaning of manufacturing equipment is an integral part of pharmaceutical manufacturing to prevent contamination of the products and ensures hygiene during manufacturing. There is no viable

	alternative to ethanol. No other substance can match ethanol's efficacy in infection control. Alternatives, such as propanol, are less effective and harsher on the skin. Not probably disinfected production equipment puts patient and consumer health at risk.
Information above is confidential	
Justification for confidentiality	
Availability	Ethanol is the only safe solvent that is reliably available worldwide in large quantities from renewable raw materials. The production of ethanol is easy and cost effective. The use of alternatives would lead to rising costs and risk of shortages due to reduced availability for the industry and therefore also for consumers.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Due to its polarity, mixability with water and its further physico-chemical properties there is no replacement for ethanol in many industrial production processes. A classification of ethanol would aggravate the use of ethanol as solvent for extraction of natural raw materials. A restriction of the use of ethanol might lead to shortage of important pharmaceutical excipients and active substances. This would influence also the availability of important registered pharmaceutical products needed for patient care. Ethanol has proven to be safe for cleaning of surfaces of manufacturing equipment for the production of pharmaceutical excipients and active substances as well as cosmetic and dietetic raw materials as it leaves no residues on the equipment and evaporates quickly. Ethanol is the most effective substance to fight a broad spectrum of organisms like for instance bacteria and non-enveloped viruses, ensuring a high level of health protection. There is no viable alternative to ethanol. No other substance can match ethanol's efficacy in infection control. Alternatives, such as propanol, are less effective and harsher on the skin. Due to the widespread use the safety profile of ethanol for the different applications is well known. A general classification of ethanol as a CMR substance might cause a shortening of disinfectants, cleaners, medicines and medicinal products leading to a deterioration of human healthcare and hygiene. This will be in contrast to the aim to "ensure a high level of protection of human health and

	the environment” of the CLP regulation and regulations of biocides and pharmaceuticals. For the pharmaceutical production in Europe European industry a general classification of ethanol as CMR substance would be a locational handicap due to massive restrictions and the resulting additional expenses. This is in contrast to the “Pharmaceutical Strategy for Europe” (COM(2020) 761 final).
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	VAH 2020: Verbund für Angewandte Hygiene e.V. et al. (Hrsg.). Ethanol ist als biozider Wirkstoff zur hygienischen Händedesinfektion unverzichtbar. Vorabveröffentlichung online www.vah-online.de , 20. Oktober 2020. HygMed 2020;45(11) EC 2020: Publications Office of the European Union, HOW THE BIOECONOMY CONTRIBUTES TO THE EUROPEAN GREEN DEAL, November 2020.
Attachments (non-confidential information)	Ethanol Summary Document_Lipoid_100425.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 58	2025/04/14 12:13
Country	Netherlands
Name of organization/institution	NVZ - Clean Hygienic Sustainable
I do not wish the name of my organisation/institution to be published on the ECHA website.	

General information	Comments on all PTs, please see attachment for full text and references. The NVZ – Clean Hygienic Sustainable is deeply concerned about the consequences of the possible classification of ethanol as carcinogenic and/or reprotoxic (CMR) category 1 under the Biocidal Products Regulation (BPR). In that context, The NVZ – Clean Hygienic Sustainable requests the EU to identify the direct and indirect consequences of these classifications before the EU decides on approval of ethanol under the BPR. The following should be considered: • First of all, it is important to ensure that the correct procedural steps are followed within the legislation. This will otherwise lead to unnecessary discussions in practice; • The NVZ – Clean Hygienic Sustainable recognises that high blood concentrations of ethanol, regardless of origin, can lead to an increased risk of cancer and/or reprotoxic effects. Such high blood concentrations of ethanol are not achieved by exposure to ethanol in non-consumption applications. Therefore, warning the user about this hazard is not of direct added value; • A CMR classification of ethanol without considering the potential exposures has far-reaching consequences that could compromise public health because of the important role ethanol plays in infection prevention. Alternatives to ethanol are not readily available because ethanol generally cannot be substituted 1-to-1 because of its diverse functionality. Therefore, care must be taken to avoid 'regrettable substitution'. It is also questionable whether, in the context of strategic independence and sustainability of the supply chain, it is desirable to substitute ethanol, which can be produced from readily available and renewable sources. A further elaboration on the points is available in the annex. Finally, we would like to reiterate the importance of looking very critically at the process steps followed for ethanol classification.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	

Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	A CMR classification of ethanol without considering the potential exposures has far-reaching consequences that could compromise public health because of the important role ethanol plays in infection prevention. Alternatives to ethanol are not readily available because ethanol generally cannot be substituted 1-to-1 because of its diverse functionality. Therefore, care must be taken to avoid 'regrettable substitution'. It is also questionable whether, in the context of strategic independence and sustainability of the supply chain, it is desirable to substitute ethanol, which can be produced from readily available and renewable sources.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	

Attachments (non-confidential information)	250414 EN NVZ-reactie consultatie alternatieven ethanol onder BPR.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 59	2025/04/14 17:41
Country	Germany
Name of organization/institution	Dr. Schumacher GmbH
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Dr. Schumacher GmbH, a leading European producer of disinfectants and hygiene products, welcomes the opportunity to comment on the proposed classification of ethanol as a “Candidate for Substitution” (CfS) under the EU Biocidal Products Regulation (BPR, Regulation (EU) No 528/2012 echa.europa.eu). We strongly oppose designating ethanol (CAS 64-17-5) as a CfS. This submission outlines our legal, scientific, and socio-economic reasons, and urges regulators to reconsider this action. Ethanol is an essential, well-characterized substance widely used for infection control and other applications; an unwarranted CfS classification could undermine public health, our company's operations, and broader societal interests. Overview of our position: We contend that the CfS proposal for ethanol is procedurally flawed and scientifically unsubstantiated. There is no harmonised EU classification of ethanol as a carcinogen or reproductive toxin under the Classification, Labelling and Packaging (CLP) Regulation, which undercuts the legal basis for CfS listing. The data used to suggest ethanol is a CMR (Carcinogenic, Mutagenic, or Reprotoxic) rely on inappropriate extrapolations from oral alcohol abuse, not on evidence relevant to biocidal uses. From a socio-economic perspective, Dr. Schumacher GmbH and the health sector at large heavily rely on ethanol for safe and effective disinfection—alternatives are neither technically equivalent nor economically feasible at the required scale. Moreover, no major international jurisdiction classifies

	ethanol as a CMR substance, highlighting the disproportionate nature of the proposed EU move. We urge ECHA and the Commission to pause the CfS classification pending a proper CLP harmonisation process with full stakeholder input. In the meantime, ethanol should be approved as biocide active substance for all PTs (1,2,4), as it is a backlog dossier. The following sections detail our concerns: (1) a legal analysis of procedural and regulatory shortcomings, (2) a scientific critique of the hazard data, (3) the socio-economic impact on our company and public health (with a COVID-19 context), (4) the infeasibility of alternatives in terms of efficacy, safety and availability, (5) international regulatory comparisons, and (6) our conclusions and request for action. We will give this contribution in form of a confidential attachment.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	

Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	In summary, ethanol's combination of broad efficacy, rapid action, safety profile, and cost-effectiveness is unparalleled. It is justifiably the most widely used active substance in disinfection due to these qualities. Other substances either do not kill as broad a range of pathogens, or pose greater health/environmental risks, or are not readily available or affordable at scale. Removing or reducing ethanol in biocidal products would likely diminish the effectiveness of hygiene protocols and increase costs and logistical burdens, with no meaningful improvement in safety. We have seen that even regulators in other domains acknowledge ethanol's unique place – for instance, the European Food Safety Authority permits ethanol for surface disinfection in food production due to its efficacy and because it leaves no residues harmful to consumers. If there were a better alternative, it would already be in widespread use; the reality is that ethanol remains irreplaceable in many critical applications . Therefore, from a technical and socio-economic perspective, classifying ethanol as CfS (which implies a push toward alternatives) is premature and impractical. It risks forcing a transition to inferior options, undermining infection control and economic efficiency.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	see attached document
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 60	2025/04/15 09:52
Country	Netherlands
Name of organization/institution	Vakcentrum
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Introduction: Vakcentrum, the trade association for independent entrepreneurs and franchisees with members in various sectors such as supermarkets, specialty food stores, and organic shops, hereby presents its position on the consultation: 'Consultations on potential candidates for substitution and on derogations conditions'. We have taken note of the consultation with interest. Our position is that ethanol is the most effective and reliable disinfection tool currently available for the food and feed industries and other markets. Ethanol cannot be replaced by an alternative in principle because there is no viable alternative that currently exists that meets the technical, operational, and practical requirements. General: Vakcentrum has taken note of this consultation along with the accompanying reports. In the reports, EPPA concludes that ethanol cannot be replaced by an alternative in principle. For PT 01, PT 02, and PT 04 intended uses, ethanol is the most effective substance. The AoA for alle three intended uses confirms that no viable alternative currently exists that meets the technical, operational, and practical requirements. This reinforces the necessity of maintaining ethanol's availability to ensure effective infection control and safeguard public health across the European Union. Ethanol remains irreplaceable for different intended uses for ensuring effective, rapid, and sustainable disinfection. Its approval under the BPR is vital for maintaining high EU food safety standards, safeguarding public health, and supporting sustainability goals. Considering recent public health crises and their impact on global value chains and the food industry, but also recent global challenges affecting food supply chains, it would be highly inappropriate to forgo the most effective and reliable disinfection tool currently available for the food and feed industries and other markets. Conclusion and recommendation Therefore, the Vakcentrum strongly suggests that the current situation be maintained and that no additional restrictive measures be

	introduced beyond the existing legislation as it stands at present.
Product Type	1,2,4
Alternative Identity and Properties	See General Information.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	See General Information.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	See General Information.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	See General Information.
Information above is confidential	
Justification for confidentiality	
Availability	See General Information.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	See General Information.
Information above is confidential	
Justification for confidentiality	
Other comments	See General Information.

Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 61	2025/04/15 15:46
Country	Netherlands
Name of organization/institution	Corbion (Purac Biochem bv)
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	
Product Type	1,2,4
Alternative Identity and Properties	L-Lactic acid (CAS 79-33-4)
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	L-Lactic acid as active substance under BPR is fully assessed. All information is publicly available. Assessment Report is attached. L-Lactic acid has been tested versus diverse viruses for PT1, including non-enveloped Nora and Rhino and is effective against a couple of them. L-Lactic acid is not sufficiently effective against Poliovirus and Hepatitis A (only log 1-2 reduction). There is only very little data available about the efficacy of L-Lactic against non-enveloped viruses. The conclusion in the AoA report that

	there is "limited antimicrobial efficacy, particularly against non-enveloped viruses" is premature. More efficacy test data are required.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	L-Lactic acid as active substance under BPR is fully assessed. All information is publicly available. Assessment Report is attached. L-Lactic acid has a much lower hazard profile than ethanol.
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	L-Lactic acid is (at least partly) an effective and certainly a safer alternative for ethanol, depending on the viruses to target. Bacterial efficacy of L-Lactic acid is equal to that of ethanol when the right combination with e.g. surfactants and a proper concentration are applied.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	

References	
Attachments (non-confidential information)	7638_1322-01-Assessment_Report.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 62	2025/04/15 16:16
Country	Germany
Name of organization/institution	Lehmann&Voss&Co. KG
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	We do not see the need for substitution of ethanol in industrial, hygiene and consumer applications because the assessment of the reproductive toxicity of ethanol is based on experience from the misuse of alcoholic beverages, mainly exclusively on oral intake. When used as an industrial chemical, this is not relevant for occupational hazard and health topics.
Product Type	1,2,4
Alternative Identity and Properties	-
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	-
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	-

Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	-
Information above is confidential	
Justification for confidentiality	
Availability	-
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	In general, and based on recent discussions, we do not see the need for substitution of ethanol in industrial, hygiene and consumer applications. As we understood the recent discussion and the proposal for re-classification of ethanol (CAS 64-17-5), the assessment of the reproductive toxicity of ethanol is based on experience from the misuse of alcoholic beverages, mainly exclusively on oral intake. When used as an industrial chemical, this is not relevant and does not play a role in occupational hazard and health topics, so these data are not suitable for classification as an industrial chemical or in consumer products. Typically, ethanol is used in the chemical industry in denatured form to prevent oral uptake. Consequently, the risk for workers/ users of ethanol in this context is significantly reduced and therefore, in our view, does not justify classification as proposed.
Information above is confidential	
Justification for confidentiality	
Other comments	-
Information above is confidential	
Justification for confidentiality	
References	

Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 63	2025/04/15 16:22
Country	Netherlands
Name of organization/institution	Corbion (Purac Biochem bv)
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	
Product Type	1,2,4
Alternative Identity and Properties	L-Lactic acid (CAS 79-33-4)
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	L-Lactic acid as active substance under BPR is fully assessed. All information is publicly available. Assessment Report is attached. There is only very little data available about the efficacy of L-Lactic against non-enveloped viruses. The conclusion in the AoA report that "The inability to inactivate non-enveloped viruses significantly limits their suitability as a broad-spectrum disinfectant, particularly in high-hygiene environments where comprehensive pathogen control is required" is premature. More efficacy test data on non-enveloped viruses are required.
Information above is confidential	
Justification for confidentiality	

Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	L-Lactic acid as active substance under BPR is fully assessed. All information is publicly available. Assessment Report is attached. L-Lactic acid has a much more favorable hazard profile than ethanol.
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	L-Lactic acid is (at least partly) an effective and certainly a safer alternative for ethanol. The observation that L-Lactic acid is less available and more expensive to produce is only temporary and will change once it has replaced ethanol in (some) PT2 uses.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	8132_1322-02_Assessment_Report.pdf
Attachments (confidential information)	

Justification for confidential attachment	

Comment 64	2025/04/15 16:52
Country	Netherlands
Name of organization/institution	Corbion (Purac Biochem bv)
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	L-Lactic acid as active substance under BPR is fully assessed. All information is publicly available. Assessment Report is attached. L-Lactic acid has been tested versus diverse viruses (incl. non-enveloped), yeasts and bacteria. There is only very little data available about the efficacy of L-Lactic against non-enveloped viruses. The conclusion in the AoA report that there is "limited antimicrobial efficacy, particularly against non-enveloped viruses" is premature. More efficacy test data are required.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	

Hazards and Risks of the Alternative	L-Lactic acid as active substance under BPR is fully assessed. All information is publicly available. Assessment Report is attached. L-Lactic acid has a much more favorable hazard profile than ethanol.
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	L-Lactic acid is (at least partly) an effective and certainly a safer alternative for ethanol. Cost effectiveness is only temporary and may never be a barrier for safe and effective alternatives to replace ethanol.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	8132_1322-02_Assessment_Report.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 65	2025/04/15 17:02
Country	France

Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	Nous préconisons l'utilisation de l'éthanol pour ses divers caractéristiques positives : - Bon marché - Efficacité biocide (bactéricide, levuricide, virucide, fongicide) rapide et spectre d'efficacité large. - Pas de risque de phénomène de résistance (les bactéries ne s'y adaptent pas). - Sans résidu - Pas d'action corrosif sur le matériel - Stable chimiquement - Peu odorant - Particulièrement respectueux de la peau
Product Type	1,2,4
Alternative Identity and Properties	- Ammoniums quaternaires - Peroxyde d'hydrogène - Isopropanol = propan-2-ol - Acide lactique
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	A ce jour, l'éthanol est utilisé dans de nombreux domaines d'activités dont le milieu médical et agroalimentaire. Ses caractéristiques à efficacité rapide et à large spectre permettent une meilleure sécurité sanitaire que les alternatives possibles. En termes de coût et de quantité celui-ci est très accessible et disponible.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Les alternatives ci-dessous comprennent des inconvénients que l'on ne retrouve pas dans l'éthanol : - Ammoniums quaternaires Non actif sur les spores et pseudomonas contrairement à l'éthanol. Action biocide inhibé par les fibres de coton. Toxique pour les organismes aquatiques. -

	Peroxyde d'hydrogène Dégagement gazeux Blanchiment de la peau Réactivité avec d'autres produits chimiques Forte toxicité et corrosif L'OMS recommande comme substitut d'utilisation l'éthanol - Isopropanol = propan-2-ol Produit nocif qui requière des EPI Très odorant Pas totalement efficace sur le plan virucide (Attention pour le milieu médical) En présence d'air et de lumière peut générer des peroxydes instables Utilisation de gants nitrile vivement recommandé - Acide lactique Blanchi la peau Formation d'odeur Pas totalement virucide
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Pas d'alternatives concluante en terme de coût, efficacité, disponibilité, risques.
Information above is confidential	
Justification for confidentiality	
Other comments	D'autre part si l'on prend en compte la rapidité d'évaporation et la dilution de l'alcool des solutions à utilisation, l'accumulation d'éthanol dans le corps reste infime, même pour une utilisation quotidienne.
Information above is confidential	
Justification for confidentiality	
References	- ECHA - INRS - Microbiologie et toxicologie des aliments (hygiène et toxicité alimentaire) auteur Guy Leyral et Elisabeth Vierling
Attachments (non-confidential information)	
Attachments (confidential information)	

Justification for confidential attachment	

Comment 66	2025/04/15 17:18
Country	France
Name of organization/institution	██████████
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	Ethanol-based hand disinfectants are widely used in hospitals, healthcare centers, the food industry, and by the general public. These products are indispensable for infection prevention, particularly during health crises such as the COVID-19 pandemic. Ethanol enables fast, effective, and safe hand hygiene practices.
Product Type	1,2,4
Alternative Identity and Properties	Ethanol is fully virucidal, including non-enveloped viruses (e.g., norovirus, poliovirus). Propanols and QACs are less effective and more irritating; QACs pose sensitization and endocrine risks. Ethanol evaporates cleanly, no systemic accumulation under typical dermal use.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Ethanol-based hand rubs require no rinsing and are compatible with current dispenser systems. Substitution would require full reformulation, new procedures, and incompatible contact requirements.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Substitution implies high costs: formulation, validation (EN 1500, 14476), training, and equipment redesign. SMEs may not withstand the burden.

Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Ethanol is safe, well-tolerated, low systemic exposure. Alternatives: irritants (propanols), sensitizers (QACs), or corrosives (acids).
Information above is confidential	
Justification for confidentiality	
Availability	Ethanol is produced in large scale across the EU, scalable during crises. Alternatives face limited supply chains and cost volatility.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol is indispensable for PT1: no equivalent in safety, efficacy, availability, and technical integration.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 67	2025/04/15 17:37
Country	France
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	Ethanol-based surface disinfectants are commonly used in hospitals, transportation, educational facilities, and workplaces. They allow for fast, effective disinfection without rinsing, particularly in high-touch and sensitive areas.
Product Type	1,2,4
Alternative Identity and Properties	Ethanol ensures effective disinfection in clean and soiled conditions. QACs are less effective in soiling; NaOCl and peracetic acid are corrosive, leave residues.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Ethanol enables quick application and drying with no residue. Substitutes may corrode surfaces and are incompatible with rapid disinfection workflows.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Major impact across sectors (healthcare, public buildings, transport) requiring new protocols and retraining. Infrastructure adaptation is costly.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Ethanol: non-corrosive, biodegradable, safe for repeated use. Others: DBP formation, environmental persistence, increased health risks.

Information above is confidential	
Justification for confidentiality	
Availability	Ethanol is reliable and easy to produce at scale. Alternatives have short shelf lives or constrained logistics.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol is superior in PT2 for technical, operational, and safety performance. No equivalent alternatives.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 68	2025/04/15 17:39
Country	France
Name of organization/institution	
I do not wish the name of my organisation/institution to be	1

published on the ECHA website.	
General information	Ethanol is widely used in the food and beverage industry to disinfect surfaces in direct or indirect contact with food, such as worktops, conveyor belts, and tools. It is recognized for its safety, speed of action, and compatibility with HACCP procedures.
Product Type	1,2,4
Alternative Identity and Properties	Ethanol is food-safe, requires no rinsing, and does not alter organoleptic properties. Alternatives (peracetic acid, H ₂ O ₂): corrosive, require rinsing, alter food or equipment.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Compatible with existing industrial lines (CIP/SIP, manual sprays). Substitution implies major HACCP changes, equipment overhaul.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Downtime, requalification, and supply chain adjustments create excessive costs. SMEs particularly impacted.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Ethanol: odorless, non-corrosive, safe in food environments. Others: toxic residues, odor, increased poisoning risk.
Information above is confidential	
Justification for confidentiality	
Availability	Ethanol is widely produced with food-grade variants. Alternatives less stable, with restrictive regulations.
Information above is confidential	

Justification for confidentiality	
Conclusion on suitability and availability of the alternative	In PT4, ethanol offers unmatched food safety compatibility, operational efficiency, and user safety. Ethanol remains the only substance capable of meeting the technical, economic, regulatory, and hygienic needs across PT1, PT2, and PT4. Its classification as a CMR would undermine essential public health and hygiene systems in Europe.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 69	2025/04/15 17:52
Country	Netherlands
Name of organization/institution	Helichem B.V.
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	
Product Type	1,2,4

Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	See attachment
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	

References	
Attachments (non-confidential information)	2025-04-15 Consultation alternatives ethanol BPR - Helichem.docx
Attachments (confidential information)	
Justification for confidential attachment	

Comment 70	2025/04/15 17:54
Country	Netherlands
Name of organization/institution	Helichem B.V.
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	

Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	See attachment
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	2025-04-15 Consultation alternatives ethanol BPR - Helichem.docx
Attachments (confidential information)	
Justification for confidential attachment	

Comment 71	2025/04/15 17:55
Country	Netherlands
Name of organization/institution	Helichem B.V.

I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	See attachment
Information above is confidential	

Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	2025-04-15 Consultation alternatives ethanol BPR - Helichem.docx
Attachments (confidential information)	
Justification for confidential attachment	

Comment 72	2025/04/15 20:45
Country	Germany
Name of organization/institution	Labor Prof. Gisela Enders MVZ GbR
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	The Enders laboratory tests approximately 5,000 to 10,000 samples daily for routine diagnoses. The samples can contain non-enveloped viruses that are resistant to disinfectants with the claim "active against enveloped virus" or "limited spectrum of virucidal activity". In order to protect our staff who unpack the samples in the sample entrance or process the stool samples in molecular biology or bacteriology, we always use the highly effective virucidal preparation Sterillium virugard (95.0 g ethanol 99 %, tertridecan-1-ol, petrol, butan-2-one). Safety is a priority!! In my opinion, there is no alternative to ethanol!!
Product Type	1,2,4
Alternative Identity and Properties	I have been testing disinfectants since 2003. I have developed the practical tests described in the EN standards EN 16777, EN 17111, EN 17430 and 4Fieldtest. I am also

responsible for the Since 2003, the primary focus of my research has been on the testing of disinfectants. I am also responsible for the development of the practical tests described in the EN standards EN 16777, EN 17111, EN 17430 and 4Fieldtest. As such, I possess extensive expertise in the efficacy of disinfectants against viruses. However, in my research, I have not been able to demonstrate the efficacy of PVP-I in combating non-enveloped viruses. The active ingredient peracetic acid was incorporated as an additive to denatured alcohol in the GDR (295 ml A.dest, 200 ml absolute ethanol, 3 ml Wofasteril (40%PAA)), but again ethanol is used in this standard virucidal GDR formulation. While isopropanolic products have been shown to be effective against murine norovirus in suspension tests, their efficacy against adenovirus is reduced, and they are ineffective against polioviruses. The latter is the test virus for determining virucidal efficacy (Eggers et al. 2021Euro Surveill. 2021;26(3):pii=2000708. <https://doi.org/10.2807/1560-7917.ES.2021.26.3.2000708>). We have now tested a large number of products in the hand test (EN 17430) against murine norovirus (MNV). Isopropanolic formulations, such as Sterillium, appear to contain additives that enhance their efficacy against MNV. However, these formulations were unable to inactivate enterovirus or poliovirus. Another propanolic product (isopropanol 70.0 g, ethanol 96% 10 g), which is effective against MNV after 15 seconds and against adenovirus after 60 seconds in the quantitative suspension test, is unfortunately inferior to the reference in the hand test. To achieve poliovirus efficacy, a minimum of 80 g of ethanol is necessary, and the 97% test method must be employed (Steinmann J et al. Virucidal activity of Formulation I of the World Health Organization's alcohol-based handrubs: impact of changes in key ingredient levels and test parameters. Antimicrob Resist Infect Control. 2013 Dec 12;2(1):34. doi: 10.1186/2047-2994-2-34). A virucidal product can also be obtained through complex formulations, such as a mixture of n-propanol, isopropanol, and ethanol, with the addition of phosphoric acid. Notwithstanding, the formulation invariably comprises primarily ethanol: 57.6 g ethanol (96%), 10 g 1-propanol, 2-butanone, and phosphoric acid (85%). Our laboratory has not yet investigated hand disinfection with chlorine products; however, there is a comprehensive review of the tolerability of chlorine products from the Ebola virus pandemic. During the Ebola virus pandemic, 493/500 healthcare workers (HCW), 550/550 Ebola virus disease (EVD) patients, and 477/500 non-Ebola virus disease (NEVD) patients were sprayed at least once with 0–5% chlorine. Following a single

	exposure, an increase in the number of eye (all three groups) and respiratory symptoms (in HCW & EVD) was reported; after multiple exposures, respiratory and skin symptoms increased. In the HCW group, multiple exposure was associated with an increase in respiratory symptoms, ocular symptoms, and skin conditions. The available personal protective equipment demonstrated neither the capacity to reduce nor to prevent the adverse effects of chlorine (Mehtar S, Bulabula AN, Nyandemoh H, Jambawai S. Deliberate exposure of humans to chlorine: the aftermath of Ebola in West Africa. Antimicrob Resist Infect Control. 2016 Nov 14;5:45. doi: 10.1186/s13756-016-0144-1. PMID: 27895903; PMCID: PMC5109677). This was also confirmed to me anecdotally by virologists who worked in Africa at the time. Furthermore, it is not clear to me whether chlorine on the hands can inactivate non-enveloped viruses.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	A supply chain that relies on a few non-national producers can drive up the price of disinfectants. We have seen this during the COVID-19 pandemic. This could, for example, endanger the protection of staff or make prevention through hygiene no longer affordable for many institutions. In these challenging times, we should be able to ensure that disinfectants and antiseptics are available to the medical sector. This would help protect people if there is a sudden need because of an attack or an emergency. It is also important to think about what would happen if there is a shortage of materials because of problems with shipping or other problems. There is no alternative to ethanol, which is inexpensive, highly compatible and effective.
Information above is confidential	
Justification for confidentiality	

Hazards and Risks of the Alternative	Hand-washing with medical soap or chlorine-based hand rubs can cause skin irritation. PVP-I products can cause allergic reactions, including thyroid problems. Also, hand washing can only reduce viruses mechanically by up to 2 log ₁₀ . This is insufficient to stop the spread of viruses, which require only infectious doses of one to ten infectious viruses to do so.
Information above is confidential	
Justification for confidentiality	
Availability	During the COVID pandemic ethanol was ensuring the supply of disinfectants that are effective and safe to use. In the midst of these challenging geopolitical circumstances, it is imperative to devise strategies that ensure the security of disinfectants and antiseptics for the medical sector during periods of significantly elevated demand. For instance, in the event of an alliance with a substantial number of war casualties and a scarcity of raw materials due to disrupted supply chains, it is essential to incorporate measures that address these contingencies into the preparation protocols. Eggers M, Baumann A, Lilienthal N, Steinmann E, Steinmann J, Hübner NO, Rabenau HF, Weinheimer V, Schwebke I. Desinfektionsmittel in der COVID-19-Pandemie: eine Herausforderung [Disinfectants during the COVID-19 pandemic: a challenge]. Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz. 2022 Jan;65(1):86-95. German. doi: 10.1007/s00103-021-03457-z. Epub 2021 Dec 8. PMID: 34878564; PMCID: PMC8652094.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	In the case that ethanol needs to be restricted because of its known danger after oral consumption, the priority should be to regulate its use in food and beverages and not its use as a biocide. The European public will not understand such a classification in category 1 a and b for use on skin or surfaces.
Information above is confidential	
Justification for confidentiality	

Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 73	2025/04/16 11:24
Country	Austria
Name of organization/institution	██████████
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	The company S.Spitz GmbH, based in Attnang-Puchheim, is one of the largest food producers in Austria with an export rate of over 50%. The company produces beverages, sweets and baked goods, as well as jams, mustard, ketchup, mayonnaise, and sauces, and is also a bottler of alcoholic beverages.
Product Type	1,2,4
Alternative Identity and Properties	Safe use of ethanol in the food industry, both for cleaning and disinfection purposes, production of alcoholic products, and product protection (shelf life). No substitutability due to the following properties: Effectiveness as a disinfectant without leaving residues in food. Currently, there are no alternative substances for this application in the food sector.
Information above is confidential	

Justification for confidentiality	
Technical Feasibility	No Substitutability
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Socio-economic impacts: Higher costs + consumer uncertainty regarding food safety + potential business-critical conditions in the industrial sector.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	No effectiveness as a disinfectant without leaving residues in food
Information above is confidential	
Justification for confidentiality	
Availability	Currently, no viable alternatives available
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Safe use of ethanol in the food industry, both for cleaning and disinfection purposes, production of alcoholic products, and product protection (shelf life). No substitutability due to the following properties: Effectiveness as a disinfectant without leaving residues in food. Currently, there are no alternative substances for this application in the food sector. Socio-economic impacts: Higher costs + consumer uncertainty regarding food safety + potential business-critical conditions in the industrial sector. EFSA/WHO confirms the safe use of ethanol in the mentioned application area. IFS standard as a guideline in the food sector.
Information above is confidential	
Justification for confidentiality	

Other comments	EFSA/WHO/IFS Food confirms the safe use of ethanol in the mentioned application area.
Information above is confidential	
Justification for confidentiality	
References	EFSA/WHO
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 74	2025/04/16 11:42
Country	Germany
Name of organization/institution	Verband Deutscher Großbäckereien / German Plant Bakers Association
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	In bakeries, ethanol is used in a large number of functions. Besides the pure technological use as a biocide, ethanol is occasionally used as part of ingredients like liqueurs, for example in some fine bakery wares. It is an important carrier for ingredients like aromes and some additives. It also sees use as a quasi-technical compound in the production of toast and other types of bakery wares to suppress microbiological degradation / infection inside MAP packages. In a technical sense, the primary use is personal hygiene like hand disinfection (PT 1, covered in separate comments)) and the disinfection of surfaces and equipment (PT 4) which will be covered here. The use of ethanol in disinfecting surfaces and equipment covers the whole bakery value chain: from the setting up of dough and handling of ingredients over the separate kneading and other production processes and baking up to the handling of fresh bakery wares: either for packing transport and sale in supermarkets, or for transport and unpacked sale in large

	outlet bakeries. In all of these steps, ethanol based disinfectants are frequently used due to their versatility, effectiveness and safe use. All of these products are based on so called denatued alcohol which is not fit for human consumption.
Product Type	1,2,4
Alternative Identity and Properties	Inside the production process of large bakeries, defined downtimes are necessary to throoughly clean machines and production lines. These downtimes are used to clean parts of these machines and production lines not easily accessible during production. Besides ethanol, other more specialised cleaning agents with distinct capabilities for special uses are applied as need prescribes. As most of these cleaning agents are either aggressive, have limited useage parameters or form undesired residues on surfaces, a thouhough washing process of all machine and production line parts after „special cleaning“ is mandatory. This complex cleaning process is not necessary when ethanol cleaning suffices, as it evaporates with no undesired residues. Among the special cleaning products are other alcohols, like iso-propanol (2-propanol) and 1-propanol. Also, peracid solutions are occasionally used. It is also technically possible to use sodium hypochlorite solutions and quarternary ammonium compounds (QAV), though their application is often altogether banned by important customers (e.g. food trade). All of these cleaning agents have serious drawbacks when not accompanied by ethanol as the most versatile and effective cleaning agent. As to the undesired drawbacks of these special cleaning agents, Chlorine generating agents and QAV may lead to undesired residues in food. Hydrogen peroxide and peracetic acid are aggressive chemicals not suitable for surfaces with food contact. Peracetic acid has corrosive properties, hydrogen peroxide is an irritant and not suitable for use with plastic materials. As already stated, these agents have their place, but are no alternatives to ethanol in themselves. As concerns propanol solutions, though less aggressive, these are less volatile and may lead to undesired residues which may transfer to food products (chemical smell/taste). Ethanol, as stated, evaporates quickly and even if traces would remain on the surfaces, they are not considered relevant given that ethanol is also naturally occurring in food.
Information above is confidential	

Justification for confidentiality	
Technical Feasibility	As shown under point 1, the alternative cleaning agents are specialised additions inside the complex and throughout cleaning process during downtime of machines and production lines. Due to residues and use limitations of these agents (e.g. corrosion, undesired residues), all surfaces and machines must be rinsed after the specialised agents are used. This is only possible during downtime of the machines. Ethanol, on the other hand, evaporates without relevant traces, has a very wide spectrum of uses against numerous soiling and potential threats and can be readily used without protective measures. No other active agent described has these capabilities.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	All of the additional specialised cleaning agents described above have to be produced in chemical plants in processes which are, in part, complex, dangerous and environmentally risky. These specialised production conditions, combined with their occasional use, leads to a distinctly higher price when compared to ethanol. Ethanol is readily available in all parts of the world and can be produced as a byproduct of agricultural and food producing processes, not only adding to its „green“ footprint but also to its competitive price.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	As stated above, specialised cleaning agents like peracid solutions, solutions using chlorine compounds and QAV are corrosive and/or dangerous, require careful handling by instructed personnel and, above all, a rinsing process after cleaning to remove the hazardous substances as well as undesired residues. This can not be done in the ongoing production process and requires downtime of machines and production lines. Propanol solutions do not have the excessive drawback of these specialised cleaning agents but, in turn, require a rinsing process after use, lest they leave undesired residues spoiling taste and smell of the product. This alone makes these substances unfit for everyday cleaning in bakeries. As regards hazards, iso-propanol as well as other alcohols are not or at least less effective against e.g. noroviruses and other pathogens,

	which would lower the excellent all-round protection ethanol provides in this and other fields. Connected to this, an indirect risk of the alternative cleaning agents is loss of versatility when disclosing ethanol as a desinfectant: losing the most effective and ready-to-use cleaning agent in the food industry may erode the will of many workers to effectively clean surfaces and machines. Because every cleaning step would then have to be accompanied by a rinsing step and even the use of protective gear. This would triple the effort of hygiene while lowering its effectiveness considerably. In general, the main risk connected with ethanol is coming from abusive drinking, which is effectively counteracted by the use of denaturated alcohol in cleaning solutions.
Information above is confidential	
Justification for confidentiality	
Availability	Ethanol is unrivaled in its quick and worldwide accessibility on short notice, combined with its other unique features mentioned above. Other products rely on certain branches of the chemical industry and, due to their specialisation, can not compete with ethanol in its availability.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	In the view of our industry, surface and machine disinfection with ethanol is the premium choice for large bakeries in all branches of their production process, starting at ingredient handling and dough kneading over all steps of bakeryware production up to packaging or sale by personnel in bakery outlets. Other substances are less versatile, more expensive and impractical in view of cross contamination, dangers to users and applicability. In addition, some of the more aggressive substances like QAV or chloride solutions are declared non-desirable by large players in the food market, which hampers their use even more. Regarding the shortcomings of propanol solutions as regards not-developed viruses, ethanol can not be dispensed of in order to not open this flank in hygiene. All of the specialised cleaning solutions occasionally used in large bakeries (Chloride solutions, peracid products, QAV and propanol solutions as well) require a mandatory rinsing step after cleaning. This reduces their use to downtime cleaning of machines and

	production lines and completely discloses them from everyday use as disinfectants in food production.
Information above is confidential	
Justification for confidentiality	
Other comments	It must be restated that ethanol as a disinfectant for surfaces and equipment is the first choice in the food industry for good reasons: no other substance combines effectiveness, proven safety, availability, versatility and competitive price like ethanol. In our view, most perceived drawbacks of ethanol in relation to use by personnel stem from its possible oral consumption / abuse. This is, however, effectively prevented by using denatured alcohol only.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 75	2025/04/16 11:52
Country	Germany
Name of organization/institution	Julius Hoesch GmbH & Co. KG
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Our product is an ethanol based ... e.g. liquid hand disinfectant. Due to its alcoholic components the product has a wide sphere of action and is bactericidal, fungicidal

	and full virucidal efficient. The product has been tested by an independent institute as particularly skin friendly.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	

Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Alternative substances are significantly more expensive and less available. Scaling up production for substitutes would require massive investments in new facilities, technologies, and regulatory approvals, facing resistance from authorities and NGOs.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	

Attachments (confidential information)	
Justification for confidential attachment	

Comment 76	2025/04/16 11:56
Country	Germany
Name of organization/institution	Verband Deutscher Großbäckereien / German Plant Bakers Association
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	In bakeries, ethanol is used in a large number of functions. On the one hand, it is occasionally used directly as an ingredient, for example in some fine bakery wares. It is an important carrier for ingredients like aromes and some additives, but also sees use as a quasi-technical compound in the production of toast and other types of bakery wares to suppress microbiological degradation / infection. In a technical sense, the primary use is for the disinfection of surfaces and equipment (PT 4, covered in seperate comments)) and personal hygiene like hand disinfection (PT 1), which will be covered here. The use of ethanol in the field of personal hygiene covers the whole bakery value chain: from the setting up of dough and handling of ingredients over the seperate kneading and other production processes and baking up to the handling of fresh bakery wares: either for packing transport and sale in supermarkets, or for transport and unpacked sale in large outlet bakeries. In all of these steps, ethanol based hand rubs are frequently used due to their versatility, effectiveness and safe use. All of these products are based on so called denatued alcohol which is not fit for human consumption.
Product Type	1,2,4
Alternative Identity and Properties	From the feedback of our members, we gather that other disinfectants are also used in the large bakery sector. Among these are peracid solutions, QAV and active chloride compounds, but none of them is used in hand rubs; they are seperately covered in our comments on PT-4 There are

	hand rub solutions where ethanol is mixed with other compounds, for example propanols.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	In hand rubs which combine ethanol with other compounds like propanols (Iso-propanol (2-propanol) or 1-propanol), these other compounds may leave undesired or hazardous traces on the handled food, while ethanol evaporates completely without the need for a second cleaning step.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Ethanol is perceived not only as the most secure and versatile but also as the most costeffective alternative for the cleaning purposes required in large-scale baking. Other alternatives (see above under No. 1 and 2) are more expensive while having distinct drawbacks when used in food production.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	As mentioned above, avoiding cross-contamination with unwanted active substances is of paramount importance in the food sector. None of the alternatives mentioned in the above points is without this drawback, which compromises their useability in many parts of food production and is an outright no-go in direct food contact. The unrivaled versatility of ethanol as a safe allround disinfectant points to an intrinsic drawback of other substances: their use is always restricted by the need to avoid cross-contamination, or by much higher requirements e.g. on protective equipment or skill of the workers. This means that without ethanol, workers might not use disinfectants any more or restrain their use to a minimum, with most unwanted results for hygiene Finally, none of the other substances for hand disinfection can rival ethanol in its wide-range effectiveness. Ethanol is the only active substance in hand rubs that is fully effective against norovirus, hepatitis viruses and rhinoviruses, an important point where propanol solutions fall short.

Information above is confidential	
Justification for confidentiality	
Availability	Ethanol is unrivaled in its quick and worldwide accessibility on short notice, combined with its other unique features mentioned above. Other products rely on certain branches of the chemical industry and, due to their specialisation, can not compete with ethanol in its availability.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	In the view of our industry, hand disinfection with ethanol is the premium choice for large bakeries in all branches of their production process, starting at ingredient handling and dough kneading over all steps of bakery ware production up to packaging or sale by personnel in bakery outlets. Other substances are less versatile, more expensive and impractical in view of cross contamination. In addition, some of the more aggressive substances like QAV or chloride solutions are declared non-desirable by large players in the food market, which hampers their use even more, even if they were used for hand rub solutions. Regarding the shortcomings of propanol solutions as regards not-enveloped viruses, ethanol can not be dispensed of in order to not open this flank in hygiene.
Information above is confidential	
Justification for confidentiality	
Other comments	It must be restated that ethanol as a hand disinfectant is the first choice in the food industry for good reasons: no other substance combines effectiveness, proven safety, availability, versatility and price like ethanol. In our view, most perceived drawbacks of ethanol in relation to use by personnel stem from its possible oral consumption. This is, however, effectively prevented by using denatured alcohol only for hand disinfection.
Information above is confidential	
Justification for confidentiality	

References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 77	2025/04/16 12:02
Country	Germany
Name of organization/institution	Julius Hoesch GmbH & Co. KG
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Our product is a ... e.g. liquid, ready to use, fast and residue-free drying surface disinfectant. The product is for the effective disinfection of sensitive, alcohol-resistant surfaces. Compatibility with most common surface materials. The product is used wherever quick and effective disinfection is required, e.g. in health facilities, medical practices, nursing homes, nursing services, fitness facilities, restaurants, food and beverage plants and other facilities in the public and industrial sector.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	

Information above is confidential	[REDACTED]
Justification for confidentiality	[REDACTED]
Economic Feasibility	[REDACTED]
Information above is confidential	[REDACTED]
Justification for confidentiality	[REDACTED]
Hazards and Risks of the Alternative	[REDACTED]
Information above is confidential	[REDACTED]
Justification for confidentiality	[REDACTED]
Availability	[REDACTED]
Information above is confidential	[REDACTED]

Justification for confidentiality	[REDACTED]
Conclusion on suitability and availability of the alternative	Alternative substances are significantly more expensive and less available. Scaling up production for substitutes would require massive investments in new facilities, technologies, and regulatory approvals, facing resistance from authorities and NGOs.
Information above is confidential	
Justification for confidentiality	
Other comments	[REDACTED]
Information above is confidential	[REDACTED]
Justification for confidentiality	[REDACTED]
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 78	2025/04/16 12:18
Country	France
Name of organization/institution	[REDACTED]
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	

Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Aucune alternative
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	

Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 79	2025/04/16 12:19
Country	France
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	

Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Aucune alternative
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 80	2025/04/16 12:47
Country	France
Name of organization/institution	

I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	While it is acknowledged that ethanol exhibits carcinogenic and reprotoxic properties, its classification as such without any exceptions poses a significant threat to public health in Europe. Ethanol stands out as the most effective and extensively utilized disinfectant in various settings, including hospitals, restaurants, crèches, homes, and other public places. Its primary advantage lies in its rapid action and minimal resistance to pathogens. The carcinogenic and reprotoxic effects of ethanol are primarily observed following oral exposure, as evidenced by peer-reviewed studies. It is challenging to justify the removal of ethanol from widespread use, especially considering its proven efficiency and utility during the COVID-19 pandemic. Furthermore, to mitigate the risk of oral exposure, technical ethanol is formulated with denaturing and bittering agents. These additives render the ethanol unpalatable and less likely to be ingested, thereby reducing the potential for adverse health effects associated with oral consumption.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	

Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	In summary, while ethanol's carcinogenic and reprotoxic properties are well-documented, its classification without exceptions may unduly restrict its use in critical applications. The inclusion of denaturing and bittering agents in technical ethanol formulations provides an additional layer of safety, ensuring that its benefits can be realized without compromising public health. Thank you very much.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 81	2025/04/17 09:55
Country	Germany

Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	ethanol based disfectants must be available without any restringtons in future

Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 82	2025/04/17 10:35
Country	Italy
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	

Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	The Italian Ministry of Health as Competent Authority for biocides (IT CA) recognizes that to address the BPR requirements, any potential alternatives should be sought among the already approved active substances in combination with the relevant product type. Be mindful that BPR requires that biocidal products to be marketed should be demonstrated safe, for humans and environment, and efficacious for their intended use. On one hand, the same requirements should be demonstrated for the approval of the biocidal active substance. IT CA believes that the Analysis of Alternatives has shown that the active substances already approved as PT 1 cannot be considered as valid alternatives to Ethanol due to both the efficacy and the hazard properties. Due to the intrinsic properties of the active substances currently approved in combination with PT 1 (hazardous to the skin and eyes) and the lack of efficacy against a wide range of viruses. Furthermore, the proposed classification - as Canc. Cat.1 and Repr. Cat.1 does not represent the final classification of Ethanol, being the decision on that under the mandate of the Risk Assessment Committee (RAC). Therefore, IT CA believes that RAC is the right Committee where the final opinion on the classification of Ethanol should be taken. IT CA strongly

	recommends before taking any decision concerning the ban of Ethanol based on its intrinsic properties, to stop the peer review process waiting for the final opinion of RAC on the harmonized classification to be adopted for Ethanol. All the above said also considering that a decision taken at biocidal level, not only might limit the availability of disinfectants on the EU market but might also have a high impact on several other sectors, such as cosmetics, pharmaceuticals, food.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	IT CA _ ANALYSIS OF ALTERNATIVES_Ethanol PT1.docx
Attachments (confidential information)	
Justification for confidential attachment	

Comment 83	2025/04/17 10:37
Country	Italy
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	
Product Type	1,2,4

Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	The Italian Ministry of Health as Competent Authority for biocides (IT CA) recognizes that to address the BPR requirements, any potential alternatives should be sought among the already approved active substances in combination with the relevant product type. Be mindful that BPR requires that biocidal products to be marketed should be demonstrated safe, for humans and environment, and efficacious for their intended use. On one hand, the same requirements should be demonstrated for the approval of the biocidal active substance. IT CA believes that the Analysis of Alternatives has shown that the active substances already approved as PT 2 cannot be considered as valid alternatives to Ethanol due to both the efficacy and the hazard properties. Due to the intrinsic properties of the

	active substances currently approved in combination with PT 2 (hazardous to the skin and eyes) and the lack of efficacy against a wide range of viruses. Furthermore, the proposed classification - as Canc. Cat.1 and Repr. Cat.1 does not represent the final classification of Ethanol, being the decision on that under the mandate of the Risk Assessment Committee (RAC). Therefore, IT CA believes that RAC is the right Committee where the final opinion on the classification of Ethanol should be taken. IT CA strongly recommends before taking any decision concerning the ban of Ethanol based on its intrinsic properties, to stop the peer review process waiting for the final opinion of RAC on the harmonized classification to be adopted for Ethanol. All the above said also considering that a decision taken at biocidal level, not only might limit the availability of disinfectants on the EU market but might also have a high impact on several other sectors, such as cosmetics, pharmaceuticals, food.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	IT CA _ ANALYSIS OF ALTERNATIVES_Ethanol PT2.docx
Attachments (confidential information)	
Justification for confidential attachment	

Comment 84	2025/04/17 12:06
Country	Germany
Name of organization/institution	Euro-Alkohol

I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Summary of the Paper's Demand Regarding the Classification of Ethanol The paper strongly opposes the planned classification of ethanol as a CMR substance under EU regulations, arguing that such a classification is scientifically unjustified and would have severe public health

	and economic consequences. Key Arguments: Scientific Flaws: The basis for classifying ethanol as CMR stems from data on alcohol abuse via oral ingestion. This is irrelevant to technical and biocidal applications where exposure is minimal, especially via dermal or inhalation routes. Toxicity Comparison: Compared to alternative biocidal solvents, ethanol demonstrates the lowest toxicity. According to oral LD50 data in rats: Ethanol: 7,060 mg/kg Isopropanol: 4,570 mg/kg N-Propanol: 1,870 mg/kg A lower LD50 indicates higher toxicity, making ethanol significantly less toxic than both alternatives. Public Health Impact: Ethanol-based disinfectants are essential for effective hygiene, especially in healthcare settings. A ban or restriction would jeopardize infection control and undermine pandemic preparedness. Environmental and Economic Impact: Ethanol derived from renewable resources has a smaller carbon footprint than petrochemical alternatives. Its forced substitution would increase environmental burdens and impose massive regulatory and financial burdens on industry. Demand: The authors demand that ethanol not be classified as a CMR substance at all. They emphasize that replacing ethanol with more toxic alternatives like isopropanol or n-propanol would paradoxically increase health risks, contradicting the intended goal of enhanced safety.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	2VDAHV Kurzposition - CMR ENG.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 85	2025/04/17 12:45
Country	Germany
Name of organization/institution	Euro-Alkohol
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Ethanol plays a vital role in Europe's transition to a sustainable and circular bioeconomy, contributing to climate targets, energy independence, and rural development. We are concerned, however, that a disproportionate classification of ethanol could undermine its essential contributions. Scientific evidence and decades of safe use must remain the foundation of regulatory decisions. Any reclassification should be based on a clear, risk-based approach that ensures consistency and predictability for industry stakeholders. We urge policymakers to consider ethanol's strategic importance and the broader socio-economic impact of potential regulatory shifts.
Product Type	1,2,4
Alternative Identity and Properties	From a scientific and regulatory standpoint, ethanol remains the most favorable biocidal alcohol compared to its petrochemical alternatives, isopropanol and n-propanol. Ethanol demonstrates the highest oral LD50 value (7,060 mg/kg), indicating significantly lower toxicity than n-propanol (1,870 mg/kg) and isopropanol (4,570 mg/kg). Moreover, ethanol exhibits better tissue compatibility and lower inhalation toxicity. Unlike its alternatives, ethanol is largely derived from renewable resources, contributing to climate protection and supply resilience—as shown during the COVID-19 pandemic, where ethanol producers rapidly scaled production. A CMR classification would likely lead to the substitution of ethanol with more toxic petrochemical substances, undermining both health protection and sustainability goals. The proposed classification, based on misuse data unrelated to technical applications, lacks scientific justification and risks weakening public health standards, especially in hygiene-critical sectors.
Information above is confidential	
Justification for confidentiality	

Technical Feasibility	Ethanol cannot be fully substituted by petrochemical alternatives such as isopropanol or n-propanol, as evidence suggests ethanol is more effective in certain critical applications. Ethanol-based disinfectants show superior efficacy against a broad spectrum of pathogens, including non-enveloped viruses, which is essential for maintaining high hygiene standards—especially in healthcare settings. Scientific literature and practical experience underscore ethanol's better tissue compatibility and lower systemic toxicity. During the COVID-19 pandemic, ethanol proved more scalable and reliable than its petrochemical counterparts, highlighting its critical role in crisis response. Replacing ethanol with less effective or more toxic alternatives would compromise public health and undermine the EU's goals for safety, sustainability, and pandemic preparedness.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Should ethanol be classified as a CMR substance and subsequently fall out of use, the entire disinfection sector would become heavily dependent on just two petrochemical alternatives: isopropanol and n-propanol. These substances are produced by only a few large industrial players, creating a significant supply chain vulnerability. As demonstrated during the COVID-19 pandemic, reliance on these limited sources led to severe availability issues and unacceptable price surges. In contrast, ethanol—especially from renewable sources—proved to be a flexible, rapidly scalable solution that ensured continued public health protection. Importantly, ethanol supply in the European Union is secured by a wide network of medium-sized producers, ensuring decentralization, competition, and resilience in the face of rising demand or crisis scenarios. Undermining ethanol's availability would not only jeopardize hygiene standards but also expose the market to monopolistic risks and critical shortages in times of crisis.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	When evaluating the suitability of isopropanol and n-propanol as alternatives to ethanol, both hazard and risk must be considered—distinguishing the inherent properties of the substances (hazard) from their actual exposure and

	use scenarios (risk). 1. Higher Toxicity (Hazard): According to toxicological data cited in the document, both isopropanol and n-propanol exhibit significantly higher acute oral toxicity than ethanol: n-Propanol: Oral LD50 (rat): 1,870 mg/kg Isopropanol: Oral LD50 (rat): 4,570 mg/kg Ethanol: Oral LD50 (rat): 7,060 mg/kg This indicates a higher hazard potential for both substitutes compared to ethanol. 2. Lower Tissue Compatibility and Higher Inhalation Risk (Hazard): The document states that 80% ethanol has better tissue compatibility than 60% isopropanol. Additionally, ethanol shows lower toxicity via inhalation, which is particularly relevant in occupational settings where exposure through the respiratory system can occur regularly. 3. Lack of Human Exposure Data (Risk): Unlike ethanol, which has been extensively studied in both technical and consumer use contexts, isopropanol and n-propanol lack robust human exposure data. This creates uncertainty in the risk assessment for these substances, especially under real-world working conditions. 4. No Observed Mutagenicity or Carcinogenicity (Risk): While the paper notes that mutagenicity, teratogenicity, or carcinogenicity have not been observed for any of the three alcohols when used in disinfectants, this conclusion depends heavily on the type and extent of available studies—where ethanol remains the best documented. Conclusion: From a hazard perspective, both isopropanol and n-propanol pose a higher toxicological risk than ethanol. From a risk perspective, ethanol is better characterized and demonstrates safer exposure profiles under actual usage conditions. Therefore, substituting ethanol with these alternatives may introduce greater health risks, especially for workers and healthcare environments, without offering a corresponding safety benefit.
Information above is confidential	
Justification for confidentiality	
Availability	Ethanol ensures a stable and resilient supply for disinfectant production, supported by numerous medium-sized producers across the European Union. In contrast, petrochemical substitutes like isopropanol and n-propanol are produced by only a few large suppliers, creating a concentrated and fragile supply chain. During the COVID-19 crisis, ethanol proved to be far more scalable and readily available, while reliance on limited producers of isopropanol and n-propanol led to critical shortages and drastic price increases. A regulatory shift away from ethanol would

	jeopardize supply security and risk future availability of essential hygiene products.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Summary Statement on Ethanol Classification Ethanol is a low-toxicity, renewable, and highly effective biocidal substance, with broad availability ensured by numerous medium-sized EU producers. In contrast, its petrochemical alternatives—n-propanol and isopropanol—are more toxic, less documented in real-world use, and sourced from a limited number of large suppliers, creating serious supply and cost risks. Ethanol offers better inhalation safety, superior tissue compatibility, and played a critical role during the COVID-19 crisis due to its flexible and decentralized production. We strongly urge policymakers to reject the proposed CMR classification of ethanol, which is scientifically unfounded and would result in both higher health risks and lower supply security across critical hygiene sectors.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	Joint Statement by KBV, BÄK, KZBV, BZÄK Germany 2025.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 86	2025/04/17 12:58

Country	Germany
Name of organization/institution	Kassenärztliche Bundesvereinigung (KBV)
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Die KBV ist der Dachverband der 17 Kassenärztlichen Vereinigung in Deutschland mit insgesamt knapp 100.000 Arztpraxen, über 180.00 Ärzten und Psychotherapeuten und weit mehr als 570 Millionen Behandlungsfälle/Jahr. Laut § 23 Abs. 3 IfSG haben die Einrichtungsleitungen, in unserem Falle also die Praxen der niedergelassenen Ärzte, sicherzustellen, dass Maßnahmen getroffen werden, um nosokomiale Infektionen zu verhüten und die Weiterverbreitung von Krankheitserregern zu vermeiden. Bei Wegfall eines wirksamen und praktikablen Desinfektionsmittels können die Verantwortlichen ihren gesetzlichen Auftrag nur eingeschränkt wahrnehmen – sowohl gegenüber Patienten als auch angestellten Mitarbeitern. Ethanol ist der wesentliche Wirkstoff von in Arztpraxen verwendeten Desinfektionsmitteln, vor allem in der Händedesinfektion. Ethanol wirkt hierbei zuverlässig gegen Bakterien und Viren und ist insbesondere alternativlos gegen praxisrelevante unbehüllte Viren wie zum Beispiel Humanes Papillomavirus, Enteroviren, Hepatitis A+E Virus. Beim Wegfall von Händedesinfektionsmitteln auf Ethanol-Basis müsste auf andere alkoholische Händedesinfektionsmittel (1-Propanol und 2-Propanol) umgestellt werden. Diese alternativen Desinfektionsmittel sind jedoch kein adäquater Ersatz, da sie unbehüllte Viren nicht ausreichend inaktivieren. Auch für die Schnelldesinfektion kleinerer Flächen wird Ethanol verwendet, hier ist der Vorteil die schnelle Wirkung und die kurze Trocknungszeit.
Product Type	1,2,4
Alternative Identity and Properties	Eine Alternative zu ethanolhaltigen Händedesinfektionsmitteln wären Produkte auf der Basis von 1-Propanol und 2-Propanol. Deren Wirkung gegen unbehüllte Viren ist jedoch nicht vergleichbar mit ethanolhaltigen Desinfektionsmitteln und aus medizinischer Sicht deshalb für die alleinige Verwendung zur Hände- und Flächendesinfektion nicht geeignet.

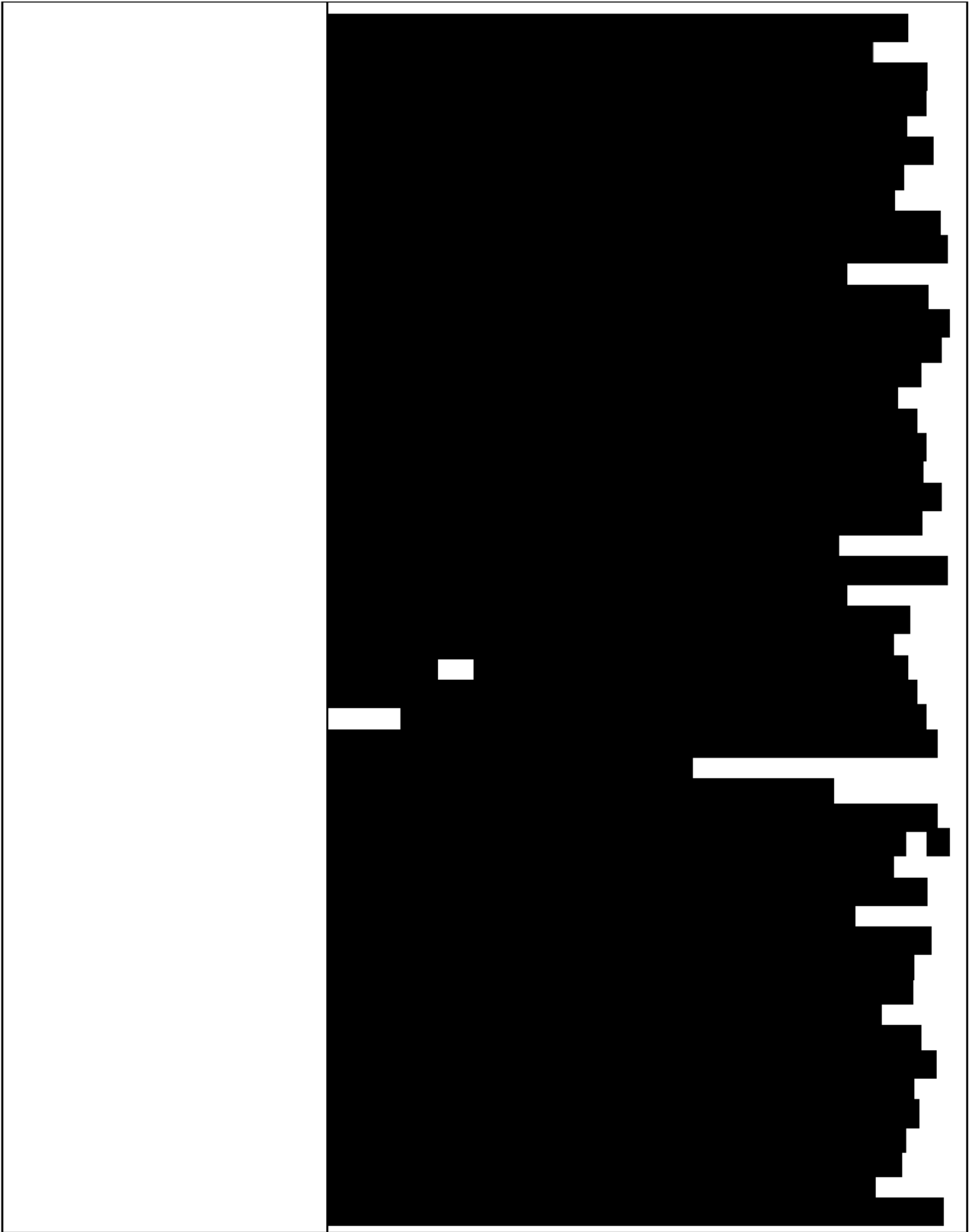
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Technical Feasibility	In den Arztpraxen wäre eine organisatorische Umstellung auf nicht-ethanolhaltige Desinfektionsmittel theoretisch möglich. Dies hätte jedoch schwerwiegende Folgen für die Infektionsprävention in der medizinischen Versorgung, denn damit einher ginge ein erhebliches Gesundheitsrisiko für die Patienten und für die Mitarbeiter, aufgrund der überlegenen Wirksamkeit ethanolhaltiger Händedesinfektionsmittel gegenüber unbehüllten Viren als biozider Wirkstoff. Beispielsweise zeigte sich während der Covid-19-Pandemie, dass Infektionsketten durch Desinfektionsmaßnahmen mittels ethanolhaltigen Präparaten sicher und schnell unterbrochen werden konnten. Zudem kann beim Auftreten von pandemischen unbehüllten Viren die schnelle Verfügbarkeit großer Mengen ethanolhaltiger Präparate relevant sein. Wir verweisen hier im Besonderen auf die Studien Kramer et. al. 2007 und 2024.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Zu den wirtschaftlichen Auswirkungen einer Umstellung auf nicht-ethanolhaltige Desinfektionsmitteln im ambulanten Bereich kann die Kassenärztliche Bundesvereinigung keine konkreten Angaben machen. Es steht jedoch zu befürchten, dass Alternativpräparate teurer sind als ethanolhaltige Desinfektionsmittel, da Ethanol als Nebenprodukt der chemischen Industrie besonders günstig ist. Darüber hinaus produzieren nur wenige Unternehmen in der EU Propanol, so dass Versorgungsengpässe zu erwarten sind.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Für die niedergelassenen Praxen wäre in Folge eines Wegfalls von Händedesinfektionsmitteln auf Ethanol-Basis zu erwarten, dass die Patienten und Mitarbeiter gesundheitlichen Risiken ausgesetzt werden. Die ambulante medizinische Versorgung von Patienten würde schweren Schaden nehmen, aber auch medizinisches Fachpersonal in den Praxen wäre gefährdet, da ethanolhaltige

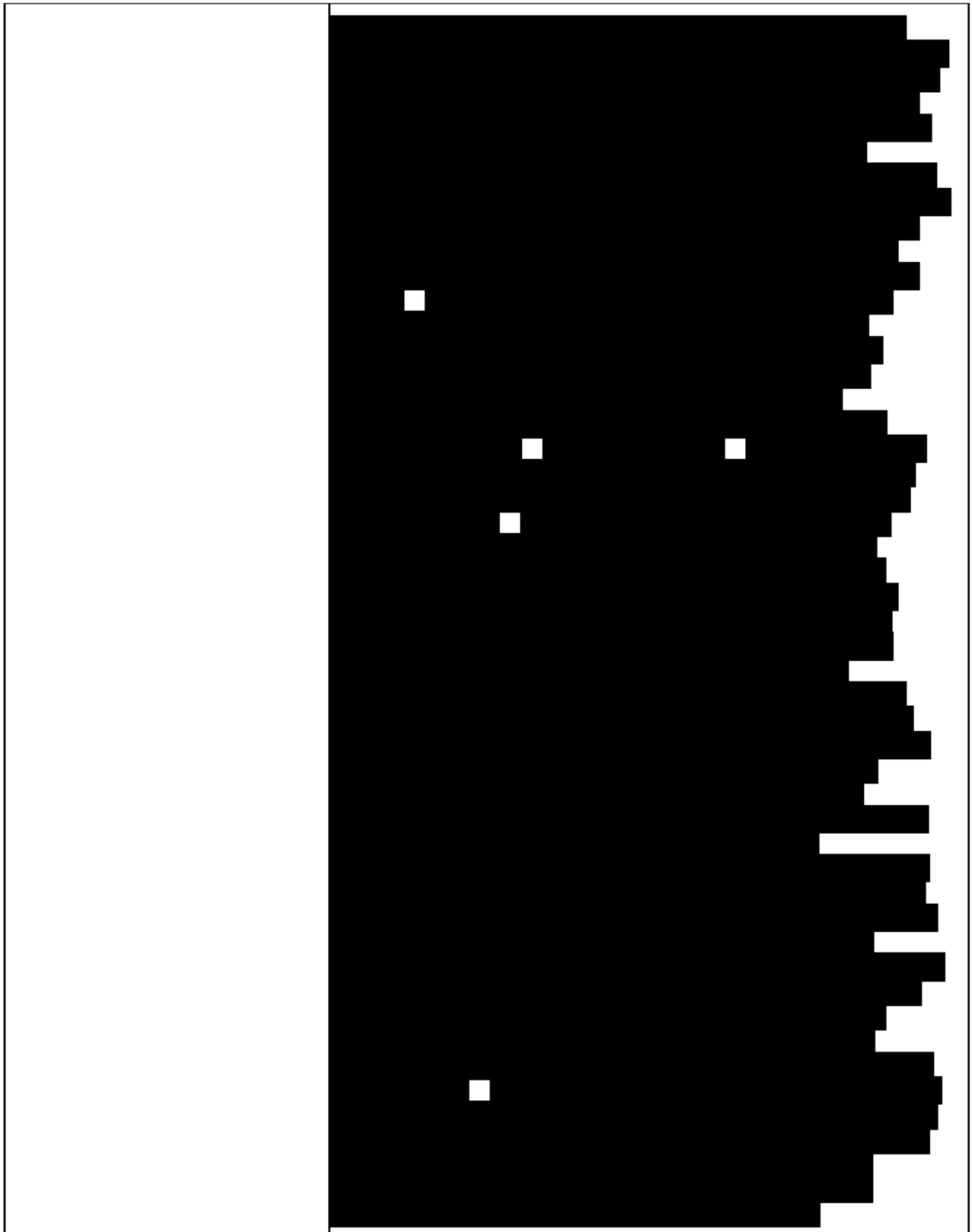
	Desinfektionsmittel gegenüber unbehüllten Viren stärker wirksam sind als propanolhaltige.
Information above is confidential	
Justification for confidentiality	
Availability	Es ist davon auszugehen, dass es durch das Verbot von ethanolhaltigen Händedesinfektionsmitteln und durch den ausschließlichen Einsatz von propanolhaltigen Desinfektionsmitteln zu Versorgungsengpässen in allen medizinischen Einrichtungen kommen kann, auch in Arztpraxen. Wobei zu berücksichtigen ist, dass propanolhaltige Desinfektionsmittel nicht die gleiche Wirkung zeigen wie ethanolhaltige Mittel gegenüber unbehüllten Viren.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Bei den niedergelassenen Praxen wäre in Folge eines Wegfalls von Händedesinfektionsmitteln auf Ethanol-Basis zu erwarten, dass Patienten und Mitarbeiter gesundheitliche Schäden erleiden. Dieses Risiko muss zwingend vermieden werden. Medizinische Fachverbände und Expertenausschüsse aus Europa, den USA, Kanada, der Asia-Pacific Region und die Weltgesellschaft für Virologie (vgl. Kramer et al. 2024) empfehlen den weiteren Einsatz von ethanolhaltigen Händedesinfektionsmittel, da es keinen bioziden Ersatzwirkstoff zur Händedesinfektion mit Wirksamkeit gegen unbehüllte Viren gibt. Auch betrachtet die Weltgesundheitsorganisation Ethanol als unersetzbaren Wirkstoff in der Desinfektion.
Information above is confidential	
Justification for confidentiality	
Other comments	None.
Information above is confidential	
Justification for confidentiality	
References	Kramer et al : BMC Infectious Diseases 2007 Kramer et al : Intern. Forum Hygiene and Infection Control 2024

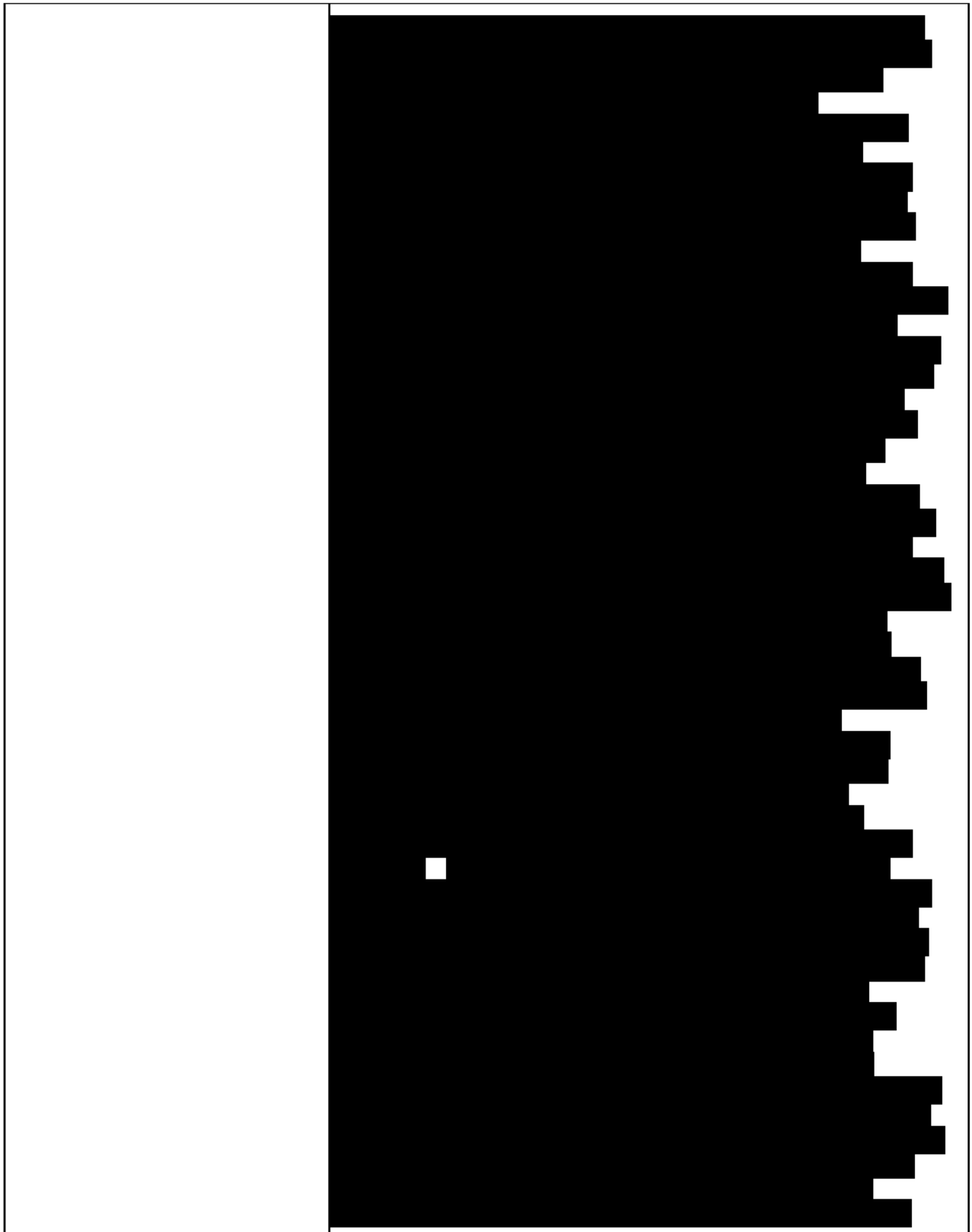
Attachments (non-confidential information)	Kramer et al 2007 and 2024.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 87	2025/04/17 13:20
Country	Italy
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	Based on our direct experience with biocidal hand-rubs in gel form, utilizing both ethanol and “propanols” (i.e., isopropanol and n-propanol) as active substances, and the factual information provided in other Sections as confidential, we confirm that “propanols” do not constitute a suitable alternative to ethanol for the following reasons: - - Lack of efficacy against non-enveloped viruses. - - Unsuitability for use by non-professional users and the pediatric population age 3-17 years old (due to H318 CLP classification, tolerability issues, etc.). - - Higher cost (nearly double) and lower availability, posing a risk of supply chain disruption during pandemic events. - - Greater environmental impact during the synthesis of “propanols” (chemical process) and during biocidal products manufacturing (necessity of appropriate personal protective equipment in most cases disposable). The classification of ethanol as a CMR (Carcinogenic, Mutagenic, or Reproductive toxicant) biocidal active substance, based on toxicological data derived from the oral abuse of alcoholic beverages, is inconsistent. The safety of alcoholic beverages falls outside the purview of ethanol's use in disinfection. The classification of ethanol as a biocidal active substance should take into account its use in a denatured, non-drinkable form, with exposure limited to dermal and inhalation routes, which is safe and poses no toxicological concerns. As also foreseen by Regulation (EC) No 1272/2008 Annex I 3.6.2.2.6, the route of exposure is a key

	factor to be considered in addressing the carcinogenicity of a substance. In addition, there is no scientific and bibliographic evidence that the dermal use of “ethanol based hand rubs” (EBHR) could cause cancer or reprotoxic effects since all data clearly demonstrate that the potential of ethanol to cause cancer or reprotoxic effects is mainly due to its first-pass metabolism pathway (i.e. acetaldehyde formation) and so connected to alcoholic beverage consumption which is relevant to food safety and not to the use of ethanol in the disinfection field. As reported in publications, key organizations such as the WHO Task Force on Alcohol-Based Hand Rubs, the WHO Collaborating Centre on Patient Safety, Infection Prevention & Control, and Antimicrobial Resistance, the Commission for Hospital Hygiene and Infection Prevention, Robert Koch Institute in Berlin, Germany, and the Association for Applied Hygiene in Germany (see references 5 and 6) strongly recommend retaining ethanol as a crucial component in hand rubs for healthcare, safe food production, and community use, particularly during outbreak situations. The absence of effective hand rubs against non-enveloped viruses such as norovirus, adenoviruses, and enteroviruses D68 and 71 (which are not vaccine-preventable) poses significant public health risks. A shift from ethanol to “propanols” for biocidal hand rubs would likely diminish infection prevention and public health protection, increasing risks without providing any tangible benefits. Additionally, the higher costs and greater environmental impact associated with “propanols” present significant concerns. Therefore, no equivalent alternative to ethanol has been identified. The evaluation of ethanol as a biocidal active substance must reasonably exclude data from the oral abuse of alcoholic beverages, as it is not applicable to the use of ethanol in disinfection. Alternatives are different and cannot be fairly compared as there is no scientific evidence on the effects arising from the ingestion of “propanols” (n-propanol and iso-propanol). Cases of accidental ingestion of “propanols” with lethal effect are reported in literature. Pursuing an inconsistent evaluation of ethanol in the context of biocidal substances could have substantial future repercussions for other categories (pharmaceuticals, cosmetics, etc.), causing increasing risks for health without any benefits and with unnecessary economic and environmental damage.
Product Type	1,2,4
Alternative Identity and Properties	





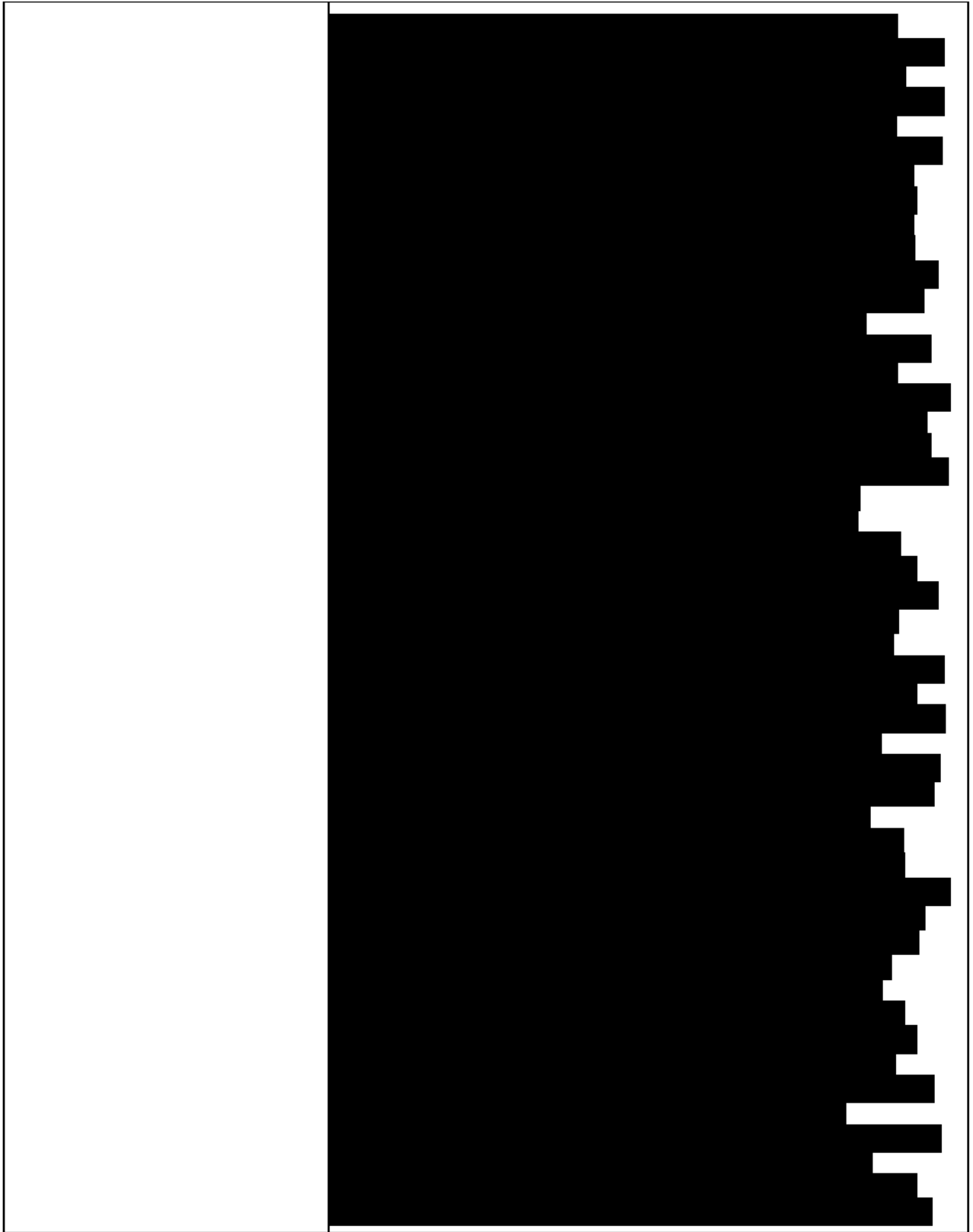


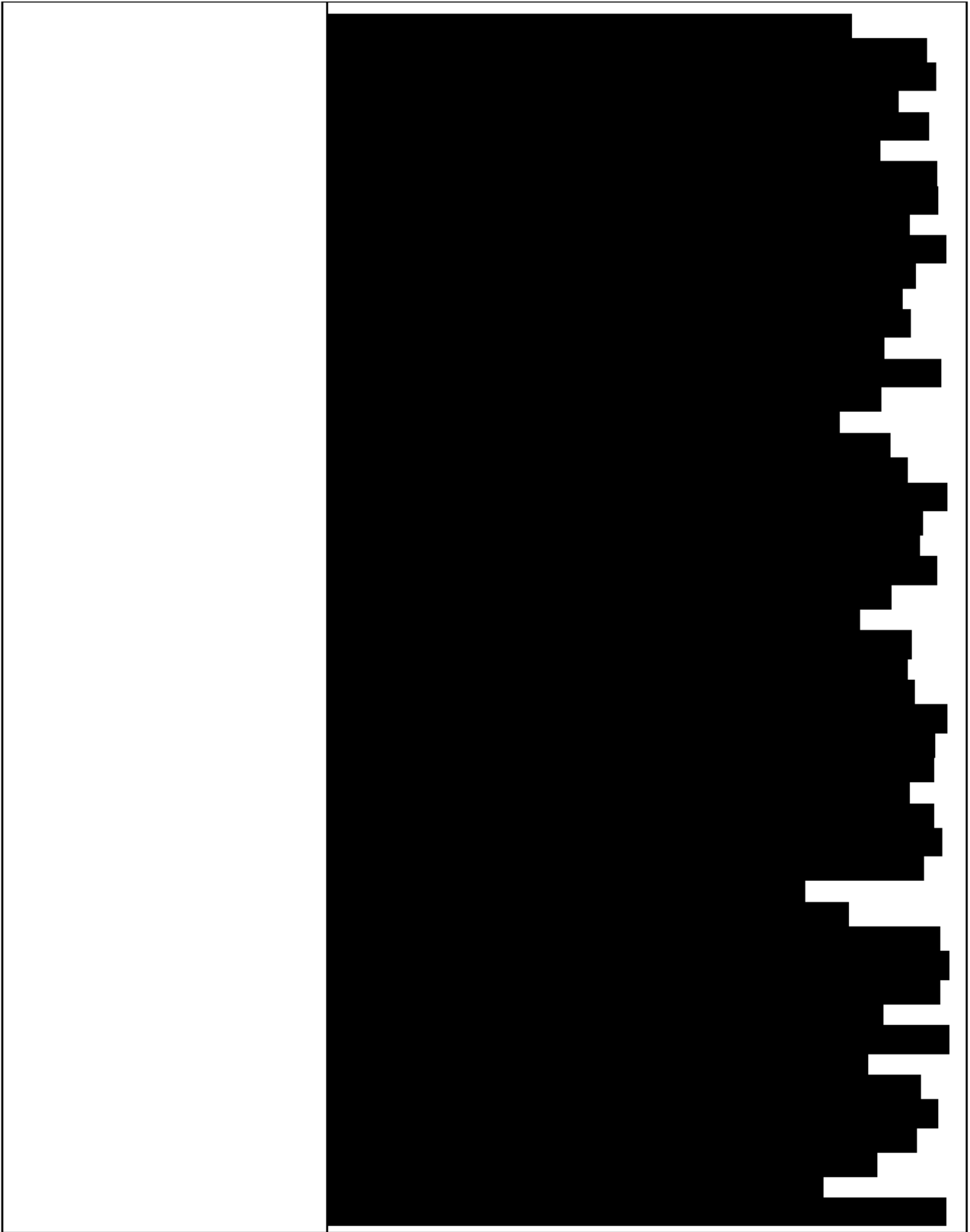
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Technical Feasibility	

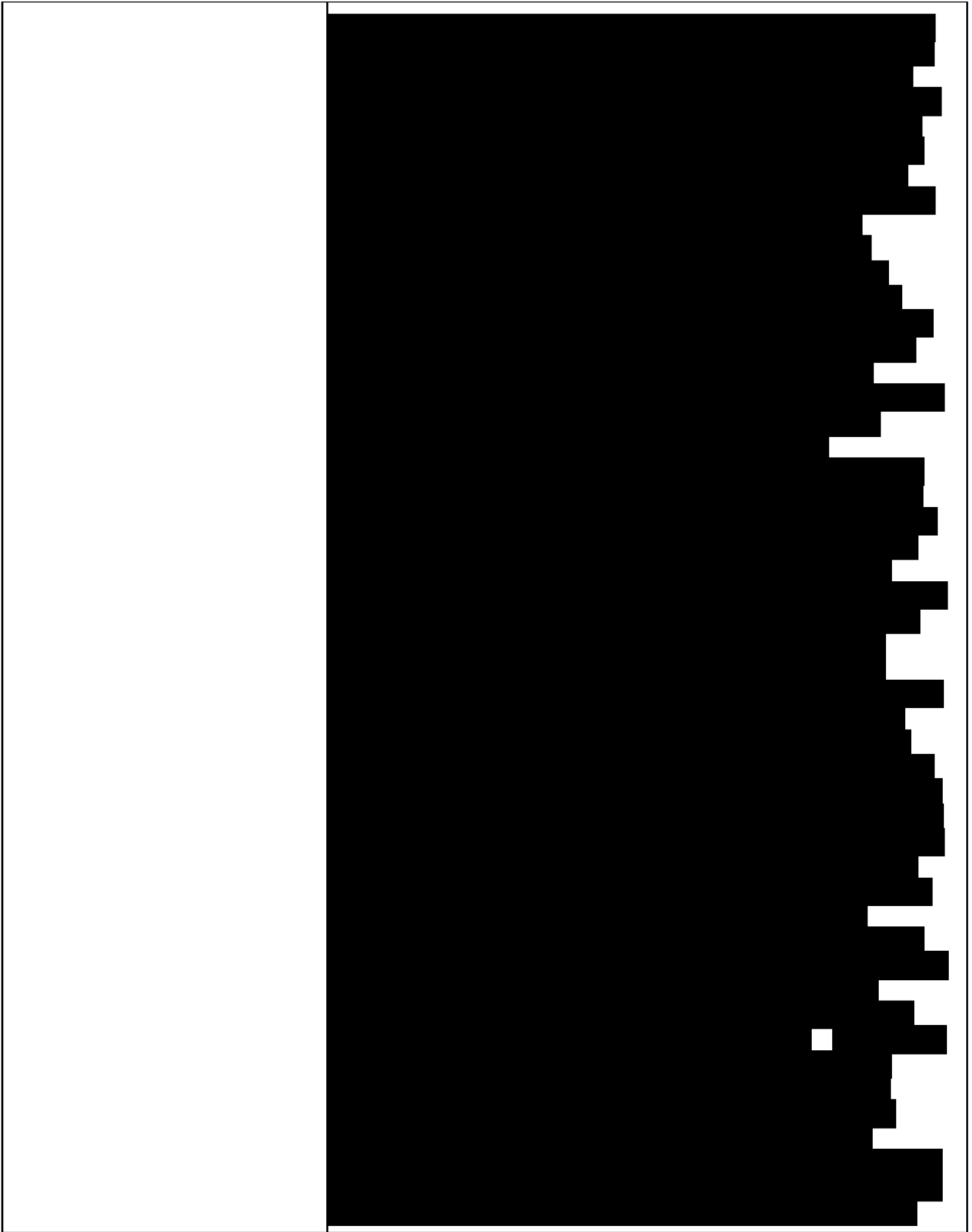
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Economic Feasibility	
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Justification for confidentiality	
Hazards and Risks of the Alternative	

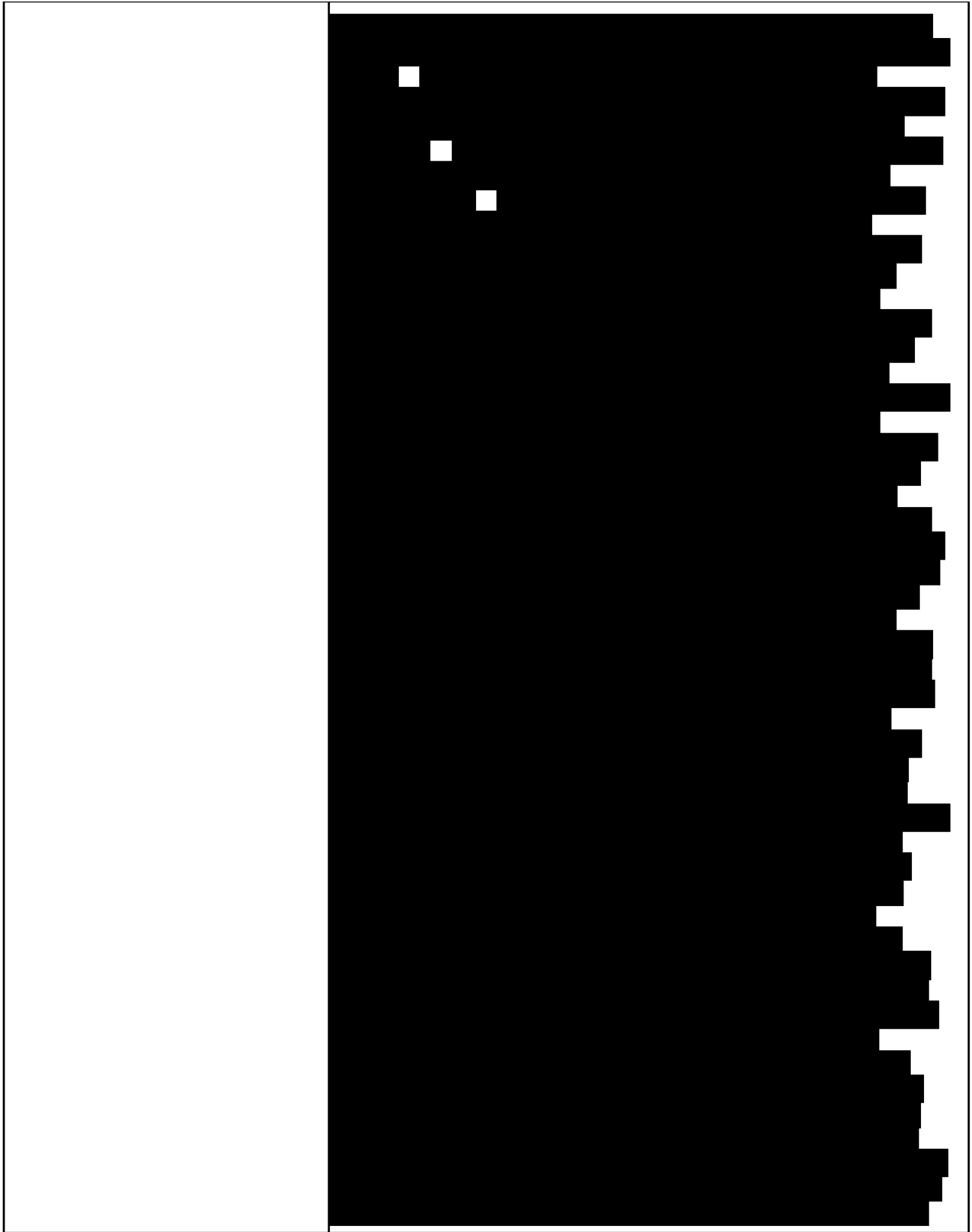
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Justification for confidentiality	
Availability	

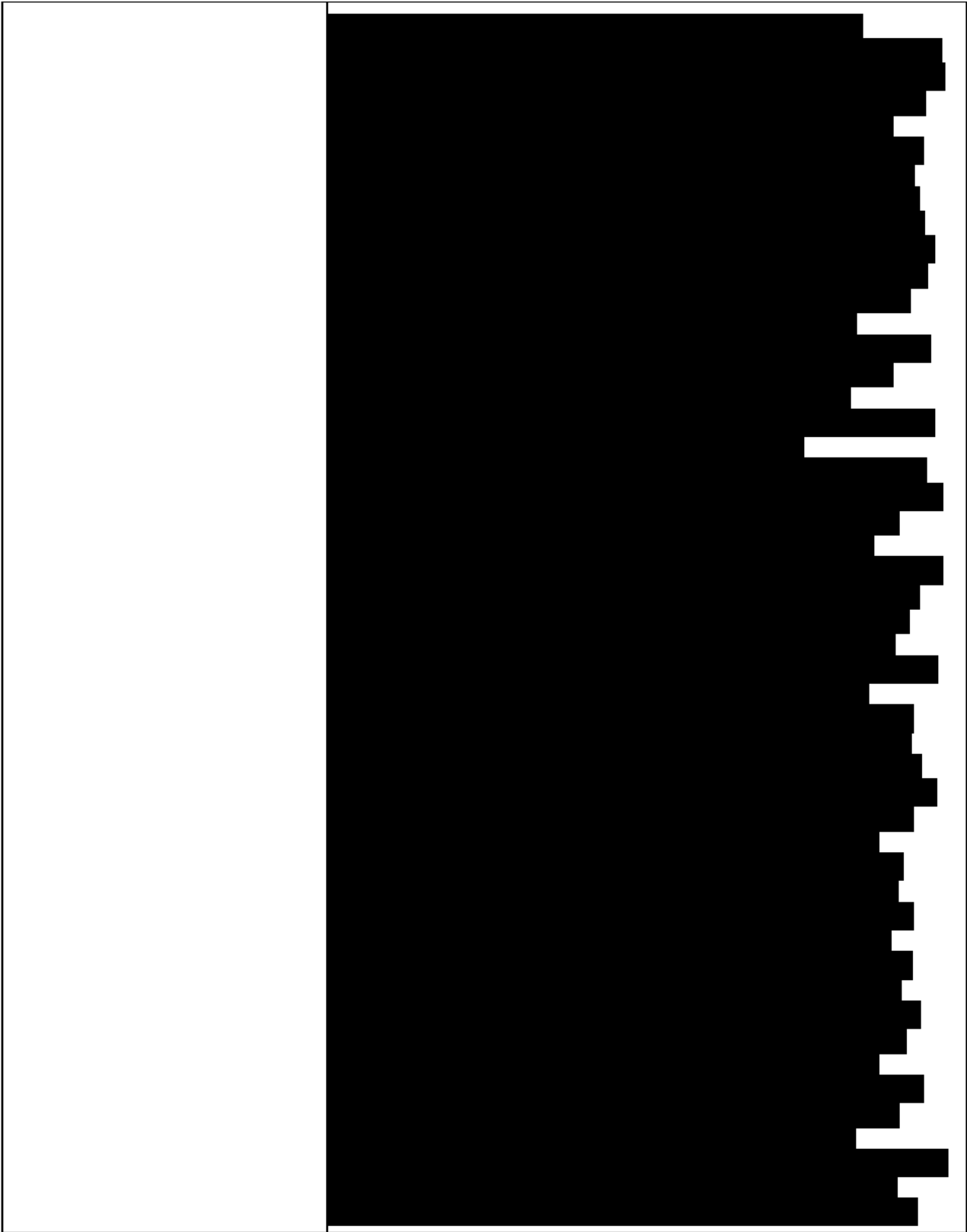
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Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol as a biocidal active substance has unique properties and no suitable alternatives can be identified to match the same levels of performance in terms of efficacy, tolerability, safety, cost, availability, secure supply chain and sustainability. As reported in publications, key organizations such as the WHO Task Force on Alcohol-Based Hand Rubs, the WHO Collaborating Centre on Patient Safety, Infection Prevention & Control, and Antimicrobial Resistance, the Commission for Hospital Hygiene and Infection Prevention, Robert Koch Institute in Berlin, Germany, and the Association for Applied Hygiene in Germany (see references 5 and 6) strongly recommend retaining ethanol as a crucial component in hand rubs for healthcare, safe food production, and community use, particularly during outbreak situations. The absence of effective hand rubs against non-enveloped viruses such as norovirus, adenoviruses, and enteroviruses D68 and 71 (which are not vaccine-preventable) poses significant public health risks. A shift from ethanol to “propanols” for biocidal hand rubs would likely diminish infection prevention and public health protection, increasing risks without providing any tangible benefits. Therefore, no equivalent alternative to ethanol has been identified. The evaluation of ethanol as a biocidal active substance must reasonably exclude data from the oral abuse of alcoholic beverages, as it is not applicable to the use of ethanol in disinfection. Pursuing an inconsistent evaluation of ethanol in the context of biocidal substances could have substantial future repercussions for other categories (pharmaceuticals, cosmetics, etc.), causing increasing risks for health without any benefits and with unnecessary economic and environmental damage.
Information above is confidential	
Justification for confidentiality	
Other comments	

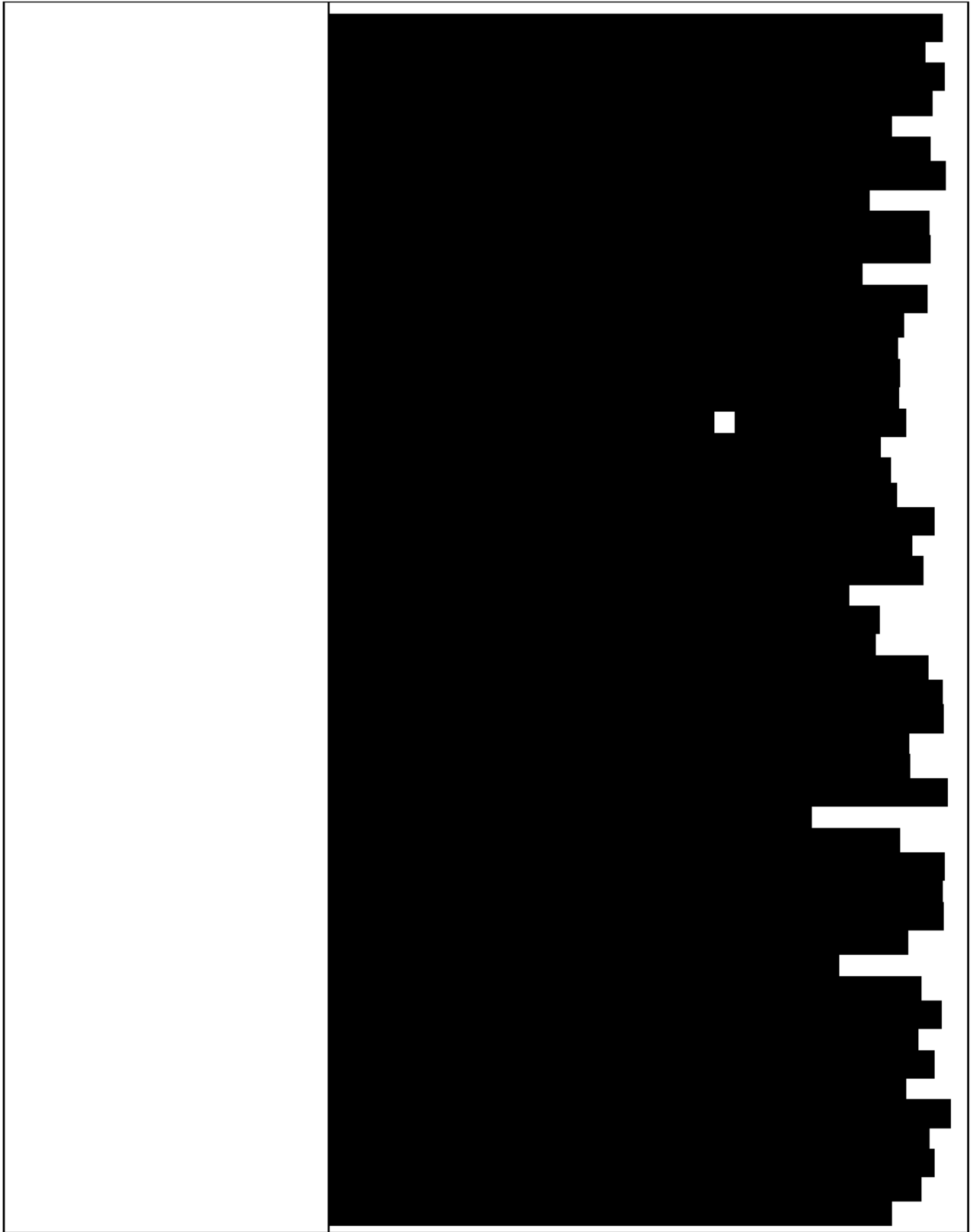


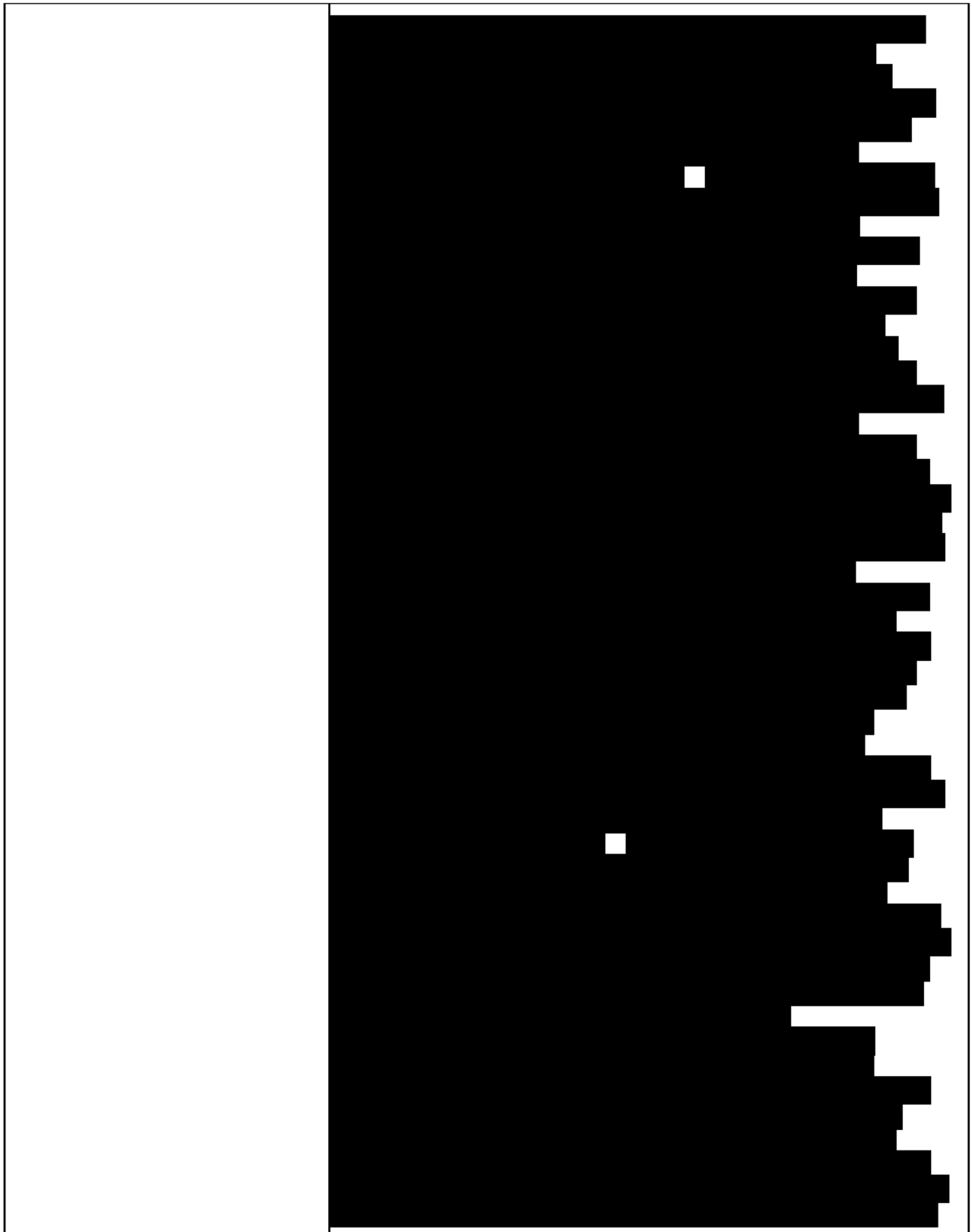


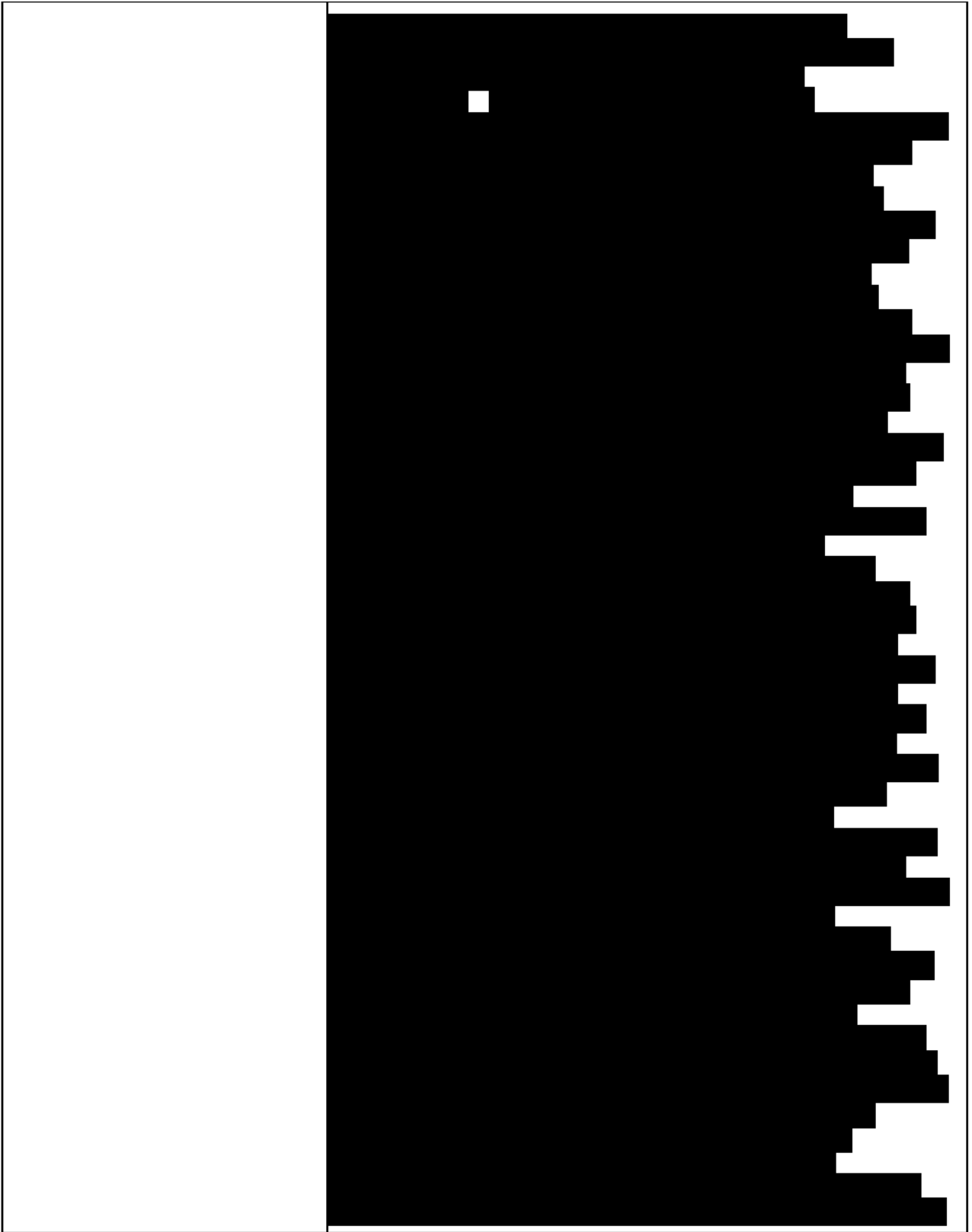


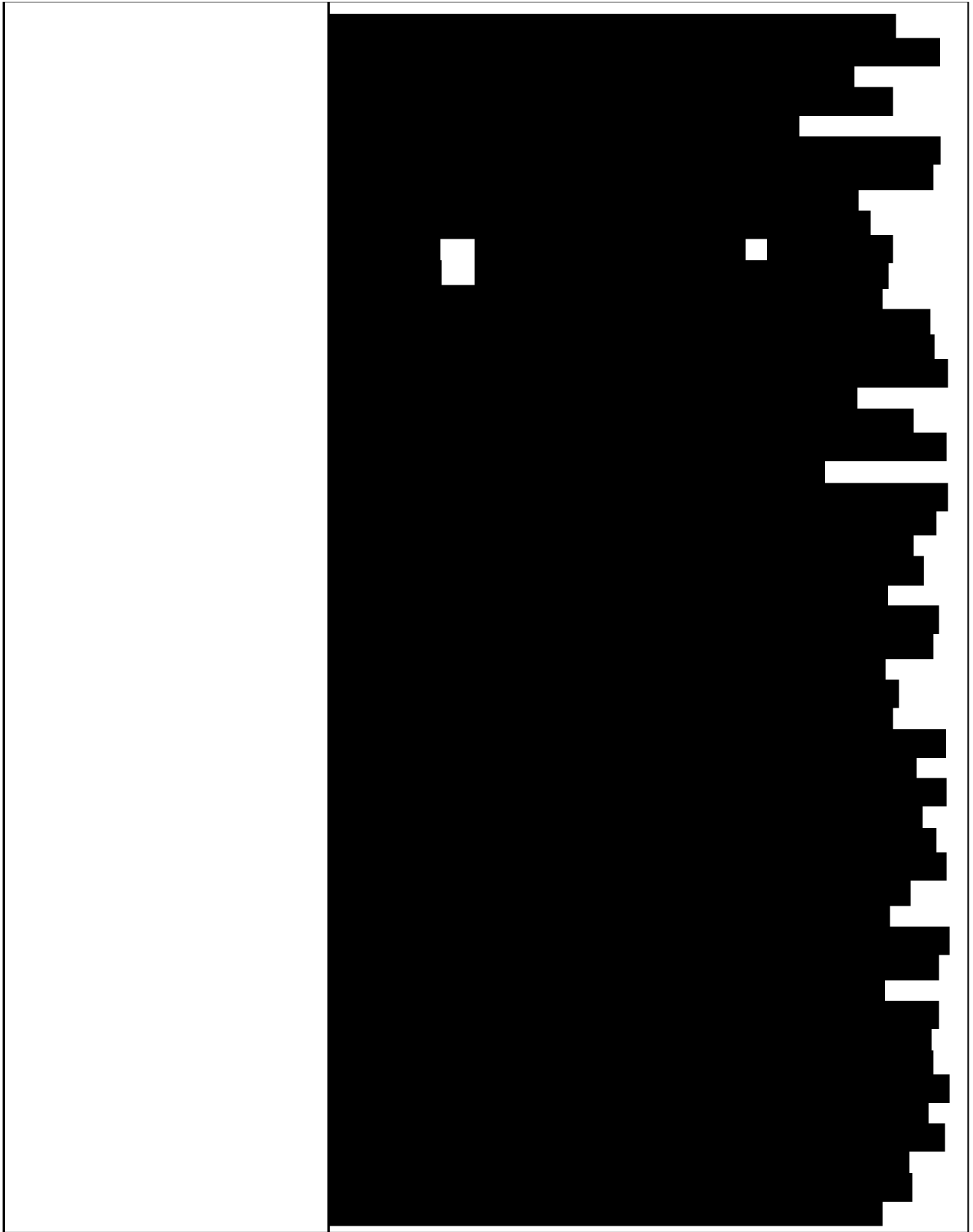












Information above is confidential	
Justification for confidentiality	
References	1. Alcohol, health and policy response in the European Union. WHO 2024 (24-10-16 EU factsheet on Alcohol Consumption) 2. https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Alcohol_consumption_statistics 3. Alcohol and Cancer Risk: The U.S. Surgeon General's Advisory (2025) 4. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans VOLUME 96 Alcohol consumption and Ethyl Carbamate (WHO, 2010) 5. Kramer A, Pittet D, Exner M, Wendt C. Medical associations and expert committees urge that ethanol be approved as a virucidal active substance for use in hand antiseptics under the European Biocidal Products Regulation, without a CMR classification. GMS Hyg Infect Control. 2024;19:Doc40. DOI: 10.3205/dgkh000495, URN: urn:nbn:de:0183-dgkh0004959 6. Kramer et al. Ethanol is indispensable for virucidal hand antisepsis: memorandum from the alcohol-based hand rub (ABHR) Task Force, WHO Collaborating Centre on Patient Safety, and the Commission for Hospital Hygiene and Infection Prevention (KRINKO), Robert Koch Institute, Berlin, Germany - Antimicrobial Resistance & Infection Control (2022) 11:93 https://doi.org/10.1186/s13756-022-01134-7 7. Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation) 8. Microbiology, spectrum of action, tolerability and users' perception of an alcohol-based hand gel rub sanitizer Capezzone de Joannon A. Gazzetta Medica Italiana - Archivio per le Scienze Mediche 2025 Mar 19 9. Hand hygiene for prevention and control of viral infections: the role of Amuchina Gel Xgerm Cermelli C. AboutOpen 2024; 11: 89-93 10. M Vujasinović, M Kočar, K Kramer, M Bunc and M Brvar Poisoning with 1-propanol and 2-propanol Human and Experimental Toxicology (2007) 26: 975–978 11. Verbund für Angewandte Hygiene (VAH) e.V. et al. (Eds.) As a biocidal active substance, ethanol is indispensable for hygienic hand disinfection. (Authorized translation). 29 October 2020, online available from https://vah-online.de/en/

Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 88	2025/04/17 14:03
Country	Poland
Name of organization/institution	The Polish Union of the Cosmetics Industry
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Cosmetic sector plays a pivotal role in consumer products that deliver essential health and wellbeing benefits. On behalf of more than 250 entrepreneurs associated in the Polish Union of the Cosmetics Industry we would like to draw attention to an issue with significant negative consequences for the cosmetics industry regarding potential reclassification of ethanol as Carcinogenic and Toxic for Reproduction (CMR) Category 1 or Category 2. Classification of ethanol as a CMR substance would have unprecedented economic, social and political impacts on many sectors – including the cosmetic sector without the intended direct health benefits and consumer protection.
Product Type	1,2,4
Alternative Identity and Properties	Ethanol serves multiple functions in cosmetics that cannot be easily replaced by a single ingredient, i.e. solubilizing properties, volatile properties, antimicrobial activity. Ethanol is a commonly used substance in cosmetic products (e.g. perfumes, after-shave products, oral care products, sunscreen, make-up, and skincare products), biocidal products (e.g. disinfection products, including disinfection of production devices used in the cosmetics industry), detergents, cleaners and fragrances. There is lack of suitable alternatives for ethanol.

Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Ethanol's intrinsic volatile and antimicrobial properties make it extremely difficult to replace with a single ingredient. For many cosmetics companies' entire product portfolios depend on the use of ethanol. The classification of ethanol as a CMR substance would have cascading effects on the cosmetics sector, potentially disrupting sometimes centuries-old products, and the supply chain economy.
Information above is confidential	
Justification for confidentiality	In the case of ethanol reclassification, more than 100.000 cosmetic formulations on the market would require reformulation (fragrance products, skin care products, suncare products, mouthwashes, hair products).
Economic Feasibility	The classification of ethanol as a CMR substance would have profound economic repercussions. The withdrawal of ethanol-containing products would disrupt the market, affecting both manufacturers and consumers. The economic fallout could lead to job losses in the cosmetics sector and its supply chain. The cost of reformulating products and replacing ethanol with less effective alternatives would most probably be passed on to consumers, raising prices. An internal survey of the Union's member companies which was conducted in January 2025 shows that the impact of the ethanol classification on Polish cosmetics companies is highly variable. For some companies (SMEs) which base their business on the production of perfume and deodorant products, the entire product portfolio depends on the use of ethanol, while for the majority of companies that participated in the survey, all or the great majority of a given product category (e.g. antiperspirants, all perfumes, nail products) uses ethanol. Constant reformulation efforts of safe products are diverting resources away from research and development, hindering sustainable innovation and threatening Europe's leadership.
Information above is confidential	
Justification for confidentiality	The main health concerns associated with ethanol are related to its consumption in alcoholic beverages and not its use in cosmetics. Given the negligible risk posed by ethanol in cosmetic applications, the classification would not

	enhance consumer safety, but rather reduce the availability and quality of cosmetic products.
Hazards and Risks of the Alternative	Classifying ethanol as a CMR substance could lead to regrettable substitutions with less effective ingredients without a 'better' profile of consumer safety. Alternatives would likely have a greater environmental impact and lack the positive climate effects of bio-based ethanol.
Information above is confidential	
Justification for confidentiality	
Availability	The need for exemptions and the lack of transparency in the exemption process would create administrative challenges. Ingredients receiving a CMR 1 classification are banned in cosmetics, despite extensive evidence supporting their safe use based on consumer use levels. A comprehensive review of the balance between the negative and positive consequences of the CMR classification of ethanol is needed, in particular with regard to its further uses in the cosmetic sector.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Classification of ethanol as a CMR substance would have widely negative consequences for the cosmetics industry, with no noticeable benefits for consumers or public health, it would disrupt the supply chain, it would increase costs, while the main risk underlying the classification, which is excessive human consumption of ethanol – is irrelevant for cosmetics use, because ethanol which is used in cosmetics (on the skin and mucous membranes) does not cause systemic exposure. A ban or strict restrictions for ethanol would be disproportionate, considering the safe use of ethanol in cosmetics and the lack of suitable alternatives.
Information above is confidential	
Justification for confidentiality	
Other comments	The European Union must urgently align its strategic priorities into concrete action. The recently published Competitiveness Compass and Clean Industrial Deal emphasize the need to prioritize competitiveness, re-

	industrialization, simplification, and strategic autonomy. However, strategic autonomy will only be achieved if policy and regulatory files align with the reality, particularly on such strategic substances like ethanol.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	Kosmetyczni.PL_Ethanol's biocidal Public Consultation_17.04.2025.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 89	2025/04/17 14:29
Country	Germany
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	In meinem Krankenhaus arbeiten wir seit vielen Jahrzehnten mit ethanolhaltigen Händedesinfektionsmittel. Keiner der vielen Mitarbeiter hat eine BG Krankheit oder Hautkrebs gehabt- über 35 Berufsjahre.
Product Type	1,2,4
Alternative Identity and Properties	Hygienefachkraft, Praxisanleiterin, Krankenschwester
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	

Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	ich kann mir kein besseres wirksamere HDM als mit dem Inhaltstoff Ethanol vorstellen.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	

Justification for confidential attachment	

Comment 90	2025/04/17 14:54
Country	Germany
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Eine Zulassungsbeschränkung von Ethanol hätte massive negative Auswirkungen auf industrielle Prozesse und die öffentliche Gesundheit. Ethanol zeichnet sich durch eine Vielzahl spezifischer Eigenschaften aus und besitzt im Vergleich zu anderen Alkoholen einige Alleinstellungsmerkmale. Dies macht Ethanol zu einem unverzichtbaren Rohstoff unter anderem für die Gesundheits-, Pharma-, Medizinprodukte- und Lebensmittelindustrie. Ethanol ist sehr gut verfügbar, den zahlreichen Ethanolproduzenten stehen wesentlich weniger Propanolhersteller gegenüber. Und: Wir brauchen die gut formulierten geprüften Produkte, um die Hautgesundheit unseres Gesundheitspersonals zu schützen. Die SARS-CoV-2-Pandemie hat gezeigt, wie wichtig standardisierte Prüfprotokolle nach den EN-Methoden sind. Sie stellen sicher, dass Desinfektionsmittel und Antiseptika im klinischen Alltag und in Ausbruchsszenarien auch wirksam und sicher sind. Ethanol wurde aufgrund seiner überlegenen Wirksamkeit gegenüber unbehüllten Viren in der Prüfnorm EN17430 als Referenz festgelegt. In der Norm wird die Wirksamkeit von Händedesinfektionsmitteln gegenüber Viren auf künstlich kontaminierten Händen geprüft. Die europäischen Normen für die Infektionsprävention und Desinfektion sind nicht nur in Europa von großer Bedeutung, sondern finden auch in den USA, Kanada oder im asiatisch-pazifischen Raum Anerkennung. Ethanol ist ein gut dokumentierter und sicherer Rohstoff, der biologisch sehr gut abbaubar ist. Eine Substitution wäre nur in wenigen Einzelfällen möglich. Wir verfügen mit Ethanol über das einzige nachhaltig aus nachwachsenden Rohstoffen hergestellte Lösungsmittel, das bei einer CMR-Einstufung durch petrochemische Lösungsmittel ersetzt werden müsste. Für den Gesundheitsschutz, z. B. im

	Desinfektionsbereich und für Endverbraucher würden zahlreiche alltägliche Produkte verloren gehen. Für die professionelle Anwendung und die Industrie sind die mittel- und langfristigen Folgen noch gar nicht absehbar. Die Produktionsprozesse von der Anlieferung bis zur Lagerung würden komplizierter und teurer werden. Die Ethanol-Lieferketten würden massiv beeinflusst und der Einkauf erschwert werden. Dies führt zu massiven Wettbewerbsnachteilen.
Product Type	1,2,4
Alternative Identity and Properties	Von allen drei zur Händedesinfektion eingesetzten Alkoholen verfügen nur ethanolhaltige Produkte über eine Wirksamkeit gegenüber hydrophilen unbehüllten Viren innerhalb praktikabler Anwendungszeiten. Während Noroviren noch von Formulierungen mit 2-Propanol und 1-Propanol inaktiviert werden können, reicht die Wirksamkeit dieser Alkohole bei Adeno-, humanen Entero- wie Echo- und Coxsackie-Viren und Polioviren nicht aus. Sogar gegen humane Papillomviren können viruzide Formulierungen eingesetzt werden. Damit ist Ethanol für Bekämpfung von Infektionen, die durch diese Viren ausgelöst werden, essenziell. Da aus regulatorischer Sicht eine Bewertung nach der Biozid-Verordnung derzeit automatisch die Einstufung nach CLP nach sich zieht und damit weitere Rechtsverordnungen angepasst werden müssen, hätte dies immense Auswirkungen insbesondere auf den Arbeitsschutz in allen betroffenen Branchen. Eine Einstufung als krebserzeugend und fortpflanzungsgefährdend käme einem Beschäftigungsverbot für schwangere und stillende Frauen gleich. In der Produktion wären erhebliche Investitionen zur Umstellung der Produktions- anlagen erforderlich. Man denke nur an die Weinherstellung – ein Weinausbau im Barrique wäre ohne den Einbau großer Lüftungsanlagen und geschlossener Systeme überhaupt nicht mehr möglich. Zudem würde die Einstufung zu einem Vertrauensverlust der Verbraucher in die Lebensmittelsicherheit führen. Als Zutat kann Ethanol nicht durch andere Stoffe ersetzt werden, aber auch als funktioneller Stoff und für die Umsetzung von Hygienekonzepten ist Ethanol in vielen Produktionsprozessen unverzichtbar. Im Bereich der Herstellung von Babynahrung und Bio-Lebensmitteln stellen ethanolhaltige Desinfektionsmittel nach dem Wegfall anderer biozider Wirkstoffe wie quartäre Ammoniumverbindungen, z. B. BAC und DDAC, und chlorhaltiger Substanzen eine der wenigen verbliebenen Alternativen zur Desinfektion von Maschinen und Anlagen dar. Ethanol besitzt besondere antimikrobielle

	Eigenschaften, ist wasserfrei und verdunstet schnell und rückstandsfrei. Dies macht Ethanol z. B. in Molkereien unersetzlich. Würde alternativ Isopropanol eingesetzt, wäre wegen möglicher Rückstände eine Nachspülung mit der Gefahr von erneutem Keimeintrag und Schimmelpilzbefall zwingend erforderlich. Ethanol besitzt einen verbindlichen AGW in Höhe von 380 mg/m³, der zur Beurteilung der inhalativen Exposition an Arbeitsplätzen im Rahmen der Gefährdungsbeurteilung und zur Überprüfung der Wirksamkeit der Schutzmaßnahmen heranzuziehen ist. Ethanol ist in der TRGS 900 „Arbeitsplatzgrenzwerte“ mit der Bemerkung „Y“ als Stoff ausgewiesen, bei dem ein Risiko der Fruchtschädigung bei Einhaltung des Arbeitsplatzgrenzwertes nicht befürchtet zu werden braucht. Bei Ethanol handelt es sich nicht um einen hautresorptiven Stoff. Wenn Stoffe hautresorptive Eigenschaften haben, können sie aufgrund ihrer physikalisch-chemischen Eigenschaften auch über die intakte Haut aufgenommen werden und zu gesundheitlichen Schäden führen. Hautresorptive Stoffe sind in der TRGS 900 mit „H“ ausgewiesen. Dies ist bei Ethanol nicht der Fall. Beim Umgang mit Ethanol ist die Einhaltung des AGW für den Schutz der Gesundheit der Beschäftigten somit ausreichend. Die BG BAU hat bei Tätigkeiten mit ethanolhaltigen Reinigungsmitteln wie beispielsweise Glasreinigern zahlreiche Arbeitsplatzmessungen durchgeführt, teilweise unter Worst-Case-Bedingungen. Bei allen Messungen wurde der AGW von Ethanol eingehalten.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	▪ Mangel an ebenso wirksamen Alternativen: Kein Ersatz-Biozid-Wirkstoff bietet die gleiche viruzide Wirksamkeit gegen unbehüllte Viren. ▪ Andere Wirkstoffe haben ein höheres Toxizitätsprofil oder hinterlassen Rückstände. ▪ Lieferketten: Alternative Stoffe sind wesentlich teurer und weniger verfügbar. ▪ Die Ausweitung der Produktion von Ersatzstoffen würde massive Investitionen in neue Anlagen, Technologien und behördliche Genehmigungen erfordern und stößt auf den Widerstand von Behörden und Nichtregierungsorganisationen. ▪ Potenzielle Risiken für die öffentliche Gesundheit: Die geringere Verfügbarkeit wirksamer Desinfektionsmittel könnte die Infektionsraten im Gesundheitswesen, in der Lebensmittelverarbeitung und in der öffentlichen Hygiene erhöhen. ▪ Die Ethanolproduktion ist gut aufgestellt und verfügt über stabile Lieferketten. ▪

	Alternative Biozide sind mit höheren Produktionskosten, geringerer Verfügbarkeit und logistischen Herausforderungen (Produktion fast ausschließlich im Nicht-EU-Ausland) verbunden. ▪ Regulierungsentscheidungen sollten die wirtschaftliche Machbarkeit und die Kontinuität der Versorgung berücksichtigen, um Marktstörungen zu vermeiden.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol ist ein weit verbreiteter biozider Wirkstoff mit breitem Wirkungsspektrum, insbesondere in Desinfektionsmitteln und Antiseptika. Die wichtigsten Eigenschaften sind: ▪ Nachgewiesene viruzide, bakterizide, fungizide und tuberkulozide Wirkung. ▪ Hohe Wirksamkeit gegen unbehüllte Viren, was für die Infektionskontrolle entscheidend ist. ▪ Keine Rückstände auf Oberflächen, wodurch es sicher für Anwendungen mit Lebensmittelkontakt ist. ▪ Schnelle Verdunstung, dadurch eine einfache Anwendung im Gesundheitswesen und in öffentlichen Einrichtungen. ▪ Gut dokumentiertes Sicherheitsprofil mit minimalen Risiken bei sachgemäßer Anwendung. Ethanol ist der einzige Alkohol, der vollständig viruzid und umfassend wirksam gegen unbehüllte Viren einschl. Enteroviren (z.B. Polioviren) ist und eine der wenigen alkoholischen Substanzen, die gegen Noroviren

	wirksam ist. Unterstützt durch WHO-Empfehlungen und Studien (z. B. Kramer et al., 2022), die seine hervorragenden Desinfektionseigenschaften hervorheben. Lange Haltbarkeit der formulierten Produkte, die Stabilität und Verwendbarkeit im Laufe der Zeit gewährleisten. Ethanol ist für den Gesundheitssektor unverzichtbar!
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	https://www.krankenhaushygiene.de/informationen/979 https://www.bpi.de/nachrichten/detail/ein-segen-fuer-die-medizin-wir-brauchen-ethanol https://www.bvmed.de/verband/presse/pressemeldungen/gemeinsame-pressemeldung-von-bpi-bvmed-iho-und-vdgh-ethanol-ist-im-medizinischen-bereich-unverzichtbar-und-muss-es-bleiben
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 91	2025/04/17 15:10
Country	Germany
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	

General information	https://www.iho.de/wp-content/uploads/0010.0056_A4_P3_web.pdf
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	There is no alternative to ethanol when used as a disinfectant. Es gibt keine Alternative zu Ethanol in Bezug auf die Verwendung als Desinfektionsmittel.
Information above is confidential	
Justification for confidentiality	
Other comments	

Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 92	2025/04/17 16:20
Country	Italy
Name of organization/institution	Arexons SpA a socio unico
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	As downstream users, we use Ethanol as main component for windscreen washers for automotive sector for both consumer and professional end users.
Product Type	1,2,4
Alternative Identity and Properties	At the moment there is not a suitable alternative on the market since Ethanol is the only substance that combines low freezing point and detergency properties with an adequate price.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	At the moment there is not a suitable alternative on the market since Ethanol is the only substance that combines low freezing point and detergency properties.

Information above is confidential	
Justification for confidentiality	
Economic Feasibility	At the moment there is not a suitable alternative with an adequate price.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Any alternative substance will cause a worsening of the performance of our products, which leads to a potential safety risk for drivers who could not clean their windscreens properly.
Information above is confidential	
Justification for confidentiality	
Availability	Any alternative substance has not the same availability of ethanol and this may cause potential discontinuity through the supply chain.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	This new CLH proposal will make our products classified as carcinogenic of category 1 (H350) and therefore not more suitable for consumer market. It's well known that Ethanol may cause cancer only through oral exposure, therefore end users are not exposed to this hazard when they manufacture or use our products.
Information above is confidential	
Justification for confidentiality	
Other comments	Ethanol is usually obtained from biomass fermentation not in conflict with food supply chain so it can be a sustainability drive for products. Any alternative substance is obtained through synthetic processes and will make our product less sustainable.

Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 93	2025/04/17 16:51
Country	Italy
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	Il mercato dell'etanolo dell'UE può essere suddiviso in tre segmenti: combustibile, alimentare e industriale. i) Carburante: l'etanolo viene utilizzato in miscela con la benzina o come carburante alternativo. L'E10, ad esempio, è un tipo di benzina che contiene fino al 10% di etanolo e può essere utilizzato nella maggior parte dei motori a combustione interna e dei veicoli ibridi di oggi, riducendo significativamente le emissioni di gas serra dei trasporti. ii) Alimentare: l'etanolo può essere utilizzato per produrre bevande spiritose, come additivo alimentare, per l'estrazione di aromi, per la conservazione degli alimenti e la produzione di aceto bianco. iii) Industriale: l'etanolo è un componente chimico rinnovabile essenziale in vari prodotti (ad es. prodotti igienizzanti, cosmetici, prodotti farmaceutici, solventi, vernici e fluidi antigelo) per garantire l'igiene e la sicurezza, nonché una materia prima rinnovabile per la produzione di sostanze chimiche rinnovabili (ad es. bioetilene). Il bioetanolo viene prodotto nelle bioraffinerie europee fermentando gli zuccheri in alcol. Nell'UE, questi zuccheri provengono tipicamente da una varietà di fonti

	agricole come grano, mais, orzo, segale, triticale e barbabietola da zucchero. In Italia il bioetanolo è ottenuto principalmente da residui della produzione del vino (e.g. vinacce e fecce di vino) ottenendo quindi un biocarburante avanzato che contribuisce significativamente alla riduzione delle emissioni di gas effetto-serra e quindi al raggiungimento degli obiettivi UE di decarbonizzazione dei trasporti. Nel 2023, i produttori europei di etanolo rinnovabile hanno prodotto 6,44 miliardi di litri di etanolo, operando all'80% dei loro 8,05 miliardi di litri di capacità installata. L'utilizzo come biocarburante ha rappresentato l'85,9% dell'utilizzo; Altri mercati, come le applicazioni industriali e le bevande, hanno rappresentato rispettivamente il 7,6% e il 6,5%. Franciacorta Creme SpA desidera fornire le sue osservazioni all'ECHA sottolineando l'uso insostituibile dell'etanolo e sottolineando che una classificazione dell'etanolo come cancerogeno o tossico per la riproduzione sarebbe dannosa per molti biocidi, creerebbe una mancanza di alternative e avrebbe conseguenze critiche per la salute pubblica.”
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	

Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Non è possibile sostituire l'etanolo con alternative valide e sicure. Il rischio è il blocco delle produzioni industriali
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 94	2025/04/17 17:08
Country	United Kingdom
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1

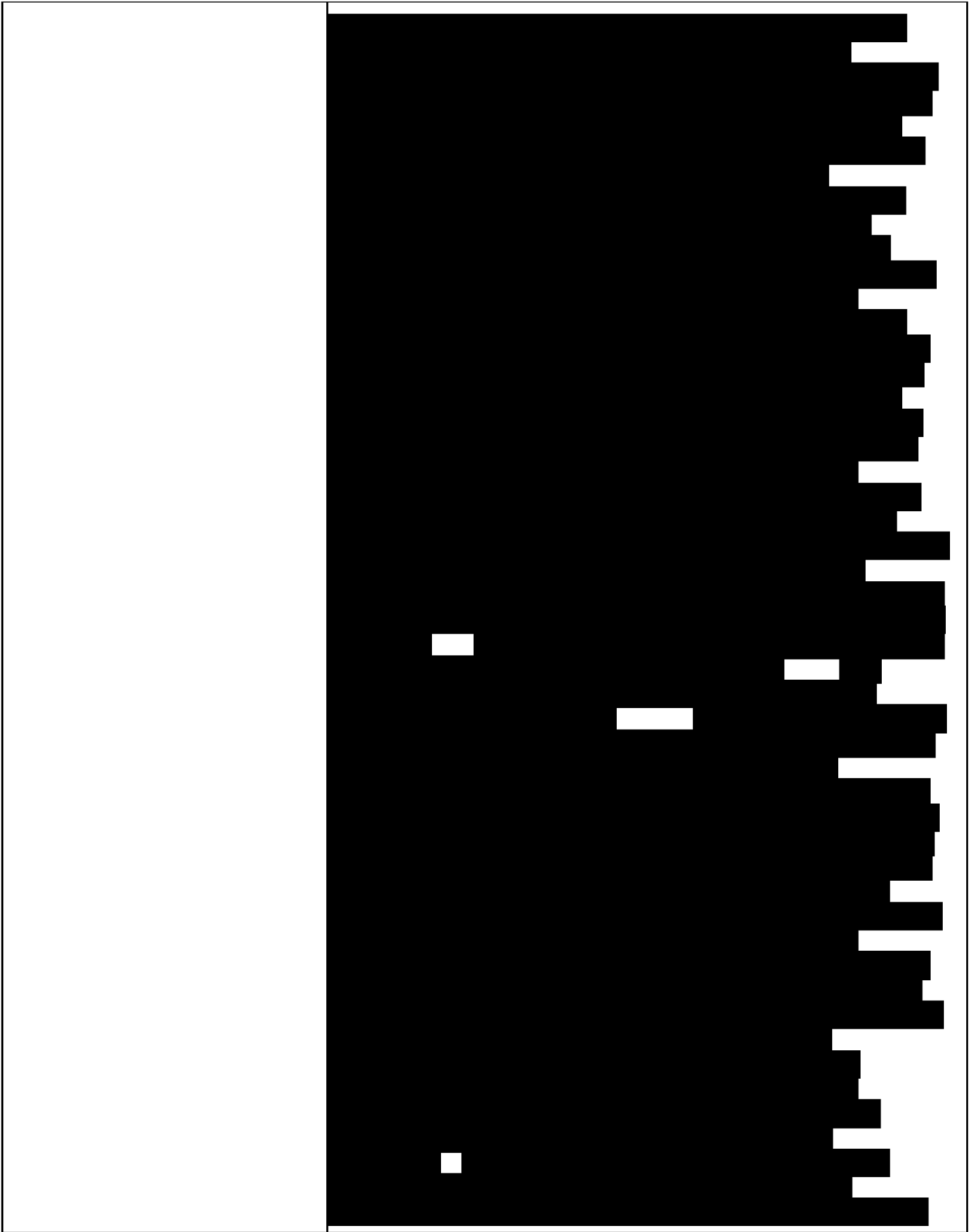
General information	We are UK manufacturers of fragrance and perfumes (PC28) with EU exporting clients.
Product Type	1,2,4
Alternative Identity and Properties	There is no technically and olfactory suitable alternative to ethanol in product type perfumes/fragrances (PC28)
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Use of other solvents/carriers do not give the olfactory properties, skin feel or the olfactory persistence required from this product type
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	As there is no suitable alternative this would mean business closure and job losses in a fragile rural economy.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	No suitable alternative for PC 28
Information above is confidential	
Justification for confidentiality	
Availability	Not applicable
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	We are a small independent manufacturing company in rural England, where the economy is already fragile and where the only products produced are fragrances, all of which include Ethanol. Ethanol is an integral part of perfume formulation and there is no alternative that is technically and olfactively suitable One assessment policy resulting in

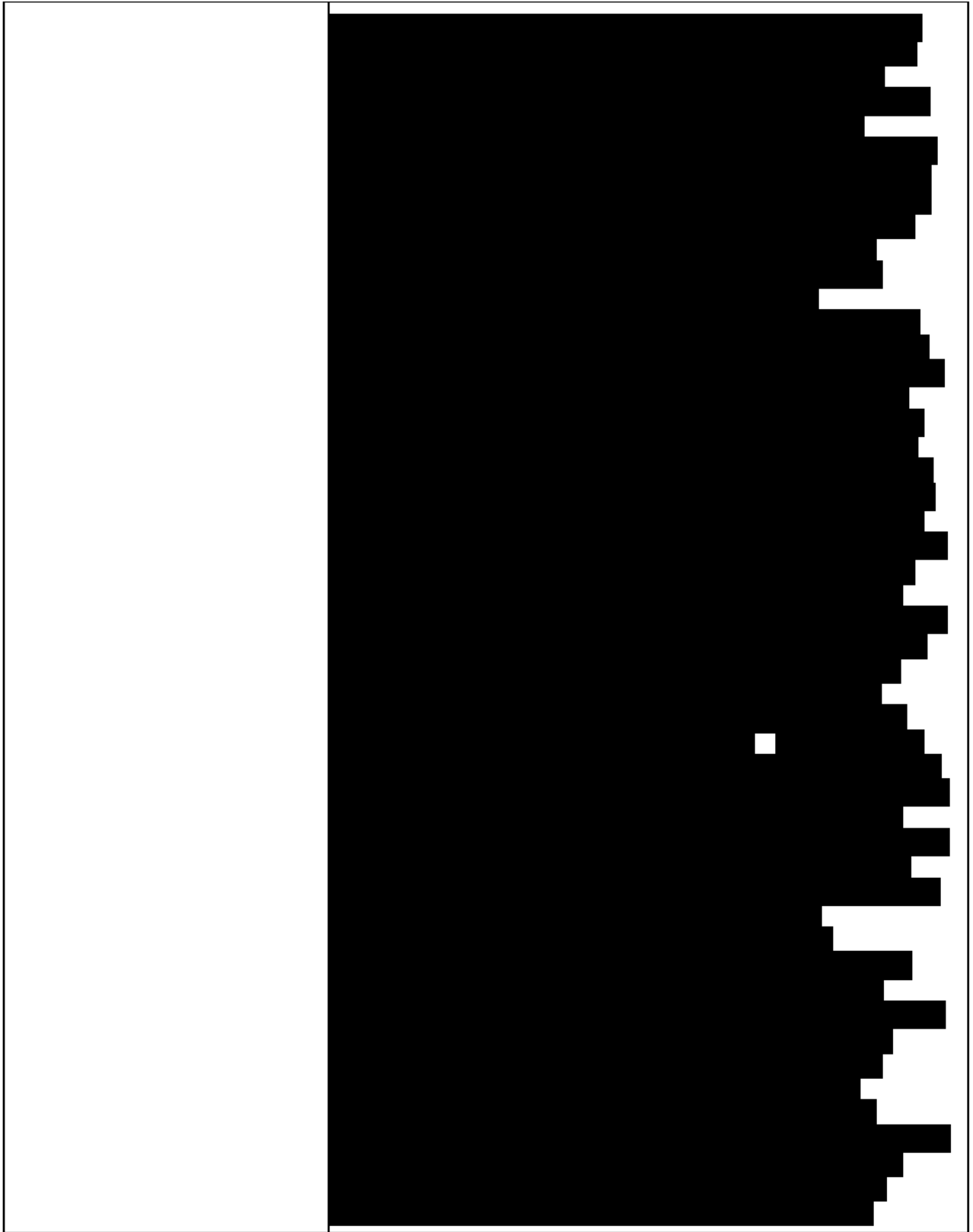
	a CMR 1B classification would, if no derogation is achieved, would mean a prohibition of Ethanol in consumer products. The impact of this classification being adopted means the company would be forced to cease trading. In an area where where the economy and job opportunities are few would have a significant impact on monies brought in to the local economy (£3.5 million) and would also mean 82 job losses in an area where job prospects are minimal.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 95	2025/04/17 17:25

Country	Germany
Name of organization/institution	L. Brüggemann GmbH & Co. KG
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Brüggemann is a manufacturer of ethanol The manu-fac-turing and sale of ethanol has been part of Brüggemann's core busi-ness since 1868. We have been deliv-ering ethanol for a wide-range of uses for more than 150 years. Through continuous analyses as well as tests carried out by a sensor panel in our labor-atory, we offer consist-ently high quality. Thanks to our two produc-tion sites in Heil-bronn and Witten-berg we can offer reli-able, fast and flex-ible delivery solu-tions at any time. Manufacturing of a biocidal product Brüggemann is manufacturing and selling either ethanol as an active ingredient for various customer biocidal products, as well as own biocidal products named Alkopharm.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	

Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	





Information above is confidential	
Justification for confidentiality	
Availability	

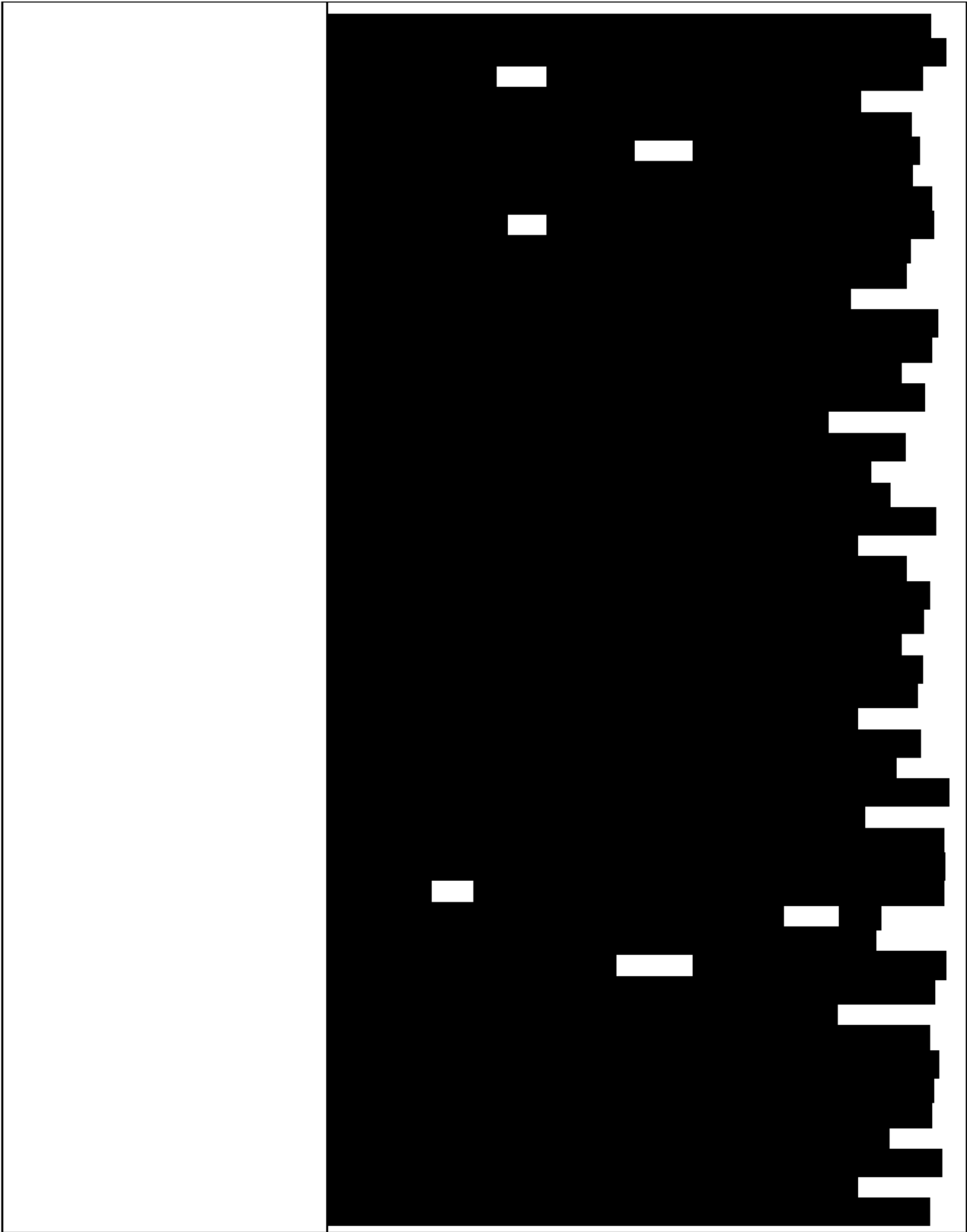
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	A classification of ethanol as a CMR substance would have far-reaching consequences beyond the biocidal sector. It would threaten the operational viability of key manufacturers, compromise hygiene and infection control measures—particularly in healthcare and food-related environments—and significantly impair pandemic preparedness. Ethanol is a safe, effective, sustainable, and widely available active substance. Its continued authorization and use under the Biocidal Products Regulation (BPR) is essential to maintain public health protection and industrial resilience across the EU.
Information above is confidential	
Justification for confidentiality	

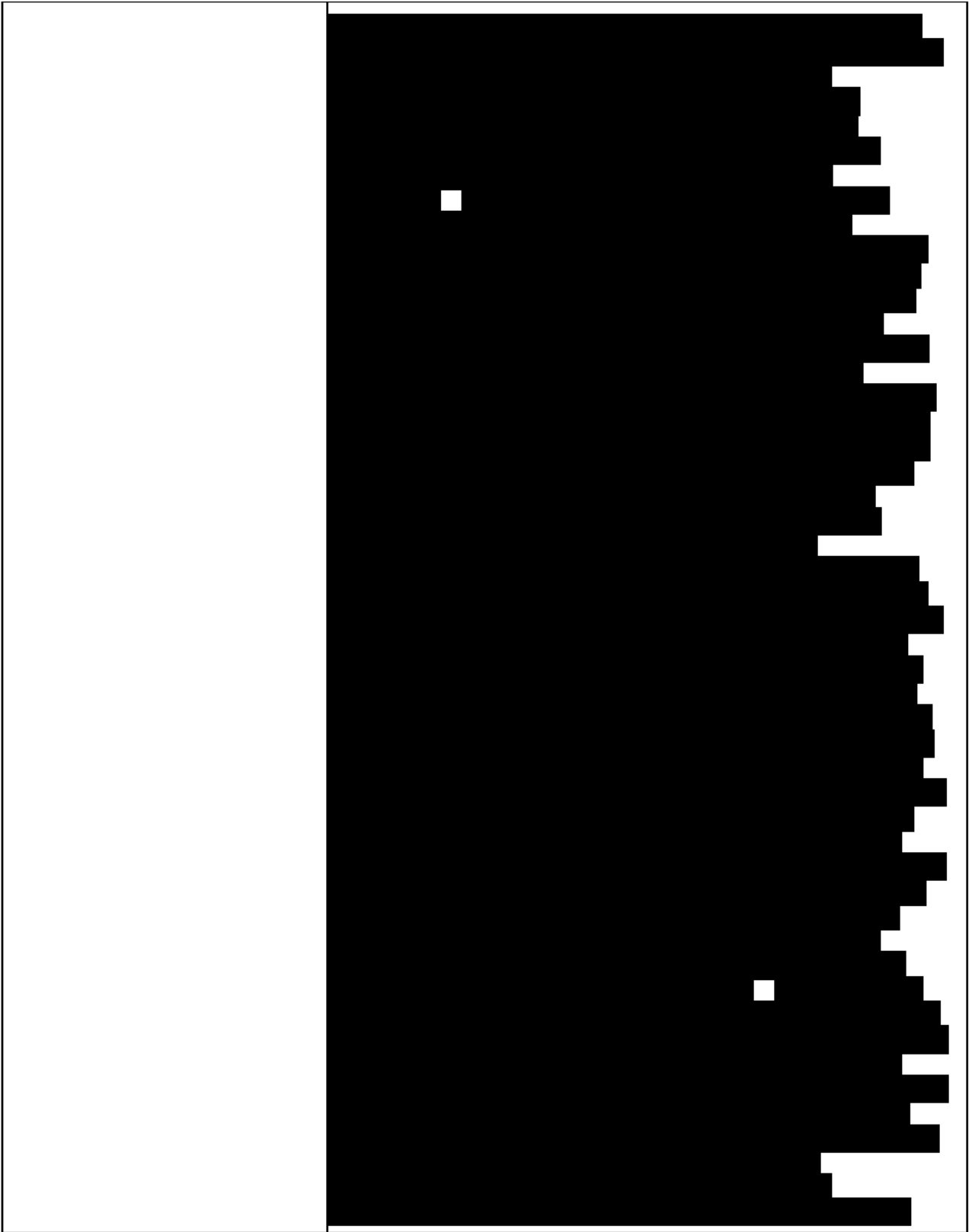
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 96	2025/04/17 17:34
Country	Germany
Name of organization/institution	BrüggemannAlcohol Heilbronn GmbH
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Brüggemann is a manufacturer of ethanol The manufacturing and sale of ethanol has been part of Brüggemann's core business since 1868. We have been delivering ethanol for a wide-range of uses for more than 150 years. Through continuous analyses as well as tests carried out by a sensor panel in our laboratory, we offer consistently high quality. Thanks to our two production sites in Heilbronn and Wittenberg we can offer reliable, fast and flexible delivery solutions at any time. Manufacturing of a biocidal product Brüggemann is manufacturing and selling either ethanol as an active ingredient for various customer biocidal products, as well as own biocidal products named Alkopharm.
Product Type	1,2,4

Alternative Identity and Properties	[REDACTED]
Information above is confidential	[REDACTED]
Justification for confidentiality	[REDACTED]
Technical Feasibility	[REDACTED]
Information above is confidential	[REDACTED]
Justification for confidentiality	[REDACTED]
Economic Feasibility	[REDACTED]

Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	





Information above is confidential	
Justification for confidentiality	
Availability	

Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	A classification of ethanol as a CMR substance would have far-reaching consequences beyond the biocidal sector. It would threaten the operational viability of key manufacturers, compromise hygiene and infection control measures—particularly in healthcare and food-related environments—and significantly impair pandemic preparedness. Ethanol is a safe, effective, sustainable, and widely available active substance. Its continued

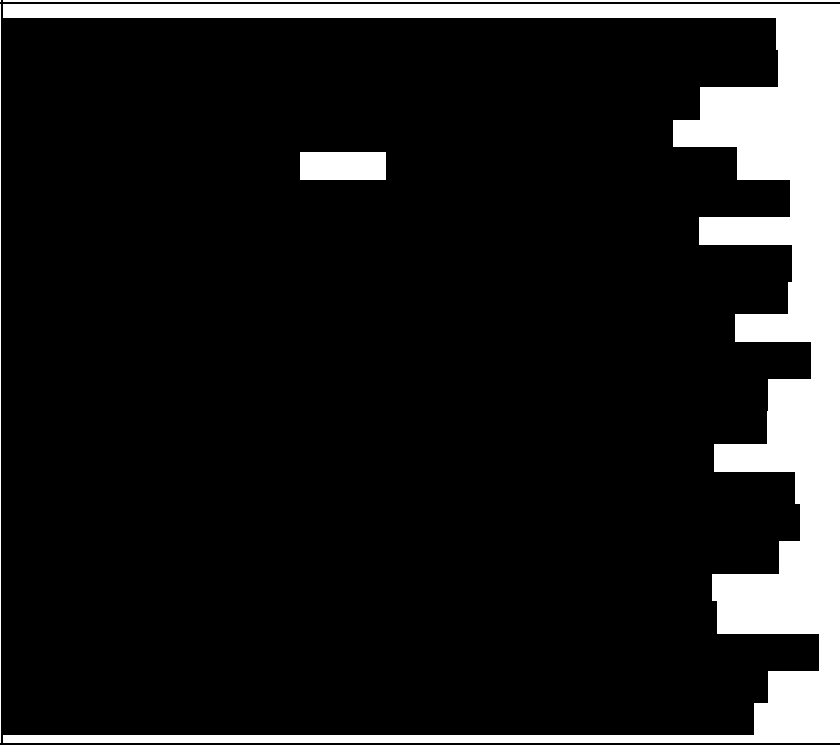
	authorization and use under the Biocidal Products Regulation (BPR) is essential to maintain public health protection and industrial resilience across the EU.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

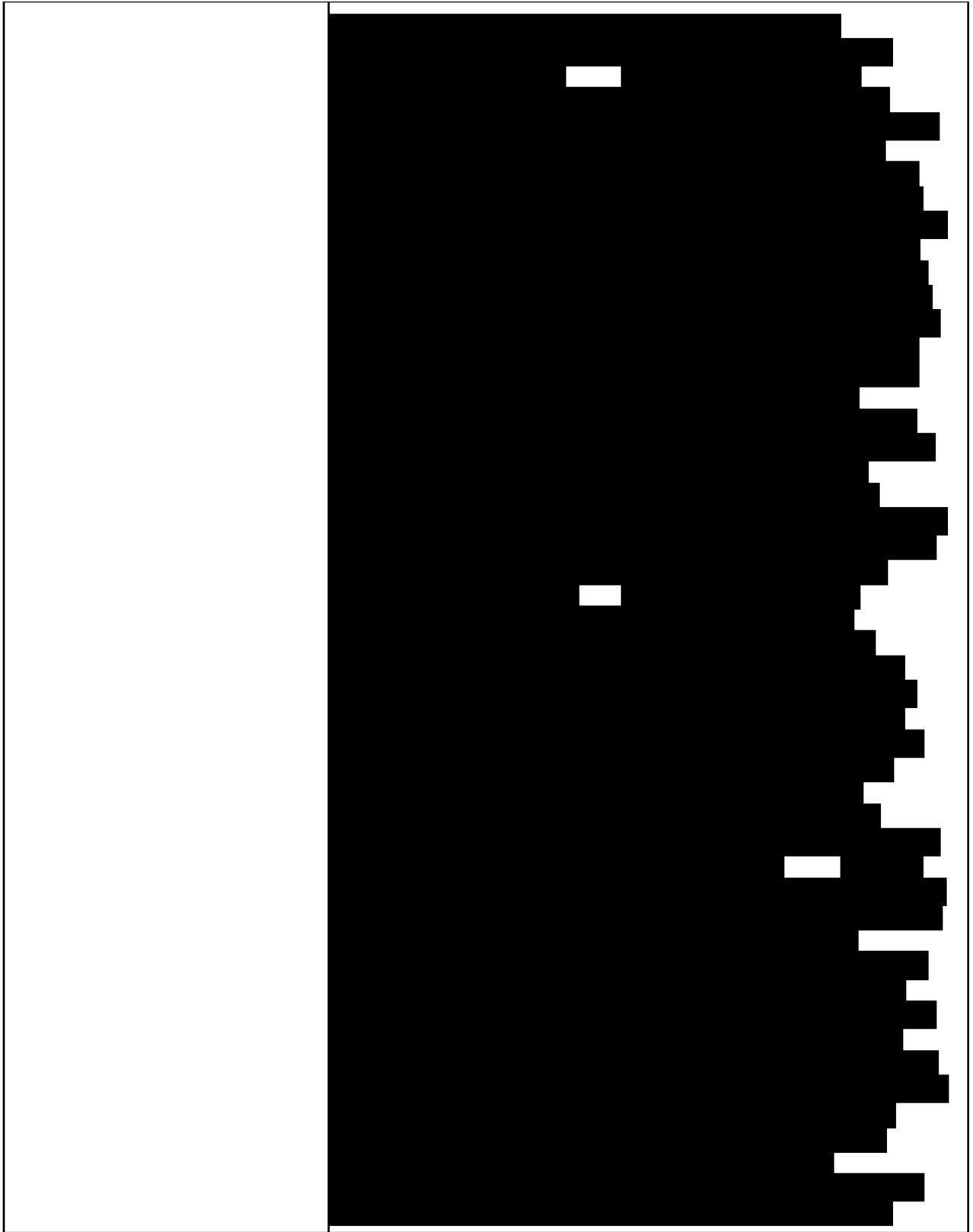
Comment 97	2025/04/17 17:50
Country	Germany
Name of organization/institution	Berkel AHK Alkoholhandel GmbH & Co. KG
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	
Product Type	1,2,4
Alternative Identity and Properties	

Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Conclusion Classifying ethanol as a CMR substance based on inappropriate oral-consumption data does not align with its actual risk profile in biocidal applications. Such a decision would jeopardize infection control, undermine regulatory credibility, and impose unjustified socio-economic burdens. We call on ECHA to adopt a science-based, exposure-specific assessment that preserves the availability of ethanol as an essential biocidal agent, thereby ensuring that European healthcare, industrial hygiene, and consumer safety remain uncompromised. We appreciate ECHA's consideration and remain available to provide further scientific and technical input as needed.
Information above is confidential	
Justification for confidentiality	

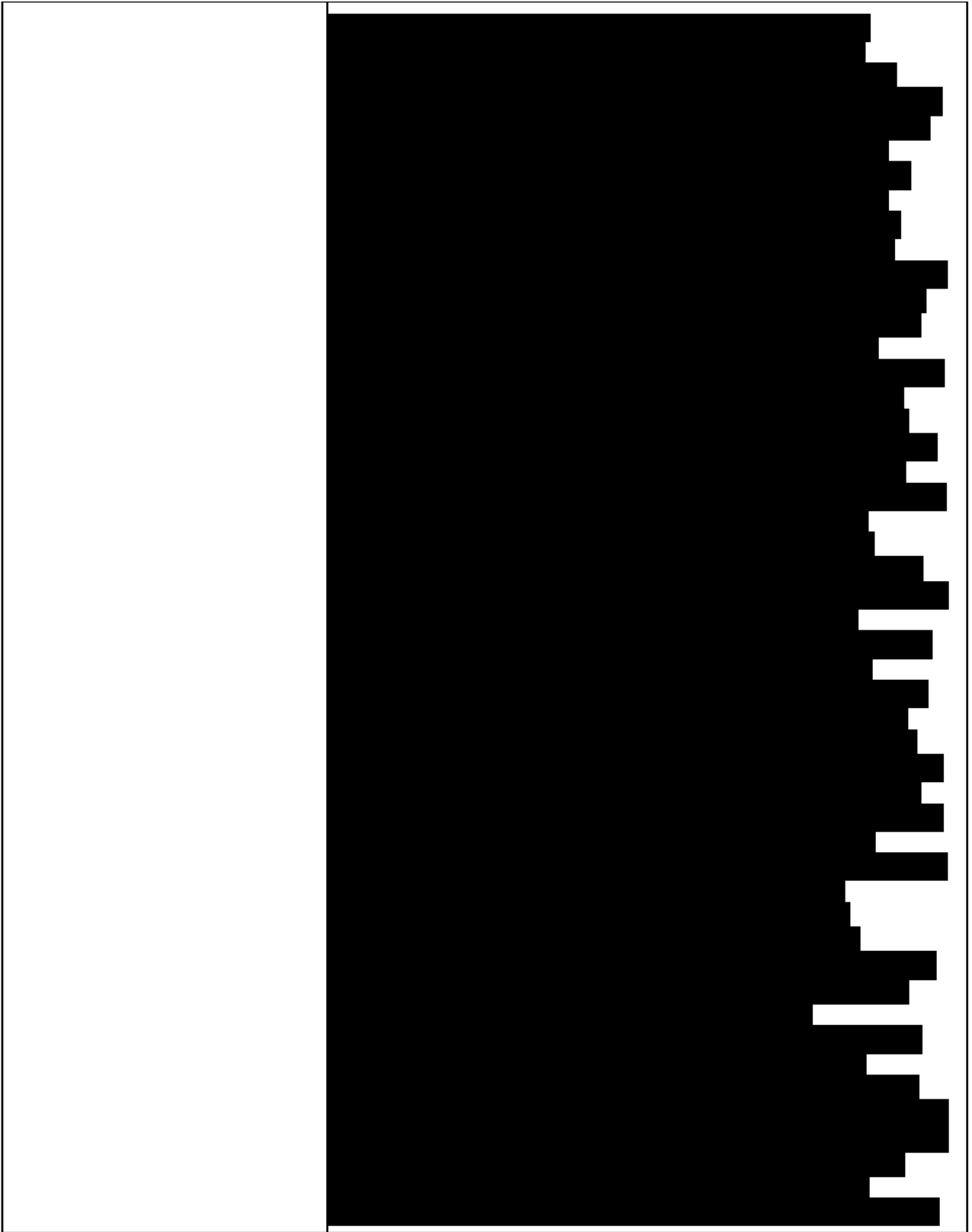
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 98	2025/04/17 22:33
Country	Spain
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1

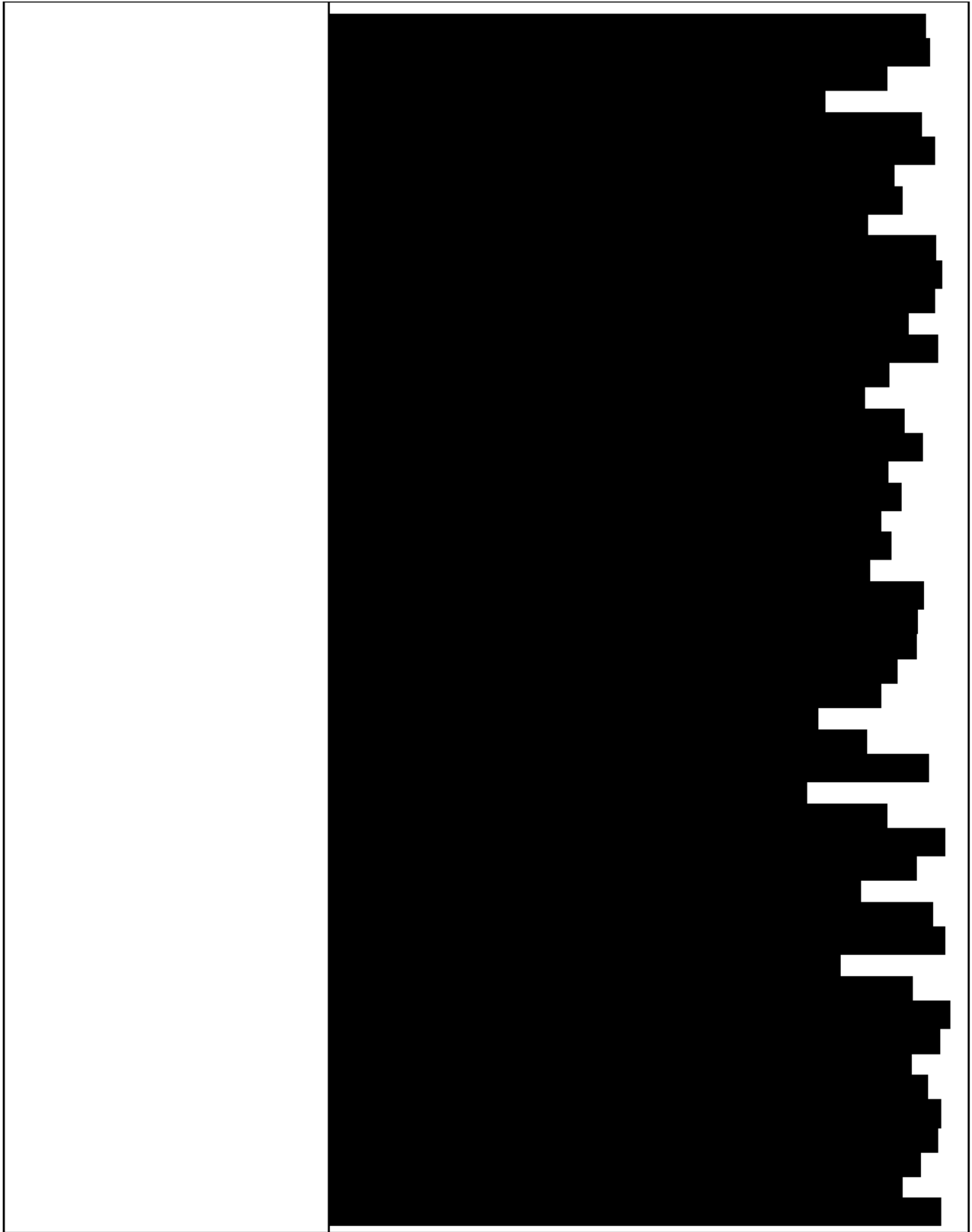
General information	Ethanol is widely utilized as a disinfectant in various applications due to its unique set of properties. In biocidal products, it serves multiple purposes including human hygiene, small surface disinfection, and disinfection in food and feed areas. For human hygiene (PT 01), ethanol-based disinfectants are employed for hand disinfection without rinsing and as skin antiseptics in medical and hygiene-sensitive environments. These include intensive care units, infection departments, and home care, among others. In private and public health areas (PT 02), ethanol is used for small surface disinfection through spraying, pouring, and wiping in healthcare institutions, laboratories, and veterinary practices. In the food and feed area (PT 04), it is used for small surface disinfection in the food processing industry. Despite several proposed alternatives such as isopropanol, n-propanol, quaternary ammonium compounds, chlorine-based oxidants, hydrogen peroxide, and physical methods, none can match ethanol's effectiveness, quick action, skin compatibility, and safety for food-contact surfaces. Ethanol's long history of safe use, broad-spectrum antimicrobial activity, and versatility make it an indispensable disinfectant in various critical applications. The comments made hereafter are made for PT1, PT2 and PT4.
Product Type	1,2,4
Alternative Identity and Properties	



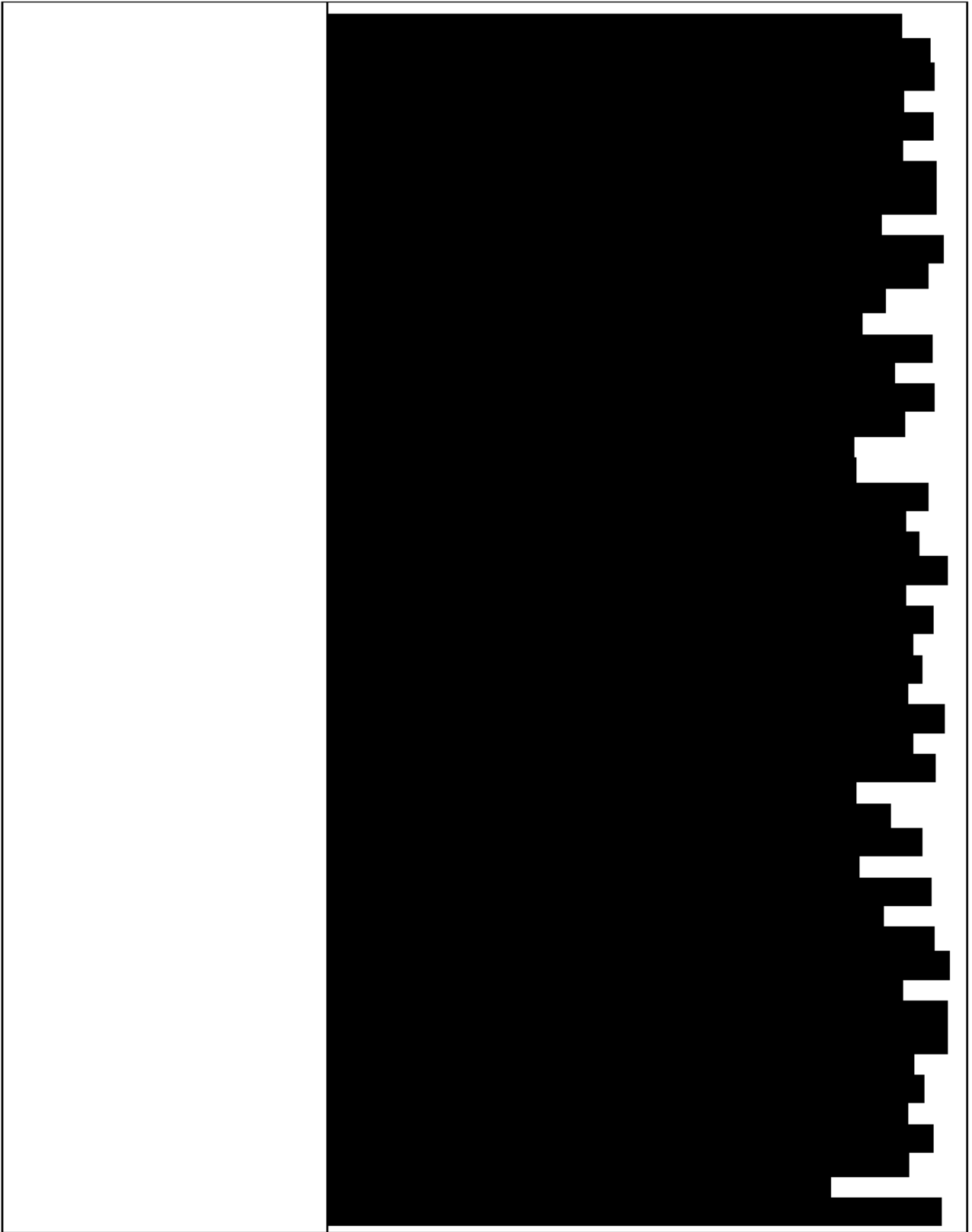
	[REDACTED]
Information above is confidential	[REDACTED]
Justification for confidentiality	[REDACTED]
Technical Feasibility	[REDACTED]

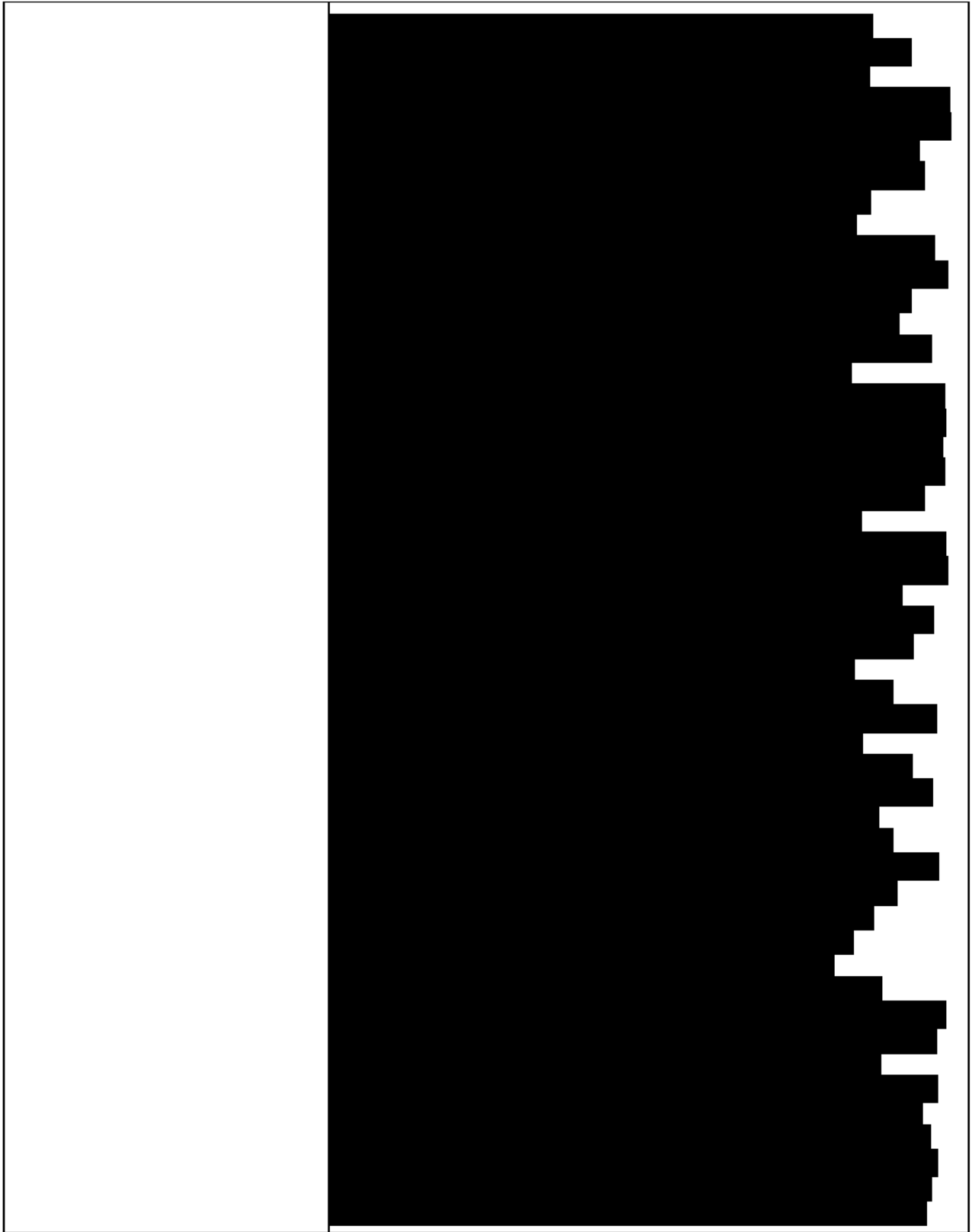


Information above is confidential	
Justification for confidentiality	
Economic Feasibility	

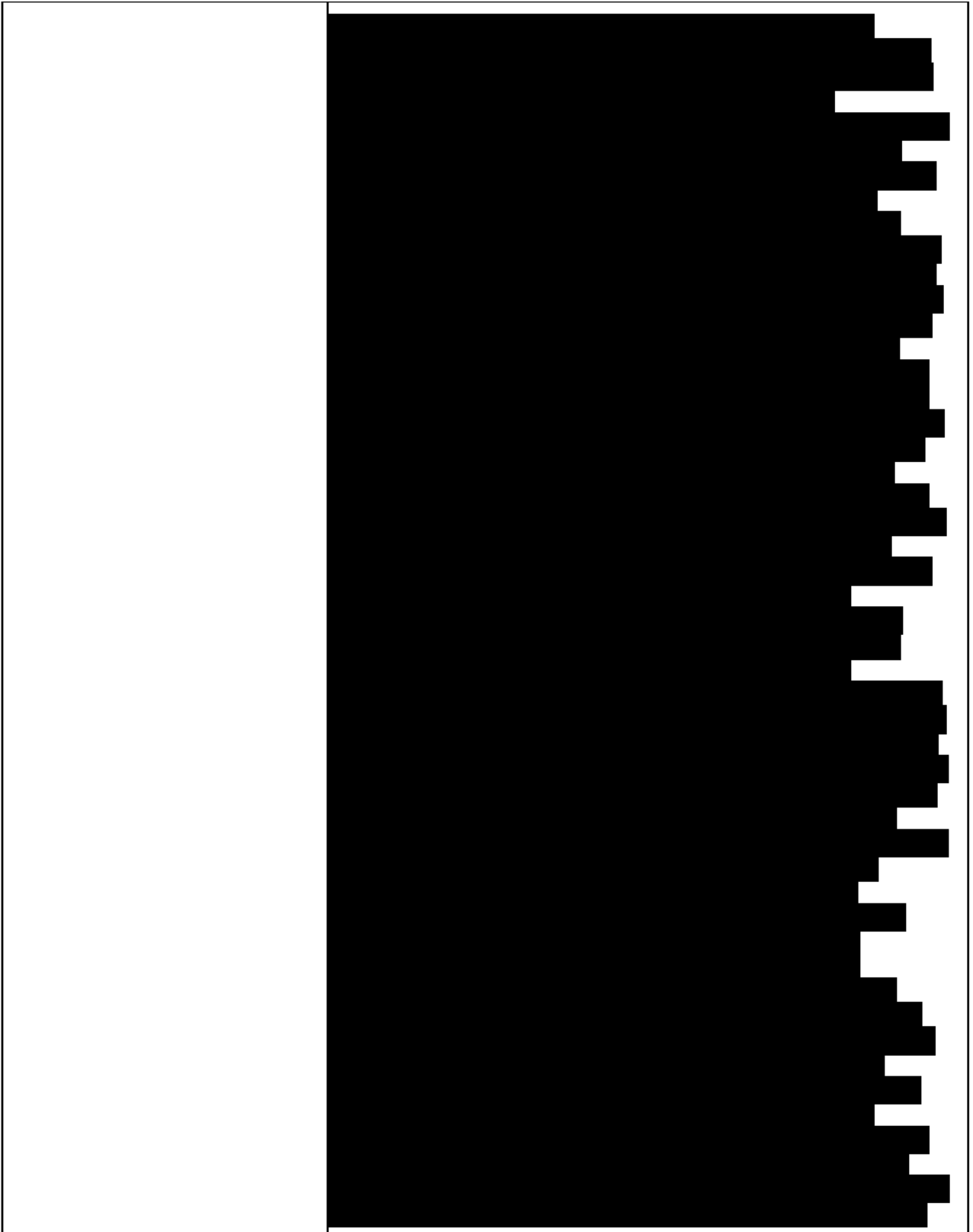


Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	



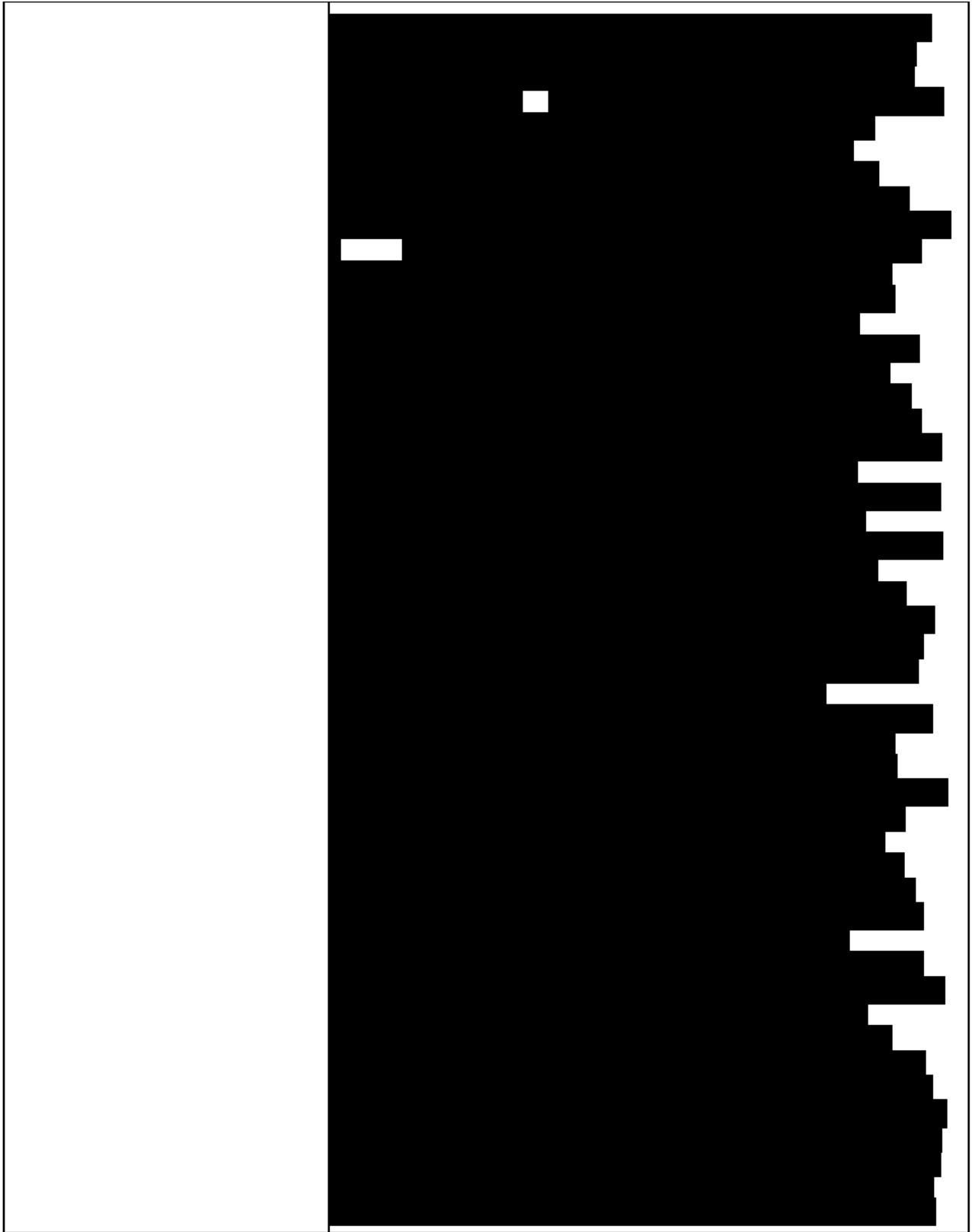


Information above is confidential	
Justification for confidentiality	
Availability	



Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	After extensive analysis, no alternative to ethanol has been found that is both technically and economically viable, available at scale, and equally safe. Ethanol is unique in delivering rapid, broad-spectrum disinfection (including against non-enveloped viruses) without residue or rinsing—essential for hand and food-contact hygiene. Technically, alternatives fall short in efficacy, compatibility, or practicality. Economically, ethanol is cost-effective, supported by existing infrastructure, and widely used by European industry. Replacing it would generate high

	reformulation costs, supply instability, and burden public health systems. Regarding safety, ethanol's risk in biocidal use is extremely low, with no evidence of harm from dermal or inhalation exposure in billions of uses. In contrast, proposed substitutes can be more hazardous (corrosive, toxic, environmentally harmful), offering no clear safety benefit. Critically, ethanol is abundantly available from renewable and petrochemical sources, with scalable production proven during the COVID-19 crisis. No other substance has this reliability or flexibility. Ethanol is therefore irreplaceable in PT1, PT2, and PT4 applications. Its continued use is not only justified but essential to protect public health and ensure effective hygiene across healthcare, household, and food sectors. The derogation conditions of BPR Article 5(2) are fully met: removing ethanol would cause a disproportionate negative impact on society and eliminate a vital health protection tool. For this reason, ethanol must remain approved as an active biocidal substance in the EU.
Information above is confidential	
Justification for confidentiality	
Other comments	



Information above is confidential	
Justification for confidentiality	
References	A.I.S.E. Webinar. Ethanol and the biocidal process. https://www.aise.eu. Kramer A, Benkhail H, Jäkel C, Zwicker P. Ethanol is indispensable for virucidal hand antisepsis and without toxic risks in daily use. GMS Hyg Infect Control. 2023 Jan 23;18:Doc02. doi: 10.3205/dgkh000428. PMID: 36875333; PMCID: PMC9978451. ECHA. Public Consultation on ethanol as a candidate for substitution (PT1, 2, 4). 2025 Feb 25. https://www.echa.europa.eu. WHO Guidelines on Hand Hygiene. Ethanol-based hand rubs classified as essential

	medicine (WHO List of Essential Medicines) and recommended as the gold standard for routine antisepsis. Retrieved from https://www.who.int .
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 99	2025/04/18 10:56
Country	Italy
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	

Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol has been used since ancient times for countless purposes and has properties that are impossible to replicate. To date, there is no product that can be used from the food to the industrial and healthcare sectors and that has a safety history comparable to ethanol. An alternative product would not be usable in all sectors where ethanol is present, causing very high economic damage and the loss of hundreds of thousands of jobs. Finally, just think of the very important role that ethanol had in the fight against the covid-19 pandemic.
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Justification for confidentiality	
Other comments	

	
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Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 100	2025/04/18 13:34
Country	Germany
Name of organization/institution	WHO task force alcohol based hand rubs
I do not wish the name of my organisation/institution to be	

published on the ECHA website.	
General information	I. Presentation of the WHO Task force "Alcohol based hand rubs" The International Conference on Prevention and Infection Control (ICPIC) hand hygiene alcohol-based hand rub (ABHR) Task Force represents a critical platform that builds upon the World Health Organization (WHO) Guidelines on Hand Hygiene in Healthcare [1]. Established in 2017, the ICPIC ABHR Task Force aims to review new knowledge and discuss gaps and future research priorities. [1] World Health Organization. WHO guidelines on hand hygiene in health care: first global patient safety challenge clean care is safer care. Geneva: WHO; 2009. Together with the WHO Collaborating Center on Patient Safety, and the Commission for Hospital Hygiene and Infection Prevention (KRINKO), Robert Koch Institute, Berlin, Germany 2022, the task force published the memorandum "Ethanol is indispensable for virucidal hand antisepsis" in the Journal Antimicrob Resist Infect Control. 2022 Jul;11(1):93. doi: 10.1186/s13756-022-01134-7 with the following message: Ethanol based hand rubs (EBHR) are essential for preventing infections caused by non-enveloped viruses, especially in healthcare, nursing homes, food industry and other areas. Propanols are effective against enveloped viruses as opposed to non-enveloped viruses but there are no other alternatives for virucidal hand antisepsis. Long-term ingestion of ethanol in the form of alcoholic beverages can cause tumours. However, lifetime exposure to ethanol from occupational exposure lower 500 ppm does not significantly contribute to the cancer risk. Mutagenic effects were observed only at doses within the toxic range in animal studies. While reprotoxicity is linked with abuse of alcoholic beverages, there is no epidemiological evidence for this from EBHR use in healthcare facilities or from products containing ethanol in non-healthcare settings. The body of evidence shows EBHRs have strong efficacy in killing non-enveloped viruses, whereas 1-propanol and 2-propanol do not kill non-enveloped viruses, that pose significant risk of infection. Ethanol absorbed through the skin during hand hygiene is similar to consumption of beverages with hidden ethanol content (lower 0.5% v/v), such as apple juice or kefir. There is no risk of carcinogenicity, mutagenicity or reprotoxicity from repeated use of EBHR. Hence, the WHO Task Force strongly recommend retaining ethanol as an essential constituent in hand rubs for healthcare. II. The following additional arguments underline the above mentioned conclusion. 1. EBHR are safe and easy to use for professional users as well as for the general public in the

	event of outbreaks, epidemics or bioterrorism situations 2. There is no epidemiological evidence of long term side effects for workers from handling ethanol-containing products in industry or from using ethanol-based hand rubs (EBHR) in healthcare facilities or in the community. 3. Ethanol is the onliest hand antiseptic, which is effective against non- enveloped viruses such as noro-, rota-, adeno-, entero-, polio- and coxsackieviruses. Additionally, vaccine-preventable non-enveloped viruses such as papillomavirus and wild poliovirus type 1 (WPV1) in regions like Afghanistan and Pakistan, are also transmitted via hands. The current detection of cVDPV2 in Europe reminds us of the fact that even regions which have previously been declared “polio-free” are at risk. Over the last decade, the emergence of several zoonotic viruses has demonstrated that previously unknown or neglected pathogens have the potential to cause epidemics or pandemics. Therefore, it is likely that future pandemics will result from a zoonotic event caused by a virus requiring immediate access to disinfectants with a proven efficacy against non-enveloped viruses for everyone, with hand antisepsis being as essential part of infection prevention and control measures. If EBHR not available in the future, no virucidal handrubs exist to interrupt outbreaks in hospitals, nursing homes, kindergartens, schools, cruise ships and other community settings and to protect food from contamination with non-enveloped viruses during the manufacturing process. Extrapolating published European data show, that the estimated burden of disease caused by non-enveloped viruses includes over 300 million cases for rhinoviruses, 73 million for rotaviruses, over 20 million for papillomavirus 6, over 2 million for coxsackieviruses, over 500,000 for enteroviruses, 232,000–452,000 for noroviruses, over 100,000 for echoviruses, 5,000 for adenovirus as the causative agent of keratoconjunctivitis epidemic. References: - Robert Koch Institute: https://www.rki.de/DE/Themen/Infektionskrankheiten/Infektionskrankheiten-A-Z/P/Polio/polio-node.html . - Neumann G, Kawaoka Y. Which Virus Will Cause the Next Pandemic? Viruses. 2023 Jan 10;15(1):199. doi: 10.3390/v15010199. - Bihl F, Negro F. Hepatitis E virus: a zoonosis adapting to humans. J Antimicrob Chemother. May 2010; 65(5): 817–21. doi:10.1093/jac/dkq085. -Lawrence P, Heung M, Nave J, Henkel C, Escudero-Pérez B. The natural virome and pandemic potential: Disease X. Curr Opinion Virol. Dec 2023: 101377. - doi: 10.1016/j.coviro.2023.101377. Buigues J, Viñals A, Martínez-Recio R, Monrós JS, Cuevas JM, Juan R. Phylogenetic evidence supporting the nonenveloped nature

of hepadnavirus ancestors. Proc Nat Acad Sci USA 2024; 121(45) (20: e2415631121. doi:10.1073/pnas.2415631121. - Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson MA, Roy SL, et al. Foodborne illness acquired in the United States – major pathogens. Emerg Infect Dis. 2011;17(1):7–15. doi: 10.3201/eid1701.p11101. -CDC. Norovirus Facts and Stats. May 2024, accessed 10 April 2025: <https://www.cdc.gov/norovirus/data-research/index.html> - Kirk MD, Pires SM, Black RE, Caipo M, Crump JA, Devleesschauwer B, et al. Correction: World Health organization estimates of the global and regional disease burden of 22 foodborne bacterial, protozoal, and viral diseases, 2010: A data synthesis. PLoS Med. 2015 Dec;12(12):e1001940. doi:10.1371/journal.pmed.1001940.

III. Facts on the false toxicological classification of ethanol as an oral stimulant instead of hand antiseptic Evaluation of a biocidal substance must be based on data relating to the intended route of exposure. Evidence for a reprotoxic effect of ethanol originates from data following the consumption of alcoholic beverages by pregnant women. There is no epidemiological evidence for toxicity for workers handling ethanol-containing chemical products in industrial workplaces or when using EBHR in healthcare facilities or ethanol-containing products in the non-healthcare setting. Neither is accidental oral ingestion of EBHR a hazard for healthcare workers. The dermal absorption of ethanol after rub-in of ethanol-based hand rubs (EBHR) are in the physiological range! The following results under use conditions confirm this: Fruit juices may contain up to 3 g ethanol per L, apple juice contains 1 g ethanol per 500 mL. Assuming an absorption rate of 90%, drinking 500 ml of apple juice will result in a blood alcohol concentration of about 85 mg/L ethanol in a 75-kg man or 125 mg/L ethanol in a 60-kg woman. Non-alcoholic beer, flavored water, and orange juice result in blood ethanol levels similar to those seen after hand antisepsis, or even higher. The concentration of ethanol naturally produced by intestinal bacteria is 1.1 mg/L, so internal amounts of ethanol resulting from topical application of EBHR are in the range of those associated with consumption of non-alcoholic beverages, which are considered safe for consumers. To clarify adverse effects on the pancreas after hand antisepsis by teaching nurses, the following scenario was considered: total rubbing of hands (3 mL of 70% EBHR) consisting of 30 persons 3 times/day in the same room (116 cm³) over a period of 48 h interrupted by one night (90 hand rubs/day in the room). Blood ethanol concentrations were predicted using a physiologically based pharmacokinetic model, which

allowed simulation of inhalation and dermal exposure. In the worst-case scenario, the simulation showed that the maximum blood ethanol concentration predicted -5.9 mg/- is of the same order of magnitude as endogenous ethanol concentration (mean = 1.1 mg/L; median = 0.4 mg/L; range = 0–35 mg/L) in humans without prior alcohol consumption. The harmlessness was confirmed in a double-blind, randomized phase I experimental study: 20 ml of hand rub (74.1% ethanol content) were applied on a 200-cm² gauze swab on skin areas; the gauze swab remained on the skin for 10 min (0.1 mL/cm² treated skin area). Comparing ethanol concentrations at baseline, and after 15 and 60 min, no significant differences could be detected. The detection limit was defined as the ethanol concentration producing an area 3 × larger than the blank area under the curve (0.5 mg/L). The harmlessness is also underlined by the fact that the use of EBHR induces concentrations of ethyl glucuronide, the marker of ethanol consumption, in urine, below any harmful or toxic levels. Thus, classification as carcinogenic, mutagenic, reprotoxic for use in hand antisepsis is not justified. This was as confirmed in scientific studies and agreed upon by the WHO ABHR Task Force and many international medical associations and expert committees. References: -

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	Kramer A, Arvand M, Christiansen B, Dancer S, Eggers M, Exner M, Müller D, Mutters NT, Schwebke I, Pittet D. Ethanol is indispensable for virucidal hand antisepsis: memorandum from the alcohol-based hand rub (ABHR) Task Force, WHO Collaborating Centre on Patient Safety, and the Commission for Hospital Hygiene and Infection Prevention (KRINKO), Robert Koch Institute, Berlin, Germany. Antimicrob Resist Infect Control. 2022 Jul;11(1):93. doi: 10.1186/s13756-022-01134-7. - Kramer A, Benkhail H, Jäkel C, Zwicker P. Ethanol is indispensable for virucidal hand antisepsis and without toxic risks in daily use. GMS Hyg Infect Control. 2023 Jan 23;18:Doc02. doi: 10.3205/dgkh000428. - Kramer A, Pittet D, Exner M, Wendt C. Medical associations and expert committees urge that ethanol be approved as a virucidal active substance for use in hand antiseptics under the European Biocidal Products Regulation, without a CMR classification. GMS Hyg Infect Control. 2024 Aug 21;19:Doc40. doi: 10.3205/dgkh000495.
Product Type	1,2,4
Alternative Identity and Properties	It exists no alternative for hand antiseptics with efficacy against non-enveloped hydrophilic viruses. Either ethanol as a single active ingredient in a concentration of 80% w/w is effective against non-enveloped viruses. In combination with PAA or phosphoric acid, lower concentrations of ethanol are also sufficient for virucidal efficacy. However, for toxicological reasons, both synergistic combination partners cannot be used as the sole active ingredient base without ethanol. Therefore Ethanol was chosen as reference alcohol for EN 17430, the test standard for virucidal disinfection activity (Phase 2/Step 2). References: - Kurtz JB, Lee TW, Parsons AJ. The action of alcohols on rotavirus, astrovirus, and enterovirus. JHI 1989;1:321-325. - Steinmann J, Becker B, Bischoff B, Magulski T, Steinmann J, Steinmann E. Virucidal activity of Formulation I of the World Health Organization's alcohol-based handrubs: impact of changes in key ingredient levels and test parameters. Antimicrob Resist Infect Control. 2013 Dec 12;2(1):34. doi: 10.1186/2047-2994-2-34. - Suchomel M, Steinmann J, Kampf G. Efficacies of the original and modified World Health Organization-recommended hand-rub formulations. J Hosp Infect. 2020 Oct;106(2):264-270. doi: 10.1016/j.jhin.2020.08.006. - Kramer A, Arvand M, Christiansen B, Dancer S, Eggers M, Exner M, Müller D, Mutters NT, Schwebke I, Pittet D. Ethanol is indispensable for virucidal hand antisepsis: memorandum from the alcohol-based hand rub (ABHR) Task Force, WHO

	Collaborating Centre on Patient Safety, and the Commission for Hospital Hygiene and Infection Prevention (KRINKO), Robert Koch Institute, Berlin, Germany. Antimicrob Resist Infect Control. 2022 Jul;11(1):93. doi: 10.1186/s13756-022-01134-7. - CEN. Chemical disinfectants and antiseptics – hygienic handrub virucidal – Test method and requirements (phase 2/step 2); German version EN 17430:2024 Use of other active substances with in vitro virucidal activity as a theoretical alternative to ethanol is out of the question Chlorine-based agents, oxidants and peracetic acid (PAA) have negative toxicological effects under in-use conditions which make them unsuitable for handrub formulations. One report described allergic contact dermatitis related to the use of high-concentrated chlorine solutions (CS) for hand antisepsis. PAA is corrosive/irritating to the eyes, mucous membranes of the respiratory tract, and skin. It causes lacrimation, extreme discomfort, and irritation to the upper respiratory tract in humans after exposure to concentrations as low as 15.6 mg peracetic acid/m³ (5 ppm) for only 3 min. The AEGL-1 value is 0.52 mg/m³ (0.17 ppm) for all exposure durations from 10 min to 8 h. During dermal application of 0.16 ml 0.12% PAA 2 times/d over 90 d in guinea pigs, the following side effects were observed: Decrease in body mass (bm), bm/spleen mass quotient and bm/kidney mass, increase in aspartate aminotransferase and alanine transaminase, decrease in lactate dehydrogenase IV and serum creatinine, severe to moderate pneumonia and liver granulomas. PAA induced chromosomal aberrations during epicutaneous application/mouse. References: - Kramer A, Weuffen W, Merka V Tichacek B. Toxizität von Peroxethansäure. In: Weuffen W, Kramer A, Bulka E, Schönenberger H (Hrsg) Handbuch der Antiseptik Bd. II/Teil 2, Fischer, Stuttgart New York, 1983; 177-187. - Paldy A, Berencsi G Kramer A, Weuffen W, Spiegelberger E. Mutagene Potenz von Wofasteril, Wofasept, Formaldehyd, Chlorhexidin und Bronopol im Knochenmarktest an der Maus. In: Kramer A, Wigert H, Kemter B (Hrsg) Aspekte der Prophylaxe und Bekämpfung des infektiösen Hospitalismus. Leipzig, Barth, 1984, 249-52. - Kramer A, Assadian O (Hrsg.). Wallhäußers Praxis der Sterilisation, Desinfektion, Antiseptik und Konservierung. Stuttgart Thieme-Verlag, 2008. - Kubilay Z, Hopman J, Allen T, Edrees H, Allegranzi B. Skin side effects of chlorine solutions used for hand hygiene: a systematic review. Antimicrob Resist Infect Control 4 (Suppl 1), P9 (2015). https://doi.org/10.1186/2047-2994-4-S1-P9 - National Research Council (US) Committee on Acute Exposure Guideline Levels. Peracetic Acid Acute Exposure Guideline

	Levels. In: Acute Exposure Guideline Levels for Selected Airborne Chemicals. Vol. 8. Washington (DC), National Academies Press (US); 2010. - Analysis of hazards https://echa.europa.eu/documents/10162/b3ce804b-1d11-f40c-931a-3d8f5605b74a
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	There are currently no biocidal products approved as PT1 which exhibit virucidal activity (ECHA database PT 1, accessed 7 April 2025). https://echa.europa.eu/documents/10162/eff25082-96b4-4193-8f47-ef183cf1df4c Ethanol can be produced anywhere in the world without highly specialized technical requirements. Even if other virucidal active ingredients could be used for hand antisepsis, their technical production is incomparably more complex than the production of ethanol.
Information above is confidential	
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Economic Feasibility	The only theoretical possible substitution of ethanol with other virucidal active substances for routine hand antisepsis, which are at present unknown, is likely to make handrub production more expensive for manufacturers and consumers and governments in Europe and worldwide.
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Justification for confidentiality	
Hazards and Risks of the Alternative	Risk of resistance development and hazards risk: Alternative PT1 substances such as quarternary compounds (QAV) – which are, however, not virucidal effective- bear a risk of developing clinically relevant resistance or tolerance towards certain target organisms. No resistance development has been described for ethanol. Added to this is the dermal irritation potency and the absorption toxicity of QAV. References: - Boyce JM. Quarternary ammonium disinfectants and antiseptics: tolerance, resistance and potential impact on antibiotic resistance. Antimicrob Resist Infect Control 2023;12(1):32. doi: 10.1186/s13756-023-01241-z. - Kampf G. Adaptive

	microbial response to low level benzalkonium chloride exposure. J Hosp Infect 2018;100: e1–e22. doi:10.1016/j.jhin.2018.05.019 - Osimitz TG, Droege W. Quaternary ammonium compounds: perspectives on benefits, hazards, and risk. Toxicology Research and Application. 2021;5. doi:10.1177/23978473211049085 - Arnold WA, Blum A, Branyan J, et al. Quaternary Ammonium Compounds: A Chemical Class of Emerging Concern. Environ Sci Technol. 2023 May 23;57(20):7645-7665. doi: 10.1021/acs.est.2c08244 Skin irritation risks: The theoretical eligible virucidal agents PAA or chlorine are not suitable for hand antisepsis due to their toxicity profile. The frequency of use in everyday clinical practice (greater 100x/day) must be taken into account. References: - Acute Exposure Guideline Levels for Selected Airborne Chemicals. Vol. 8. National Research Council (US) Committee on Acute Exposure Guideline Levels. Washington (DC): National Academies Press (US); 2010. - Goh CF, Ming LC, Wong LC. Dermatologic reactions to disinfectant use during the COVID-19 pandemic. Clin Dermatol. 2021 Mar-Apr;39(2):314-322. doi: 10.1016/j.clindermatol.2020.09.005. Risk of impairment of the skin microbiome: Washing with antiseptic soaps with added benzalkonium chloride or triclocarban disrupts the skin's microbiome. The same applies, for example, to skin antiseptics with PVP iodine and chlorhexidine. In contrast, the microbiome of the skin is not impaired by EBHR, but the resident flora tends to be promoted. References: - Two AM, Nakatsuji T, Kotol PF, et al. The Cutaneous Microbiome and Aspects of Skin Antimicrobial Defense System Resist Acute Treatment with Topical Skin Cleansers. J Invest Dermatol 2016; 136 (10): 1950-4. doi:10.1016/j.jid.2016.06.612 - Prat M, Guenezan J, Drugeon B, et al. Impact of Skin Disinfection on Cutaneous Microbiota, before and after Peripheral Venous Catheter Insertion. Antibiotics (Basel). 2022 Sep 7;11(9):1209. doi: 10.3390/antibiotics11091209. - Townsend EC, Xu K, De La Cruz K, Huang L, Sandstrom S, et al. Still not sterile: viability-based assessment of the skin microbiome following pre-surgical application of a broad-spectrum antiseptic reveals transient pathogen enrichment and long-term recovery. Microbiol Spectr 0:e02873-24. doi:/10.1128/spectrum.02873-24 - Kramer A, Borg Dahl M, Bengtsson MM, Boyce JM, Heckmann M, Meister M, Papke R, Pittet D, Reinhard A, Slevogt H, Wang H, Zwicker P, Ulrich T, Seifert U. No detrimental effect on the hand microbiome of health care staff by frequent alcohol-based antisepsis. Am J Infect Control. 2024 Nov 15:S0196-6553(24)00846-0. doi: 10.1016/j.ajic.2024.11.006. Epub ahead of print. -

	Lademann O, Kramer A, Richter H, Patzelt A, Meinke MC, Czaika V, Weltmann KD, Hartmann B, Koch S. Skin disinfection by plasma-tissue interaction: comparison of the effectivity of tissue-tolerable plasma and a standard antiseptic. <i>Skin Pharmacol Physiol.</i> 2011;24(5):284-8. doi: 10.1159/000329913. Epub 2011 Jun 25. Stability hazards: Chlorine-based disinfectants are unstable and very sensitive to temperature changes. User information on the stability after opening is not mandatory for manufacturers of biocides according to the BPR. Users might not know the exact date when to discard the residual amount from opened dispensers as a consequence of insufficient active substance content. On the other hand, product-specific information on EBHR stability which is available from some manufacturers, indicates that ethanol has favorable stability properties if stored and maintained correctly (with the lid tightly closed). References: - Jurado J. The Stability of Disinfectants Used in Brewery CIP. <i>MBAA TechnQuart.</i> 1993; 30: 58-63 - Zazouli MA, Hashempour Y, Dashtban N. Evaluating the influence of environmental factors on the stability of commercial chlorine-based sanitizers using response surface modeling. <i>Avicenna J Environ Health Eng.</i> 2024; 11(1):39-46. doi:10.34172/ajehe.5404 Infection hazards: Due to the lack of virucidal efficacy of other active agents usable for hand antisepsis, the interruption of transmission of non-enveloped viruses, thereby protecting staff and patients and the general public is not possible without EBHR. As a result, the very objective of using a biocide, which is to protect human health, cannot be achieved. Compliance hazards: Some alternatively used substances such as peracetic acid or sodium hypochlorite have a pungent odor and a higher skin irritation potential. Compliance with the indications for hygienic hand antisepsis by the user is likely to decrease with less accepted substances which in turn will result in a health hazard for both, personnel and patients. Sustainability: Comparative life cycle assessment data for bioethanol and other active substances should be taken into consideration. The carbon footprint (CF) is for chlorine liquid 1.08 kg CO₂e/kg, for bioethanol lowest 0.04 kg CO₂-eq ethanol acetic acid 1.7 kg CO₂e/kg References: - https://apps.carboncloud.com/climatehub/product-reports/id/67148333700 - https://apps.carboncloud.com/climatehub/product-reports/id/2249149424980#:~:text=%E2%80%9DChlorine%2C%20liquid%E2%80%9D%20currently%20has,of%201.08%20kg%20CO%E2%82%82e%2Fkg. - Muñoz I., Flury K., Jungbluth N., Rigarlsford R., Milà i Canals L. and King H. (2013) Life Cycle Assessment of bio-based ethanol produced

	from different agricultural feedstocks. In: Int J LCA, Online First, pp., DOI 10.1007/s11367-013-0613-1.
Information above is confidential	
Justification for confidentiality	
Availability	Ethanol is produced at a much larger scale in Europe than propanols or other alternative substances. Ethanol is used in a much larger variety of industrial applications than other biocidal substances for handrubs and widely available. An analysis on active agents used in hand antiseptics (HA) in Germany shows a clear shift to use ethanol based hand rubs (EBHR). While 20 different active agents were used in the HAs in 2004, only 14 were used in 2012 and 15 in 2024. Benzoic acid, chlorocresol, chlorophene, octenidine dihydrochloride, peracetic acid, polyhexanide and triclosan are no longer used as additives to alcohol based hand rubs (ABHR). At the same time, the number of active ingredients per product fell. In the period from 2002 to 2022, there was an increase in ABHR, so that in 2022, only four HAs did not contain alcohol: three were based on PVP iodine and one was based on quaternary ammonium compounds. While 2-propanol still dominated as the first-named active ingredient in 2004 and 2022, in 2022 mainly ABHR with ethanol as the first-named active ingredient were certified. The percentage share of ethanol in ABHR, measured against all VAH-listed HA and as the main active ingredient, increased by 43.4% between 2004 and 2022. At the same time, there has been a 33.2% decrease in ABHR of 2-propanol as active ingredient. There are probably two reasons for the decrease in the total number of active ingredients used. The addition of antiseptic agents to ABHR does not increase their residual effectiveness. At the same time, the antimicrobials added to ABHR are less well tolerated than alcohols, so that ethics requires they not be used. The increase of EBHR suggests that these are preferred by users. One explanation may be that, unlike ethanol, 1-propanol can have an irritating effect on both healthy and atopic skin. The conclusion is, that ethanol must be retained as an active ingredient for ABHR for the following reasons: ethanol is the only active ingredient that can be used for HA with comprehensive efficacy against non-enveloped viruses; both propanols are less physiological for the human organism than ethanol; ethanol is better tolerated by the skin than 1-propanol; and an adverse effect on the skin microbiome has been ruled out for ethanol. This must be considered when discussing the possible biocide classification of ethanol as CMR,

	especially because such a classification has absolutely no scientific basis. Ethanol is on the list of essential medicines of the WHO and ingredient of the WHO standard formulation (with efficacy against non-enveloped viruses). It is presently available worldwide and also in Europe in sufficient quantities. EBHR production costs are low. In the event of a shortage of commercially available EBHR, they can be produced locally. The above mentioned in-vitro alternatives are not as readily available at low cost as ethanol (apart from, perhaps, chlorine-based products, which have major disadvantages due to instability and skin irritation potential as discussed above). References - https://echa.europa.eu/documents/10162/b3ce804b-1d11-f40c-931a-3d8f5605b74 - https://www.epure.org/wp-content/uploads/2024/09/240904-DEF-PR-European-renewable-ethanol-Key-figures-2023-WEB.pdf ePURE, https://echa.europa.eu/documents/10162/0/art_95_list_en+%282%29.pdf/fabafba4-c021-9424-1ddd-8cf89faba774?t=1729688502218 - Grashoff P, Mutters NT, Kramer A, Ilschner C, Rausch M, Gebel J. Development of the active ingredient composition of hand antiseptics in Germany from 2004 to 2022 with special consideration of ethanol as active agent. GMS Hyg Infect Control. 2025;20:Doc. DOI: 10.3205/dgkh000, URN: urn:nbn:de:0183-dgkh0001
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Hand antisepsis is the most effective measure to prevent infections. Alcohol-based handrubs are the gold standard and only ethanol-based handrubs exhibit a virucidal effect.
Information above is confidential	
Justification for confidentiality	
Other comments	Instead of advantage for the protection of human and animal health and environment if ethanol is banned from routine use in hand antiseptics, the only disadvantage is that a virucidal hand antiseptic is no longer available, with has catastrophic consequences not only during epidemic outbreaks and pandemics caused by non-enveloped viruses, but there is then a lack of a virucidal hand antiseptics for infection control in all areas of life, e.g. hospitals, kinder gardens, nursing homes, food production, on cruise ships.

	Hazard analysis of a biocide must be based on the intended use and route of exposure. The only hazard for ABHR identified by WHO - which is applicable to all ABHR (incl. propanols which are already approved as biocidal substance) - is a fire hazard. Precautions must be and can be taken. Also, if misuse as oral consumption of alcohol-based handrubs is indeed considered a real risk for some individuals or institutions, this misuse can be avoided, e.g. by locking formulations in wall dispensers. Cf: https://www.who.int/news-room/questions-and-answers/item/alcohol-based-handrub-risks-hazards Hand antisepsis is the most effective measure to prevent infections. Alcohol-based handrubs are the gold standard and only ethanol-based handrubs exhibit a virucidal effect. 42 experts in infection prevention and control (IPC) convened at the 3rd International Conference on Prevention and Infection Control (ICPIC) ABHR Taskforce in Geneva, Switzerland, 2023 to provide a synthesis of recent evidence and formulate a research agenda on four critical areas for the implementation of effective hand hygiene practices. There was a consensus among these experts that "There is no risk of carcinogenicity, mutagenicity, or reproductive toxicity due to the repeated use of EBHR." The following medical associations and expert committees with specialized knowledge in infection prevention and clinical virology from Europe, the USA, Canada, the Asia-Pacific region, and globally active societies unequivocally recommend that ethanol-based hand rubs be approved as an active substance for PT1-biocides and not be classified as a reproductive toxicant category 2: Asia-Pacific Society for Infection Control - Australasian College for Infection Prevention and Control - Austrian Society for Hospital Hygiene - Austrian Society for Hygiene, Microbiology and Preventive Medicine - Bulgarian Association for Prevention and Infection Control - Dutch Society for Infection Control - European Society for Clinical Virology - European Society of Clinical Microbiology and Infectious Diseases - European Committee on Infection Control - Infectious Disease Society of Finland - Finnish Society for the Study of Infectious Diseases - French Society of Hospital Hygiene - Société de Pathologie Infectieuse de Langue Française - German Association for the Control of Virus Diseases - German Society for Hygiene and Microbiology - German Society for Infectiology - German Society of General and Hospital Hygiene - Paul-Ehrlich-Society for Infection Therapy - German Society of Virology e.V. - Central Committee on Biological Safety, Germany - Healthcare Infection Society - Hellenic Society for Infection Control - Norwegian Society of Infectious Diseases - Society for Healthcare Epidemiology

	America - Sociedad Española de Enfermedades Infecciosas y Microbiología Clínica - Spanish Society for Prevention Medicine - Swiss Society for Microbiology - Turkish Disinfection, Antisepsis and Sterilization Association - World Society for Virology. They give the following vote: "There is no reason not to use ethanol as a biocidal active ingredient in ethanol-based hand rubs (EBHR) for healthcare settings, the food industry, and public areas to prevent infections caused by non-enveloped viruses. The classification of EBHR as a reprotoxin category 2 is not supported by current scientific research, and no alternative biocidal substance with proven efficacy against non-enveloped viruses exists. Therefore, key organizations such as the WHO Task Force on Alcohol-Based Hand Rubs, the WHO Collaborating Centre on Patient Safety, Infection Prevention & Control, and Antimicrobial Resistance, the Commission for Hospital Hygiene and Infection Prevention, Robert Koch Institute in Berlin, Germany, and the Association for Applied Hygiene in Germany strongly recommend retaining ethanol as a crucial component in hand rubs for healthcare, safe food production, and community use, particularly during outbreak situations. The absence of effective hand rubs against non-enveloped viruses such as norovirus, adenoviruses, and enteroviruses D68 and 71 (which are not vaccine-preventable) poses significant public health risks. Additionally, economic losses will arise not only from increased morbidity but also from the potential need to relocate ethanol production outside Europe for domestic use. Moreover, it is currently unknown whether controlling outbreaks and pandemics caused by new and emerging viruses might depend on ethanol as the only effective virucidal agent available for hand antisepsis. References: - Kramer A, Benkhail H, Jäkel C, Zwicker P. Ethanol is indispensable for virucidal hand antisepsis and without toxic risks in daily use. <i>GMS Hyg Infect Control.</i> 2023;18:Doc02. DOI: 10.3205/dgkh000428 -WHO guidelines on hand hygiene in health care. 2009https://www.who.int/publications/i/item/97892415
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	

Attachments (confidential information)	
Justification for confidential attachment	

Comment 101	2025/04/18 13:58
Country	Italy
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	“Il mercato dell'etanolo dell'UE può essere suddiviso in tre segmenti: uso carburazione, alimentare e industriale. i) Uso Carburazione: l'etanolo viene utilizzato in miscela con la benzina o come carburante alternativo. L'E10, ad esempio, è un tipo di benzina che contiene fino al 10% di etanolo e può essere utilizzato nella maggior parte dei motori a combustione interna e dei veicoli ibridi di oggi, riducendo significativamente le emissioni di gas serra dei trasporti. ii) Alimentare: l'etanolo può essere utilizzato per produrre bevande spiritose, come additivo alimentare, per l'estrazione di aromi, per la conservazione degli alimenti e la produzione di aceto bianco. iii) Industriale: l'etanolo è un componente chimico rinnovabile essenziale in vari prodotti (ad es. prodotti igienizzanti, cosmetici, prodotti farmaceutici, solventi, vernici e fluidi antigelo) per garantire l'igiene e la sicurezza, nonché una materia prima rinnovabile per la produzione di sostanze chimiche rinnovabili (ad es. bioetilene). Il bioetanolo viene prodotto nelle bioraffinerie europee fermentando gli zuccheri in alcol. Nell'UE, questi zuccheri provengono tipicamente da una varietà di fonti agricole come grano, mais, orzo, segale, triticale e barbabietola da zucchero. In Italia il bioetanolo è ottenuto principalmente da residui della produzione del vino (e.g. vinacce e fecce di vino) ottenendo quindi un biocarburante avanzato che contribuisce significativamente alla riduzione delle emissioni di gas effetto-serra e quindi al raggiungimento degli obiettivi UE di decarbonizzazione dei trasporti. Nel 2023, i produttori europei di etanolo rinnovabile hanno prodotto 6,44 miliardi di litri di etanolo, operando all'80% dei loro 8,05 miliardi di litri di capacità

	installata. L' Industria Meridionale Alcolici srl desidera fornire le sue osservazioni all'ECHA sottolineando l'uso insostituibile dell'etanolo e sottolineando che una classificazione dell'etanolo agricolo come cancerogeno o tossico per la riproduzione sarebbe dannosa per molti biocidi, creerebbe una mancanza di alternative e avrebbe conseguenze critiche per la salute pubblica.”
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Non riteniamo ci possano essere delle alternative valide e sicure come l' etanolo agricolo utilizzato con un azione disinfettante e biocida. L' etanolo uso industriale ha delle caratteristiche ben precise di elevata qualità.

Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 102	2025/04/18 18:40
Country	Italy
Name of organization/institution	Confindustria Dispositivi Medici
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Confindustria Dispositivi Medici, the trade association in Italy, which units, represents and enhances companies in the medical device sector, welcomes the opportunity to contribute to the ECHA Consultation regarding the availability of alternatives for ethanol in product types 1, 2, and 4. Medical device and in vitro diagnostic sectors are now subject to a strict sectorial legislation governed by Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/746 (IVDR). Confindustria Dispositivi Medici members are committed in supporting the use of the safest chemicals, supporting the European chemical strategy. The possibility to replace ethanol in the medical technology industry largely depends on how it is used within individual companies and applications. In healthcare, especially in the medical device

	technology field, ethanol plays a vital role in sterilization and disinfection, commonly found in surface disinfectants, hand sanitizers, and products for instruments and device reprocessing. It also functions as a solvent in various substance-based medical device formulations, and it is used by medical device manufacturers for applying coatings and as a cleaning agent. Furthermore, ethanol is present in products like inks, lubricants, dyes, and degreasers that are essential in the manufacturing process of a wide range of medical devices, including implantable and life-saving devices. Its disinfectant effectiveness stems from its ability to kill bacteria and viruses, while being both safe and biodegradable. The World Health Organization (WHO) has deemed ethanol-based hand sanitizers essential, particularly for their proven effectiveness against tough non-enveloped viruses like poliovirus. Additionally, ethanol's high purity and quick evaporation rate make it crucial for maintaining sterile conditions in the manufacturing environment of medical devices. Considering the variety of applications that ethanol has in the medical device field, it is not possible to identify alternative substances on a general level, since the evaluation for a valued alternative shall be made case-by-case, considering the specific application. In those cases when Ethanol is used with a disinfectant function, it results very difficult to identify equally effective alternatives for infection control. In the same way, given the versatility of ethanol as a solvent, it is very difficult to find an alternative with the same potential of compatibility in a wide spectrum of formulations. In the above-mentioned applications in the medical device field, ethanol is primarily used in situations which may lead to an indirect contact of ethanol with the patient or users through parenteral, dermal and inhalation routes, rather than the ingestion one. As a result, toxicity evaluations that rely mainly on data from chronic oral exposure (ingestion) may not accurately reflect the real risk associated with its use in this field. A potential classification of ethanol as a CMR 1A/1B substance under the Biocidal Products Regulation (EU) No 528/2012 would have far-reaching effects on its use in healthcare and medical device manufacturing. In healthcare, such a designation could greatly limit access to ethanol-based disinfectants, significantly raise production costs, and potentially drive manufacturers to shift operations outside the EU. In manufacturing, it would restrict access to essential components like inks, lubricants, dyes, degreasers and coatings that depend on ethanol as a solvent, leading to increased reliance on alternative agents with less-favourable safety profiles. Confindustria Dispositivi Medici emphasizes the need for thoughtful evaluation of these key

	considerations when reviewing ethanol's future use in the medical technology field, underscoring the need for risk assessments that consider specific exposure routes. An important aspect that must be taken into account is the regulatory complexity associated with a restriction of ethanol under the Biocidal Products Regulation (BPR) and/or its classification as a CMR 1A/1B substance under the Classification, Labelling and Packaging (CLP) Regulation. Should ethanol be classified as CMR 1A/1B under CLP, it would automatically trigger specific obligations under the Medical Device Regulation (Regulation (EU) 2017/745 - MDR), specifically Section 10.4.1, and the In-Vitro Diagnostic Regulation (Regulation (EU) 2017/746 – IVDR). Should ethanol become unavailable for medical device manufacturing, alternatives would need to be identified and go through rigorous qualification, verification, and validation processes. For medical devices, particularly for the highest risk class devices as the class III implantable, this would involve extensive testing and regulatory re-approvals, which could take over a decade. Indeed, MDR and IVDR impose stringent requirements for material selection, biocompatibility, design validation, safety, quality, and design change upon necessity. However, this is not the end of process because the change shall be register and approved by the Notified Body, the third-party entity responsible for the issue and maintenance of the CE certificate. Obviously, the final goal is to ensure that only effective and safe devices are placed in the European market. If restrictions under the BPR were implemented before alternative solutions are ready, access to essential medical technologies could be severely compromised, with potential impacts on patient health and safety. We therefore strongly recommend that the potential consequences—especially those affecting the uninterrupted supply of ethanol for essential non-biocidal uses—be thoroughly evaluated and carefully considered in the regulatory decision-making process. Replacing ethanol would not only reduce efficacy in healthcare applications but also raise operational costs, potentially encouraging companies to shift production outside the EU. Moreover, it could lead to inadequate disinfection and sterilization, posing serious risks to patient safety. A restriction or ban under the BPR would introduce significant uncertainty regarding the continued availability of ethanol for essential non-biocidal functions, which could disrupt access to critical medical technologies and negatively affect patient care. Given ethanol well-established safety when used under controlled conditions, any regulatory actions must be proportionate. It is crucial that decision-making strikes a careful balance between risk

	management and real-world impact, ensuring the continued effectiveness and economic viability of essential healthcare and industrial operations. About Confindustria Dispositivi Medici Confindustria Dispositivi Medici is the trade association in Italy, which units, represents and enhances companies in the medical device sector, including diagnostics, digital health, medical imaging, radiotherapy, electromedical industries, borderlines, and complex and hearing aids. It represents over 500 companies, from start-up and small-medium enterprises up to multinationals and plays a vital role in advancing innovation in the health technology space.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	

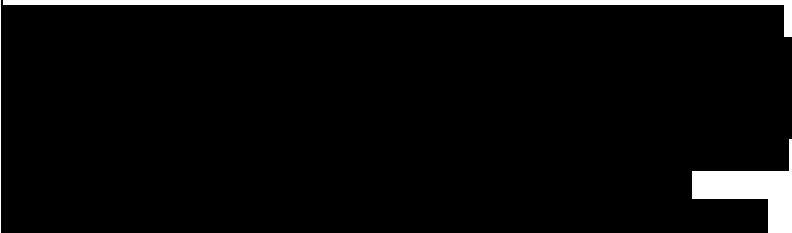
Conclusion on suitability and availability of the alternative	As reported in the general information section, Confindustria Dispositivi Medici emphasizes the need for thoughtful risk evaluation of ethanol, underscoring the need for risk assessments that consider specific exposure routes and specific applications.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 103	2025/04/19 13:23
Country	Germany
Name of organization/institution	Podo deutschland Landesverband Bayern
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Hand and skin disinfection of Patients with Ethanol is necessary at podiatric ambulances.
Product Type	1,2,4
Alternative Identity and Properties	

Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Alcoholic wipes are for years substitute for spraying, therefore better for users, and Patients.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Alcoholic wipes and Hand and skin disinfection is cheap, effective and was especially at Covid available for affordable prices.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Biguanid for example is more expensive and less effective.
Information above is confidential	
Justification for confidentiality	
Availability	Alcoholic disinfection is very good available.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	The Alternative to alcoholic disinfection is not effective, available nor lower in risks.
Information above is confidential	
Justification for confidentiality	
Other comments	The User is known with alcoholic disinfection, the Patient also, the Alternatives are not so known, and both expensive and of unknown risks.

Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 104	2025/04/21 15:20
Country	Switzerland
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	

Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Based on our own experience and the experience and knowledge of our customers, ethanol is of paramount importance compared to all potential substitute products: • Better risk profile (toxicity) despite best efficacy against target organisms • Better, ecological profile (based on renewable raw materials, is easily recyclable, good degradability, etc.) • Easy storage and high stability with appropriate storage • Has the potential to replace other, problematic solvents and components in formulations. • Etc. Based on the current state of knowledge, we do not see an alternative to ethanol, both from a technical, ecological and economic point of view, not to mention the advantages in terms of effectiveness and the advantages in terms of risks and dangers for people and the environment. Ultimately, ethanol is based almost exclusively on renewable raw materials and is characterized by a high availability practically almost worldwide.
Information above is confidential	
Justification for confidentiality	
Other comments	

Justification for confidential attachment	

Comment 105	2025/04/22 10:33
Country	Germany
Name of organization/institution	Bundeswehr
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	

Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol ist für die meisten Luftfahrzeuge der Bundeswehr zugelassen.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 106	2025/04/22 11:01
Country	Finland
Name of organization/institution	Nordic Society of Clinical Microbiology and Infectious Diseases
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Ethanol-based handrubs in health care cannot be safely changed by alternative products which all leave some potential pathogens outside their effect or which are not suitable for hand disinfection due to need of long acting contact time. Ethanol is effective against almost all resistant

	bacteria as well as viruses and fungi. Resistant microbes and institutional outbreaks of viral infections are one the most evident threats for modern health care and the life of the patients.
Product Type	1,2,4
Alternative Identity and Properties	No alternatives with similar microbiological efficacy or suitability for rapid use in frequent hand disinfection in health care facilities exist
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Alcohol based hand rubs are easy to produce and cheap and their production can be easily scaled up in critical situations like in during the recent COVID-19 pandemic.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Quaternary compounds are not as effective against bacteria and they lack virucidal activity. Chlorhexine alone has been linked to outbreaks of resistant organism within institutions/wards. Resistance to quaternary compounds can develop easily. Chlorine based disinfectants are harmful for the user and the environment. Propanol may be toxic when ingested which happens because the hand rubs need to be openly and widely available in health care institutions.
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	

Justification for confidentiality	
Conclusion on suitability and availability of the alternative	We see no possibilities to substitute the use of alcohol based hand rubs in health care without risking the possibilities to prevent the spread of resistant microorganisms and risk of institutional outbreaks. The costs in human lives lost and increase of health care costs would be tremendous. OECD has pointed out that hand hygiene is one of the most cost effective way to reduce the spread of resistant organisms in health care and in reducing the increase of costs of health care due to them.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	- Kramer A, Borg Dahl M, Bengtsson MM, Boyce JM, Heckmann M, Meister M, Papke R, Pittet D, Reinhard A, Slevogt H, Wang H, Zwicker P, Urich T, Seifert U. No detrimental effect on the hand microbiome of health care staff by frequent alcohol-based antisepsis. Am J Infect Control. 2024 Nov 15:S0196-6553(24)00846-0. doi: 10.1016/j.ajic.2024.11.006. Epub ahead of print. - Lademann O, Kramer A, Richter H, Patzelt A, Meinke MC, Czaika V, Weltmann KD, Hartmann B, Koch S. Skin disinfection by plasma-tissue interaction: comparison of the effectivity of tissue-tolerable plasma and a standard antiseptic. Skin Pharmacol Physiol. 2011;24(5):284-8. doi: 10.1159/000329913. Epub 2011 Jun 25. - Boyce JM. Quaternary ammonium disinfectants and antiseptics: tolerance, resistance and potential impact on antibiotic resistance. Antimicrob Resist Infect Control 2023;12(1):32. doi: 10.1186/s13756-023-01241-z. - Kampf G. Adaptive microbial response to low level benzalkonium chloride exposure. J Hosp Infect 2018;100: e1–e22. doi:10.1016/j.jhin.2018.05.019 - Kurtz JB, Lee TW, Parsons AJ. The action of alcohols on rotavirus, astrovirus, and enterovirus. JHI 1989;1:321-325. - Steinmann J, Becker B, Bischoff B, Magulski T, Steinmann J, Steinmann E. Virucidal activity of Formulation I of the World Health Organization's alcohol-based handrubs: impact of changes in key ingredient levels and test parameters. Antimicrob

	Resist Infect Control. 2013 Dec 12;2(1):34. doi: 10.1186/2047-2994-2-34. - Suchomel M, Steinmann J, Kampf G. Efficacies of the original and modified World Health Organization-recommended hand-rub formulations. J Hosp Infect. 2020 Oct;106(2):264-270. doi: 10.1016/j.jhin.2020.08.006. - Kramer A, Arvand M, Christiansen B, Dancer S, Eggers M, Exner M, Müller D, Mutters NT, Schwebke I, Pittet D. Ethanol is indispensable for virucidal hand antisepsis: memorandum from the alcohol-based hand rub (ABHR) Task Force, WHO Collaborating Centre on Patient Safety, and the Commission for Hospital Hygiene and Infection Prevention (KRINKO), Robert Koch Institute, Berlin, Germany. Antimicrob Resist Infect Control. 2022 Jul;11(1):93. doi: 10.1186/s13756-022-01134-7. - Global report on infection prevention and control. Geneva: World Health Organization; 2022. - Cravo Oliveira Hashiguchi Tiago , Ait Ouakrim Driss , Padget Michael, Cassini Alessandro, Cecchini Michele. Resistance proportions for eight priority antibiotic-bacterium combinations in OECD, EU/EEA and G20 countries 2000 to 2030: a modelling study. Euro Surveill. 2019;24(20):pii=1800445. https://doi.org/10.2807/1560-7917.ES.2019.24.20.1800445 - GBD 2021 Antimicrobial resistance collaborators, Global burden of bacterial antimicrobial resistance 1990-2021: a systematic analysis with forecast to 2050, The Lancet 2024, https://doi.org/10.1016/S0140-6736(24)01867-1 - National infection prevention and control manual for England, NHS England 15 February 2024, v2.9. Publication reference: PRN00908 - OECD (2018), Stemming the Superbug Tide: Just A Few Dollars More, OECD Publishing, Paris. https://doi.org/10.1787/9789264307599-en
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 107	2025/04/22 11:27
Name of organization/institution	PENTAX Europe GmbH

I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Ethanol for medical devices and in vitro diagnostics (IVDs) Medical devices and IVDs are massively affected by the potential categorisation of ethanol as a CMR substance: Ethanol is used in a variety of ways in production, including for the cleaning and disinfection of equipment, preparation for production processes (bonding, processes (gluing, coating), as a solvent for inks for labels, etc. inks for labels, etc., but also for the protection of personnel (cleaning and disinfection). Ethanol is used as an auxiliary substance in products and products and reagents in in-vitro diagnostics (e.g. as a solvent, carrier as a solvent, carrier, preservative or extraction preservative or extraction agent). Ethanol is used as the main active ingredient in products. This includes both medical products, but also so-called dual-use products. These disinfectants are intended to be used both as disinfectants for medical devices and IVDs and their devices as well as surface/hand disinfectants and are placed on the market placed on the market as biocidal and medical devices. Classification of ethanol as a CMR substance of category 1 would possibly constitute a 'justification' for the use of a of a CMR substance in medical devices according to Annex I point 10.4.1 of the Medical Device Regulation (MDR) [4]. This could be considered a substantial modification of products, accompanied by corresponding conformity assessment procedures, which take at least 18-24 months.
Product Type	1,2,4
Alternative Identity and Properties	none
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Substitutes are not available.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	n/a

Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Since no alternatives are available, significant risks to public health will result from the unavailability of ethanol.
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	In order to ensure a secure supply of disinfectants, cleaning agents, medicinal products, medical devices and IVDs to the population, as well as the ability to produce and supply the corresponding end products, it is necessary to avoid classifying ethanol as a CMR substance as toxic to reproduction and/or as a CMR substance. The classification of ethanol as a CMR substance as toxic to reproduction and/or carcinogenic (category 1 or 2) must be urgently avoided. The classification of ethanol as a CMR substance would the purpose of the biocide and CLP regulations, which is to improve human health, by far. Instead, there would be a significant deterioration in hygiene and healthcare. A corresponding CMR classification would be disproportionate and inappropriate, as it would be based solely on a based assessment of the findings of (abusive) oral intake of ethanol mixtures. It should also be noted that denatured alcohol is used in hygiene and other applications so that oral intake is prevented. In addition, application to the skin and surfaces is surfaces is effective and safe. Ethanol used in production processes and for the manufacture of disinfectants disinfectants, pharmaceuticals, medical devices or IVDs is effective, safe and indispensable. In addition the protection of vulnerable patient groups, particularly in hospitals and the outpatient sector, but also during sector, but also in times of a pandemic. Possible exemptions seem unlikely given the regulatory and bureaucratic effort involved.
Information above is confidential	

Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	ethanol-im-gesundheitswesen.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 108	2025/04/22 11:54
Country	France
Name of organization/institution	French Society for Hospital Hygiene (SF2H)
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	We have been following the ethanol evaluation process, under the European Biocide Directive, with concern and feelings ranging from disbelief to astonishment over the months. Hand disinfection with hydroalcoholic solutions raised great hopes in France at the beginning of the century (1) which materialized spectacularly with the decline in methicillin-resistant <i>Staphylococcus aureus</i> infections in healthcare settings (2). The prospect of suddenly going back a quarter of a century is obviously very worrying. We have had the opportunity to join forces with most of the world's learned societies responsible for the prevention of infectious risks to explain why the CMR labeling of ethanol seems unjustified and dangerous (3). We, however, have the impression that the process initiated by the European body has a certain inevitability that is impervious to any form of argument. The discussion on substitution has been conducted and we believe it is essential, but it calls for

	some comments from us. This document clearly captures the public health stakes, which go far beyond the simple healthcare environment, as we saw during the Covid crisis. However, the proposal of exemption does not seem like a viable solution to us and will only last for five years anyway. If ethanol were to obtain a CMR label, it would amount to, for us, formalizing through a European agency what we have been fighting for years as fake news. While this will not change our scientific analysis of the issue, it will change from a regulatory and ethical perspective. In France, the primary obstacle to the use of hydroalcoholic solutions for hand disinfection by healthcare professionals is the fear of their toxicity (4). It is therefore difficult to imagine promoting a product, officially classified as teratogenic, to young healthcare professionals. Moreover, it is possible that major manufacturers in this sector will not take the risk of continuing to market these products given the associated legal potential issues. Authorizing the exemption of the CMR pictogram on hydroalcoholic solutions for hand rubs would obviously be a step forward, but it would be rather artificial.
Product Type	1,2,4
Alternative Identity and Properties	Furthermore, it seems impossible to jump into the void without any possible substitution prospects in the short or medium term. It is imperative to continue analyzing products already on the market, particularly those based on lactic acid and hypochlorous acid, even though the current limitations of these molecules were clearly highlighted in the agency's document. Manufactured products are available in Europe with studies starting to evaluate their tolerance among healthcare professionals. In addition, Tork Hand Sanitizing Alcohol-Free Foam is a lactic acid based TP01 registered biocide manufactured by the French company Salveco. If Europe bans ethanol as a biocide product the on-field question will not be "which is an appropriate candidate for substitution" but "which is the best one available to protect what could still be protected".
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	

Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Hypochlorous acid has limitations in terms of stability and toxicity and lactic acid has a known more limited effectiveness, particularly against enveloped viruses.
Information above is confidential	
Justification for confidentiality	
Availability	The production capacity of these two products in Europe is currently very limited and a large-scale transition would probably not be easy. Furthermore, it is not certain that large industrial groups producing ethanol-based products would want to launch these products with more uncertain chemistry.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	In summary, the decision facing the European agency at this time is probably the most crucial in terms of public health that Europe has faced in a long time. CMR labeling of ethanol would risk plunging our continent into the equivalent of a post-antibiotic era in terms of hand hygiene and transmission of healthcare-associated and community-acquired infections. In a century where the threat of infection is greater than ever for populations, nations, and their economies, this prospect, based according to us on scientific data unsuitable for the intended use, seems to us a foolish gamble for the future of our continent.
Information above is confidential	
Justification for confidentiality	
Other comments	One should keep in mind that prevention is a long and difficult process to implement but an easy and fast one to destroy.
Information above is confidential	

Justification for confidentiality	
References	(1) Girou E, Oppein F. Handwashing compliance in a French university hospital: new perspective with the introduction of hand-rubbing with a waterless alcohol-based solution. J Hosp Infect. 2001 Aug;48 Suppl A:S55-7. doi: 10.1016/s0195-6701(01)90015-5. (2) Jarlier V, Trystram D, Brun-Buisson C, Fournier S, Carbonne A, Marty L, Andreumont A, Arlet G, Buu-Hoi A, Carlet J, Decré D, Gottot S, Gutmann L, Joly-Guillou ML, Legrand P, Nicolas-Chanoine MH, Soussy CJ, Wolf M, Lucet JC, Aggoune M, Brücker G, Régnier B; Collégiale de Bactériologie-Virologie-Hygiène des Hôpitaux Universitaires de l'Île de France. Curbing methicillin-resistant Staphylococcus aureus in 38 French hospitals through a 15-year institutional control program. Arch Intern Med. 2010 Mar 22;170(6):552-9. doi: 10.1001/archinternmed.2010.32. (3) Axel Kramer, Didier Pittet, Martin Exner, Constanze Wendt. Medical associations and expert committees urge that ethanol be approved as a virucidal active substance for use in hand antiseptics under the European Biocidal Products Regulation, without a CMR classification. GMS Hyg Infect Control. 2024 Aug 21;19:Doc40. doi: 10.3205/dgkh000495 (4) Nicolas Calcagni, Anne-Gaëlle Venier, Raymond Nasso, Guillaume Broc, Eva Ardichen, Bruno Jarrige, Pierre Parneix, Bruno Quintard. Barriers and facilitators on hand hygiene and hydro-alcoholic solutions' use: representations of health professionals and prevention perspectives. Infect Prev Pract. 2021 Aug 14;3(4):100169. doi: 10.1016/j.infpip.2021.100169.
Attachments (non-confidential information)	ECHA_Ethanol_SF2H_2025_def.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 109	2025/04/22 16:56
Country	Germany
Name of organization/institution	

I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	As a small, medium-sized enterprise specializing in the production of specialty cleaning agents, we have been using ethanol in our cleaning products since the company was founded over 40 years ago. Our product portfolio includes not only detergents but also biocidal products that contain ethanol as an active ingredient.
Product Type	1,2,4
Alternative Identity and Properties	Ethanol is one of the most important industrial solvents due to its ability to dissolve both hydrophilic and lipophilic substances. Further advantages of ethanol over other alcohols (for example 1- or 2-propanol) are - Established starting material for many applications: Ethanol has been used safely and effectively for decades in various technical applications with no evidence of risk to humans or the environment. The dermal or inhalative uptake (e.g. in the context of hand disinfection) is far below the toxicologically relevant concentrations. - Highly biodegradable: Ethanol is highly biodegradable and therefore does not accumulate in the environment in the long term. - Effective in disinfectants: In disinfectants, ethanol (e.g. for hand disinfection) is extremely important for effective antimicrobial, antifungal and antiviral use. The highest effectiveness is achieved with a mixture of 70 percent ethanol with water. The Robert Koch Institute classifies a mixture with 70 percent isopropanol used for hand disinfection as limited virucidal, i.e. it is only effective against enveloped viruses. Propanol is optimally effective against non-enveloped viruses, such as murine noroviruses, at a concentration of 80 percent, whereas 90 percent mixtures are no longer effective. - even combined with other active ingredient ethanol can increase the effectiveness of biocidal products significantly - Less odour - Manufactured from renewable raw materials - recommended active ingredient for hand-disinfection during corona crisis. From our company's history, we are not aware of any cases of poisoning or workers' illness that can be attributed to the handling or use of ethanol in our products.
Information above is confidential	
Justification for confidentiality	

Technical Feasibility	- Residue-free application: Due to its low molecular weight, ethanol volatilizes very quickly and dries without leaving any residue - an advantage, for example, in the rapid disinfection of surfaces. - Unrivaled virus effectiveness among alcohols: A unique selling point of ethanol is its effectiveness against non-enveloped viruses, which cannot be deactivated by other alcohols such as 1-propanol and 2-propanol, e.g. polioviruses, Coxsackieviruses, Echoviruses and Enterovirus A71. - broad application: Ethanol is very well suited for combination with other active ingredients such as acids and with excipients like glycerine. This means that appropriate formulations can increase the effectiveness and skin compatibility of hand sanitizers, for example. - High safety and tolerability: Inhalation or dermal absorption, e.g. during hand disinfection, is far below toxicologically relevant concentrations. Ethanol does not accumulate in the environment in the long term. - International relevance: Ethanol is used worldwide as an active ingredient in hand sanitizers. The WHO lists ethanol as an indispensable active ingredient for antiseptic applications.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Good consumer acceptance: Ethanol is considered relatively environmentally friendly and is well-known and accepted by consumers as an active ingredient in disinfectants and cleaners. Products with well-known ingredients are easier to market, reducing marketing costs Cost-effective production: Ethanol can be produced relatively inexpensively, especially when derived from renewable raw materials such as sugarcane, corn, or other biomass sources. Large-scale availability: Due to its broad application (e.g., in fuels, industry, and pharmaceuticals), there is a well-developed infrastructure for production and distribution, which keeps prices stable.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	

Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Proven Efficacy Ethanol has demonstrated broad-spectrum antimicrobial activity, including virucidal, bactericidal, and fungicidal effects, making it highly effective across multiple application types. Long-Term Industry Use With over 40 years of experience using ethanol in our product formulations, we have found it to be both technically and operationally reliable. No adverse health effects related to ethanol use in our products have been reported. Availability and Cost-Effectiveness Ethanol is widely produced and globally available, ensuring a stable supply chain. Its production from renewable sources also supports cost efficiency and sustainability. Regulatory Acceptance Ethanol is already approved as a biocidal active substance under relevant regulations (e.g., EU BPR) and has a well-understood safety profile, simplifying compliance and reducing regulatory burden. High Consumer Acceptance Ethanol-based products are trusted and accepted by consumers due to their familiarity and perceived safety, facilitating marketability. Environmental and Safety Benefits Compared to some synthetic alternatives, ethanol has a lower environmental impact and is biodegradable. It also poses relatively low long-term health risks when handled appropriately.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	

Attachments (confidential information)	
Justification for confidential attachment	

Comment 110	2025/04/23 09:47
Country	Germany
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	
Product Type	1,2,4
Alternative Identity and Properties	Isopropanol (CAS 67-63-0) H225, H319, H336
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Due to its effectiveness, isopropanol cannot be a one-to-one replacement for ethanol, because it does not achieve the virucidal efficacy. Additional active ingredients would have to be added, resulting in more complex formulations and higher approval costs. In addition, other raw materials can lead to poorer skin compatibility (chlorhexiding) or to poorer material compatibility.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Ethanol and isopropanol are comparable in price. However, formulation changes/new developments would cost approximately €16,000 to €35,000 per product for expert opinions. The cost for the regulatory authority are also added.

Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Other raw materials can lead to poorer skin compatibility (chlorhexidine) or to poorer material compatibility.
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	As manufacturer of disinfectants for medical devices, the classification of ethanol indirectly affects us. Our products will lose acceptance among users if they have to be labeled as carcinogens. Due to its effectiveness, isopropanol cannot be a one-to-one replacement for ethanol. Additional active ingredients must be added to the formulations. Evidence of efficacy, material compatibility, and, if applicable, biocompatibility must be verified by expert opinions. Formula changes/new developments must be certified according to MDR and EN 13485.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	

Justification for confidential attachment	

Comment 111	2025/04/23 11:13
Country	Italy
Name of organization/institution	Distillerie Mazzari S.p.A.
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	The EU ethanol market can be divided into three areas of use: fuel, food and industrial. I) Fuel: ethanol is used in a mixture with gasoline or as an alternative fuel. E10, for example, is a type of gasoline that contains up to 10% ethanol and can be used in most internal combustion engines and hybrid vehicles today, significantly reducing greenhouse gas emissions from transport. Ii) Food: The Reg. (EU) No. 2019/787 provides that only ethyl alcohol of agricultural origin may be used for the preparation of spirit drinks. Spirit drinks represent a major outlet for the Union agricultural sector, and the production of spirit drinks is strongly linked to that sector. That link determines the quality, safety and reputation of the spirit drinks produced in the Union. Ethanol can be used also as a food additive, for the extraction of flavours, for food preservation and the production of white vinegar. Iii) Industrial: ethanol is an essential renewable chemical component in various products (e.g. sanitisers, cosmetics, pharmaceuticals, solvents, paints and antifreeze fluids) to ensure hygiene and safety, as well as a renewable raw material for the production of renewable chemicals (e.g. bioethylene). Bioethanol is produced in European biorefineries by fermenting sugars into alcohol. In the EU, these sugars typically come from a variety of agricultural sources such as wheat, corn, barley, rye, triticale and sugar beet. In Italy, bioethanol is obtained mainly from residues of wine production (e.g. grape marc and wine lees) thus obtaining an advanced biofuel that contributes significantly to the reduction of greenhouse gas emissions and therefore to the achievement of EU transport decarbonisation objectives. In 2023, European renewable ethanol producers produced 6.44 billion litres of ethanol, operating 80% of their 8.05 billion litres of installed capacity. Use as a biofuel accounted for 68,4% of the use;

	Other markets, such as industrial applications and beverages, accounted for 16,8% and 14,8% respectively. Distillerie Mazzari S.p.A., headquartered in 48020 S. Agata sul Santerno (Italy) wishes to provide its observations to ECHA by highlighting the irreplaceable use of ethanol and pointing out that a classification of ethanol as carcinogenic or toxic to reproduction would be harmful to many biocides, would create a lack of alternatives and would have critical consequences for public health.. Not only, it would oblige companies to make large and unnecessary investments for the handling and storage of the product thus classified, taking into account that there are no studies that testify to correlations between the production of ethyl alcohol and cases of tumours deriving from this activity
Product Type	1,2,4
Alternative Identity and Properties	No alternative product is available for food use
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	

Justification for confidentiality	
Conclusion on suitability and availability of the alternative	No alternative product is available for fuel or food use and even in the industrial sector, any alternatives are not available if not at higher costs (for example: isopropyl alcohol today costs about 20% more than ethanol). In any case, the alternatives derive exclusively from the fractionation of oil and are therefore not renewable and have a negative environmental impact and in contradiction with the guidelines of the European Union regarding the reduction of greenhouse gas emissions.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	ethyl-alcohol-2023 production-disposal-trade_.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 112	2025/04/23 12:11
Country	Sweden
Name of organization/institution	Sekab Biofuels & Chemicals AB
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	See Attachment

Product Type	1,2,4
Alternative Identity and Properties	See Attachment
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	See Attachment
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	See Attachment
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	See Attachment
Information above is confidential	
Justification for confidentiality	
Availability	See Attachment
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	See Attachment
Information above is confidential	
Justification for confidentiality	
Other comments	See Attachment
Information above is confidential	

Justification for confidentiality	
References	
Attachments (non-confidential information)	Consultation on ethanol as a candidate for substitution under the Biocidal Products Regulation -BPR _2025-04-23_Sekab.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 113	2025/04/23 12:14
Country	Sweden
Name of organization/institution	Sekab Biofuels & Chemicals AB
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	See Attachment
Product Type	1,2,4
Alternative Identity and Properties	See Attachment
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	See Attachment
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	See Attachment
Information above is confidential	

Justification for confidentiality	
Hazards and Risks of the Alternative	See Attachment
Information above is confidential	
Justification for confidentiality	
Availability	See Attachment
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	See Attachment
Information above is confidential	
Justification for confidentiality	
Other comments	See Attachment
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	Consultation on ethanol as a candidate for substitution under the Biocidal Products Regulation -BPR _2025-04-23_Sekab.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 114	2025/04/23 12:15
Country	Sweden

Name of organization/institution	Sekab Biofuels & Chemicals AB
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	See Attachment
Product Type	1,2,4
Alternative Identity and Properties	See Attachment
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	See Attachment
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	See Attachment
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	See Attachment
Information above is confidential	
Justification for confidentiality	
Availability	See Attachment
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	See Attachment

Information above is confidential	
Justification for confidentiality	
Other comments	See Attachment
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	Consultation on ethanol as a candidate for substitution under the Biocidal Products Regulation -BPR _2025-04-23_Sekab.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 115	2025/04/23 12:17
Country	Sweden
Name of organization/institution	Sekab Biofuels & Chemicals AB
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	See Attachment
Product Type	1,2,4
Alternative Identity and Properties	See Attachment
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	See Attachment

Information above is confidential	
Justification for confidentiality	
Economic Feasibility	See Attachment
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	See Attachment
Information above is confidential	
Justification for confidentiality	
Availability	See Attachment
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	See Attachment
Information above is confidential	
Justification for confidentiality	
Other comments	See Attachment
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	Consultation on ethanol as a candidate for substitution under the Biocidal Products Regulation -BPR _2025-04-23_Sekab.pdf
Attachments (confidential information)	

Justification for confidential attachment	

Comment 116	2025/04/23 12:30
Country	Denmark
Name of organization/institution	KiiltoClean Oy
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	KiiltoClean strongly supports the findings in AoA for the use of ethanol as disinfectant as submitted by Alcohol Task Force/EPPA. Ethanol, a versatile and widely used biocidal active substance, plays a crucial role in maintaining hygiene and infection control across various applications. Its broad-spectrum efficacy against bacteria, fungi, and viruses, including both enveloped and non-enveloped types, makes ethanol indispensable in healthcare and public spaces, but also in domestic environments during epidemics or pandemic outbreaks. The industry started to deliver efficacious and easily accessible ethanol-based hand disinfectants to the healthcare sector in the 1990s. We believe that easy access to effective ethanol-based disinfectants is a major factor in good hygiene routines. If we do not have the possibility to continue the use of ethanol as a major active substance in disinfectant products, then compliance with hygiene routines in hospitals and food processing facilities are in danger. Additionally, ethanol remains the most cost-effective disinfectant due to its widespread availability, ease of production, and scalability, particularly during high-demand scenarios such as pandemics.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	

Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	In summary KiiltoClean do not see any good alternative for ethanol in many critical use applications that benefit the safety of humans and surfaces.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	Kiilto reply_PT1_Analysis of Alternatives of ethanol_11-04-2025.docx
Attachments (confidential information)	

Justification for confidential attachment	

Comment 117	2025/04/23 12:36
Country	Denmark
Name of organization/institution	KiiltoClean Oy
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	KiiltoClean strongly supports the findings in AoA for the use of ethanol as disinfectant as submitted by Alcohol Task Force/EPPA. Ethanol, a versatile and widely used biocidal active substance, plays a crucial role in maintaining hygiene and infection control across various applications. Its broad-spectrum efficacy against bacteria, fungi, and viruses, including both enveloped and non-enveloped types, makes ethanol indispensable in healthcare and public spaces, but also in domestic environments during epidemics or pandemic outbreaks. The industry started to deliver efficacious and easily accessible ethanol-based hand disinfectants to the healthcare sector in the 1990s. We believe that easy access to effective ethanol-based disinfectants is a major factor in good hygiene routines. If we do not have the possibility to continue the use of ethanol as a major active substance in disinfectant products, then compliance with hygiene routines in hospitals and food processing facilities are in danger. Additionally, ethanol remains the most cost-effective disinfectant due to its widespread availability, ease of production, and scalability, particularly during high-demand scenarios such as pandemics.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	

Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	In summary KiiltoClean do not see any good alternative for ethanol in many critical use applications that benefit the safety of humans and surfaces.
Information above is confidential	
Justification for confidentiality	
Other comments	For use in PT2, one of the main limitations of ethanol alternatives, such as propanols, lactic acid, or peracetic acid is their high corrosivity potential to surfaces. These alternatives also have distinctive off-odour smells, which are not favored by users. Water-based quat-based products have the ability to induce microbial resistance flora in healthcare settings. Ethanol remains irreplaceable in PT2 applications due to its unique combination of rapid efficacy, broad-spectrum antimicrobial activity, surface compatibility, and cost-effectiveness. These attributes make it indispensable for maintaining hygiene in public, private, and industrial environments.

Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	Kiilto reply_PT2_Analysis of Alternatives of ethanol_11-04-2025.docx
Attachments (confidential information)	
Justification for confidential attachment	

Comment 118	2025/04/23 12:40
Country	Denmark
Name of organization/institution	KiiltoClean Oy
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	KiiltoClean strongly supports the findings in AoA for the use of ethanol as disinfectant as submitted by Alcohol Task Force/EPPA. Ethanol, a versatile and widely used biocidal active substance, plays a crucial role in maintaining hygiene and infection control across various applications. Its broad-spectrum efficacy against bacteria, fungi, and viruses, including both enveloped and non-enveloped types, makes ethanol indispensable in healthcare and public spaces, but also in domestic environments during epidemics or pandemic outbreaks. The industry started to deliver efficacious and easily accessible ethanol-based hand disinfectants to the healthcare sector in the 1990s. We believe that easy access to effective ethanol-based disinfectants is a major factor in good hygiene routines. If we do not have the possibility to continue the use of ethanol as a major active substance in disinfectant products, then compliance with hygiene routines in hospitals and food processing facilities are in danger. Additionally, ethanol remains the most cost-effective disinfectant due to its widespread availability, ease of production, and scalability,

	particularly during high-demand scenarios such as pandemics.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	In summary KiiltoClean do not see any good alternative for ethanol in many critical use applications that benefit the safety of humans and surfaces.
Information above is confidential	
Justification for confidentiality	

Other comments	In PT4 food industry environments the safety issues are most important. Many kinds of disinfectants are used in food industries and all of them have their unique purpose to guarantee safety in various processing areas. Ethanol-based products are especially suitable for disinfecting small objects quickly and residue-free. Other water-based alternatives are used in places where you rinse the surfaces after use of disinfectant. The limitation with propanols is their lower efficacy to non-enveloped viruses. Their slower evaporation rate as compared to ethanol is impacting operational efficiency. In contrast, ethanol combines rapid microbial efficacy, a broad-spectrum activity that includes bacteria, fungi, and viruses – both enveloped and non-enveloped - and minimal skin irritation. Its rapid evaporation minimizes prolonged contact with surfaces, making it particularly suitable for intensive-use scenarios in the food and feed sectors, such as disinfection of equipment, small surfaces, and high-frequency touchpoints in processing and storage environments.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	Kiilto reply_PT4_Analysis of Alternatives of ethanol_11-04-2025.docx
Attachments (confidential information)	
Justification for confidential attachment	

Comment 119	2025/04/23 13:00
Country	Germany
Name of organization/institution	Kassenzahnärztliche Bundesvereinigung (KZBV)
I do not wish the name of my organisation/institution to be published on the ECHA website.	

General information	In Zahnarztpraxen in Deutschland wird als Desinfektionsmittel vor allem zur Händedesinfektion Ethanol als Wirkstoff verwendet. Ethanol wirkt hierbei zuverlässig gegen Bakterien und Viren und ist insbesondere alternativlos gegen unbehüllte Viren wie zum Beispiel Polioviren. Auch für die Schnelldesinfektion kleinerer Flächen wird Ethanol verwendet, hier ist der Vorteil die schnelle Wirkung und die kurze Trocknungszeit. Beim Wegfall von Händedesinfektionsmitteln auf Ethanol-Basis müsste auf andere alkoholische Händedesinfektionsmittel (1-Propanol und 2-Propanol) umgestellt werden. Diese alternativen Desinfektionsmittel sind jedoch kein adäquater Ersatz, da sie unbehüllte Viren nicht ausreichend inaktivieren.
Product Type	1,2,4
Alternative Identity and Properties	Als theoretische Alternative zu alkoholischen Händedesinfektionsmitteln kommen Produkte auf der Basis von 1-Propanol und 2-Propanol infrage. Die Wirkung dieser Mittel ist jedoch nicht vergleichbar mit ethanolhaltigen Desinfektionsmitteln. Aus zahnmedizinischer Sicht sind sie deshalb für die alleinige Verwendung zur Hände- und Flächendesinfektion in der täglichen Praxis nicht geeignet.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Eine Umstellung auf nicht-ethanolhaltige Desinfektionsmittel wäre den Zahnarztpraxen in Deutschland möglich. Dies hätte jedoch unerwünschte und möglicherweise schwerwiegende Folgen für die Hygiene in der zahnmedizinischen Versorgung, denn damit einher ginge ein erhebliches Gesundheitsrisiko für die Patienten und für die Mitarbeiter, da eine gleich gute Wirkung der Desinfektion wie mittels ethanolhaltiger Präparate nicht als gesichert angesehen werden kann. Beispielsweise zeigte sich während der Covid-19-Pandemie, dass Infektionsketten durch Desinfektionsmaßnahmen mittels ethanolhaltigen Präparaten sicher und schnell unterbrochen werden konnten. Wir verweisen hier im Besonderen auf die Studie Kramer et. al. 2024
Information above is confidential	
Justification for confidentiality	

Economic Feasibility	Es ist zu befürchten, dass Alternativpräparate deutlich teurer sind als ethanolhaltige Desinfektionsmittel, da Ethanol als Nebenprodukt der chemischen Industrie besonders günstig ist.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Für die niedergelassenen Zahnarztpraxen in Deutschland wäre in Folge eines Wegfalls von Händedesinfektionsmitteln auf Ethanol-Basis zu erwarten, dass die Patienten und Mitarbeiter beim Einsatz von nicht gleich wirksamen Alternativen gesundheitlichen Risiken ausgesetzt werden. Die ambulante zahnmedizinische Versorgung würde im Hinblick auf den angestrebten Gesundheitsschutz und die Qualitätsstandards unnötigen Risiken ausgesetzt und insgesamt Schaden nehmen.
Information above is confidential	
Justification for confidentiality	
Availability	Wenn Ethanol auf dem Markt nicht mehr angeboten werden dürfte, wird es den Zahnarztpraxen in Deutschland möglich sein, sich Alternativprodukte beschaffen zu können.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Bei den niedergelassenen Zahnarztpraxen wäre in Folge eines Wegfalls von Händedesinfektionsmitteln auf Ethanol-Basis zu erwarten, dass Patienten und Mitarbeiter gesundheitliche Schäden erleiden können. Dieses Risiko muss zwingend vermieden werden. Zahnmedizinische und medizinische Fachverbände und Expertenausschüsse aus Europa, den USA, Kanada, der Asia-Pacific Region und die Weltgesellschaft für Virologie (vgl. Kramer et al. 2024) empfehlen den weiteren Einsatz von ethanolhaltigen Händedesinfektionsmitteln, da es keinen bioziden Ersatzwirkstoff zur Händedesinfektion mit Wirksamkeit gegen unbehüllte Viren gibt. Auch betrachtet die Weltgesundheitsorganisation Ethanol als unersetzbaren Wirkstoff in der Desinfektion.

Information above is confidential	
Justification for confidentiality	
Other comments	Keine!
Information above is confidential	
Justification for confidentiality	
References	Kramer et al. 2024
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 120	2025/04/23 13:57
Country	Germany
Name of organization/institution	Verbund für Angewandte Hygiene e.V., Association of Applied Hygiene
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	About VAH As the Disinfectants Commission of the Association of Applied Hygiene (VAH) we are (industry-independent) experts in assessing the efficacy of disinfectants, including PT1 and PT2 categorized disinfectants. We have gathered experience in disinfectant efficacy testing for more than 60 years and we have significantly contributed to the development of current European test standards (CEN/TC 216). VAH assessment of efficacy test reports and expert opinions for disinfectants available on the market in Germany and other European countries and passing the requirements for proof of efficacy show ethanol to be the single most important active substance in PT1. VAH certification for disinfectants is a unique and reliable indicator of the quality and effectiveness

of disinfectant products, providing consumers with a means to identify products that have undergone thorough evaluation by industry-independent experts. Safe and easy use as handrub for professional users and the general public. There is no epidemiological evidence of toxicity for workers from handling ethanol-containing products in industry or from using ethanol-based hand rubs (EBHR) in healthcare facilities or in the community. EBHR are safe and easy to use for professional users as well as for the general public in the event of outbreaks, epidemics or bioterrorism situations. Ethanol has unique efficacy against non-enveloped viruses. Non-enveloped viruses are highly transmissible via hands and pose significant outbreak risks, particularly in the absence of vaccines. These viruses include noro-, rota-, adeno-, entero-, and coxsackievirus. Additionally, vaccine-preventable non-enveloped viruses such as papillomavirus and wild poliovirus type 1 (WPV1) in regions like Afghanistan and Pakistan, are also transmitted via hands. The current detection of cVDPV2 in Europe reminds us of the fact that even regions which have previously been declared "polio-free" are at risk. Over the last decade, the emergence of several zoonotic viruses has demonstrated that previously unknown or neglected pathogens have the potential to cause epidemics or pandemics, hence posing a threat to global public health. Therefore, it is likely that future pandemics will result from a zoonotic event caused by a virus requiring immediate access to disinfectants with a proven efficacy against viruses for everyone, with hand hygiene (and surface disinfection) being a major non-pharmaceutical constituent of infection prevention and control measures. This is vitally important especially in situations/phases where immunization by vaccines is not possible/available (yet) (see COVID-19). EBHR are routinely used in all (medical and care) facilities when efficacy against non-enveloped viruses must be guaranteed. This applies to the treatment and care of patients with widespread infections such as adenoviruses, rotaviruses or noroviruses as well as HPV. If EBHR are no longer readily available, no virucidal handrubs exist to interrupt outbreaks in hospitals, nursing homes, kindergartens, schools, cruise ships and other community settings and to protect food from contamination with non-enveloped viruses during the manufacturing process. The FDA Model Food Code recommends the use of EBHR as an alternative to handwashing when heavy soiling is absent. For example, norovirus is responsible for approximately 58% of foodborne illness cases of known etiology in the US, leading to around 125 million cases annually. Extrapolating published data from 5 to 33 European countries, the

	estimated burden of disease caused by non-enveloped viruses includes over 300 million cases for rhinoviruses, 73 million for rotaviruses, over 20 million for papillomavirus 6, over 2 million for coxsackieviruses, over 500,000 for enteroviruses, 232,000–452,000 for noroviruses, over 100,000 for echoviruses, 5,000 for adenovirus as the causative agent of keratoconjunctivitis epidemic. References: - Robert Koch Institute: https://www.rki.de/DE/Themen/Infektionskrankheiten/Infektionskrankheiten-A-Z/P/Polio/polio-node.html . - Neumann G, Kawaoka Y. Which Virus Will Cause the Next Pandemic? <i>Viruses</i>. 2023 Jan 10;15(1):199. doi: 10.3390/v15010199. - Bihl F, Negro F. Hepatitis E virus: a zoonosis adapting to humans. <i>J Antimicrob Chemother</i>. May 2010; 65(5): 817–21. doi:10.1093/jac/dkq085. -Lawrence P, Heung M, Nave J, Henkel C, Escudero-Pérez B. The natural virome and pandemic potential: Disease X. <i>Curr Opin Virol</i>. Dec 2023: 101377. - Buigues J, Viñals A, Martínez-Recio R, Monrós JS, Cuevas JM, Sanjuán R. Phylogenetic evidence supporting the nonenveloped nature of hepadnavirus ancestors. <i>Proc Natl Acad Sci U S A</i>. 2024 Nov 5;121(45):e2415631121. doi: 10.1073/pnas.2415631121. Epub 2024 Oct 29. - Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson MA, Roy SL, et al. Foodborne illness acquired in the United States – major pathogens. <i>Emerg Infect Dis</i>. 2011;17(1):7–15. doi: 10.3201/eid1701.p11101. -CDC. Norovirus Facts and Stats. May 2024, accessed 10 April 2025: https://www.cdc.gov/norovirus/data-research/index.html - Kirk MD, Pires SM, Black RE, Caipo M, Crump JA, Devleesschauwer B, et al. Correction: World Health organization estimates of the global and regional disease burden of 22 foodborne bacterial, protozoal, and viral diseases, 2010: A data synthesis. <i>PLoS Med</i>. 2015 Dec;12(12):e1001940. doi: 10.1371/journal.pmed.1001940. Scientifically flawed classification of ethanol for the intended use as biocide Ethanol as an active substance for biocides was evaluated on the basis of data from oral consumption and alcohol abuse. However, ethanol as an active substance for biocides (PT1, PT2, PT4) is not an alcoholic beverage or foodstuff and its intended use is dermal application or application on non-porous surfaces. Evidence for a reprotoxic effect of ethanol originates from data following the consumption of alcoholic beverages by pregnant women. There is no epidemiological evidence for toxicity for workers handling ethanol-containing chemical products in industrial workplaces or when using EBHR in healthcare facilities or ethanol-containing products in the non-healthcare setting.

Neither is accidental oral ingestion of EBHR a hazard for healthcare workers. Evaluation of a biocidal substance must be based on data relating to the intended route of exposure. Thus, comparative evaluation of alternatives must also be based on data for that same intended route of exposure and not on general intrinsic properties of a substance. Route of exposure: Minimal dermal absorption. The quantities of ethanol absorbed from dermal application are in the physiological range. Fruit juices may contain up to 3 g ethanol per L, apple juice contains 1 g ethanol per 500 mL. Assuming an absorption rate of 90%, drinking 500 ml of apple juice will result in a blood alcohol concentration of about 85 mg/L ethanol in a 75-kg man or 125 mg/L ethanol in a 60-kg woman. Non-alcoholic beer, flavored water, and orange juice result in blood ethanol levels similar to those seen after hand antisepsis, or even higher. The concentration of ethanol naturally produced by intestinal bacteria is 1.1 mg/L, so internal amounts of ethanol resulting from topical application of EBHR are in the range of those associated with consumption of non-alcoholic beverages, which are considered safe for consumers. To clarify adverse effects on the pancreas after hand antisepsis by teaching nurses, the following scenario was considered: total rubbing of hands (3 mL of 70% EBHR) consisting of 30 persons 3 times/day in the same room (116 cm³) over a period of 48 h interrupted by one night (90 hand rubs/day in the room). Blood ethanol concentrations were predicted using a physiologically based pharmacokinetic model, which allowed simulation of inhalation and dermal exposure. In the worst-case scenario, the simulation showed that the maximum blood ethanol concentration predicted -5.9 mg/L- is of the same order of magnitude as endogenous ethanol concentration (mean = 1.1 mg/L; median = 0.4 mg/L; range = 0–35 mg/L) in humans without prior alcohol consumption. The harmlessness was confirmed in a double-blind, randomized phase I experimental study: 20 ml of hand rub (74.1% ethanol content) were applied on a 200-cm² gauze swab on skin areas; the gauze swab remained on the skin for 10 min (0.1 mL/cm² treated skin area). Comparing ethanol concentrations at baseline, and after 15 and 60 min, no significant differences could be detected. The detection limit was defined as the ethanol concentration producing an area 3 × larger than the blank area under the curve (0.5 mg/L). The harmlessness is also underlined by the fact that the use of EBHR induces concentrations of ethyl glucuronide, the marker of ethanol consumption, in urine, below any harmful or toxic levels. Thus, classification as carcinogenic, mutagenic, reprotoxic for use in hand antisepsis is not justified. This was as

	confirmed in scientific studies and agreed upon by the WHO ABHR Task Force and many international medical associations and expert committees. References: - Kramer A, Below H, Bieber N, Kampf G, Toma CD, Huebner NO, et al. Quantity of ethanol absorption after excessive hand disinfection using three commercially available hand rubs is minimal and below toxic levels for humans. BMC Infect Dis. 2007;7:117. doi:10.1186/1471-2334-7-117.) - Kirschner MH, Lang RA, Breuer B, Breuer M, Gronover CS, Zwingers T, et al. Transdermal resorption of an ethanol- and 2-propanol-containing skin disinfectant. Langenbecks Arch Surg. 2009;394(1):151–157. doi: 10.1007/s00423-007-0237-7. - Below H, Partecke I, Huebner NO, Bieber N, Nicolai T, Usche A, et al. Dermal and pulmonary absorption of propan-1-ol and propan-2-ol from hand rubs. Am J Infect Control. 2012;40(3):250–7. https://doi.org/10.1016/j.ajic.2011.03.009. - Huynh-Delerme C, Artigou C, Bodin L, Tardif R, Charest-Tardif G, Verdier C, et al. Short communication: is ethanol-based hand sanitizer involved in acute pancreatitis after excessive disinfection? an evaluation with the use of PBPK model. J Toxicol. 2012;2012(3):959070. doi: 10.1155/2012/959070. - Gessner S, Below E, Diedrich S, Wegner C, Gessner W, Kohlmann T, et al. Ethanol and ethyl glucuronide urine concentrations after ethanol-based hand antisepsis with and without permitted alcohol consumption. Am J Infect Control. 2016;44(9):999–1003. doi:10.1016/j.ajic.2016.02.021. - Kramer A, Arvand M, Christiansen B, Dancer S, Eggers M, Exner M, Müller D, Mutters NT, Schwebke I, Pittet D. Ethanol is indispensable for virucidal hand antisepsis: memorandum from the alcohol-based hand rub (ABHR) Task Force, WHO Collaborating Centre on Patient Safety, and the Commission for Hospital Hygiene and Infection Prevention (KRINKO), Robert Koch Institute, Berlin, Germany. Antimicrob Resist Infect Control. 2022 Jul;11(1):93. doi: 10.1186/s13756-022-01134-7. - Kramer A, Benkhail H, Jäkel C, Zwicker P. Ethanol is indispensable for virucidal hand antisepsis and without toxic risks in daily use. GMS Hyg Infect Control. 2023 Jan 23;18:Doc02. doi: 10.3205/dgkh000428. - Kramer A, Pittet D, Exner M, Wendt C. Medical associations and expert committees urge that ethanol be approved as a virucidal active substance for use in hand antiseptics under the European Biocidal Products Regulation, without a CMR classification. GMS Hyg Infect Control. 2024 Aug 21;19:Doc40. doi: 10.3205/dgkh000495.
Product Type	1,2,4

Alternative Identity and Properties	No alternatives with comparable activity against hydrophilic non-enveloped viruses which can be used in handrubs. Ethanol exhibits unique activity in 80 % w/w concentration against hydrophilic non-enveloped viruses. There are no alternative substances which are effective against enteroviruses and which can be used as an active substance in handrubs, including isopropanol. Ethanol was chosen as reference alcohol for EN 17430, the test standard for virucidal disinfection activity (Phase 2/Step 2). The decision was based on its efficacy and the fact that the majority of virucidal handrubs (activity against non-enveloped viruses) are based on ethanol. References: - Kurtz JB, Lee TW, Parsons AJ. The action of alcohols on rotavirus, astrovirus, and enterovirus. JHI 1989;1:321-325. - Steinmann J, Becker B, Bischoff B, Magulski T, Steinmann J, Steinmann E. Virucidal activity of Formulation I of the World Health Organization's alcohol-based handrubs: impact of changes in key ingredient levels and test parameters. Antimicrob Resist Infect Control. 2013 Dec 12;2(1):34. doi: 10.1186/2047-2994-2-34. - Suchomel M, Steinmann J, Kampf G. Efficacies of the original and modified World Health Organization-recommended hand-rub formulations. J Hosp Infect. 2020 Oct;106(2):264-270. doi: 10.1016/j.jhin.2020.08.006. - Kramer A, Arvand M, Christiansen B, Dancer S, Eggers M, Exner M, Müller D, Mutters NT, Schwebke I, Pittet D. Ethanol is indispensable for virucidal hand antisepsis: memorandum from the alcohol-based hand rub (ABHR) Task Force, WHO Collaborating Centre on Patient Safety, and the Commission for Hospital Hygiene and Infection Prevention (KRINKO), Robert Koch Institute, Berlin, Germany. Antimicrob Resist Infect Control. 2022 Jul;11(1):93. doi: 10.1186/s13756-022-01134-7. - CEN. Chemical disinfectants and antiseptics – hygienic handrub virucidal – Test method and requirements (phase 2/step 2); German version EN 17430:2024. New data on efficacy against dermatophytes. Hitherto unpublished data from current test series commissioned by VAH show that ethanol is also superior in its efficacy against epidemiologically relevant fungal pathogens such as T. tonsurans. In fact, commercially available handrubs based on isopropanol or n-propanol proved to be insufficiently effective against T. tonsurans. Toxicological hazards of potential alternatives with virucidal activity in handrubs. Even though chlorine-based agents, oxidants and peracetic acid show in-vitro activity against non-enveloped viruses, these substances have negative toxicological effects under in-use conditions which make them unsuitable for handrub formulations. They are usually available in formulations combined with other active

	substances (often with ethanol). One report described allergic contact dermatitis related to the use of high-concentrated chlorine solutions (CS) for hand antisepsis. Peracetic acid (PAA) is corrosive/irritating to the eyes, mucous membranes of the respiratory tract, and skin. It causes lacrimation, extreme discomfort, and irritation to the upper respiratory tract in humans after exposure to concentrations as low as 15.6 mg peracetic acid/m³ (5 ppm) for only 3 min. The AEGL-1 value is 0.52 mg/m³ (0.17 ppm) for all exposure durations from 10 min to 8 h. During dermal application of 0.16 ml 0.12% PAA 2 times/d over 90 d in guinea pigs, the following side effects were observed: Decrease in body mass (bm), bm/spleen mass quotient and bm/kidney mass, increase in aspartate aminotransferase and alanine transaminase, decrease in lactat dehydrogenase IV and serum creatinine, severe to moderate pneumonia and liver granulomas. PAA induced chromosomal aberrations during epicutaneous application/mouse. References: - Kramer A, Weuffen W, Merka V Tichacek B. Toxizität von Peroxethansäure. In: Weuffen W, Kramer A, Bulka E, Schönenberger H (Hrsg) Handbuch der Antiseptik Bd. II/Teil 2, Fischer, Stuttgart New York, 1983; 177-187. - Paldy A, Berencsi G Kramer A, Weuffen W, Spiegelberger E. Mutagene Potenz von Wofasteril, Wofasept, Formaldehyd, Chlorhexidin und Bronopol im Knochenmarktest an der Maus. In: Kramer A, Wigert H, Kemter B (Hrsg) Aspekte der Prophylaxe und Bekämpfung des infektiösen Hospitalismus. Leipzig, Barth, 1884,249-52. - Kramer A, Assadian O (Hrsg.). Wallhäußers Praxis der Sterilisation, Desinfektion, Antiseptik und Konservierung. Stuttgart Thieme-Verlag, 2008. - Kubilay Z, Hopman J, Allen T, Edrees H, Allegranzi B. Skin side effects of chlorine solutions used for hand hygiene: a systematic review. Antimicrob Resist Infect Control 4 (Suppl 1), P9 (2015). https://doi.org/10.1186/2047-2994-4-S1-P9 - National Research Council (US) Committee on Acute Exposure Guideline Levels. Peracetic Acid Acute Exposure Guideline Levels. In: Acute Exposure Guideline Levels for Selected Airborne Chemicals. Vol. 8. Washington (DC), National Academies Press (US); 2010. - Analysis of hazards https://echa.europa.eu/documents/10162/b3ce804b-1d11-f40c-931a-3d8f5605b74a
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Technical Feasibility	No products with virucidal activity approved by ECHA as PT1. To our knowledge, there are currently no biocidal products approved as PT1 which exhibit virucidal activity (ECHA database PT 1, accessed 7 April 2025). https://echa.europa.eu/documents/10162/eff25082-96b4-4193-8f47-ef183cf1df4c Contact time At present, contact times of 30 s are typical for most handrubs. However, there are discussions among experts and practitioners advocating contact times for handrubs which are 15 s (for bacteria and yeasts). Currently, a modified test method for a contact time of 15 s is being validated in VAH ring trials taking into consideration rubbing technique, volumes and wetting capacity. As of now, a clear statement regarding this new contact time cannot be made by VAH. However, the point is that shorter contact times would have a major impact on the practical use of handrubs, with fast action and fast evaporation of handrubs being even more important than for a 30 s contact time. EBHR are known for their fast action and fast evaporation. References - Desinfektionsmittel-Kommission im VAH unter Mitwirkung der „4+4“ Arbeitsgruppe. Stellungnahme der Desinfektionsmittel-Kommission zur Methodenentwicklung für eine Verkürzung der hygienischen Händedesinfektion auf 15 Sekunden. Stand 8.10.24. HygMed 2024;49(10):273-274. - Desinfektionsmittel-Kommission im VAH. Stellungnahme der Desinfektionsmittel-Kommission zur Verkürzung der Einwirkzeit der hygienischen Händedesinfektion auf 15 Sekunden. Stand 24.9.24. HygMed 2024;49(10):241-243. Problems when having multiple disinfectants in stock Theoretically, handrubs with active substances other than ethanol could be used in some areas or situations, depending on the activity spectrum needed. This would require the purchase and stocking of a variety of disinfectants, e.g. in the same hospital. Stocking and provision of various products would, however, entail a higher risk for incorrect use: expiry dates differ, hand care needs differ, applicable volumes differ (the dispensers must be calibrated correctly), multiple handling instructions and risk evaluations according to rules and regulations and occupational safety provisions are necessary.
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Economic Feasibility	See 5. Availability and analysis of alternatives https://echa.europa.eu/documents/10162/b3ce804b-1d11-f40c-931a-3d8f5605b74a The substitution of ethanol with

	other virucidal active substances for routine hand antisepsis, which are at present unknown, is likely to make handrub production more expensive for manufacturers and consumers and governments in Europe and worldwide.
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Hazards and Risks of the Alternative	Resistance and health hazards Alternative PT1 substances such as quarternary compounds – which are, however, not virucidal - bear a risk of developing clinically relevant resistance or tolerance towards certain target organisms. No resistance development has been described for ethanol. References: - Boyce JM. Quaternary ammonium disinfectants and antiseptics: tolerance, resistance and potential impact on antibiotic resistance. Antimicrob Resist Infect Control 2023;12(1):32. doi: 10.1186/s13756-023-01241-z. - Kampf G. Adaptive microbial response to low level benzalkonium chloride exposure. J Hosp Infect 2018;100: e1–e22. doi:10.1016/j.jhin.2018.05.019 Stability (efficacy) hazards Chlorine-based disinfectants are unstable and very sensitive to temperature changes. User information on the stability after opening is not mandatory for manufacturers of biocides according to the BPR. Users might not know the exact date when to discard the residual amount from opened dispensers as a consequence of insufficient active substance content. On the other hand, product-specific information on EBHR stability which is available from some manufacturers, indicates that ethanol has favorable stability properties if stored and maintained correctly (with the lid tightly closed). References: - Desinfektionsmittel-Kommission im VAH. Lagerbedingungen und Aufbrauchfristen für chlorbasierte Desinfektionsmittel. Stand: 14.01.2025. HygMed 2025;50(3):34-35. - Zazouli MA, Hashempour Y, Dashtban N. Evaluating the influence of environmental factors on the stability of commercial chlorine-based sanitizers using response surface modeling. Avicenna J Environ Health Eng. 2024; 11(1):39-46. doi:10.34172/ajehe.5404 Skin irritation hazards The above mentioned alternative active substances with in-vitro virucidal activity are not suitable as active substances for hand antisepsis due to their toxicity profile. The frequency of use in everyday clinical practice (more than 100x/day) must be taken into account. In this respect, it is particularly noteworthy that ethanol does not induce any changes in the microbiome of the hand. A change in the hand microbiome can be assumed for other

	active substances with in-vitro virucidal effect because, unlike alcohols, they penetrate into deeper skin layers. References: - Kramer A, Borg Dahl M, Bengtsson MM, Boyce JM, Heckmann M, Meister M, Papke R, Pittet D, Reinhard A, Slevogt H, Wang H, Zwicker P, Urich T, Seifert U. No detrimental effect on the hand microbiome of health care staff by frequent alcohol-based antisepsis. <i>Am J Infect Control</i>. 2024 Nov 15:S0196-6553(24)00846-0. doi: 10.1016/j.ajic.2024.11.006. Epub ahead of print. - Lademann O, Kramer A, Richter H, Patzelt A, Meinke MC, Czaika V, Weltmann KD, Hartmann B, Koch S. Skin disinfection by plasma-tissue interaction: comparison of the effectivity of tissue-tolerable plasma and a standard antiseptic. <i>Skin Pharmacol Physiol</i>. 2011;24(5):284-8. doi: 10.1159/000329913. Epub 2011 Jun 25. Toxicological hazards Ethanol is superior to all other active substances including propanols for handrubs with regard to its wide activity spectrum including virucidal action, skin tolerability and lack of toxicity. It is widely accepted by users throughout the world for exactly those reasons. Even if bactericidal/yeastcidal/limited virucidal spectrum of activity (i.e. activity against enveloped viruses) is the focus of attention rather than virucidal activity, ethanol-based products are toxicologically more favorable than the frequently proposed propanol-based products: The blood level of 1- and 2-propanol is between 1,800 and 10,000 times above the baseline value, whereas for ethanol this value is at most around 157 times higher in a worst case exposure situation, which is still in the physiological range. Reference - Below H, Partecke I, Huebner NO, Bieber N, Nicolai T, Usche A, et al. Dermal and pulmonary absorption of propan-1-ol and propan-2-ol from hand rubs. <i>Am J Infect Control</i>. 2012;40(3):250–7. https://doi.org/10.1016/j.ajic.2011.03.009. Infection hazards Due to the lack of virucidal efficacy of other active agents usable for hand antisepsis, the interruption of transmission of non-enveloped viruses, thereby protecting staff and patients and the general public is not possible without EBHR. As a result, the very objective of using a biocide, which is to protect human health, cannot be achieved. Compliance hazards Some alternatively used substances such as peracetic acid or sodium hypochlorite have a pungent odor and a higher skin irritation potential. Compliance with the indications for hygienic hand antisepsis by the user is likely to decrease with less accepted substances which in turn will result in a health hazard for both, personnel and patients. Environmental hazards Comparative life cycle assessment data for ethanol, bioethanol and other active substances should be taken into

	consideration. The carbon foot print for the propanols is much less favourable than the one for ethanol (https://ecoinvent.org/)
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Availability	Ethanol is produced at a much larger scale in Europe than propanols or other alternative substances (cf. https://echa.europa.eu/documents/10162/b3ce804b-1d11-f40c-931a-3d8f5605b74a). Ethanol is used in a much larger variety of industrial applications than other biocidal substances for handrubs and widely available (cf. https://www.epure.org/wp-content/uploads/2024/09/240904-DEF-PR-European-renewable-ethanol-Key-figures-2023-WEB.pdf ePURE, https://echa.europa.eu/documents/10162/0/art_95_list_en+%282%29.pdf/fabafba4-c021-9424-1ddd-8cf89faba774?t=1729688502218) Ethanol is on the list of essential medicines of the WHO and ingredient of the WHO standard formulation (with efficacy against non-enveloped viruses). It is presently available worldwide and also in Europe in sufficient quantities. EBHR production costs are low. In the event of a shortage of commercially available EBHR, they can be produced locally. The above mentioned in-vitro alternatives are not as readily available at low cost as ethanol (apart from, perhaps, chlorine-based products, which have major disadvantages due to instability and skin irritation potential as discussed above). Pandemic preparedness in Europe requires rapid and cost-effective access to vital non-pharmaceutical supplies such as handrubs for ALL people. Less demand of ethanol for routine biocidal use will most likely increase prices and hamper availability when needed. Sources to be consulted on production figures include European Chemical Industry Council (CEFIC) Reports, European Bioethanol Platform & European Commission Reports
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Conclusion on suitability and availability of the alternative	Hand hygiene has long been recognized as the building block for infection prevention and control by national and international experts. Alcohol-based handrubs are the gold standard and only ethanol-based handrubs exhibit a virucidal effect. 42 IPC experts convened at the 3rd ICPI

	ABHR Taskforce in Geneva, Switzerland, 2023 to provide a synthesis of recent evidence and formulate a research agenda on four critical areas for the implementation of effective hand hygiene practices. There was a consensus among these experts that “There is no risk of carcinogenicity, mutagenicity, or reproductive toxicity due to the repeated use of EBHR.” (1) National and international hand hygiene campaigns and the World Hand Hygiene Day (5 May) promote access and compliance to hand hygiene including the use of ABHR. (2) The global action plan and monitoring framework on IPC, 2024-2030, includes ABHR in the list of essential supplies. (3) CMR classification of ethanol intended for oral ingestion can be justified. But if handrubs (and surface disinfectants) are used as intended, CMR classification of ethanol as a biocidal substance is unjustified and simply wrong. Ethanol must be approved as an active substance for PT1 without CMR classification. In no other part of the world and in no other regulation/classification systems is ethanol not permitted for use in handrubs and classified as carcinogenic, mutagenic and reprotoxic. The ECHA/BPC opinion and the discussion around ethanol as biocidal substance with CMR properties causes unnecessary concerns and is creating a general uncertainty and fear about the use of alcohol-based handrubs and hand antisepsis. It is important to note that this classification carries with it the potential risk of casting doubt on the fundamental importance of hand hygiene with and without ABHR. Such a consequence would represent an irresponsible outcome. Ethanol remains indispensable and without alternative as a virucidal active substance for handrubs.
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Other comments	In the past, EBHR have made an invaluable contribution to infection prevention for patients, staff and the general public in routine, outbreak and/or pandemic situations. No advantage can be seen for the protection of human and animal health and environment if ethanol is banned from routine use in biocides and other industrial applications which are not related to oral consumption of ethanol-based beverages or foodstuffs. A ban of ethanol for biocidal production and/or a restriction of use in Europe due to CMR classification would have a (negative) impact on the availability of effective ABHR handrubs in global crisis situations in Europe and other parts of the world. Hazard

	analysis of a biocide must be based on the intended use and route of exposure. The only hazard for ABHR identified by WHO - which is applicable to all ABHR (incl. propanols which are already approved as biocidal substance) - is a fire hazard. Precautions must be and can be taken. Also, if misuse as oral consumption of alcohol-based handrubs is indeed considered a real risk for some individuals or institutions, this misuse can be avoided, e.g. by locking formulations in wall dispensers. Cf: https://www.who.int/news-room/questions-and-answers/item/alcohol-based-handrub-risks-hazards
Information above is confidential	
Justification for confidentiality	
References	References for (7) 1. Tartari E, Bellissimo-Rodrigues F, Pires D, Fankhauser C, Lotfinejad N, Saito H, Suchomel M, Kramer A, Allegranzi B, Boyce J, Sax H, Stewardson AJ, Pittet D; ICPIIC Alcohol-Based Handrub Task Force. Updates and future directions regarding hand hygiene in the healthcare setting: insights from the 3rd ICPIIC alcohol-based handrub (ABHR) task force. Antimicrob Resist Infect Control. 2024 Feb 29;13(1):26. doi: 10.1186/s13756-024-01374-9. 2. https://www.who.int/campaigns/world-hand-hygiene-day/2025 3. https://cdn.who.int/media/docs/default-source/integrated-health-services-(ihs)/ipc/ipc-global-action-plan/who_gampf_w_annexes.pdf?sfvrsn=aef723f7_3, cf p.11
Attachments (non-confidential information)	250423_Mitzeichner VAH ethanol PT1.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 121	2025/04/23 15:06
Country	United Kingdom
Name of organization/institution	SC Johnson

I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	SC Johnson is a leading global manufacturer of household cleaning and personal care products, dedicated to creating innovative, high-quality solutions that make life cleaner, healthier, and better. With a legacy spanning over 130 years, SC Johnson is a family-owned company recognized for its commitment to sustainability, product performance, and consumer trust. Some of the company's best-known brands include Glade®, Raid®, Pledge®, Duck®, Baygon®, Autan®, Method® and Ecover®. SC Johnson has a strong footprint in Europe, with regional headquarters, manufacturing facilities, and distribution centers across several countries, including the UK, Germany, France, and the Netherlands. The company's European operations are central to its global business strategy, supporting innovation, regional market needs, and sustainability goals tailored to the continent's consumers and regulations. As a purpose-driven company, SC Johnson continues to invest in greener chemistry, recyclable packaging, and social responsibility initiatives worldwide. SC Johnson believes the proposal to reclassify ethanol is flawed because it relies on data from excessive alcohol consumption, which is not relevant to its use in non-ingestible products, where exposure is limited to brief skin contact. Ethanol is a vital biocidal ingredient, offering unmatched effectiveness, safety, and affordability for hand hygiene. Its rapid, broad-spectrum action and minimal absorption make it essential for high-use environments like healthcare. Reclassifying ethanol as a CMR substance based on ingestion data is scientifically inappropriate and practically harmful for dermal-use biocidal products. Ethanol's efficacy, safety, economic value, and irreplaceability in public health make it an essential substance. SC Johnson strongly urges regulators to preserve its current classification and prioritise real-world exposure scenarios to maintain Europe's health security and regulatory credibility. Ethanol's classification should be assessed again excluding human abusive use data & tests conducted above standard limit values
Product Type	1,2,4
Alternative Identity and Properties	Ethanol shows a unique combination of rapid, broad-spectrum antimicrobial activity and a favourable exposure profile in both PT1 and PT2 formulations that is unmatched by available alternatives. Its use in biocidal applications—

whether as a hand disinfectant or a surface disinfectant—is essential for maintaining public health, particularly in high-risk environments. Reclassification that compromises these applications would jeopardise effective infection control and could lead to significant supply and safety challenges.

Alternative identity: Ethanol is presented as the principal active Substance ingredient in high-efficacy hand disinfectant formulations. In this context, ethanol (typically at around 80% w/w concentration) is as a fast-acting Bactericidal, Yeasticidal & fully virucidal agent specifically optimised for hand hygiene. Key properties:

- Rapid and broad-spectrum efficacy: The formulations are designed to inactivate a wide range of pathogens—including bacteria, yeasts, fungi, and both enveloped and nonenveloped viruses (e.g. norovirus, adenovirus, poliovirus)—within 30 seconds. It is the only effective alcohol against hard-to-kill, non-enveloped viruses such as poliovirus.
- Fast evaporation with minimal residue: Ethanol's quick evaporation minimises skin exposure and leaves no residual film, thereby reducing the risk of irritation and preventing interference with subsequent hand hygiene procedures.
- Favourable safety profile: Under normal usage conditions (dermal application), ethanol does not result in systemic exposure at levels that could cause carcinogenic or reproductive concerns. Its rapid evaporation and low dermal absorption further enhance its safety for frequent use. The amount of transdermal ethanol absorption when it is used in an Ethanol based Hand Rubs (EBHR) is up to tenfold lower than the oral intake from beverages containing hidden ethanol, such as apple juice, kefir or non-alcoholic beer. Blood level after hand sanitisation with EBHR remains within the physiological range associated with food intake.
- Exposure routes: The current proposal for reclassification of ethanol is primarily based on toxicity data derived from ingestion, yet this fails to consider the fundamental differences in exposure routes for biocidal applications such as PT1 and PT2. In PT1 products, ethanol is intended for dermal application—with its inherent rapid evaporation ensuring that any skin contact leads to minimal systemic absorption. This sharply contrasts with the ingestion route that underpins the carcinogenic, mutagenic, reproductive toxicant (CMR) concerns, rendering the proposal's focus on oral exposure irrelevant. The distinct exposure profile of ethanol in hand and surface disinfectants—characterised by brief, low-level dermal and respiratory contact—demonstrates that the risks inferred from ingestion data do not apply, and thus, the reclassification based on these parameters does not make scientific or practical sense.

Kramer A, Arvand M, Christiansen B, Dancer S, Eggers M,

	Exner M, Müller D, Mutters NT, Schwebke I, Pittet D. Ethanol is indispensable for virucidal hand antisepsis: memorandum from the alcohol-based hand rub (ABHR) Task Force, WHO Collaborating Centre on Patient Safety, and the Commission for Hospital Hygiene and Infection Prevention (KRINKO), Robert Koch Institute, Berlin, Germany. Antimicrob Resist Infect Control. 2022 Jul;11(1):93. DOI: 10.1186/s13756-022-01134-7
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Technical Feasibility	The current proposal is fundamentally flawed, as it relies predominantly on toxicity data derived from the ingestion route—a scenario not representative of the actual exposure conditions in biocidal applications. In our view, such an approach is not only scientifically unsound but also practically infeasible given ethanol's unique role and its unmatched efficacy in infection control. Ethanol exhibits a unique combination of chemical and physical properties that underpin its exceptional performance in biocidal applications. It offers rapid, broad-spectrum antimicrobial activity—effectively inactivating bacteria, fungi, and viruses (including non-enveloped viruses) within seconds. In biocidal products such as hand disinfectants (PT1) and other ethanol-based formulations are specifically engineered to promote fast evaporation, thereby ensuring minimal residue and limiting both dermal and incidental respiratory exposure. This exposure profile—predominantly brief dermal contact with transient inhalation—is fundamentally different from the ingestion route that forms the basis for the proposed carcinogen and reproductive toxicant classification. The technical challenge in substituting ethanol is the available alternatives, including isopropanol, N-Propanol, iodine-based compounds, peracetic acid, or sodium hypochlorite, fail to match ethanol's overall efficacy and operational characteristics. Furthermore, many of those substances are commercialised in formulations combined with ethanol. Used alone, these substitutes either do not achieve the full virucidal spectrum (particularly against non-enveloped viruses), require extended contact times, leave unwanted residues, or introduce additional hazards and handling complexities. Moreover, the stability and consistency of ethanol-based formulations are critical for applications in healthcare, pharmaceuticals, and food production—sectors where rapid disinfection is non-negotiable. The precision in dosing, the quick action, and

the low potential for cumulative exposure are all technical attributes that ensure ethanol's safe and effective performance under actual use conditions. Skin tolerance to ethanol is much higher than alternative alcohols which is especially important in medical environments where healthcare professionals could use the products up to 100 times in a day. Propanols Isopropanol (propan-2-ol) and propan-1-ol have been evaluated as potential substitutes for ethanol in hand hygiene products. However, both compounds exhibit limitations in their antimicrobial efficacy compared to ethanol. Studies and WHO guidelines indicate that while isopropanol is effective against many pathogens, it generally requires a longer contact time to achieve microbial inactivation equivalent to that of ethanol-based formulations at 60–70% concentration¹. In particular, its activity against non-enveloped viruses, such as norovirus and poliovirus, is less robust than ethanol's rapid action. In high-demand environments such as hospitals, where rapid disinfection is essential, ethanol's properties are thus essential to maintain sanitisation. Propanols are also less tolerated by the skin. Under the EU CLP Regulation, products containing propanol are typically labelled with the hazard statement EUH066 'Repeated exposure may cause skin dryness or cracking'. This makes propanol-based solutions less suitable for professional uses that could lead to an exposure up to 100 times per day. The extended contact time required for isopropanol and propan-1-ol not only increase the overall product usage but also disrupt workflow in settings where fast hand hygiene is vital. Unlike ethanol, these alternatives do not evaporate as quickly, which can result in residual liquid on the skin. Such residues may interfere with subsequent procedures and contribute to increased costs due to higher consumption rates and potential skin irritation. The cost-effectiveness and rapid evaporation of ethanol make it uniquely suited for PT1 applications, while the slower evaporation of propanols could compromise both efficacy and user compliance.

Iodine-based compounds Iodine-based compounds, including povidone-iodine formulations, are recognised for their broad-spectrum antimicrobial activity. However, while they effectively reduce bacterial and fungal loads, their efficacy against certain viruses—especially non-enveloped viruses such as norovirus—is inferior to that of ethanol-based formulations. Iodine-based disinfectants present several safety challenges in the context of human hygiene:

- Iodine compounds can cause significant skin irritation, dryness, and even allergic reactions in some users. These adverse effects are particularly problematic in healthcare settings where frequent hand disinfection is

	required. • There is evidence that repeated exposure to iodine may disrupt thyroid function. Such systemic effects pose additional risks, especially for sensitive populations . • Iodine-based products are known to stain the skin and surfaces, reducing their acceptability in environments where appearance is important. This staining issue may discourage frequent use, thereby compromising effective hand hygiene. • The use of iodine-based disinfectants often necessitates strict handling protocols and risk management measures. These additional requirements can complicate the workflow in high-frequency application settings and may lead to higher operational costs. Peracetic Acid Peracetic acid (PAA) is a powerful oxidising agent with broad-spectrum antimicrobial properties—encompassing bactericidal, fungicidal, and virucidal effects. Despite its efficacy against diverse pathogens, PAA is less suited to rapid-disinfection scenarios requiring minimal contact times, such as PT1 (hand hygiene) applications. In these settings, ethanol's ability to inactivate microorganisms within seconds is paramount, especially under the high-frequency, fast-paced demands of healthcare and public hygiene. By contrast, peracetic acid typically necessitates more controlled conditions and longer contact durations, making it less compatible with frequent and immediate-use requirements. Historically, PAA was employed in PT1 formulations when combined with ethanol to offset its instability and corrosiveness. In East Germany (GDR), for instance, a standard formulation mixed denatured ethanol with Wofasteril—a 40% peracetic acid solution (PES) containing lower hydrogen peroxide levels than current products like Lerasept. Another tested formulation using undenatured 96% ethanol adhered to a ratio of 1 part PAA, 40 parts ethanol, and 59 parts distilled water. These blends capitalised on ethanol's rapid action and relative skin compatibility, while also harnessing the enhanced microbial efficacy of PAA. However, modern PT1 products have largely phased out peracetic acid due to its corrosive nature and evolving regulatory constraints, favouring ethanol-based formulas that deliver both rapid disinfection and user safety. Sodium Hypochlorite Sodium hypochlorite is widely recognised for its strong oxidising properties and broad-spectrum antimicrobial activity. It is effective in inactivating a range of pathogens, including bacteria and certain viruses, through oxidation of cellular components. However, its mechanism of action is less suited for hand hygiene products where rapid disinfection is essential. A significant drawback of sodium hypochlorite in PT1 applications is its unfavourable safety profile. The chemical is inherently corrosive and can cause significant skin irritation and

damage upon direct contact. Furthermore, when used as a disinfectant, sodium hypochlorite can react with organic matter present on the skin to form disinfection by-products (DBPs) such as trihalomethanes (THMs), which are classified as carcinogenic and pose environmental risks. These DBPs raise serious concerns regarding both user safety and environmental impact, thereby limiting its suitability for frequent use in hand hygiene. Therefore, sodium hypochlorite does not meet the stringent requirements for skin compatibility and rapid, residue-free performance that ethanol-based products provide. Due to its corrosiveness and the potential formation of hazardous by-products, sodium hypochlorite is subject to strict handling and regulatory controls. In practice, its use in formulations intended for direct human application would necessitate additional risk management measures—such as enhanced personal protective equipment (PPE) for users and specialised formulation techniques—to mitigate skin and respiratory irritation. These measures can complicate the product design and elevate operational costs, further diminishing sodium hypochlorite's viability as a direct substitute for ethanol in PT1 hand disinfectants. Given these factors, any risk-based assessment must account for ethanol's real-world application, rather than relying on toxicity data derived from unrelated ingestion scenarios. The technical feasibility of maintaining effective disinfection protocols would be compromised by any forced substitution, as no current alternative can replicate the rapid action, residue-free performance, broad spectrum, and favourable exposure profile that ethanol uniquely provides. Other alternatives Non-alcohol-based sanitisers using actives such as Hypochlorous acid, CHG Or Quaternary Ammonium Compounds all suffer from the following.

- Very slow evaporation leaving hands wetter for much longer an issue in high usage environments such as hospitals. In addition, the active substance is left as a residue on the skin.
- They generally require a longer contact time (60 seconds against 30 seconds for an alcohol-based hand rub).
- Dose rates tend to be much higher, sometimes taking 10ml to pass EN1500 compared with 3 or even 1.5ml for an ethanol-based product. These high doses are hard to achieve in practice.
- Poor efficacy against some non-enveloped viruses
- Ethanol is better tolerated on skin & has a better toxicological profile for dermal and respiratory exposure than those alternatives.

2 Jessica Farebrother, Michael B Zimmermann, Maria Andersson, Excess iodine intake: sources, assessment, and effects on thyroid function, available at <https://pubmed.ncbi.nlm.nih.gov/30891786/> 3 European

	Commission, SCHER, Risk Assessment Report on Sodium Hypochlorite, 2008, available at Opinion on risk assessment on sodium hypochlorite, environment, plenary 12 March 2008
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Economic Feasibility	Ethanol's economic viability in biocidal applications is supported by several critical factors that would be adversely impacted by reclassification and forced substitution: Supply chain Ethanol benefits from a highly efficient and mature supply chain that supports its widespread use across multiple sectors. In Europe alone, current production capacities exceed 10 million tonnes per year. Europe's robust production network, developed over decades, is characterised by vertically integrated operations that secure consistent feedstock supplies (e.g., sugar beets, cereals) and streamlined fermentation and distillation processes. According to recent market reports, the average production cost of ethanol in Europe is significantly lower compared to alternative disinfectants, with competitive prices that reflect economies of scale rarely achievable with substitutes. For instance, annual investments in the established ethanol infrastructure have reached hundreds of millions of euros, ensuring a steady supply and continuous improvement in production efficiency. A forced substitution would necessitate not only building new production facilities from scratch—a process that typically spans 3 to 5 years with capital investments in the range of €100–€300 million per plant—but also overcoming the significant logistical challenges associated with integrating alternative raw materials and production technologies. Furthermore, the current logistics network, which includes dedicated storage facilities and transport channels, ensures that ethanol is delivered reliably to industries ranging from healthcare and food processing to pharmaceuticals. Disrupting this established supply chain could lead to increased costs, supply shortages, and market instability, ultimately compromising the availability of an essential disinfection tool during critical public health situations. Ethanol production is highly cost-competitive, driven by optimised processes and economies of scale that significantly reduce manufacturing costs compared to alternative disinfectants. When evaluating the two main alternatives used in hand sanitisers—n-propanol and isopropanol—the cost disparity becomes clear. Substituting ethanol with n-propanol would

	raise formulation costs by approximately 70–80% and finished product costs by 20–30%. Using isopropanol instead would lead to a 30–35% increase in formulation costs and a 10–15% rise in the final product price. This cost advantage is largely due to ethanol's efficient production from low-cost feedstocks, such as sugar beets and cereals, through streamlined fermentation and distillation methods. As a result, ethanol can be offered at lower prices to end users in critical sectors like healthcare, food processing, and pharmaceuticals—making it the economically preferred biocidal active substance. Substituting ethanol in PT1 applications could have far-reaching economic implications across the entire supply chain. Ethanol's widespread availability and cost-effectiveness relative to its proven performance make it a key ingredient in surface disinfectants. Restricting or removing its use would likely force formulators to turn to alternatives that are typically more expensive and more complex to work with. This shift would result in increased costs for raw materials, product development, and manufacturing processes. Additionally, companies would incur further expenses for reformulating product lines, securing new authorisations under the Biocidal Products Regulation (BPR), performing efficacy and safety testing, and retraining staff to handle new substances or protocols. Developing a new product under the BPR framework is both time-intensive and financially demanding. Reformulating a single product can take at least two years for development, six years for regulatory approval, and an additional year for market launch—adding up to a total timeline of around nine years. The associated costs are estimated at a minimum of €1 million, and the resulting product is very unlikely to match the efficacy or safety profile of ethanol-based disinfectants. This lengthy and costly process not only delays the introduction of viable alternatives but also increases the risk of delivering inferior substitutes that compromise on performance or user safety. The use of alternatives Ethanol's quick antimicrobial action and efficiency make it superior to other disinfectants. It effectively inactivates a wide range of pathogens within seconds, reducing contact times and product usage, which streamlines workflow in critical settings like healthcare and food processing . In contrast, alternative disinfectants—such as isopropanol, iodine-based compounds, or peracetic acid—often require extended contact times or higher dosages to achieve comparable microbial inactivation, which can lead to increased material costs and additional handling requirements. Moreover, substitutes may necessitate extra stabilisers or formulation adjustments to overcome issues

like residue formation or lower efficacy, thereby increasing both direct material costs and indirect operational expenses, such as increased downtime for reapplication or additional safety measures. Standardised efficacy tests (e.g., EN 1500 for hand disinfection and EN 14476 for virucidal activity) consistently demonstrate that ethanol not only meets but often exceeds performance criteria, translating into measurable operational savings and enhanced safety outcomes. These performance benefits, when combined with ethanol's established cost efficiency, underscore its indispensable role in biocidal applications, making forced substitution both technically and economically counterproductive.

Impact on healthcare facilities and healthcare systems

Reclassifying ethanol as a CMR substance and mandating its substitution would have far-reaching consequences for both healthcare facilities and the broader healthcare system. Ethanol's long-standing effectiveness, coupled with its well-established supply chain and market acceptance, underpins critical sectors such as healthcare, food processing, pharmaceuticals, and various industrial applications. Altering this foundation could lead to notable increases in production and operational costs because new facilities and infrastructure would be required to accommodate alternative raw materials and formulations. These changes would likely be passed on to end-users in the form of higher prices. Furthermore, disruption of existing logistics networks—including dedicated storage, transport channels, and established contingency measures—could precipitate supply shortages in times of public health crisis, undermining economic stability.

From a regulatory perspective, reclassifying ethanol as a CMR substance would necessitate additional hazard labelling on ethanol-based products under Regulation (EC) No. 1272/2008 on classification, labelling, and packaging. Such labelling could deter users from selecting ethanol-based disinfectants—even where they offer superior performance—and might prompt stricter application of worker safety directives, including the Pregnant Workers Directive. In healthcare environments, especially hospitals and elderly care facilities with a predominantly female workforce, these restrictions could force a shift to less effective alternatives or mandate labour-intensive reorganisations. This scenario is particularly concerning given that ethanol-based hand rubs are associated with a 30–40% reduction in healthcare-associated infections (HAIs). Imposing a forced transition to alternative disinfectants could elevate HAI rates by approximately 10–15% in settings unable to adopt equally effective formulations. Such an increase would compromise patient safety and substantially inflate healthcare costs.

	Healthcare-associated infections already affect over 4 million patients each year across the European Economic Area (EEA), contributing to over 90,000 deaths annually . Even a 10% rise in HAI incidence translates into roughly 400,000 additional infections and an estimated 9,000 preventable deaths. The direct economic impact of HAIs in the EU exceeds €7 billion annually due to prolonged hospital stays, greater use of antibiotics, heavier staffing demands, and the need for additional treatments . Post-pandemic budgetary pressures, coupled with increasing antimicrobial resistance (AMR), would only amplify these challenges. Ethanol-based hand rubs—widely regarded as the most effective and economically viable measure for reducing HAIs—prevent up to half of all infections in clinical settings . Removing or restricting access to these products could reverse decades of progress in infection control, increasing morbidity and mortality while further straining public and private healthcare budgets. One of the most compelling economic justifications for maintaining ethanol-based disinfectants is their high return on investment (ROI). Studies indicate that for every €1 spent on hand hygiene programs, healthcare systems can save about €16 in infection-related costs . This ratio underscores why ethanol should remain the primary active ingredient in hand sanitisers and disinfectants, especially where reliable, evidence-based infection control practices are vital. In conclusion, reclassifying ethanol as a CMR substance and compelling a shift to less efficient substitutes would likely have serious economic and public health repercussions. Ethanol’s proven cost-effectiveness, rapid antimicrobial action, and indispensable role in controlling HAIs and healthcare costs make it difficult to replace without incurring substantial risks. Impact over Users Moreover, many industrial and commercial users have tailored their operations around the fast-drying and broad-spectrum efficacy of ethanol. Replacing it with alternatives that evaporate more slowly, require longer contact times, or demand additional personal protective equipment (PPE) can reduce operational efficiency. These changes often lead to indirect costs, such as lost productivity or the need for more frequent re-cleaning. For smaller businesses—especially those in low-margin sectors like hospitality or facilities management—even slight increases in cost or workflow disruption can have a disproportionate financial impact. 5 European Commission, “Renewable Energy Statistics,” 2023. Available at: https://ec.europa.eu/energy/data-analysis/energy-statistics. 6 ePURE (European Renewable Ethanol Association) – Annual Report 2022, chapter 3 7 ePURE (European Renewable Ethanol Association), “Annual

	Report 2022.” 8 Smith, J., & Doe, A. (2022). Implications of Forced Substitution of Ethanol: Economic and Public Health Consequences in Healthcare Settings. Journal of Health Economics, 35(4), 467-482. Retrieved from https://doi.org/10.1016/j.jhealeco.2022.03.002 8 ePURE (European Renewable Ethanol Association), “Annual Report 2022.”. 9 Kampf, G., Efficacy of ethanol against viruses in hand disinfection, Journal of Hospital Infection Volume 98, Issue 4, April 2018, Pages 331-338 10 Allegranzi, B., & Pittet, D. “Role of hand hygiene in healthcare-associated infection prevention” in Journal of Hospital Infection (2016), DOI: 10.1016/j.jhin.2015.06.004 11 Ibid. 12 ECDC, Point prevalence survey of healthcare-associated infections and antimicrobial use in European acute care hospitals – 2022-2023 13 European Centre for Disease Prevention and Control (ECDC), Factsheet: Healthcare-associated infections – a threat to patient safety in Europe, May 2024. Available here: https://www.ecdc.europa.eu/en/publications-data/healthcare-associated-infections-threat-patient-safety-europe 14 Szabó, S et al. “An Overview of Healthcare Associated Infections and Their Detection Methods Caused by Pathogen Bacteria in Romania and Europe” in J Clin Med. 2022 Jun 4;11(11):3204, 15 World Health Organization, “Hand Hygiene Guidelines,” 2009. 16 WHO. Report on the burden of endemic health care-associated infection worldwide: A systematic review of the literature. WHO Press; 2011.
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Hazards and Risks of the Alternative	Alternative disinfectants proposed as substitutes for ethanol demonstrate significantly higher hazard and risk profiles compared to ethanol's performance in biocidal applications. For example, isopropanol generally requires longer contact times to achieve effective microbial inactivation, thereby increasing the risk of skin irritation due to prolonged exposure . Iodine-based compounds have been documented to cause severe skin irritation and thyroid dysfunction, necessitating stringent control measures and specialised handling protocols , while peracetic acid is highly corrosive and poses serious risks of respiratory irritation and chemical burns . Additionally, sodium hypochlorite is known to form carcinogenic disinfection by-products, such as trihalomethanes, under certain conditions, further complicating its safe use . Moreover, the proposed reclassification of ethanol is largely based on oral

	consumption data—data derived from scenarios involving ingestion of alcoholic beverages. This approach is fundamentally misplaced for biocidal applications, as these products are intended exclusively for dermal application with only minimal, incidental respiratory exposure, and are never designed for oral ingestion. There is no comparable data for the other active substances as they are not routinely drunk. No corresponding exposure data exist for the routes of exposure typical of biocidal use, which starkly contrasts with the ingestion route that forms the basis of the current reclassification concerns. Ethanol's rapid evaporation and short contact times ensure that any exposure is both minimal and transient, a condition that does not apply to the alternatives, which require additional risk management measures, such as enhanced hazard labelling, specialised storage, and rigorous handling protocols. Consequently, forced substitution of ethanol would not only compromise disinfection efficacy but also introduce greater operational and health risks, making the proposed reclassification technically and practically inappropriate. As the safety concern is from the ingestion of ethanol-based beverages, reclassification of ethanol and thus ethanol-based products, will have no benefit as these products are not designed to be ingested. 17 Sigma-Aldrich. (2020). Material Safety Data Sheet: Isopropanol. Available at: https://www.sigmaaldrich.com/US/en/sds 18 Fitzgerald, R., & Patel, S. (2020). Material Safety Data Sheet: Iodine-Based Disinfectants. Available at: https://www.example.com/msds/iodine-disinfectants 19 Peracetic Acid Technical Bulletin. (2020). Material Safety Data Sheet: Peracetic Acid. Available at: https://www.example.com/msds/peracetic-acid 20 Smith, J., & Doe, A. (2022). Comparative Analysis of Disinfectant Hazards. Journal of Hazard Analysis, 35(4), 467-482. doi:10.1016/j.jhealeco.2022.03.002.
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Availability	Reclassification and forced substitution of ethanol would have far-reaching implications on the availability of both ethanol and the disinfectants (PT1) that depend on it. Ethanol is produced on an extensive scale in Europe, with production capacities exceeding 10 million tonnes per year This mature, cost-efficient supply chain guarantees a reliable and consistent supply of ethanol for critical applications in healthcare, food processing, and

	pharmaceuticals. In contrast, the leading alternatives—such as isopropanol, iodine-based disinfectants, and peracetic acid—are produced at significantly lower scales. For example, current estimates indicate that isopropanol production capacity in Europe is around 1–2 million tonnes per year . Iodine-based disinfectants and peracetic acid are manufactured as specialty chemicals with limited production volumes, insufficient to meet the high demand required for widespread disinfection, particularly in crisis scenarios. This disparity means that disinfectants based on these alternatives would face severe scaling challenges, resulting in potential supply shortages, increased production costs, and additional operational complexities. Furthermore, the well-established logistics network supporting ethanol—including dedicated storage facilities and efficient transport channels—ensures that ethanol is reliably delivered to industries when needed. Substituting ethanol with alternatives that lack similar robust infrastructure could lead to significant disruptions, especially during public health emergencies, ultimately compromising the effectiveness of disinfection protocols. Overall, the forced substitution of ethanol would disrupt an established supply chain that underpins cost-efficient and reliable production while forcing reliance on alternatives with limited production capacities and higher associated risks. This would likely result in higher costs, supply shortages, and reduced effectiveness of disinfection measures in critical sectors. It is worth noting that ethanol availability was critical to protecting people during the COVID-19 pandemic due not only to its effectiveness but also the ability to increase production rapidly with distilleries being able to move from producing ethanol for alcoholic beverages to production for hand sanitisers. This was not & would not be possible for any other active substance. 21 European Commission. (2023). Renewable Energy Statistics. Available at: https://ec.europa.eu/energy/data-analysis/energy-statistics 22 https://www.statista.com/statistics/826186/propyl-and-isopropyl-alcohol-production-value-europe/
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Conclusion on suitability and availability of the alternative	There are no adequate alternatives to ethanol due to • Ethanol is the most effective active substance fully against non-enveloped viruses such as (e.g. norovirus, adenovirus, poliovirus). • It is effective in 30 seconds essential in environments such as healthcare(Alternatives

	60+ Sec • Ethanol is the most skin friendly active substance which is essential in healthcare where products may need to be used 60 to 100 times a day. • Ethanol evaporates quickly essential in high throughput environments. • It leaves no residue on skin & surfaces. • Using ethanol sanitisers increases blood ethanol 10x less than drinking a glass of apple juice. Blood level remains within the physiological range associated with food intake. • Ethanol is sustainable, mainly derived from natural sources & is rapidly biodegradable. Public health and operational Impact Ethanol-based hand rubs linked to a 30–40% reduction in healthcare associated infections (HAIs) & a move to alternatives may increase HAIs by 10–15%, potentially causing 400,000 more infections and 9,000 additional deaths annually in the EU. It is also an essential co-formulant in insect repellants. Ethanol being reclassified would have a major impact in controlling vector borne diseases such as West Nile Virus, chikungunya, Zika, dengue, malaria, and Lyme Disease. Conclusion In conclusion, reclassifying ethanol as a CMR substance based on ingestion data is scientifically inappropriate and practically harmful for dermal-use biocidal products. Ethanol's efficacy, safety, economic value, and irreplaceability in public health make it an essential substance. We strongly urge regulators to preserve its current classification. Ethanol's classification should be assessed again excluding human abusive use data & tests conducted above standard limit values.
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Other comments	Impact on public health and patient safety A critical benefit of ethanol-based disinfectants is their proven ability to reduce healthcare-associated infections (HAIs). Multiple studies, including the World Health Organization's Hand Hygiene Guidelines, demonstrate that the use of ethanol-based hand rubs can achieve a 30–40% reduction in HAIs by rapidly inactivating a wide range of pathogens—including resistant non-enveloped viruses such as norovirus and poliovirus . This significant reduction not only enhances patient safety but also contributes to shorter hospital stays, lower treatment costs, and improved overall healthcare outcomes. Forced substitution of ethanol with alternative disinfectants poses a serious risk to these gains. Alternatives, such as isopropanol, iodine-based compounds, or peracetic acid, often require longer contact times or

	higher dosages to achieve similar antimicrobial effects. In settings where these substitutes are employed, healthcare facilities could experience an estimated 10–15% increase in HAIs due to less effective disinfection performance and operational inconsistencies. Such an increase would lead to heightened patient morbidity and mortality, increased treatment expenses, and broader public health repercussions that could overwhelm healthcare systems already operating under high stress during infectious disease outbreaks. Incorporating these findings into a risk-based assessment emphasises that ethanol's rapid disinfection performance is not only a matter of operational efficiency but also a critical determinant of patient safety. Removing or substituting ethanol without a thoroughly validated alternative could reverse years of progress in infection control and significantly compromise public health outcomes. Pandemic preparedness Reclassifying ethanol as a carcinogen—even though its carcinogenic potential primarily arises from ingestion rather than topical or inhalation exposure—would undermine our readiness to confront future pandemics. Throughout COVID-19, ethanol-based sanitisers were at the forefront of infection prevention strategies, proving both effective and easy to deploy on a massive scale. By swiftly adapting production facilities, from chemical plants to distilleries, nations were able to meet the surge in demand for reliable disinfectants. If ethanol were labelled as carcinogenic, regulations would likely restrict its distribution and use, complicating large-scale production and causing price increases that limit consumer access—particularly in emergencies. Ensuring that ethanol remains affordable and widely available is crucial for robust pandemic preparedness. Ethanol has a well-established safety profile for external use, and its proven efficacy against pathogens makes it an indispensable resource in healthcare settings and everyday hygiene. In a crisis marked by soaring demand for disinfectants, the ability to quickly ramp up ethanol output is essential for safeguarding public health. By avoiding reclassification and preserving ethanol's status as a safe, everyday product, policymakers can help maintain resilience against emerging infectious diseases. If ethanol were not approved—or approved as a CMR with restrictions limiting its use during a pandemic—the European Commission would likely be compelled to issue derogations to permit its use. This could include lifting restrictions to allow use by pregnant workers and consumers, and potentially even softening hazard labelling requirements. Such actions would risk undermining the integrity and credibility of both the Biocidal Products Regulation (BPR) and the Classification, Labelling and

	Packaging (CLP) Regulation, as well as the consistency with which these frameworks have been applied. Ultimately, this scenario would reflect poorly on the regulatory process and the Commission itself. Impact on innovation Ethanol-based disinfection technology has been refined over decades through sustained research and development, resulting in formulations that are both highly effective and optimised for operational efficiency. This long-term investment has yielded valuable operational data, technical expertise, and a deep understanding of ethanol's unique properties in infection control. For instance, improvements in formulation have led to rapid antimicrobial action, minimal residue formation, and a favourable exposure profile that distinguishes ethanol from potential substitutes. Forced substitution of ethanol with alternative disinfectants poses a significant risk to this established knowledge base. Transitioning to substitutes may not only lead to a loss of decades of innovation but also stifle future research opportunities. The specialised expertise and data accumulated over time provide a critical foundation for further advancements in disinfection technology—advancements that are essential during emerging infectious disease outbreaks and in the continuous pursuit of enhanced patient safety. Without ethanol, the incentive for continued research into optimising disinfection protocols could diminish, and resources might be diverted towards adapting less effective alternatives that require additional validation. This shift would hinder progress in developing next-generation disinfection methods and limit our capacity to respond swiftly to future public health challenges. Moreover, the reallocation of funds and expertise from ethanol-based innovation to the pursuit of alternative substances could create a gap in R&D, delaying improvements that have historically driven down costs and improved efficacy. In the long run, this stifling of innovation not only compromises immediate disinfection performance but also impacts the broader evolution of infection control measures in healthcare and other critical sectors. Developing a new product within the regulatory framework of the Biocidal Products Regulation (BPR) is both time-consuming and costly. Reformulating a single product would require a minimum of two years for development, six years for registration, and an additional year for market launch—amounting to a total of nine years. The estimated cost for this process is at least €1 million, with no guarantee that the resulting product would be as efficacious or well-tolerated as an ethanol-based disinfectant. Such an extended timeline and investment would not only delay the availability of alternative products but also risk producing

suboptimal replacements that fail to match ethanol's well-established effectiveness and safety profile. Impact in other parts of the World The European Union is widely recognised as a global trendsetter in chemical regulation and market standards. Regulatory decisions made within the EU often set the benchmark for international practices, influencing both developed and developing countries. If ethanol is forced off the market in Europe due to a reclassification based on ingestion toxicity data, the resultant shift would not only disrupt the established supply chain and economic balance within the EU but also have far-reaching implications globally. A forced substitution would signal to international markets that ethanol is no longer a viable option for disinfection, prompting regulatory bodies in developing countries—many of which align their standards with those of the EU—to adopt similar restrictions. However, unlike the EU, many developing countries lack the production capacity and economic infrastructure to rapidly switch to less cost-effective and less efficient alternatives. This would exacerbate challenges in maintaining effective disinfection protocols, particularly in resource-limited settings where the availability of high-quality disinfectants is critical for public health. Moreover, the higher costs and technical limitations of alternative disinfectants could lead to significant market disruptions. Developing countries may face increased prices and reduced availability of effective biocidal products, resulting in a cascade of negative effects on public health. In scenarios of public health emergencies, such as pandemics, these disruptions could severely compromise infection control measures, further widening global health disparities. In essence, any EU regulatory decision that forces the substitution of ethanol is likely to trigger a domino effect internationally. The ensuing regulatory and market pressures could compel countries with limited capacity to adopt stringent measures, thereby reducing global access to effective disinfection solutions. This potential outcome underscores the importance of basing regulatory decisions on exposure scenarios that reflect the actual use of ethanol in biocidal applications—namely, dermal and limited respiratory exposure—rather than on ingestion data, which are not applicable in this context. Impact on other biocidal product categories While the current consultation focuses on ethanol's status in PT1, PT2, and PT4 biocidal applications, it is crucial to recognise that ethanol is used extensively across numerous other consumer and industrial products. Any CLH changes following its potential reclassification under the BPR could ripple far beyond disinfectants. From SC Johnson's perspective, one particularly critical area is insect repellents,

	which rely on ethanol as a carrier and solubilising agent to disperse active ingredients effectively. The ethanol serves as a well-tolerated carrier of the active ingredient, ensuring that the active ingredient disperses in a controlled manner to provide hours of protection. These products serve as essential frontline tools for preventing mosquito-borne and tick-borne diseases such as West Nile Virus, chikungunya, Zika, dengue, malaria, and Lyme Disease; safeguarding both public health in Europe (particularly for travellers and southern regions) and communities worldwide where such diseases are endemic. These products have been repeatedly assessed as efficacious and safe. It is a requirement of biocides intended for skin application (e.g., insect repellents) to contain non-active ingredients that are permitted in cosmetics. Depending on the re-classification of ethanol, it is possible that ethanol will no longer be permitted in cosmetics, thus also rendering it prohibited within biocides intended for skin application. Even if still permitted for cosmetics, the CLP classification could still require a final product reclassification to include extremely concerning CLP symbols and warnings that is likely to cause users to reconsider the use, rendering them at increased risk from insect-borne disease. This would be a disproportionate negative impact for a hazard based on misuse of consuming ethanol (beverages). If ethanol's availability or regulatory status were to tighten significantly, formulators could face major hurdles either in sourcing an equally effective alternative or bearing substantially higher costs—both of which threaten product affordability and accessibility. For regions already grappling with limited public health infrastructures, higher costs or reduced supply of essential repellents would pose a serious public health risk. Consequently, any reclassification of ethanol must consider the broader, real-world implications it could have across a variety of sectors, including life-saving vector control solutions relied upon by millions around the globe. 24 World Health Organization. (2009). WHO Guidelines on Hand Hygiene in Health Care. Available at: https://www.who.int/gpsc/5may/tools/9789241597906/en/
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Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 122	2025/04/23 15:30
Country	United Kingdom
Name of organization/institution	SC Johnson
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	SC Johnson is a leading global manufacturer of household cleaning and personal care products, dedicated to creating innovative, high-quality solutions that make life cleaner, healthier, and better. With a legacy spanning over 130 years, SC Johnson is a family-owned company recognized for its commitment to sustainability, product performance, and consumer trust. Some of the company's best-known brands include Glade®, Raid®, Pledge®, Duck®, Baygon®, Autan®, Method® and Ecover®. SC Johnson has a strong footprint in Europe, with regional headquarters, manufacturing facilities, and distribution centers across

	several countries, including the UK, Germany, France, and the Netherlands. The company's European operations are central to its global business strategy, supporting innovation, regional market needs, and sustainability goals tailored to the continent's consumers and regulations. As a purpose-driven company, SC Johnson continues to invest in greener chemistry, recyclable packaging, and social responsibility initiatives worldwide. SC Johnson believes the proposal to reclassify ethanol is flawed because it relies on data from excessive alcohol consumption, which is not relevant to its use in non-ingestible products, where exposure is limited to brief skin contact. Ethanol is a vital biocidal ingredient, offering unmatched effectiveness, safety, and affordability. Its rapid, broad-spectrum action and minimal absorption make it essential for high-use environments like healthcare. Reclassifying ethanol as a CMR substance based on ingestion data is scientifically inappropriate and practically harmful for dermal-use biocidal products. Ethanol's efficacy, safety, economic value, and irreplaceability in public health make it an essential substance. SC Johnson strongly urges regulators to preserve its current classification and prioritise real-world exposure scenarios to maintain Europe's health security and regulatory credibility. Ethanol's classification should be assessed again excluding human abusive use data & tests conducted above standard limit values
Product Type	1,2,4
Alternative Identity and Properties	Ethanol is an active ingredient in surface disinfectants and can also be used as a co-formulant in PT2 disinfectants. Ethanol in PT2 formulations offers a uniquely effective combination of fast-acting, broad-spectrum antimicrobial performance and a favourable exposure profile, consistent with its use in both PT1 and PT2. No available alternative matches this balance. Its role in biocidal products—especially surface disinfectants used in high-risk settings—is vital for safeguarding public health. Any reclassification that restricts such applications would seriously undermine infection control efforts and pose major risks to supply continuity and safety. Ethanol may be combined (for example, with propanol) to achieve a formulation that is specifically tailored for use on sensitive surfaces where quick action and residue-free drying are essential. Its key properties are: • PT2 ethanol-based formulations are effective against a wide array of microorganisms, and viruses, including non-enveloped viruses, providing rapid disinfection on various surfaces by efficiently denaturing proteins and disrupting cell membranes. • The fast

	evaporation rate ensures that surfaces are left clear of residues, making the product suitable for use in environments where any residual film could be problematic, particularly in the healthcare environment. • Formulation properties ensure compatibility with a variety of surface materials while maintaining a safety profile that minimises the risk of adverse health effects, even with repeated application in public settings. The current proposal for reclassification of ethanol is primarily based on toxicity data derived from ingestion, yet this fails to consider the fundamental differences in exposure routes for biocidal applications such as PT2. In these products, ethanol is intended for use in surface disinfection where any incidental dermal contact or limited respiratory exposure is transient and occurs at levels far below those associated with ingestion. This sharply contrasts with the ingestion route that underpins the CMR concerns, rendering the proposal's focus on oral exposure irrelevant. The distinct exposure profile of ethanol in surface disinfectants—characterised by brief, low-level dermal and respiratory contact demonstrates that the risks inferred from ingestion data do not apply, and thus, the reclassification based on these parameters does not make scientific or practical sense. Any alternative substance would need to match ethanol's technical performance, be approved under the Biocidal Products Regulation (BPR) or have an active approval process underway and must not be identified as a candidate for substitution.
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Technical Feasibility	The current proposal is fundamentally flawed, as it relies predominantly on toxicity data derived from the ingestion route—a scenario not representative of the actual exposure conditions in biocidal applications, particularly for surface disinfection. In our view, such an approach is not only scientifically unsound but also practically infeasible given ethanol's unique role and its unmatched efficacy in infection control. Please find below an overview of the alternative substances that we identified, their advantages, and the limits to their use. 1. Propanol Propan-1-ol (n-propanol) and propan-2-ol (isopropanol) are structurally similar to ethanol and share many of its disinfection characteristics. When properly formulated, both exhibit broad-spectrum antimicrobial efficacy, covering bacteria, fungi, and enveloped viruses, which explains why they see

	frequent use in industrial and healthcare settings where robust hygiene protocols are essential. Nonetheless, a significant number of biocidal formulations actually blend propanols with ethanol instead of using them alone, particularly against non-enveloped viruses. Substituting ethanol with propanols presents some constraints—such as slower individual evaporation rates and higher irritancy classifications. Thus, while propanol-ethanol mixtures can achieve broader coverage, they do not universally match the combination of fast action, minimal residue, and user safety that makes pure ethanol-based disinfectants so versatile in PT2 applications. 2. Biphenyl-2-ol (o-phenylphenol) Biphenyl-2-ol (o-phenylphenol) is a phenolic compound that demonstrates robust bactericidal, yeasticidal, and fungicidal activity, making it a practical ingredient in a variety of disinfectant products. Formulators often turn to biphenyl-2-ol for its proven efficacy against common bacterial and fungal contaminants, and it is sometimes included in surface disinfectant blends alongside other actives to create a more rounded antimicrobial profile. Its relative stability and compatibility with different formulation components mean it can be successfully incorporated into certain professional cleaning protocols, especially when controlling bacterial and fungal growth is a priority. However, when viewed strictly as a replacement for ethanol in PT2 disinfectants, biphenyl-2-ol comes with limitations. Most notably, its virucidal performance—particularly against non-enveloped viruses—is generally less validated than ethanol's, so standalone biphenyl-2-ol-based products may not reliably achieve broad-spectrum virus inactivation. It also tends to leave more residue behind, meaning the rapid evaporation and relatively “residue-free” finish that ethanol provides cannot be matched. From a regulatory perspective, under the CLP Regulation, biphenyl-2-ol (o-phenylphenol) is classified primarily for its eye-damaging and skin-irritating properties (e.g., Eye Dam. 1, H318 and Skin Irrit. 2, H315). Therefore, while it can serve as a valuable component in specialised disinfectants—especially for bacterial and fungal control—biphenyl-2-ol typically does not match the versatility and overall coverage that ethanol offers in many PT2 applications. 3. L-(+)-Lactic Acid L-(+)-Lactic Acid is a mild organic acid often appreciated for its comparatively lower toxicity profile, particularly when stacked against strong oxidisers (e.g., peracetic acid) or quaternary ammonium compounds. In many disinfectant formulations, lactic acid demonstrates reliable bactericidal and fungicidal efficacy. It also boasts good material compatibility, making it suitable in “green” or gentle cleaning products, where harsh chemicals are

	undesirable. Especially in contexts like food-processing surfaces (though technically PT4, rather than PT2), lactic acid-based disinfectants align well with safety objectives, offering effective microbial control with minimal chemical residues or adverse effects. However, as a PT2 substitute for ethanol, lactic acid faces notable constraints. Its virucidal coverage is more limited, especially against non-enveloped viruses, which can be critical in high-traffic or high-risk public spaces. While lactic acid can handle bacterial and fungal contamination effectively, it might not provide the comprehensive antiviral efficacy often demanded in busy environments like schools or mass transit. Another consideration is user experience: lactic acid-based products can produce a residual film or affect the surface's look and feel. Whereas ethanol evaporates quickly without leaving a noticeable trace, lactic acid cleaners may linger, complicating rapid-use scenarios where a quick-drying, residue-free finish is preferred. 4. Peracetic acid Peracetic acid is a highly potent disinfectant with robust bactericidal, fungicidal, and virucidal properties, even against many non-enveloped viruses. Its powerful oxidising capacity makes it indispensable in certain industrial contexts—like dairies, breweries, or CIP (clean-in-place) systems—where a wide range of pathogens must be eliminated swiftly and reliably. Another advantage is its low persistence: once it finishes oxidising contaminants, peracetic acid readily breaks down into oxygen and acetic acid (vinegar), thereby avoiding persistent residues in wastewater or the broader environment when used responsibly. However, these same potent oxidative qualities can be a disadvantage in more routine PT2 settings. At higher concentrations, peracetic acid is both corrosive and strongly irritating, requiring careful surface selection, dedicated ventilation, and vigilant use of personal protective equipment (PPE). Its pungent odour and potential to irritate eyes and airways make it less suitable for everyday disinfection in public or lightly controlled spaces, such as schools, offices, and shops. Even in industrial facilities, special handling protocols are necessary to manage the chemical's corrosivity and volatility. Consequently, while peracetic acid excels in heavily controlled or automated processes that demand broad-spectrum coverage, it cannot be seen as a first-line substitute for ethanol in typical PT2 applications. 5. Non-chemical alternatives Non-chemical technologies like UV-C light and steam can be useful adjuncts for disinfection in certain, well-controlled scenarios. UV-C light excels at inactivating a wide range of bacteria and viruses when surfaces are fully exposed—such as in closed chambers or specifically designed HVAC

	systems. Meanwhile, high-temperature steam is a powerful option for sanitising surfaces or equipment without leaving chemical residues; it is widely used in some food-processing lines and certain hospital sterilisation protocols. However, both methods face practical limitations that often prevent them from serving as primary disinfectants in typical PT2 settings. Because UV-C treatment requires direct “line-of-sight” exposure, cleaning large, complex, or irregularly shaped spaces can be tricky. Steam, on the other hand, is not feasible for moisture-sensitive environments and can require significant downtime. Beyond these application constraints, both UV-C and steam carry high equipment costs, involve more complicated safety protocols, and usually necessitate that occupants vacate or avoid the area being disinfected. Consequently, while UV-C and steam can complement chemical disinfection under certain conditions, they seldom match the swift, broad-spectrum utility and straightforward application that ethanol-based solutions provide for most PT2 disinfection needs.
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Economic Feasibility	Substituting ethanol in PT2 applications can have significant economic ramifications throughout the entire supply chain. Because ethanol is both widely available and relatively inexpensive for its level of performance, removing or restricting its use in surface disinfectants would likely drive formulators to rely on alternatives that are often pricier or less straightforward to handle. This can translate to higher costs for raw materials, product development, and manufacturing. Companies would also face increased expenditures for reformulating product lines, obtaining new authorisations under the Biocidal Products Regulation (BPR), conducting efficacy testing, and retraining staff to handle new chemicals or processes. Developing a new product within the regulatory framework of the Biocidal Products Regulation (BPR) is both time-consuming and costly. Reformulating a single product would require a minimum of two years for development, six years for registration, and an additional year for market launch—amounting to a total of nine years. The estimated cost for this process is at least €1 million, with no guarantee that the resulting product would be as efficacious or well-tolerated as an ethanol-based disinfectant. Such an extended timeline and investment would not only delay the availability of alternative products but also risk producing suboptimal

	replacements that fail to match ethanol's well-established effectiveness and safety profile. Ethanol is produced at high volume, benefits from well-established supply chains, and often leverages economies of scale that help keep unit costs relatively low. By contrast, propanols, phenolic compounds (like biphenyl-2-ol), or organic acids (like lactic acid) may be produced in smaller volumes or have more limited sourcing options, pushing their per-kilogram prices higher. Logistical considerations can compound these higher base prices. For instance, certain oxidisers or advanced disinfectants might require specialised transport conditions (e.g., insulated or controlled-environment shipping), additional safety measures in transit, or more frequent replenishment cycles due to shorter shelf lives. Each of these factors raises costs further along the supply chain, with downstream formulators, distributors, and end users ultimately bearing the financial burden. Consequently, even relatively modest cost differentials per kilogram can add up to substantial expenses in large-volume applications, making it economically burdensome for manufacturers to move away from ethanol and adopt alternatives at scale. Moreover, many industrial and commercial users have optimised their workflows around the fast-drying, broad-spectrum attributes of ethanol. Substituting it with substances that evaporate more slowly, require longer contact times, or necessitate additional personal protective equipment (PPE) can decrease operational efficiency, leading to indirect expenses such as lost productivity or more frequent re-cleaning. For smaller businesses—particularly those operating in tight-margin sectors such as hospitality or facilities management—even modestly higher costs or workflow disruptions can have an outsized financial impact. Ultimately, while alternatives do exist, the aggregate effect of retooling production, distributing costlier products, and adjusting everyday disinfection practices can make large-scale ethanol substitution both financially and logistically challenging for many stakeholders across Europe.
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Hazards and Risks of the Alternative	Alternative disinfectants proposed as substitutes for ethanol demonstrate significantly higher hazard and risk profiles compared to ethanol's performance in biocidal applications. For example, isopropanol generally requires longer contact times to achieve effective microbial inactivation, thereby

	increasing the risk of skin irritation due to prolonged exposure. Iodine-based compounds have been documented to cause severe skin irritation and thyroid dysfunction, necessitating stringent control measures and specialised handling protocols, while peracetic acid is highly corrosive and poses serious risks of respiratory irritation and chemical burns. Additionally, sodium hypochlorite is known to form carcinogenic disinfection by-products, such as trihalomethanes, under certain conditions, further complicating its safe use. Moreover, the proposed reclassification of ethanol is largely based on oral consumption data—data derived from scenarios involving ingestion by pregnant women. This approach is fundamentally misplaced for biocidal applications, as these products are intended exclusively for dermal application with only minimal, incidental respiratory exposure, and are never designed for oral ingestion. There is no comparable data for the other active substances as they are not routinely drunk. No corresponding exposure data exist for the routes of exposure typical of biocidal use, which starkly contrasts with the ingestion route that forms the basis of the current reclassification concerns. Ethanol's rapid evaporation and short contact times ensure that any exposure is both minimal and transient, a condition that does not apply to the alternatives, which require additional risk management measures, such as enhanced hazard labelling, specialised storage, and rigorous handling protocols. Consequently, forced substitution of ethanol would not only compromise disinfection efficacy but also introduce greater operational and health risks, making the proposed reclassification technically and practically inappropriate. As the safety concern is from the ingestion of ethanol-based beverages, reclassification of ethanol and thus ethanol-based products, will have no benefit as these products are not designed to be ingested. European Centre for Disease Prevention and Control (ECDC), Factsheet: Healthcare-associated infections – a threat to patient safety in Europe, May 2024. Available here: https://www.ecdc.europa.eu/en/publications-data/healthcare-associated-infections-threat-patient-safety-europe
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Availability	Reclassification and forced substitution of ethanol would have far-reaching implications on the availability of both

	ethanol and the disinfectants (PT1, PT2 and PT4) that depend on it. Ethanol is produced on an extensive scale in Europe, with production capacities exceeding 10 million tonnes per year, supported by over 200 production facilities operating at high-capacity factors. This mature, cost-efficient supply chain guarantees a reliable and consistent supply of ethanol for critical applications in healthcare, food processing, and pharmaceuticals. In contrast, the leading alternatives—such as isopropanol, iodine-based disinfectants, and peracetic acid—are produced at significantly lower scales. For example, current estimates indicate that isopropanol production capacity in Europe is around 1–2 million tonnes per year. Iodine-based disinfectants and peracetic acid are manufactured as specialty chemicals with limited production volumes, insufficient to meet the high demand required for widespread disinfection, particularly in crisis scenarios. This disparity means that disinfectants based on these alternatives would face severe scaling challenges, resulting in potential supply shortages, increased production costs, and additional operational complexities. Furthermore, the well-established logistics network supporting ethanol—including dedicated storage facilities and efficient transport channels—ensures that ethanol is reliably delivered to industries when needed. Substituting ethanol with alternatives that lack similar robust infrastructure could lead to significant disruptions, especially during public health emergencies, ultimately compromising the effectiveness of disinfection protocols. Overall, the forced substitution of ethanol would disrupt an established supply chain that underpins cost-efficient and reliable production while forcing reliance on alternatives with limited production capacities and higher associated risks. This would likely result in higher costs, supply shortages, and reduced effectiveness of disinfection measures in critical sectors. It is worth noting that ethanol availability was critical to protecting people during the COVID-19 pandemic due not only to its effectiveness but also the ability to increase production rapidly with distilleries being able to move from producing ethanol for alcoholic beverages to production for hand sanitisers. This was not and would not be possible for any other active substance.
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Conclusion on suitability and availability of the alternative	There are no adequate alternatives to ethanol due to • Ethanol is the most effective active substance fully against non-enveloped viruses such as (e.g. norovirus, adenovirus, poliovirus). • It is effective in 30 seconds essential in environments such as healthcare(Alternatives 60+ Sec • Ethanol is the most skin friendly active substance which is essential in healthcare where products may need to be used 60 to 100 times a day. • Ethanol evaporates quickly essential in high throughput environments. • It leaves no residue on skin & surfaces. • Using ethanol sanitisers increases blood ethanol 10x less than drinking a glass of apple juice. Blood level remains within the physiological range associated with food intake. • Ethanol is sustainable, mainly derived from natural sources & is rapidly biodegradable. Conclusion In conclusion, reclassifying ethanol as a CMR substance based on ingestion data is scientifically inappropriate and practically harmful for dermal-use biocidal products. Ethanol's efficacy, safety, economic value, and irreplaceability in public health make it an essential substance. We strongly urge regulators to preserve its current classification. Ethanol's classification should be assessed again excluding human abusive use data & tests conducted above standard limit values.
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Other comments	Impact on public health and patient safety From a purely public-health perspective, any move to reclassify or restrict ethanol in PT2 disinfectants raises serious concerns about the ease and consistency of disinfection practices in public spaces. Because ethanol-based products balance high efficacy, quick evaporation, and relatively mild hazard labelling, they have become the default choice for routine surface disinfection in schools, offices, gyms, and transport hubs—locations where daily cleaning is vital to prevent disease transmission. If reclassification imposes more stringent labelling or complicates their use, cleaning personnel may be more hesitant or even restricted from applying these disinfectants as frequently. This could allow pathogens to survive on surfaces, driving up the risk of outbreaks and placing added strain on healthcare systems, which then must deal with avoidable infections. Substitutes with weaker broad-spectrum activity or more challenging safety requirements could exacerbate the problem, leading to inconsistent use or incomplete coverage. In short, public

	health would likely suffer if ethanol were replaced or heavily regulated out of common practice, as the tried-and-true methods of rapid, reliable disinfection would become more difficult—or more costly—to sustain at scale. Pandemic preparedness Reclassifying ethanol as a carcinogen—even though its carcinogenic potential primarily arises from ingestion rather than topical or inhalation exposure—would undermine our readiness to confront future pandemics. Throughout COVID-19, ethanol-based sanitisers were at the forefront of infection prevention strategies, proving both effective and easy to deploy on a massive scale. By swiftly adapting production facilities, from chemical plants to distilleries, nations were able to meet the surge in demand for reliable disinfectants. If ethanol were labelled as carcinogenic, regulations would likely restrict its distribution and use, complicating large-scale production and causing price increases that limit consumer access—particularly in emergencies. Ensuring that ethanol remains affordable and widely available is crucial for robust pandemic preparedness. Ethanol has a well-established safety profile for external use, and its proven efficacy against pathogens makes it an indispensable resource in healthcare settings and everyday hygiene. In a crisis marked by soaring demand for disinfectants, the ability to quickly ramp up ethanol output is essential for safeguarding public health. By avoiding reclassification and preserving ethanol's status as a safe, everyday product, policymakers can help maintain resilience against emerging infectious diseases. If ethanol were not approved—or approved as a CMR with restrictions limiting its use during a pandemic—the European Commission would likely be compelled to issue derogations to permit its use. This could include lifting restrictions to allow use by pregnant workers and consumers, and potentially even softening hazard labelling requirements. Such actions would risk undermining the integrity and credibility of both the Biocidal Products Regulation (BPR) and the Classification, Labelling and Packaging (CLP) Regulation, as well as the consistency with which these frameworks have been applied. Ultimately, this scenario would reflect poorly on the regulatory process and the Commission itself. Impact on innovation Ethanol-based disinfection technology has been refined over decades through sustained research and development, resulting in formulations that are both highly effective and optimised for operational efficiency. This long-term investment has yielded valuable operational data, technical expertise, and a deep understanding of ethanol's unique properties in infection control. For instance, improvements in formulation have led to rapid antimicrobial action, minimal residue

	formation, and a favourable exposure profile that distinguishes ethanol from potential substitutes. Forced substitution of ethanol with alternative disinfectants poses a significant risk to this established knowledge base. Transitioning to substitutes may not only lead to a loss of decades of innovation but also stifle future research opportunities. The specialised expertise and data accumulated over time provide a critical foundation for further advancements in disinfection technology—advancements that are essential during emerging infectious disease outbreaks and in the continuous pursuit of enhanced patient safety. Without ethanol, the incentive for continued research into optimising disinfection protocols could diminish, and resources might be diverted towards adapting less effective alternatives that require additional validation. This shift would hinder progress in developing next-generation disinfection methods and limit our capacity to respond swiftly to future public health challenges. Moreover, the reallocation of funds and expertise from ethanol-based innovation to the pursuit of alternative substances could create a gap in R&D, delaying improvements that have historically driven down costs and improved efficacy. In the long run, this stifling of innovation not only compromises immediate disinfection performance but also impacts the broader evolution of infection control measures in healthcare and other critical sectors. Developing a new product within the regulatory framework of the Biocidal Products Regulation (BPR) is both time-consuming and costly. Reformulating a single product would require a minimum of two years for development, six years for registration, and an additional year for market launch—amounting to a total of nine years. The estimated cost for this process is at least €1 million, with no guarantee that the resulting product would be as efficacious or well-tolerated as an ethanol-based disinfectant. Such an extended timeline and investment would not only delay the availability of alternative products but also risk producing suboptimal replacements that fail to match ethanol's well-established effectiveness and safety profile. Impact in other parts of the World The European Union is widely recognised as a global trendsetter in chemical regulation and market standards. Regulatory decisions made within the EU often set the benchmark for international practices, influencing both developed and developing countries. If ethanol is forced off the market in Europe due to a reclassification based on ingestion toxicity data, the resultant shift would not only disrupt the established supply chain and economic balance within the EU but also have far-reaching implications globally. A forced substitution would signal to

	international markets that ethanol is no longer a viable option for disinfection, prompting regulatory bodies in developing countries—many of which align their standards with those of the EU—to adopt similar restrictions. However, unlike the EU, many developing countries lack the production capacity and economic infrastructure to rapidly switch to less cost-effective and less efficient alternatives. This would exacerbate challenges in maintaining effective disinfection protocols, particularly in resource-limited settings where the availability of high-quality disinfectants is critical for public health. Moreover, the higher costs and technical limitations of alternative disinfectants could lead to significant market disruptions. Developing countries may face increased prices and reduced availability of effective biocidal products, resulting in a cascade of negative effects on public health. In scenarios of public health emergencies, such as pandemics, these disruptions could severely compromise infection control measures, further widening global health disparities. In essence, any EU regulatory decision that forces the substitution of ethanol is likely to trigger a domino effect internationally. The ensuing regulatory and market pressures could compel countries with limited capacity to adopt stringent measures, thereby reducing global access to effective disinfection solutions. This potential outcome underscores the importance of basing regulatory decisions on exposure scenarios that reflect the actual use of ethanol in biocidal applications—namely, dermal and limited respiratory exposure—rather than on ingestion data, which are not applicable in this context.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 123	2025/04/23 15:41

Country	Germany
Name of organization/institution	AVT Abfüll- und Verpackungstechnik GmbH
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Ethanol is a widely used biocidal active ingredient for disinfectants in consumer products with a broad spectrum of activity. Its most important advantages are its proven virucidal, bactericidal and fungicidal effect, as well as its high effectiveness against non-enveloped viruses. Furthermore, ethanol leaves no residue on surfaces due to its rapid evaporation so is safe for food contact applications. Ethanol has a well-documented safety profile with minimal risks when used properly
Product Type	1,2,4
Alternative Identity and Properties	Ethanol is the only commercial available alcohol that is completely virucidal and comprehensively effective against non-enveloped viruses including enteroviruses (e.g. polioviruses) and one of the few alcoholic substances that is effective against noroviruses. This is supported by WHO recommendations and studies (e.g. Kramer et al., 2022), which emphasise its excellent disinfecting properties. The advantage of ethanol is the long shelf life of the formulated products, stability and usability over time.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Ethanol does not cause any toxicologically relevant residues on consumer goods and the skin, or permanent environmental pollution. There are no reported cases of skin sensitisation during normal, intended use. Compared to alternatives, ethanol has a lower risk of accidental poisoning due to rapid evaporation. Ethanol does not cause food contamination, is odourless and therefore suitable for food-related applications. The same applies to non-food contact surfaces.
Information above is confidential	

Justification for confidentiality	
Economic Feasibility	There is a lack of comparably effective alternatives: no substitute biocidal active ingredient offers the same virucidal efficacy against non-enveloped viruses. • Other active ingredients have a higher toxicity profile or leave residues. • Alternative substances are much more expensive and less available. • Expanding the production of substitute substances would require massive investment in new facilities, technologies and regulatory approvals and is met with resistance from authorities and non-governmental organisations. • Potential risks to public health would be the reduced availability of effective disinfectants. This could increase infection rates in healthcare, food processing and public hygiene
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Ethanol is assessed for possible classification as carcinogenic and/or toxic for reproduction. However: • • There is no conclusive evidence for the carcinogenicity of real routes/values of exposure. • • In the toxicological assessment, a distinction should be made between ingestion and exposure through inhalation. • Any classification of substances, whether according to biocide legislation or REACH, must be carried out as a risk-based assessment and not as a pure hazard classification.
Information above is confidential	
Justification for confidentiality	
Availability	Ethanol production has a stable supply chain. Alternative biocides are associated with higher production costs, lower availability and logistical challenges. The production of these active ingredients takes place almost exclusively in non-EU countries. Regulatory decisions should consider economic feasibility and continuity of supply to avoid market disruption.
Information above is confidential	
Justification for confidentiality	

Conclusion on suitability and availability of the alternative	Ethanol is essential for public health. It allows consumers to easily disinfect food contact materials and other utensils independently of the healthcare system. The use of oral toxicological test results is excessive for products that are not intended for oral use. This is an assessment of the hazard and not an assessment of the actual risk. This could happen at present, because this can also be observed for the new REACH. We do not agree with this, as it deprives us of substances that may continue to be used under a risk assessment. In order to ensure a well-founded discussion, the different interests of industry, healthcare and the various competent authorities should be heard.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 124	2025/04/23 15:42
Country	Germany
Name of organization/institution	AVT Abfüll- und Verpackungstechnik GmbH
I do not wish the name of my organisation/institution to be published on the ECHA website.	

General information	Ethanol is a widely used biocidal active ingredient for disinfectants in consumer products with a broad spectrum of activity. Its most important advantages are its proven virucidal, bactericidal and fungicidal effect, as well as its high effectiveness against non-enveloped viruses. Furthermore, ethanol leaves no residue on surfaces due to its rapid evaporation so is safe for food contact applications. Ethanol has a well-documented safety profile with minimal risks when used properly
Product Type	1,2,4
Alternative Identity and Properties	Ethanol is the only commercial available alcohol that is completely virucidal and comprehensively effective against non-enveloped viruses including enteroviruses (e.g. polioviruses) and one of the few alcoholic substances that is effective against noroviruses. This is supported by WHO recommendations and studies (e.g. Kramer et al., 2022), which emphasise its excellent disinfecting properties. The advantage of ethanol is the long shelf life of the formulated products, stability and usability over time.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Ethanol does not cause any toxicologically relevant residues on consumer goods and the skin, or permanent environmental pollution. There are no reported cases of skin sensitisation during normal, intended use. Compared to alternatives, ethanol has a lower risk of accidental poisoning due to rapid evaporation. Ethanol does not cause food contamination, is odourless and therefore suitable for food-related applications. The same applies to non-food contact surfaces.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	There is a lack of comparably effective alternatives: no substitute biocidal active ingredient offers the same virucidal efficacy against non-enveloped viruses. • Other active ingredients have a higher toxicity profile or leave residues. • Alternative substances are much more expensive and less available. • Expanding the production of substitute substances would require massive investment in new facilities, technologies and regulatory

	approvals and is met with resistance from authorities and non-governmental organisations. • Potential risks to public health would be the reduced availability of effective disinfectants. This could increase infection rates in healthcare, food processing and public hygiene
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Ethanol is assessed for possible classification as carcinogenic and/or toxic for reproduction. However: • ▪ There is no conclusive evidence for the carcinogenicity of real routes/values of exposure. • ▪ In the toxicological assessment, a distinction should be made between ingestion and exposure through inhalation. • Any classification of substances, whether according to biocide legislation or REACH, must be carried out as a risk-based assessment and not as a pure hazard classification.
Information above is confidential	
Justification for confidentiality	
Availability	Ethanol production has a stable supply chain. Alternative biocides are associated with higher production costs, lower availability and logistical challenges. The production of these active ingredients takes place almost exclusively in non-EU countries. Regulatory decisions should consider economic feasibility and continuity of supply to avoid market disruption.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol is essential for public health. It allows consumers to easily disinfect food contact materials and other utensils independently of the healthcare system. The use of oral toxicological test results is excessive for products that are not intended for oral use. This is an assessment of the hazard and not an assessment of the actual risk. This could happen at present, because this can also be observed for the new REACH. We do not agree with this, as it deprives us of substances that may continue to be used under a risk assessment. In order to ensure a well-founded discussion,

	the different interests of industry, healthcare and the various competent authorities should be heard.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 125	2025/04/23 15:42
Country	Germany
Name of organization/institution	AVT Abfüll- und Verpackungstechnik GmbH
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Ethanol is a widely used biocidal active ingredient for disinfectants in consumer products with a broad spectrum of activity. Its most important advantages are its proven virucidal, bactericidal and fungicidal effect, as well as its high effectiveness against non-enveloped viruses. Furthermore, ethanol leaves no residue on surfaces due to its rapid evaporation so is safe for food contact applications. Ethanol has a well-documented safety profile with minimal risks when used properly
Product Type	1,2,4

Alternative Identity and Properties	Ethanol is the only commercial available alcohol that is completely virucidal and comprehensively effective against non-enveloped viruses including enteroviruses (e.g. polioviruses) and one of the few alcoholic substances that is effective against noroviruses. This is supported by WHO recommendations and studies (e.g. Kramer et al., 2022), which emphasise its excellent disinfecting properties. The advantage of ethanol is the long shelf life of the formulated products, stability and usability over time.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Ethanol does not cause any toxicologically relevant residues on consumer goods and the skin, or permanent environmental pollution. There are no reported cases of skin sensitisation during normal, intended use. Compared to alternatives, ethanol has a lower risk of accidental poisoning due to rapid evaporation. Ethanol does not cause food contamination, is odourless and therefore suitable for food-related applications. The same applies to non-food contact surfaces.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	There is a lack of comparably effective alternatives: no substitute biocidal active ingredient offers the same virucidal efficacy against non-enveloped viruses. • Other active ingredients have a higher toxicity profile or leave residues. • Alternative substances are much more expensive and less available. • Expanding the production of substitute substances would require massive investment in new facilities, technologies and regulatory approvals and is met with resistance from authorities and non-governmental organisations. • Potential risks to public health would be the reduced availability of effective disinfectants. This could increase infection rates in healthcare, food processing and public hygiene
Information above is confidential	
Justification for confidentiality	

Hazards and Risks of the Alternative	Ethanol is assessed for possible classification as carcinogenic and/or toxic for reproduction. However: • There is no conclusive evidence for the carcinogenicity of real routes/values of exposure. • In the toxicological assessment, a distinction should be made between ingestion and exposure through inhalation. • Any classification of substances, whether according to biocide legislation or REACH, must be carried out as a risk-based assessment and not as a pure hazard classification.
Information above is confidential	
Justification for confidentiality	
Availability	Ethanol production has a stable supply chain. Alternative biocides are associated with higher production costs, lower availability and logistical challenges. The production of these active ingredients takes place almost exclusively in non-EU countries. Regulatory decisions should consider economic feasibility and continuity of supply to avoid market disruption.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol is essential for public health. It allows consumers to easily disinfect food contact materials and other utensils independently of the healthcare system. The use of oral toxicological test results is excessive for products that are not intended for oral use. This is an assessment of the hazard and not an assessment of the actual risk. This could happen at present, because this can also be observed for the new REACH. We do not agree with this, as it deprives us of substances that may continue to be used under a risk assessment. In order to ensure a well-founded discussion, the different interests of industry, healthcare and the various competent authorities should be heard.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	

Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 126	2025/04/23 15:44
Country	United Kingdom
Name of organization/institution	SC Johnson
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	SC Johnson is a leading global manufacturer of household cleaning and personal care products, dedicated to creating innovative, high-quality solutions that make life cleaner, healthier, and better. With a legacy spanning over 130 years, SC Johnson is a family-owned company recognized for its commitment to sustainability, product performance, and consumer trust. Some of the company's best-known brands include Glade®, Raid®, Pledge®, Duck®, Baygon®, Autan®, Method® and Ecover®. SC Johnson has a strong footprint in Europe, with regional headquarters, manufacturing facilities, and distribution centers across several countries, including the UK, Germany, France, and the Netherlands. The company's European operations are central to its global business strategy, supporting innovation, regional market needs, and sustainability goals tailored to the continent's consumers and regulations. As a purpose-driven company, SC Johnson continues to invest in greener chemistry, recyclable packaging, and social responsibility initiatives worldwide. SC Johnson believes the proposal to reclassify ethanol is flawed because it relies on data from excessive alcohol consumption, which is not relevant to its use in non-ingestible products, where exposure is limited to brief skin contact. Ethanol is a vital

	biocidal ingredient, offering unmatched effectiveness, safety, and affordability for Surface disinfection. Its rapid, broad-spectrum action and minimal absorption make it essential for high-use environments like healthcare. Reclassifying ethanol as a CMR substance based on ingestion data is scientifically inappropriate and practically harmful for dermal-use biocidal products. Ethanol's efficacy, safety, economic value, and irreplaceability in public health make it an essential substance. SC Johnson strongly urges regulators to preserve its current classification and prioritise real-world exposure scenarios to maintain Europe's health security and regulatory credibility. Ethanol's classification should be assessed again excluding human abusive use data & tests conducted above standard limit values
Product Type	1,2,4
Alternative Identity and Properties	Ethanol is defined as the core active substance in a surface disinfectant formulation intended for PT4 (food and feed area). In PT4 applications, ethanol may be combined (for example, with propanol) to produce a formulation specifically tailored for food-handling environments, where rapid disinfection and minimal residual presence are critical to ensure both efficacy and safety. Its key properties are: • Ethanol-based formulations in PT4 are highly effective against a wide array of microorganisms, efficiently denaturing proteins and disrupting cell membranes on surfaces commonly found in food-processing or food-preparation areas. • Rapid evaporation ensures surfaces are left largely residue-free, an especially important factor in food settings where any film or chemical residue could pose contamination or quality concerns. • The formulation's properties help maintain compatibility with diverse surface materials (e.g., stainless steel, plastics) while upholding a safety profile that minimises potential health risks, even with repeated application. This is essential for environments where staff frequently disinfect surfaces to maintain hygiene standards. The current proposal to reclassify ethanol relies primarily on toxicity data from ingestion, yet this approach does not account for the fundamentally different exposure routes in biocidal applications such as PT4.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	The current proposal is fundamentally flawed, as it relies predominantly on toxicity data derived from the ingestion route—a scenario not representative of the actual exposure

	conditions in biocidal applications, particularly for surface disinfection. In our view, such an approach is not only scientifically unsound but also practically infeasible given ethanol's unique role and its unmatched efficacy in infection control. Please find below an overview of the alternative substances that we identified, their advantages, and the limits to their use. 1. Propanol Propan-1-ol (n-propanol) and propan-2-ol (isopropanol) are structurally similar to ethanol and share many of its disinfection characteristics. When properly formulated, both exhibit broad-spectrum antimicrobial efficacy, covering bacteria, fungi, and enveloped viruses, which explains why they see frequent use in industrial and healthcare settings where robust hygiene protocols are essential. Nonetheless, a significant number of biocidal formulations actually blend propanols with ethanol instead of using them alone, particularly against non-enveloped viruses. Substituting ethanol with propanols presents some constraints—such as slower individual evaporation rates and higher irritancy classifications. Thus, while propanol-ethanol mixtures can achieve broader coverage, they do not universally match the combination of fast action, minimal residue, and user safety that makes pure ethanol-based disinfectants so versatile in PT4 applications. 2. Biphenyl-2-ol (o-phenylphenol) Biphenyl-2-ol (o-phenylphenol) is a phenolic compound that demonstrates robust bactericidal, yeasticidal, and fungicidal activity, making it a practical ingredient in a variety of disinfectant products. Formulators often turn to biphenyl-2-ol for its proven efficacy against common bacterial and fungal contaminants, and it is sometimes included in surface disinfectant blends alongside other actives to create a more rounded antimicrobial profile. Its relative stability and compatibility with different formulation components mean it can be successfully incorporated into certain professional cleaning protocols, especially when controlling bacterial and fungal growth is a priority. However, when viewed strictly as a replacement for ethanol in PT4 disinfectants, biphenyl-2-ol comes with limitations. Most notably, its virucidal performance—particularly against non-enveloped viruses—is generally less validated than ethanol's, so standalone biphenyl-2-ol-based products may not reliably achieve broad-spectrum virus inactivation. It also tends to leave more residue behind, meaning the rapid evaporation and relatively “residue-free” finish that ethanol provides cannot be matched. From a regulatory perspective, under the CLP Regulation, biphenyl-2-ol (o-phenylphenol) is classified primarily for its eye-damaging and skin-irritating properties (e.g., Eye Dam. 1, H318 and Skin Irrit. 2, H315). Therefore, while it can serve

	as a valuable component in specialised disinfectants—especially for bacterial and fungal control—biphenyl-2-ol typically does not match the versatility and overall coverage that ethanol offers in many PT4 applications. 3. L-(+)-Lactic Acid L-(+)-Lactic Acid is a mild organic acid often appreciated for its comparatively lower toxicity profile, particularly when stacked against strong oxidisers (e.g., peracetic acid) or quaternary ammonium compounds. In many disinfectant formulations, lactic acid demonstrates reliable bactericidal and fungicidal efficacy. It also boasts good material compatibility, making it suitable in “green” or gentle cleaning products, where harsh chemicals are undesirable. Especially in contexts like food-processing surfaces (though technically PT4, rather than PT2), lactic acid-based disinfectants align well with safety objectives, offering effective microbial control with minimal chemical residues or adverse effects. However, as a PT4 substitute for ethanol, lactic acid faces notable constraints. Its virucidal coverage is more limited, especially against non-enveloped viruses, which can be critical in high-traffic or high-risk public spaces. While lactic acid can handle bacterial and fungal contamination effectively, it might not provide the comprehensive antiviral efficacy often demanded in busy environments like schools or mass transit. Another consideration is user experience: lactic acid-based products can produce a residual film or affect the surface’s look and feel. Whereas ethanol evaporates quickly without leaving a noticeable trace, lactic acid cleaners may linger, complicating rapid-use scenarios where a quick-drying, residue-free finish is preferred. 4. Peracetic acid Peracetic acid is a highly potent disinfectant with robust bactericidal, fungicidal, and virucidal properties, even against many non-enveloped viruses. Its powerful oxidising capacity makes it indispensable in certain industrial contexts—like dairies, breweries, or CIP (clean-in-place) systems—where a wide range of pathogens must be eliminated swiftly and reliably. Another advantage is its low persistence: once it finishes oxidising contaminants, peracetic acid readily breaks down into oxygen and acetic acid (vinegar), thereby avoiding persistent residues in wastewater or the broader environment when used responsibly. However, these same potent oxidative qualities can be a disadvantage in more routine PT2 settings. At higher concentrations, peracetic acid is both corrosive and strongly irritating, requiring careful surface selection, dedicated ventilation, and vigilant use of personal protective equipment (PPE). Its pungent odour and potential to irritate eyes and airways make it less suitable for everyday disinfection in public or lightly controlled spaces, such as

	schools, offices, and shops. Even in industrial facilities, special handling protocols are necessary to manage the chemical's corrosivity and volatility. Consequently, while peracetic acid excels in heavily controlled or automated processes that demand broad-spectrum coverage, it cannot be seen as a first-line substitute for ethanol in typical PT4 applications. 5. Non-chemical alternatives Non-chemical technologies like UV-C light and steam can be useful adjuncts for disinfection in certain, well-controlled scenarios. UV-C light excels at inactivating a wide range of bacteria and viruses when surfaces are fully exposed—such as in closed chambers or specifically designed HVAC systems. Meanwhile, high-temperature steam is a powerful option for sanitising surfaces or equipment without leaving chemical residues; it is widely used in some food-processing lines and certain hospital sterilisation protocols. However, both methods face practical limitations that often prevent them from serving as primary disinfectants in typical PT settings. Because UV-C treatment requires direct “line-of-sight” exposure, cleaning large, complex, or irregularly shaped spaces can be tricky. Steam, on the other hand, is not feasible for moisture-sensitive environments and can require significant downtime. Beyond these application constraints, both UV-C and steam carry high equipment costs, involve more complicated safety protocols, and usually necessitate that occupants vacate or avoid the area being disinfected. Consequently, while UV-C and steam can complement chemical disinfection under certain conditions, they seldom match the swift, broad-spectrum utility and straightforward application that ethanol-based solutions provide for most PT4 disinfection needs.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Substituting ethanol in PT4 applications can have significant economic ramifications throughout the entire supply chain. Because ethanol is both widely available and relatively inexpensive for its level of performance, removing or restricting its use in surface disinfectants would likely drive formulators to rely on alternatives that are often pricier or less straightforward to handle. This can translate to higher costs for raw materials, product development, and manufacturing. Companies would also face increased expenditures for reformulating product lines, obtaining new authorisations under the Biocidal Products Regulation (BPR), conducting efficacy testing, and retraining staff to handle

	new chemicals or processes. Developing a new product within the regulatory framework of the Biocidal Products Regulation (BPR) is both time-consuming and costly. Reformulating a single product would require a minimum of two years for development, six years for registration, and an additional year for market launch—amounting to a total of nine years. The estimated cost for this process is at least €1 million, with no guarantee that the resulting product would be as efficacious or well-tolerated as an ethanol-based disinfectant. Such an extended timeline and investment would not only delay the availability of alternative products but also risk producing suboptimal replacements that fail to match ethanol's well-established effectiveness and safety profile. Ethanol is produced at high volume, benefits from well-established supply chains, and often leverages economies of scale that help keep unit costs relatively low. By contrast, propanols, phenolic compounds (like biphenyl-2-ol), or organic acids (like lactic acid) may be produced in smaller volumes or have more limited sourcing options, pushing their per-kilogram prices higher. Logistical considerations can compound these higher base prices. For instance, certain oxidisers or advanced disinfectants might require specialised transport conditions (e.g., insulated or controlled-environment shipping), additional safety measures in transit, or more frequent replenishment cycles due to shorter shelf lives. Each of these factors raises costs further along the supply chain, with downstream formulators, distributors, and end users ultimately bearing the financial burden. Consequently, even relatively modest cost differentials per kilogram can add up to substantial expenses in large-volume applications, making it economically burdensome for manufacturers to move away from ethanol and adopt alternatives at scale. Moreover, many industrial and commercial users have optimised their workflows around the fast-drying, broad-spectrum attributes of ethanol. Substituting it with substances that evaporate more slowly, require longer contact times, or necessitate additional personal protective equipment (PPE) can decrease operational efficiency, leading to indirect expenses such as lost productivity or more frequent re-cleaning. For smaller businesses—particularly those operating in tight-margin sectors such as hospitality or facilities management—even modestly higher costs or workflow disruptions can have an outsized financial impact. Ultimately, while alternatives do exist, the aggregate effect of retooling production, distributing costlier products, and adjusting everyday disinfection practices can make large-scale ethanol substitution both financially and

	logistically challenging for many stakeholders across Europe.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Alternative disinfectants proposed as substitutes for ethanol demonstrate significantly higher hazard and risk profiles compared to ethanol's performance in biocidal applications. For example, isopropanol generally requires longer contact times to achieve effective microbial inactivation, thereby increasing the risk of skin irritation due to prolonged exposure. Iodine-based compounds have been documented to cause severe skin irritation and thyroid dysfunction, necessitating stringent control measures and specialised handling protocols, while peracetic acid is highly corrosive and poses serious risks of respiratory irritation and chemical burns. Additionally, sodium hypochlorite is known to form carcinogenic disinfection by-products, such as trihalomethanes, under certain conditions, further complicating its safe use. Moreover, the proposed reclassification of ethanol is largely based on oral consumption data—data derived from scenarios involving ingestion by pregnant women. This approach is fundamentally misplaced for biocidal applications, as these products are intended exclusively for dermal application with only minimal, incidental respiratory exposure, and are never designed for oral ingestion. There is no comparable data for the other active substances as they are not routinely drunk. No corresponding exposure data exist for the routes of exposure typical of biocidal use, which starkly contrasts with the ingestion route that forms the basis of the current reclassification concerns. Ethanol's rapid evaporation and short contact times ensure that any exposure is both minimal and transient, a condition that does not apply to the alternatives, which require additional risk management measures, such as enhanced hazard labelling, specialised storage, and rigorous handling protocols. Consequently, forced substitution of ethanol would not only compromise disinfection efficacy but also introduce greater operational and health risks, making the proposed reclassification technically and practically inappropriate. As the safety concern is from the ingestion of ethanol-based beverages, reclassification of ethanol and thus ethanol-based products, will have no benefit as these products are not designed to be ingested. European Centre for Disease Prevention and Control (ECDC), Factsheet:

	Healthcare-associated infections – a threat to patient safety in Europe, May 2024. Available here: https://www.ecdc.europa.eu/en/publications-data/healthcare-associated-infections-threat-patient-safety-europe
Information above is confidential	
Justification for confidentiality	
Availability	Reclassification and forced substitution of ethanol would have far-reaching implications on the availability of both ethanol and the disinfectants (PT1, PT2 and PT4) that depend on it. Ethanol is produced on an extensive scale in Europe, with production capacities exceeding 10 million tonnes per year, supported by over 200 production facilities operating at high-capacity factors. This mature, cost-efficient supply chain guarantees a reliable and consistent supply of ethanol for critical applications in healthcare, food processing, and pharmaceuticals. In contrast, the leading alternatives—such as isopropanol, iodine-based disinfectants, and peracetic acid—are produced at significantly lower scales. For example, current estimates indicate that isopropanol production capacity in Europe is around 1–2 million tonnes per year. Iodine-based disinfectants and peracetic acid are manufactured as specialty chemicals with limited production volumes, insufficient to meet the high demand required for widespread disinfection, particularly in crisis scenarios. This disparity means that disinfectants based on these alternatives would face severe scaling challenges, resulting in potential supply shortages, increased production costs, and additional operational complexities. Furthermore, the well-established logistics network supporting ethanol—including dedicated storage facilities and efficient transport channels—ensures that ethanol is reliably delivered to industries when needed. Substituting ethanol with alternatives that lack similar robust infrastructure could lead to significant disruptions, especially during public health emergencies, ultimately compromising the effectiveness of disinfection protocols. Overall, the forced substitution of ethanol would disrupt an established supply chain that underpins cost-efficient and reliable production while forcing reliance on alternatives with limited production capacities and higher associated risks. This would likely result in higher costs, supply shortages, and reduced effectiveness of disinfection measures in critical sectors. It is worth noting that ethanol availability was critical to protecting people

	during the COVID-19 pandemic due not only to its effectiveness but also the ability to increase production rapidly with distilleries being able to move from producing ethanol for alcoholic beverages to production for hand sanitisers. This was not and would not be possible for any other active substance.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	There are no adequate alternatives to ethanol due to • Ethanol is the most effective active substance fully against non-enveloped viruses such as (e.g. norovirus, adenovirus, poliovirus). • It is effective in 30 seconds essential in environments such as healthcare (Alternatives 60+ Sec • Ethanol is the most skin friendly active substance which is essential in healthcare where products may need to be used 60 to 100 times a day. • Ethanol evaporates quickly essential in high throughput environments. • It leaves no residue on skin & surfaces. • Using ethanol sanitisers increases blood ethanol 10x less than drinking a glass of apple juice. Blood level remains within the physiological range associated with food intake. • Ethanol is sustainable, mainly derived from natural sources & is rapidly biodegradable. Conclusion In conclusion, reclassifying ethanol as a CMR substance based on ingestion data is scientifically inappropriate and practically harmful for dermal-use biocidal products. Ethanol's efficacy, safety, economic value, and irreplaceability in public health make it an essential substance. We strongly urge regulators to preserve its current classification. Ethanol's classification should be assessed again excluding human abusive use data & tests conducted above standard limit values.
Information above is confidential	
Justification for confidentiality	
Other comments	Impact on public health and patient safety From a purely public-health perspective, any move to reclassify or restrict ethanol in PT2 disinfectants raises serious concerns about the ease and consistency of disinfection practices in public spaces. Because ethanol-based products balance high efficacy, quick evaporation, and relatively mild hazard labelling, they have become the default choice for routine surface disinfection in schools, offices, gyms, and transport

	hubs—locations where daily cleaning is vital to prevent disease transmission. If reclassification imposes more stringent labelling or complicates their use, cleaning personnel may be more hesitant or even restricted from applying these disinfectants as frequently. This could allow pathogens to survive on surfaces, driving up the risk of outbreaks and placing added strain on healthcare systems, which then must deal with avoidable infections. Substitutes with weaker broad-spectrum activity or more challenging safety requirements could exacerbate the problem, leading to inconsistent use or incomplete coverage. In short, public health would likely suffer if ethanol were replaced or heavily regulated out of common practice, as the tried-and-true methods of rapid, reliable disinfection would become more difficult—or more costly—to sustain at scale. Pandemic preparedness Reclassifying ethanol as a carcinogen—even though its carcinogenic potential primarily arises from ingestion rather than topical or inhalation exposure—would undermine our readiness to confront future pandemics. Throughout COVID-19, ethanol-based sanitisers were at the forefront of infection prevention strategies, proving both effective and easy to deploy on a massive scale. By swiftly adapting production facilities, from chemical plants to distilleries, nations were able to meet the surge in demand for reliable disinfectants. If ethanol were labelled as carcinogenic, regulations would likely restrict its distribution and use, complicating large-scale production and causing price increases that limit consumer access—particularly in emergencies. Ensuring that ethanol remains affordable and widely available is crucial for robust pandemic preparedness. Ethanol has a well-established safety profile for external use, and its proven efficacy against pathogens makes it an indispensable resource in healthcare settings and everyday hygiene. In a crisis marked by soaring demand for disinfectants, the ability to quickly ramp up ethanol output is essential for safeguarding public health. By avoiding reclassification and preserving ethanol's status as a safe, everyday product, policymakers can help maintain resilience against emerging infectious diseases. If ethanol were not approved—or approved as a CMR with restrictions limiting its use during a pandemic—the European Commission would likely be compelled to issue derogations to permit its use. This could include lifting restrictions to allow use by pregnant workers and consumers, and potentially even softening hazard labelling requirements. Such actions would risk undermining the integrity and credibility of both the Biocidal Products Regulation (BPR) and the Classification, Labelling and Packaging (CLP) Regulation, as well as the consistency with

	which these frameworks have been applied. Ultimately, this scenario would reflect poorly on the regulatory process and the Commission itself. Impact on innovation Ethanol-based disinfection technology has been refined over decades through sustained research and development, resulting in formulations that are both highly effective and optimised for operational efficiency. This long-term investment has yielded valuable operational data, technical expertise, and a deep understanding of ethanol's unique properties in infection control. For instance, improvements in formulation have led to rapid antimicrobial action, minimal residue formation, and a favourable exposure profile that distinguishes ethanol from potential substitutes. Forced substitution of ethanol with alternative disinfectants poses a significant risk to this established knowledge base. Transitioning to substitutes may not only lead to a loss of decades of innovation but also stifle future research opportunities. The specialised expertise and data accumulated over time provide a critical foundation for further advancements in disinfection technology—advancements that are essential during emerging infectious disease outbreaks and in the continuous pursuit of enhanced patient safety. Without ethanol, the incentive for continued research into optimising disinfection protocols could diminish, and resources might be diverted towards adapting less effective alternatives that require additional validation. This shift would hinder progress in developing next-generation disinfection methods and limit our capacity to respond swiftly to future public health challenges. Moreover, the reallocation of funds and expertise from ethanol-based innovation to the pursuit of alternative substances could create a gap in R&D, delaying improvements that have historically driven down costs and improved efficacy. In the long run, this stifling of innovation not only compromises immediate disinfection performance but also impacts the broader evolution of infection control measures in healthcare and other critical sectors. Developing a new product within the regulatory framework of the Biocidal Products Regulation (BPR) is both time-consuming and costly. Reformulating a single product would require a minimum of two years for development, six years for registration, and an additional year for market launch—amounting to a total of nine years. The estimated cost for this process is at least €1 million, with no guarantee that the resulting product would be as efficacious or well-tolerated as an ethanol-based disinfectant. Such an extended timeline and investment would not only delay the availability of alternative products but also risk producing suboptimal replacements that fail to match ethanol's well-

	established effectiveness and safety profile. Impact in other parts of the World The European Union is widely recognised as a global trendsetter in chemical regulation and market standards. Regulatory decisions made within the EU often set the benchmark for international practices, influencing both developed and developing countries. If ethanol is forced off the market in Europe due to a reclassification based on ingestion toxicity data, the resultant shift would not only disrupt the established supply chain and economic balance within the EU but also have far-reaching implications globally. A forced substitution would signal to international markets that ethanol is no longer a viable option for disinfection, prompting regulatory bodies in developing countries—many of which align their standards with those of the EU—to adopt similar restrictions. However, unlike the EU, many developing countries lack the production capacity and economic infrastructure to rapidly switch to less cost-effective and less efficient alternatives. This would exacerbate challenges in maintaining effective disinfection protocols, particularly in resource-limited settings where the availability of high-quality disinfectants is critical for public health. Moreover, the higher costs and technical limitations of alternative disinfectants could lead to significant market disruptions. Developing countries may face increased prices and reduced availability of effective biocidal products, resulting in a cascade of negative effects on public health. In scenarios of public health emergencies, such as pandemics, these disruptions could severely compromise infection control measures, further widening global health disparities. In essence, any EU regulatory decision that forces the substitution of ethanol is likely to trigger a domino effect internationally. The ensuing regulatory and market pressures could compel countries with limited capacity to adopt stringent measures, thereby reducing global access to effective disinfection solutions. This potential outcome underscores the importance of basing regulatory decisions on exposure scenarios that reflect the actual use of ethanol in biocidal applications—namely, dermal and limited respiratory exposure—rather than on ingestion data, which are not applicable in this context.
Information above is confidential	
Justification for confidentiality	
References	

Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 127	2025/04/23 15:51
Country	Germany
Name of organization/institution	AVT-Abfüll- und Verpackungstechnik GmbH
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Ethanol is a widely used biocidal active ingredient for disinfectants in consumer products with a broad spectrum of activity. Its most important advantages are its proven virucidal, bactericidal and fungicidal effect, as well as its high effectiveness against non-enveloped viruses. Furthermore, ethanol leaves no residue on surfaces due to its rapid evaporation so is safe for food contact applications. Ethanol has a well-documented safety profile with minimal risks when used properly
Product Type	1,2,4
Alternative Identity and Properties	Ethanol is the only commercial available alcohol that is completely virucidal and comprehensively effective against non-enveloped viruses including enteroviruses (e.g. polioviruses) and one of the few alcoholic substances that is effective against noroviruses. This is supported by WHO recommendations and studies (e.g. Kramer et al., 2022), which emphasise its excellent disinfecting properties. The advantage of ethanol is the long shelf life of the formulated products, stability and usability over time.
Information above is confidential	
Justification for confidentiality	

Technical Feasibility	Ethanol does not cause any toxicologically relevant residues on consumer goods and the skin, or permanent environmental pollution. There are no reported cases of skin sensitisation during normal, intended use. Compared to alternatives, ethanol has a lower risk of accidental poisoning due to rapid evaporation. Ethanol does not cause food contamination, is odourless and therefore suitable for food-related applications. The same applies to non-food contact surfaces.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	There is a lack of comparably effective alternatives: no substitute biocidal active ingredient offers the same virucidal efficacy against non-enveloped viruses. • Other active ingredients have a higher toxicity profile or leave residues. • Alternative substances are much more expensive and less available. • Expanding the production of substitute substances would require massive investment in new facilities, technologies and regulatory approvals and is met with resistance from authorities and non-governmental organisations. • Potential risks to public health would be the reduced availability of effective disinfectants. This could increase infection rates in healthcare, food processing and public hygiene
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Ethanol is assessed for possible classification as carcinogenic and/or toxic for reproduction. However: • • There is no conclusive evidence for the carcinogenicity of real routes/values of exposure. • • In the toxicological assessment, a distinction should be made between ingestion and exposure through inhalation. • Any classification of substances, whether according to biocide legislation or REACH, must be carried out as a risk-based assessment and not as a pure hazard classification.
Information above is confidential	
Justification for confidentiality	

Availability	Ethanol production has a stable supply chain. Alternative biocides are associated with higher production costs, lower availability and logistical challenges. The production of these active ingredients takes place almost exclusively in non-EU countries. Regulatory decisions should consider economic feasibility and continuity of supply to avoid market disruption.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol is essential for public health. It allows consumers to easily disinfect food contact materials and other utensils independently of the healthcare system. The use of oral toxicological test results is excessive for products that are not intended for oral use. This is an assessment of the hazard and not an assessment of the actual risk. This could happen at present, because this can also be observed for the new REACH. We do not agree with this, as it deprives us of substances that may continue to be used under a risk assessment. In order to ensure a well-founded discussion, the different interests of industry, healthcare and the various competent authorities should be heard.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 128	2025/04/23 15:52
Country	Germany
Name of organization/institution	AVT Abfüll- und Verpackungstechnik GmbH
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Ethanol is a widely used biocidal active ingredient for disinfectants in consumer products with a broad spectrum of activity. Its most important advantages are its proven virucidal, bactericidal and fungicidal effect, as well as its high effectiveness against non-enveloped viruses. Furthermore, ethanol leaves no residue on surfaces due to its rapid evaporation so is safe for food contact applications. Ethanol has a well-documented safety profile with minimal risks when used properly
Product Type	1,2,4
Alternative Identity and Properties	Ethanol is the only commercial available alcohol that is completely virucidal and comprehensively effective against non-enveloped viruses including enteroviruses (e.g. polioviruses) and one of the few alcoholic substances that is effective against noroviruses. This is supported by WHO recommendations and studies (e.g. Kramer et al., 2022), which emphasise its excellent disinfecting properties. The advantage of ethanol is the long shelf life of the formulated products, stability and usability over time.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Ethanol does not cause any toxicologically relevant residues on consumer goods and the skin, or permanent environmental pollution. There are no reported cases of skin sensitisation during normal, intended use. Compared to alternatives, ethanol has a lower risk of accidental poisoning due to rapid evaporation. Ethanol does not cause food contamination, is odourless and therefore suitable for food-related applications. The same applies to non-food contact surfaces.

Information above is confidential	
Justification for confidentiality	
Economic Feasibility	There is a lack of comparably effective alternatives: no substitute biocidal active ingredient offers the same virucidal efficacy against non-enveloped viruses. • Other active ingredients have a higher toxicity profile or leave residues. • Alternative substances are much more expensive and less available. • Expanding the production of substitute substances would require massive investment in new facilities, technologies and regulatory approvals and is met with resistance from authorities and non-governmental organisations. • Potential risks to public health would be the reduced availability of effective disinfectants. This could increase infection rates in healthcare, food processing and public hygiene
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Ethanol is assessed for possible classification as carcinogenic and/or toxic for reproduction. However: • • There is no conclusive evidence for the carcinogenicity of real routes/values of exposure. • • In the toxicological assessment, a distinction should be made between ingestion and exposure through inhalation. • Any classification of substances, whether according to biocide legislation or REACH, must be carried out as a risk-based assessment and not as a pure hazard classification.
Information above is confidential	
Justification for confidentiality	
Availability	Ethanol production has a stable supply chain. Alternative biocides are associated with higher production costs, lower availability and logistical challenges. The production of these active ingredients takes place almost exclusively in non-EU countries. Regulatory decisions should consider economic feasibility and continuity of supply to avoid market disruption.
Information above is confidential	

Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol is essential for public health. It allows consumers to easily disinfect food contact materials and other utensils independently of the healthcare system. The use of oral toxicological test results is excessive for products that are not intended for oral use. This is an assessment of the hazard and not an assessment of the actual risk. This could happen at present, because this can also be observed for the new REACH. We do not agree with this, as it deprives us of substances that may continue to be used under a risk assessment. In order to ensure a well-founded discussion, the different interests of industry, healthcare and the various competent authorities should be heard.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 129	2025/04/23 15:51
Country	Germany
Name of organization/institution	AVT Abfüll- und Verpackungstechnik GmbH
I do not wish the name of my organisation/institution to be published on the ECHA website.	

General information	Ethanol is a widely used biocidal active ingredient for disinfectants in consumer products with a broad spectrum of activity. Its most important advantages are its proven virucidal, bactericidal and fungicidal effect, as well as its high effectiveness against non-enveloped viruses. Furthermore, ethanol leaves no residue on surfaces due to its rapid evaporation so is safe for food contact applications. Ethanol has a well-documented safety profile with minimal risks when used properly
Product Type	1,2,4
Alternative Identity and Properties	Ethanol is the only commercial available alcohol that is completely virucidal and comprehensively effective against non-enveloped viruses including enteroviruses (e.g. polioviruses) and one of the few alcoholic substances that is effective against noroviruses. This is supported by WHO recommendations and studies (e.g. Kramer et al., 2022), which emphasise its excellent disinfecting properties. The advantage of ethanol is the long shelf life of the formulated products, stability and usability over time.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Ethanol does not cause any toxicologically relevant residues on consumer goods and the skin, or permanent environmental pollution. There are no reported cases of skin sensitisation during normal, intended use. Compared to alternatives, ethanol has a lower risk of accidental poisoning due to rapid evaporation. Ethanol does not cause food contamination, is odourless and therefore suitable for food-related applications. The same applies to non-food contact surfaces.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	There is a lack of comparably effective alternatives: no substitute biocidal active ingredient offers the same virucidal efficacy against non-enveloped viruses. • Other active ingredients have a higher toxicity profile or leave residues. • Alternative substances are much more expensive and less available. • Expanding the production of substitute substances would require massive investment in new facilities, technologies and regulatory

	approvals and is met with resistance from authorities and non-governmental organisations. • Potential risks to public health would be the reduced availability of effective disinfectants. This could increase infection rates in healthcare, food processing and public hygiene
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Ethanol is assessed for possible classification as carcinogenic and/or toxic for reproduction. However: • ▪ There is no conclusive evidence for the carcinogenicity of real routes/values of exposure. • ▪ In the toxicological assessment, a distinction should be made between ingestion and exposure through inhalation. • Any classification of substances, whether according to biocide legislation or REACH, must be carried out as a risk-based assessment and not as a pure hazard classification.
Information above is confidential	
Justification for confidentiality	
Availability	Ethanol production has a stable supply chain. Alternative biocides are associated with higher production costs, lower availability and logistical challenges. The production of these active ingredients takes place almost exclusively in non-EU countries. Regulatory decisions should consider economic feasibility and continuity of supply to avoid market disruption.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol is essential for public health. It allows consumers to easily disinfect food contact materials and other utensils independently of the healthcare system. The use of oral toxicological test results is excessive for products that are not intended for oral use. This is an assessment of the hazard and not an assessment of the actual risk. This could happen at present, because this can also be observed for the new REACH. We do not agree with this, as it deprives us of substances that may continue to be used under a risk assessment. In order to ensure a well-founded discussion,

Justification for confidentiality	We cannot include substances of equal quality in our formulations.
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Our company produces detergents and disinfectants in which ethanol is often present because it is an excellent solvent and disinfectant, fast drying and low cost. We do not have equally effective alternatives and it would be a big problem to have to replace it. Furthermore, additional testing costs would have to be sustained to insert new active ingredients in our formulations. We are absolutely against the worsening of the proposed classification.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	

Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 131	2025/04/23 17:14
Country	Germany
Name of organization/institution	Sartorius
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Sartorius is a leading international technology provider and partner for the biopharma, pharmaceutical and laboratory industry. Our products and technology solutions are supporting our customers to develop and produce drugs safely, timely and economically. Sartorius offers a broad portfolio of products for process filtration, fluid handling and management, cell culture technology and Lab systems & Services with focus on Life Science.
Product Type	1,2,4
Alternative Identity and Properties	We do not know any potential alternatives to Ethanol, which like Ethanol do not meet the exclusion criteria for active substances listed in Article 5(1) (a) – e)) of the BPR and which has a comparable suitability as an active substance for biocidal product types in focus. According to the ECHA Registry of Classification and Labelling (CLH) Intentions until Outcome it is planned to change the existing harmonised CLP classification of Ethanol from Flam. Liq. 2 (H225) to Flam. Liq. 2 (H225), Eye Irrit. 2 (H319), Repr. 2 (H361d), Lact. (H362), STOT SE 3 (H336) and STOT RE 2 (H373). This CLP classification is not in conflict with one of the conditions for approval according to Article 5(1) and 19(4) of the BPR. The Greek competent authority has

	evaluated the hazardous properties of Ethanol and the risks from using it in representative biocidal products in its draft report and came to a different conclusion. The ECHA information page on Ethanol writes: "If the Biocidal Products Committee (BPC) concludes that ethanol is carcinogenic, mutagenic or reprotoxic, (category 1A or 1B), ethanol will be regarded as a substance meeting the exclusion criteria and as a candidate for substitution for its use in biocidal products." (https://echa.europa.eu/de/hot-topics/biocides)
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	no comment
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	no comment
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	no comment
Information above is confidential	
Justification for confidentiality	
Availability	no comment
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	no comment
Information above is confidential	

Justification for confidentiality	
Other comments	Our problem of concern is the intention to classify Ethanol to be carcinogenic, mutagenic and reprotoxic (category 1A or 1B). This will complicate the use of Ethanol for all existing applications. Sartorius is not a producer of biocides. The company uses ethanol as a solvent, processing aid and shipment solution for filtration and chromatography products to maintain low bioburden of our products. These are only some of the many uses of Ethanol in the industry and for food & beverage, pharmaceuticals, cosmetics, disinfectants, fuel, etc.. We primarily use it in water mixtures with different concentrations above 20% Ethanol. Additionally, we are using Ethanol as a surface disinfectant in our cell culture processes, where clean and sterile surfaces are required to grow e.g. mammalian cells for process development in the biopharmaceutical industry. Ethanol has many advantages for the use in industrial manufacturing processes and as an additive for filtration and chromatography products. It is a chemical substance with a very long cultural history and conditions of safe use are widely known, which facilitates the safe use. Furthermore, it is a solvent with an excellent compatibility with most plastic materials used for filtration and chromatography products. Ethanol can be easily removed from surfaces after application due to its high vapor pressure. Finally, it is a chemical substance which can be produced naturally by fermentation and is fully biodegradable. Therefore, we strongly prefer using of Ethanol over other chemical substances in our applications. Our concern is that the potential Ethanol classification as carcinogenic, mutagenic or reprotoxic (category 1A or 1B) leads to the requirement to substitute Ethanol in many applications. The substitution would have a significant socio-economic impact. Commercial alternatives, which are comparable and suitable for our range of applications and which are qualified and validated are not available. Substitution would require changing manufacturing processes and production equipment, as well as modifying analytical processes and test equipment. Additionally, alternative substances that are not yet available must be developed, qualified for products, and for manufacturing and testing processes, and validated for use. These development, qualification and validation processes are time-consuming and costly, especially for products for the biopharmaceutical industry. Potential alternatives bare the risk of becoming quickly regrettable substitutes.

Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 132	2025/04/24 11:19
Country	Belgium
Name of organization/institution	Bundesverband des Deutschen Lebensmittelhandels e.V.
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Innerhalb des Deutschen Lebensmittelhandels werden zahlreiche Desinfektionsmittel auf Ethanolbasis verwendet. Der Wirkstoff Ethanol ist allgemein hin dafür bekannt, dass er auf Oberflächen oder aber bei der Handdesinfektion zuverlässig Mikroorganismen, also beispielsweise Bakterien, Viren oder Pilze, abtötet und daher nach Anwendung eine keimfreie Umgebung gegeben ist. Diese Tatsache ist im sensiblen Bereich des Lebensmittelhandels, aber auch in allen anderen Stufen der Lebensmittelwertschöpfung, von fundamentaler Bedeutung: Lebensmittelsicherheit muss die allerhöchste Priorität haben. Alternativstoffe besitzen zwar auch abtötende Eigenschaften, diese reichen allerdings nicht an die von Ethanol heran, da sie nur begrenzt viruzid wirken. Ethanol ist daher zur Oberflächen- (PT 4) und Handdesinfektion (PT 1) im Lebensmittelhandel als unerlässlich anzusehen. Nutzungseinschränkungen zögen beträchtliche Folgen mit sich. Desinfektionsmittel auf Ethanolbasis werden im Lebensmittelhandel zur Oberflächendesinfektion genutzt, um optimale Bedingungen an verschiedensten Orten und Stellen der Handelsfläche zu

	garantieren. So nutzt der Handel diese ethanolhaltige Mittel zur Desinfektion und Sicherstellung der Lebensmittelsicherheit an Theken, wie Fleischtheken und Wursttheken, Fischtheken, Käsetheken, Bäckereitheken, Eistheken, Salattheken, Warmhaltestellen oder aber auch in Feinkostabteilungen. In diesen Bereichen ist eine exzellente Lebensmittelhygiene von allerhöchster Wichtigkeit. Oberflächen, die mit ethanolhaltigen Mitteln gereinigt werden, sind hier beispielsweise Schneidebretter, Messer und andere Werkzeuge, Gerätschaften, Schneidemaschinen und Arbeitsplatten. Auch Lebensmittelkontaktbereiche werden mittels Ethanols gereinigt. So werden ebenfalls Einkaufswagen, Kassenschalter und Kassenscheiben mit ethanolhaltigen Mitteln desinfiziert. Eine saubere Oberflächenbeschaffenheit im sensiblen Lebensmittelbereich ist für Hygiene, Lebensmittelsicherheit und einen allgemeinen Verbraucherschutz unabdingbar. Auch die Hygiene der im Lebensmittelhandel berufstätigen Personen muss gewährleistet werden. Dies geschieht unter anderem mit grundlegenden Hygieneregeln, wie dem Händewaschen. Dennoch: auch die Handdesinfektion ist ein zentrales Element der dauerhaften Sicherstellung von Lebensmittelsicherheit und zentraler Bestandteil der Hygiene im Lebensmittelhandel. Durch die Handdesinfektion werden weniger Mikroorganismen in den Märkten über Hände verbreitet und gleichzeitig fungiert die Desinfektion als wichtiger Baustein innerhalb des Gesundheitsschutzes der Mitarbeiterinnen und Mitarbeiter des Handels, aber ebenso der Kundinnen und Kunden (bspw. bei der Reinigung der Einkaufswagen). Im vergangenen Jahr warnten vier deutsche Verbände der Gesundheitsindustrie vor einer Einstufung von Ethanol als CMR-Wirkstoff. Auch die Weltgesundheitsorganisation (WHO) sieht laut des Bundesverbands der Medizintechnik (BVMed) Desinfektionsmittel auf Ethanolbasis als unverzichtbar an, da Ethanol „spezifisch und alternativlos gegen unbehüllte Viren“ wirkt. Dieser Wirkmechanismus garantiert neben einer makellosen Lebensmittelhygiene ebenfalls, dass die Gesundheit der Mitarbeitenden sowie der Verbraucherinnen und Verbraucher im Lebensmittelhandel weniger stark gefährdet ist und sich so beispielsweise Norovirusausbrüche deutlich besser eindämmen lassen.
Product Type	1,2,4
Alternative Identity and Properties	Es existieren Alternativstoffe, die in Desinfektionsmitteln zu finden sind und die auch im Lebensmittelhandel punktuell eingesetzt werden. Dabei handelt es sich zum Beispiel um Isopropanol, Milchsäure oder Produkte auf Quads-Basis.

	Hierbei ist aber zu betonen, dass diese Mittel Einschränkungen aufweisen, die Ethanol nicht aufweist und daher als Mittel „zweiter Wahl“ zu charakterisieren sind. Ethanol ist, wie oben bereits beschrieben, für die Virenbekämpfung unverzichtbar, da auch unbehüllte Viren abgetötet werden können. Andere Alkohole, wie beispielsweise 1-Propanol oder 2-Propanol gelten lediglich als begrenzt viruzid. Des Weiteren ist ein Vorteil des Stoffes, dass er sich ohne Rückstände schnell an der Luft verflüchtigt und dadurch keine Rückstände durch die Nutzung des Desinfektionsmittels gegeben sind. Ebenfalls positiv: die hohe Sicherheit und Verträglichkeit des Stoffes.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Es liegen hierzu keine genauen Daten vor. Dennoch lässt sich bereits jetzt abschätzen, dass Alternativstoffe, die nachgewiesenerweise bei der Bekämpfung von Mikroorganismen weniger effizient wirken, Desinfektionsvorgänge komplizierter gestalten würden, da diese deutlich häufiger wiederholt werden müssten oder aber Wirkstoffe müssten in höherer Dosierung im Desinfektionsmittel vorhanden sein. Da Ethanol alle wichtigen, und für den Lebensmittelbereich vorteilhaften desinfizierenden Charakteristika aufweist, wäre die Nutzung von Alternativstoffen als äußerst nachteilig zu bewerten.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Es liegen hierzu keine genauen Daten vor. Ethanol gilt als günstig zu produzierender Stoff. Die weltweit große Verfügbarkeit der Substanz Ethanol macht die Nutzung wirtschaftlich sinnvoll. Ein Ausweichen auf Alternativstoffe und Produkte ohne Ethanol hätte mit ziemlich großer Sicherheit negative, wirtschaftliche Effekte für Unternehmen.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Wie bereits beschrieben, ist die Substanz Ethanol in der Lage, Mikroorganismen effizient zu beseitigen. So werden

	auch unbehüllte Viren durch Ethanol unschädlich gemacht. Andere Stoffe haben diese positiven Eigenschaften nicht unbedingt. Dadurch besteht die realistische Möglichkeit, dass nicht alle Keime beseitigt werden und eine vollständige und zufriedenstellende Desinfektion von Oberflächen und Händen innerhalb des Lebensmittelsektors nicht zu garantieren ist, wenn nur noch alternative Stoffe genutzt werden. Die geringere Verfügbarkeit von wirksamen, alternativen Desinfektionsmitteln könnte die Infektionsraten daher allgemein ansteigen lassen, was vor allem in sensiblen und systemrelevanten Einrichtungen äußerst problematisch erscheint. Auch der Lebensmittelhandel kann als systemrelevant charakterisiert werden. Bei eingeschränkter Nutzung von Ethanol im Lebensmittelhandel sehen wir u.a. die folgenden Gefahren: - Unzureichende Lebensmittelsicherheit in Lebensmittelbetrieben - Gesundheitsgefahren für die Verbraucherinnen und Verbraucher
Information above is confidential	
Justification for confidentiality	
Availability	Ethanol ist dauerhaft verfügbar und daher auch überall einsetzbar. Es gibt hingegen massive Zweifel an der permanenten Verfügbarkeit von Alternativsubstanzen.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Der deutsche Lebensmittelhandel und viele weitere Bereiche bspw. die Lebensmittelproduktion sind auf Ethanol in Desinfektionsmitteln angewiesen. Ethanol besitzt wichtige Eigenschaften, die für den Erhalt der Lebensmittelsicherheit und grundlegender Hygiene notwendig sind (bspw. geruchslos, schnell und rückstandslos verdunstend). Außerdem bekämpft Ethanol unbehüllte Viren, die durch andere Substanzen nicht zuverlässig bekämpft werden können. Eine Einstufung von Ethanol als CMR-Stoff brächte massive Auswirkungen mit sich: vor allem die Lebensmittelsicherheit und die Gesundheit der Bevölkerung stünden auf dem Spiel. Für den Lebensmittelhandel ist daher von allergrößter Wichtigkeit weiterhin Ethanol zur Desinfektion für Hände und Oberflächen nutzen zu können.
Information above is confidential	

Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	IHO (2025): Wirkstoff Ethanol. Wirksam, sicher, unverzichtbar. URL: https://www.iho.de/wp-content/uploads/0010.0056_A4_P3_web.pdf (zuletzt aufgerufen am 15.04.2025). BVMed (2024): Ethanol ist im medizinischen Bereich unverzichtbar. URL: https://www.bvmed.de/verband/presse/pressemeldungen/gemeinsame-pressemeldung-von-bpi-bvmed-iho-und-vdgh-ethanol-ist-im-medizinischen-bereich-unverzichtbar-und-muss-es-bleiben (zuletzt aufgerufen am 15.04.2025).
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 133	2025/04/24 11:24
Country	Belgium
Name of organization/institution	Bundesverband des Deutschen Lebensmittelhandels e.V.
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Innerhalb des Deutschen Lebensmittelhandels werden zahlreiche Desinfektionsmittel auf Ethanolbasis verwendet. Der Wirkstoff Ethanol ist allgemein hin dafür bekannt, dass er auf Oberflächen oder aber bei der Handdesinfektion zuverlässig Mikroorganismen, also beispielsweise Bakterien, Viren oder Pilze, abtötet und daher nach Anwendung eine keimfreie Umgebung gegeben ist. Diese Tatsache ist im sensiblen Bereich des Lebensmittelhandels, aber auch in allen anderen Stufen der Lebensmittelwertschöpfung, von

	fundamentaler Bedeutung: Lebensmittelsicherheit muss die allerhöchste Priorität haben. Alternativstoffe besitzen zwar auch abtötende Eigenschaften, diese reichen allerdings nicht an die von Ethanol heran, da sie nur begrenzt viruzid wirken. Ethanol ist daher zur Oberflächen- (PT 4) und Handdesinfektion (PT 1) im Lebensmittelhandel als unerlässlich anzusehen. Nutzungseinschränkungen zögen beträchtliche Folgen mit sich. Desinfektionsmittel auf Ethanolbasis werden im Lebensmittelhandel zur Oberflächendesinfektion genutzt, um optimale Bedingungen an verschiedensten Orten und Stellen der Handelsfläche zu garantieren. So nutzt der Handel diese ethanolhaltige Mittel zur Desinfektion und Sicherstellung der Lebensmittelsicherheit an Theken, wie Fleischtheken und Wursttheken, Fischtheken, Käsetheken, Bäckereitheken, Eistheken, Salattheken, Warmhaltestellen oder aber auch in Feinkostabteilungen. In diesen Bereichen ist eine exzellente Lebensmittelhygiene von allerhöchster Wichtigkeit. Oberflächen, die mit ethanolhaltigen Mitteln gereinigt werden, sind hier beispielsweise Schneidebretter, Messer und andere Werkzeuge, Gerätschaften, Schneidemaschinen und Arbeitsplatten. Auch Lebensmittelkontaktbereiche werden mittels Ethanols gereinigt. So werden ebenfalls Einkaufswagen, Kassenschalter und Kassensänder mit ethanolhaltigen Mitteln desinfiziert. Eine saubere Oberflächenbeschaffenheit im sensiblen Lebensmittelbereich ist für Hygiene, Lebensmittelsicherheit und einen allgemeinen Verbraucherschutz unabdingbar. Auch die Hygiene der im Lebensmittelhandel berufstätigen Personen muss gewährleistet werden. Dies geschieht unter anderem mit grundlegenden Hygieneregeln, wie dem Händewaschen. Dennoch: auch die Handdesinfektion ist ein zentrales Element der dauerhaften Sicherstellung von Lebensmittelsicherheit und zentraler Bestandteil der Hygiene im Lebensmittelhandel. Durch die Handdesinfektion werden weniger Mikroorganismen in den Märkten über Hände verbreitet und gleichzeitig fungiert die Desinfektion als wichtiger Baustein innerhalb des Gesundheitsschutzes der Mitarbeiterinnen und Mitarbeiter des Handels, aber ebenso der Kundinnen und Kunden (bspw. bei der Reinigung der Einkaufswagen). Im vergangenen Jahr warnten vier deutsche Verbände der Gesundheitsindustrie vor einer Einstufung von Ethanol als CMR-Wirkstoff. Auch die Weltgesundheitsorganisation (WHO) sieht laut des Bundesverbands der Medizintechnik (BVMed) Desinfektionsmittel auf Ethanolbasis als unverzichtbar an, da Ethanol „spezifisch und alternativlos gegen unbehüllte Viren“ wirkt. Dieser Wirkmechanismus garantiert neben einer makellosen Lebensmittelhygiene ebenfalls, dass die

	Gesundheit der Mitarbeitenden sowie der Verbraucherinnen und Verbraucher im Lebensmittelhandel weniger stark gefährdet ist und sich so beispielsweise Norovirusausbrüche deutlich besser eindämmen lassen.
Product Type	1,2,4
Alternative Identity and Properties	Es existieren Alternativstoffe, die in Desinfektionsmitteln zu finden sind und die auch im Lebensmittelhandel punktuell eingesetzt werden. Dabei handelt es sich zum Beispiel um Isopropanol, Milchsäure oder Produkte auf Quads-Basis. Hierbei ist aber zu betonen, dass diese Mittel Einschränkungen aufweisen, die Ethanol nicht aufweist und daher als Mittel „zweiter Wahl“ zu charakterisieren sind. Ethanol ist, wie oben bereits beschrieben, für die Virenbekämpfung unverzichtbar, da auch unbehüllte Viren abgetötet werden können. Andere Alkohole, wie beispielsweise 1-Propanol oder 2-Propanol gelten lediglich als begrenzt viruzid. Des Weiteren ist ein Vorteil des Stoffes, dass er sich ohne Rückstände schnell an der Luft verflüchtigt und dadurch keine Rückstände durch die Nutzung des Desinfektionsmittels gegeben sind. Ebenfalls positiv: die hohe Sicherheit und Verträglichkeit des Stoffes.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Es liegen hierzu keine genauen Daten vor. Dennoch lässt sich bereits jetzt abschätzen, dass Alternativstoffe, die nachgewiesenerweise bei der Bekämpfung von Mikroorganismen weniger effizient wirken, Desinfektionsvorgänge komplizierter gestalten würden, da diese deutlich häufiger wiederholt werden müssten oder aber Wirkstoffe müssten in höherer Dosierung im Desinfektionsmittel vorhanden sein. Da Ethanol alle wichtigen, und für den Lebensmittelbereich vorteilhaften desinfizierenden Charakteristika aufweist, wäre die Nutzung von Alternativstoffen als äußerst nachteilig zu bewerten.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Es liegen hierzu keine genauen Daten vor. Ethanol gilt als günstig zu produzierender Stoff. Die weltweit große Verfügbarkeit der Substanz Ethanol macht die Nutzung wirtschaftlich sinnvoll. Ein Ausweichen auf Alternativstoffe

	und Produkte ohne Ethanol hätte mit ziemlich großer Sicherheit negative, wirtschaftliche Effekte für Unternehmen.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Wie bereits beschrieben, ist die Substanz Ethanol in der Lage, Mikroorganismen effizient zu beseitigen. So werden auch unbehüllte Viren durch Ethanol unschädlich gemacht. Andere Stoffe haben diese positiven Eigenschaften nicht unbedingt. Dadurch besteht die realistische Möglichkeit, dass nicht alle Keime beseitigt werden und eine vollständige und zufriedenstellende Desinfektion von Oberflächen und Händen innerhalb des Lebensmittelsektors nicht zu garantieren ist, wenn nur noch alternative Stoffe genutzt werden. Die geringere Verfügbarkeit von wirksamen, alternativen Desinfektionsmitteln könnte die Infektionsraten daher allgemein ansteigen lassen, was vor allem in sensiblen und systemrelevanten Einrichtungen äußerst problematisch erscheint. Auch der Lebensmittelhandel kann als systemrelevant charakterisiert werden. Bei eingeschränkter Nutzung von Ethanol im Lebensmittelhandel sehen wir u.a. die folgenden Gefahren: - Unzureichende Lebensmittelsicherheit in Lebensmittelbetrieben - Gesundheitsgefahren für die Verbraucherinnen und Verbraucher
Information above is confidential	
Justification for confidentiality	
Availability	Ethanol ist dauerhaft verfügbar und daher auch überall einsetzbar. Es gibt hingegen massive Zweifel an der permanenten Verfügbarkeit von Alternativsubstanzen.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Der deutsche Lebensmittelhandel und viele weitere Bereiche bspw. die Lebensmittelproduktion sind auf Ethanol in Desinfektionsmitteln angewiesen. Ethanol besitzt wichtige Eigenschaften, die für den Erhalt der Lebensmittelsicherheit und grundlegender Hygiene notwendig sind (bspw. geruchslos, schnell und rückstandslos verdunstend).

	Außerdem bekämpft Ethanol unbehüllte Viren, die durch andere Substanzen nicht zuverlässig bekämpft werden können. Eine Einstufung von Ethanol als CMR-Stoff brächte massive Auswirkungen mit sich: vor allem die Lebensmittelsicherheit und die Gesundheit der Bevölkerung stünden auf dem Spiel. Für den Lebensmittelhandel ist daher von allergrößter Wichtigkeit weiterhin Ethanol zur Desinfektion für Hände und Oberflächen nutzen zu können.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	IHO (2025): Wirkstoff Ethanol. Wirksam, sicher, unverzichtbar. URL: https://www.iho.de/wp-content/uploads/0010.0056_A4_P3_web.pdf (zuletzt aufgerufen am 15.04.2025). BVMed (2024): Ethanol ist im medizinischen Bereich unverzichtbar. URL: https://www.bvmed.de/verband/presse/pressemeldungen/gemeinsame-pressemeldung-von-bpi-bvmed-iho-und-vdgh-ethanol-ist-im-medizinischen-bereich-unverzichtbar-und-muss-es-bleiben (zuletzt aufgerufen am 15.04.2025).
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 134	2025/04/24 12:40
Country	Germany
Name of organization/institution	Kraul & Wilkening u. Stelling GmbH & Co. KG (KWST)
I do not wish the name of my organisation/institution to be	

published on the ECHA website.	
General information	KWST is an Ethanol manufacturer and distributor, producing over 200 qualities for fuel, food, animal and human health as well as chemical industry. KWST exclusively uses sustainable and renewable raw materials or intermediate products from sustainable and renewable raw materials. KWST is a midsize company, with 70 employees, 200 million Euros annual turnover, manufacturing Ethanol in Hannover-Misburg (Germany) since 1856.
Product Type	1,2,4
Alternative Identity and Properties	Ethanol is a highly effective microbiozide preventing infection even with nosocomial multiresistent microorganisms to humans as well as animals applied as disinfectant on skin and contact surfaces. It is well tolerated in humans and most other species. It is produced from sustainable and renewable raw materials with a low carbon footprint and available world wide. It is the only skin-tolerated substance in humans and most animals, that is inactivating non-enveloped viruses. The only alternatives with similar antimicrobial effect, however, not inactivating non-enveloped viruses, and possibly similar tolerability in humans and animals are n-Propanol and Isopropanol. The general usage of those two alternatives is therefore in combination with ethanol to ensure the required antimicrobial effect in disinfectants used in human hygiene. According to the Robert Koch Institute for the combination considering the type of exposure no cancerogenicity, teratogenicity and mutagenicity has been described until today.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	n-Propanol and Isopropanol are effective antimicrobial biozides however, no properties of inactivating non-enveloped viruses e. g. polio- and entero- and noroviruses have been proven. Both products are contrary to Ethanol not produced from renewable feed stock. They are a byproduct from petrol refinery, processing crude oil or natural gas. Therefore the carbon footprint of those products is very high compared to ethanol.
Information above is confidential	

Justification for confidentiality	
Economic Feasibility	n-Propanol and Isopropanol are due to their limited availability (see below) and their cost intensive production process significantly higher priced (today 50% above ethanol) and highly price volatile. The main reason for price characteristics of those products is the limited availability from less than 10 sources worldwide. As seen during the Covid-19 pandemic limited availability of n-Propanol and Isopropanol led to dramatic price increase. Hence, a limitation to those two alternatives would put governments worldwide, especially in developing countries under dramatic economical pressure in the effect of future endemic and pandemic situations.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	The intention to classify Ethanol as CMR is solely based on the description of hazardous absussive ingestion, while local topical use has been proven to be save. Evenmore Ethanol is a less toxic solvent compared to n-Propanol and Isopropanol. According to the seafety data sheets the oral LD50 in rats is much lower for the alternatives (n-Propanol 1.870 mg/kg; Isopropanol 4.570 mg/kg) than for Ethanol (7.060 mg/kg). Hence, possible accidental oral intake of n-Propanol and Isopropanol desinfectants would be much more dangerous compared to Ethanol products.
Information above is confidential	
Justification for confidentiality	
Availability	n-Propanol and Isopropanol is prouced by less than 10 sources worldwide (e. g. Shell, Ineos, Exxon). These are mainly petro giants that produce n-Propanol and Isopropanol from byproducts from petrol raffinery, processing crude oil or natural gas. This also limits the total future availability as well as todays sourcing locally. The estimated produced volumes p. a. of n-Propanol and Isopropanol in Europe are 100k mt and 700k mt respectively. In comparison 5 million mt Ethanol are produced in Europe p. a. In Europe alone, Ethanol is availble from over 100 producers. Since Ethanol is plant based it is available in all regions world wide. Furthermore future availability is secured due to renewable raw materials. As seen during the Covid-19 pandemic only Ethanol producers

	were therefore able to increase volumes over night, flexibly and locally.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	As shown the possible alternative products are suitable to replace ethanol in terms of effectiveness, availability, economic feasibility, sustainability and safety. Furthermore it can not be excluded that a classification of the alternatives as CMR might be justified. We strongly recommend to abstain from a CMR classification of Ethanol, due to the following reasons. 1. Ethanol needs to remain available for usage in human hygiene as established over milleniums due to its above mentioned beneficial characteristics. 2. The classification is based on studies that analysed risks, which are not in connection with its usage in human hygiene. 3. The classification from our point of view is as justified in 2. not logical and therefore could lower the acceptance of institutions of the EU and its targets in terms of sustainability, indenpence, competitiveness and reduction of bureaucracy. 4. It results in higher costs and threats to the industry while no positive effect for human hygiene or health in general is gained.
Information above is confidential	
Justification for confidentiality	
Other comments	The intended classification of Ethanol as CMR is based on data ot suitable to evaluate the risk of usage in human hygiene. Cancerogenicity, reprotoxicity and possibly mutagenicity have only been proven to occur due to abusive and extensive ingestion of ethanol, while the topical local usage has been proven to be save. CMR may also be proven for n-Propanol and Isopropanol if effects of ingestion by humans could be evaluated to the same extend. However, Ethanol is probably the only microbiozide which also exists as ingredient of food and beverages in higher concentrations. CMR classification of Ethanol threatens the existence of hundreds of products and even companies along the value chain of Ethanol containing products in the European Union, will increase bureaucracy, costs and dependency from producers from third countries.
Information above is confidential	

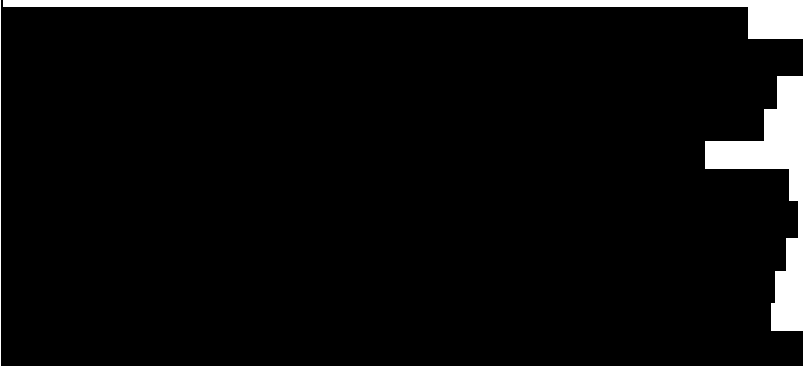
Justification for confidentiality	
References	https://pubmed.ncbi.nlm.nih.gov/34991177/
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Attachments (confidential information)	
Justification for confidential attachment	

Comment 135	2025/04/24 12:46
Country	Germany
Name of organization/institution	BODE Chemie GmbH / Paul Hartmann AG
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	As one of Europe's leading manufacturers, BODE Chemie GmbH offers product solutions for disinfection, cleaning, care and skin antiseptics, together with expert advice, training and digital services. Headquartered in Hamburg, Germany. BODE Chemie GmbH is a subsidiary of PAUL HARTMANN AG, Heidenheim, Germany. Together, they offer comprehensive system solutions for the healthcare sector that are used in over 50 countries worldwide. BODE Chemie GmbH is an applicant for the approval of ethanol under the Biocidal Products Regulation (BPR) and member of the Alcohol Task Force (ATF). The ATF is submitter of the Analysis of Alternatives for the use of ethanol in PT1, PT2 and PT4. Ethanol reacts mainly by denaturing proteins of cell membranes and virus particles as well as of other cellular components, solubilization of lipids and dehydration. Due to the unspecific mode of action of the alcohols, there is no risk of resistance phenomena. Inherent properties of ethanol include a fast and efficient killing effect, rapid evaporation from surfaces during action, no residues on surfaces, long shelf life of formulated products, low degree of deterioration for open packages, and no formation of disinfection byproducts or other toxicologically relevant chemical species for human health and environment.

	Ethanol is naturally produced by intestinal bacteria. Fruit juices may contain up to 3 g ethanol per L, and apple juice contains 1 g ethanol per 500 mL. When using ethanol-based hand disinfectants, the data show that absorption via the skin and respiratory tract is low. There is only a slight increase in the naturally occurring alcohol concentration in the blood. Internal amounts of ethanol resulting from application of hand disinfectant are similar to the consumption of food and in the range of non-alcoholic beverages or even lower. In contrast, blood levels from consumption of alcoholic beverages are of a magnitude that is not reached by occupational or environmental exposure. The exposure from application of disinfectant and use of ethanol as chemical is not comparable to the consumption of alcoholic beverages and lifetime occupational exposure is within the standard deviation of the endogenous exposure. Ethanol-based hand and surface disinfection products have been used for decades. Comprehensive safety assessment has been performed for products in the context of medicinal product, biocidal product or medical device approval. So far, there is no evidence for any cancerogenic, mutagenic or reprotoxic effect resulting from the intended use of ethanol-based hand and surface disinfection products.
Product Type	1,2,4
Alternative Identity and Properties	PT1/PT2 The most effective protective measures against bacterial and viral infections have been proven to include hand disinfection and surface disinfection with ethanol. Propan-1-ol (EC: 200-746-9) and propan-2-ol (EC: 200-661-7) are also effective antimicrobial agents with significant market relevance and are already approved under BPR until 30/04/2029 and until 30/06/2026, respectively. Several BPR authorizations based on propanols are available in the ECHA database for biocidal products. However, these products do not achieve a full virucidal activity in relevant time. PT2 Strong oxidizing substances like peracetic acid and hydrogen peroxide, both approved for PT2, have a broad-spectrum efficacy, including virucidal activity, but are corrosive and highly irritant, requiring Personal Protective Equipment (PPE). Quaternary Ammonium compounds (QACs) include several different active substances, only some of them such as ADBAC (C12-C16) and Didcyldimethylammonium chloride (DDAC) are already approved for PT2. They have limited activity, particularly against non-enveloped viruses. Acids such as acetic and lactic acid are eligible for the simplified authorization procedure under BPR due to their low toxicity but have limited activity against viruses. Aldehydes such as

	glutaraldehyde and formaldehyde are approved for PT2, but both are candidates for substitution, glutaraldehyde due to respiratory sensitization and formaldehyde due to carcinogenic properties. Biphenyl-2-ol, a phenolic substance, is approved for PT2 but has limited efficacy in particular against viruses and is evaluated as a carcinogenic category 2. Phenoxyethanol has not yet been approved under BPR and therefore does not meet the criteria for a viable alternative. Active chlorine releasers are approved for PT2 but for specific uses such as swimming pools and sewage treatment. A major disadvantage of active chlorine substances is the generation of disinfection by-products, with chlorate being the main metabolite of concern. Conclusion Ethanol remains the most cost-effective disinfectant due to its widespread availability, ease of production, and scalability. In contrast, propan-1-ol and propan-2-ol are less cost-effective, with higher production costs and limited supply chains, particularly during high-demand scenarios such as pandemics. The lack of an effective and rapid alternative against non-enveloped viruses would cause further costs for the healthcare systems, as infections would not be controllable anymore. Considering up to 600.000 already apparent nosocomial infections in Germany it is predictable that there will be a steep increase in infections of non-enveloped viruses according to German Robert Koch-Institute (RKI). Considering furthermore that nosocomial infections cause already nowadays up to 20.000 deaths in Germany (RKI), and the lack of adequate infection prevention would predictably cause more such casualties, there is not only the economic impact of the loss of lives but also the unbearable ethical situation in which a safe and effective active substance is withheld from the ones who need it such as healthcare employees, elderly care workers and the overall public.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Efficacy Ethanol used in disinfectants is an effective and safe active substance for the prevention of healthcare associated infections and spread of antimicrobial resistance. Ethanol is valued for its broad-spectrum efficacy against bacteria (including mycobacteria), fungi, as well as against enveloped and non-enveloped viruses. Non-enveloped viruses have a significantly higher stability towards chemical agents than enveloped viruses. Of the three alcohols used

	in hand rub formulations (ethanol, propan-1-ol and propan-2-ol), only ethanol-based formulations proved to be effective within 30–60 s against non-enveloped viruses such as adeno-, polio-, human entero-, echo- and coxsackie viruses in quantitative suspension assays. Formulations containing propan-1-ol and propan-2-ol are not sufficiently active against non-enveloped viruses. Propan-1-ol was not effective against coxsackie, poliovirus and human enterovirus at a 90% concentration within 5 min. Within 2 min, 80%, 90% and 97% propan-1-ol and propan-2-ol, and within 3 min, 70% and 90% propan-1-ol and propan-2-ol, were ineffective against poliovirus. In contrast, ethanol was effective in concentrations of $\geq 70\%$ in suspension tests and in vivo on hands. PT1 Sodium hypochlorite, active chlorine, QACs, acids such as acetic or lactic acid, biguanide, phenols or phenoxyethanol fail to meet the application criteria as alternative as they are primarily suitable for hand washing formulation or applied in combination with alcohol. PT2 Active substances with market relevance such as N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine (Diamine) (EC: 219-145-8) or Magnesium monoperoxyphthalate hexahydrate (MMPP) (279-013-0) are not yet approved under BPR for PT2 and therefore fail to fulfil the selection criteria for a potential alternative. Quaternary Ammonium Compounds (QACs) are well-known active substances in surface disinfectants and some QACs are approved under BPR for PT2. Compared to ethanol, these substances have limited efficacy against gram-negative bacteria and are non-efficacious against non-enveloped viruses. Therefore, they are no viable alternative for ethanol as an active substance in surface disinfection. Regarding efficacy oxidizing agents such as hydrogen peroxide and peracetic acid have a broad-spectrum antimicrobial activity against bacteria, fungi, enveloped and non-enveloped viruses, as well as against spores. Peracetic acid and hydrogen peroxide are approved under BPR for surface disinfection (PT2 and PT4). Due to the requirement of PPE professional use is limited and use for the general public is restricted. Sodium hypochlorite and active chlorine are unstable and fail to meet the application criteria as alternative as they may have strong odor formation. Aldehydes such as glutaraldehyde, formaldehyde and formaldehyde releasers have a broad-spectrum of efficacy, including virucidal activity. Glutaraldehyde and formaldehyde fail to meet the application criteria as alternatives as they are candidates for substitution. Formaldehyde releasers are no longer supported as active substances for surface disinfection. Acids such as acetic or lactic acid fail to meet the application criteria as alternative as they lack full virucidal activity, may

	have strong odor formation, and potential material compatibility issues. Efficacy against viruses other than enveloped viruses is usually not achieved by acid-based products, and they usually lack a rapid efficacy that is required in several applications such as in the medical area. 2-Phenoxyethanol, biphenyl-2-ol and chlorocresol are excluded as viable alternatives to ethanol in PT2 applications due to their limited target spectrum. In contrast to alcohol-based products, products based on alternatives are not residue-free and residues remain on treated surfaces. This has a negative impact for the environment and may require rinsing in critical areas as an additional step. Conclusion Ethanol is a cornerstone of infection control and indispensable for alcohol-based hand rubs (ABHRs) and surface disinfectants due to its superior efficacy against both, non-enveloped and enveloped viruses. Propan-1-ol and propan-2-ol are effective against enveloped viruses but lack sufficient activity against key non-enveloped viruses. There are no viable alternatives due to different reasons such as lack of efficacy, material incompatibility or unfavorable hazard profiles. WHO lists ethanol-formulations as essential medicines. According to WHO ethanol is indispensable and essential for preventing infections. Led by VAH (Association for Applied Hygiene c/o Institute for Hygiene and Public Health) and DGKH (the German Society for General and Hospital Hygiene), the scientific community and healthcare sector have also been pushing against the reclassification, With the support of 35 organizations worldwide, leading hygiene experts have published a scientific article urging ECHA to approve ethanol as a virucidal active substance for use in hand antiseptics without a CMR classification.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	

Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Ethanol is classified under the harmonized classification system according to CLP Regulation as flammable liquid Category 2 with hazard statement H225. In addition to this harmonized classification, several REACH registrants also self-classify ethanol as eye irritant Category 2 with hazard statement H319. Ethanol is currently under assessment as biocidal active substance. The BPR Working Group concluded that it meets the exclusion criteria for carcinogenicity and reproductive toxicity. No decision on mutagenicity was made. The conclusion is mainly based on oral consumption data. However, for biocidal products oral

intake is prevented by denaturant and the available human data from oral consumption do not represent a 'reasonably expected use' for ethanol as chemical and biocidal active substance and does not fit for purpose with the CLP Regulation. The 'reasonably expected use' is defined in the CLP Guidance:

- Any process, including production, handling, maintenance, storage, transport or disposal.
- All technical operations/manufacturing activities like e.g. spraying, filing, and sawing.
- Any putative consumer contact through e.g. do-it-yourself or household chemicals.
- All professional and non-professional uses include reasonably foreseeable accidental exposure but not abuse such as criminal or suicidal uses.

Human data on adverse effects should obviously be related to the sector of chemical substances (e.g. occupational data and data from accident databases). Data from oral consumption is not suitable to determine the hazard of ethanol from biocidal use, and former assessments from different institutions support this conclusion: The International Agency for Research on Cancer (IARC) has not classified ethanol as chemical substance but explicitly alcoholic beverages as carcinogenic to humans (Group 1). OECD has also evaluated ethanol and focused on its use as an industrial chemical. OECD concluded that ethanol possesses properties that indicate a hazard for human health, but these are manifest only at doses associated with consumption of alcoholic beverages. In the context of an industrial chemical, these hazards do not warrant further work as they are not likely to result from the manufacture and use of ethanol and ethanol containing products. The ECHA Risk Assessment Committee (RAC) has indicated in the cases of acetaldehyde (main metabolite of ethanol) and nicotine that consumption data (drink or tobacco) is not relevant for hazard assessment of a chemical substance. In another case, RAC considered only human data from environmental or occupational exposure as relevant for hazard assessment. In animal studies, adverse effects of ethanol are only observed after oral administration of very high doses that were designed to resemble binge drinking in humans. In rat, mice and rabbit, a No Observed Adverse Effect Level (NOAEL) for CMR properties was determined above the limit dose of 1000 mg/kg bw/d according to the BPR dossier and REACH documentation. According to the CLP Regulation such a chemical is of low toxicological concern and is normally not classified as hazardous. An assessment of alternatives is reasonable if comparable data is available, and assessment criteria are consistently applied. The assessment approach of the BPC WG to classify a chemical of low toxicological concern in the most severe classification category based on

	data that is not relevant in the context of an industrial chemical does not allow for a reliable assessment of alternatives. If comparable data related to the context of industrial chemical is applied for ethanol, ethanol would not be of concern and even show a higher level of safety compared to several other approved active substances of the BPR Review programme for the relevant product types. Classification is a hazard-based approach and does not consider the actual risk of the user from inhalation and dermal exposure. It is obvious that the route of exposure has a major impact and exposure to disinfectants is not comparable to oral consumption of alcoholic beverages. Ethanol evaporates rapidly from the skin and uptake via the dermal route is low. Air concentrations of ethanol at workplaces are generally expected to be well below national occupational exposure limits. Occupational exposure does not lead to a significant increase in the concentration of ethanol in the blood. Exposure up to exposure limits applicable in Germany and the Netherlands does not contribute significantly to a cancer risk. Moreover, Dutch DECOS and the German MAK Commission concluded that blood levels are the relevant parameter for developmental and reproductive effects. According to DECOS maximal blood ethanol concentration after one (oral) drink is approximately 10-100 times higher than after inhalation to 1300 mg/m³ in 8 hours (three to five times higher than the occupational limits specified at 260 mg/m³ and 380 mg/m³). In line the German MAK Commission concluded that blood levels relevant for developmental effects will never be reached if the standard is observed (DECOS 2006, MAK 2018). Hence, lifetime occupational exposure to ethanol via application to the skin or by inhalation from the use of biocidal products remains within the standard deviation of the endogenous body burden and an acceptable risk can be established for inhalation and the dermal route. Alcohol-based surface disinfectant products can usually be applied without PPE if infection protection in medical areas allows for work without gloves as no hazard or risk is identified for the dermal route. Hazard profile of the alternatives PT1 / PT2 Propan-1-ol is already approved under BPR, making it a viable alternative. However, it poses flammability risks (H225), is classified as eye damage Category 1 (H318) and may cause drowsiness or dizziness (H336, STOT SE 3). Due to the classification as eye corrosive, products with concentrations above 3% may not be sold to the general public. Propan-2-ol is approved under BPR, making it a viable alternative. Like propan-1-ol, it has flammability risks (H225), causes eye irritation Category 2 (H319) and may cause drowsiness or dizziness

(H336, STOT SE 3). While propan-2-ol has a similar risk level compared to ethanol, propan-2-ol does not meet the efficacy requirement as rapidly acting virucidal disinfectant.

PT2 Hydrogen peroxide / Peracetic acid Hydrogen peroxide is approved under BPR, making it a viable alternative. Hydrogen peroxide is classified as Acute Tox.4 (H302, and H332) and Skin Corrosion 1A (H314). Occupational exposure limits and toxicological reference values exist for hydrogen peroxide that are significantly lower than for ethanol. A few biocidal products are authorized and the request for PPE such as respiratory masks or RMMs that rooms cannot be entered for specific uses indicates that the use of peroxides may be of concern. Therefore, peroxide-based products do not represent alternatives for ethanol. Moreover, the use of peroxides for professional use is limited and restricted for the general public due to the requirement of PPE to avoid either irritant effect or whitening of skin when used repeatedly. Hydrogen peroxide has been shown to be carcinogenic and mutagenic in animal studies at very high concentrations but is not classified according to CLP Regulation. Aldehyde such as glutaraldehyde, formaldehyde and formaldehyde releaser are of concern due to sensitizing or carcinogenic properties. Sodium hypochlorite and active chlorine are corrosive. The formation of harmful byproducts is of toxicological concern and may require rinsing in critical areas. The substances may pose a risk for exothermic reactions and chlorine gas release. Products may require PPE such as gloves. QACs are classified as corrosive (e.g. skin or eye damage Category 1 (H318)) and pose a hazard for the environment. Residues remain on treated surfaces. This has a negative impact for the environment and may require rinsing in critical areas as an additional step. Acid such as acetic or lactic acid are corrosive, their mode of action is related to pH. Acid-based products may require PPE such as gloves if regularly used several times a day. Conclusion Ethanol-based hand and surface disinfection products have been used for decades. Comprehensive safety assessment has been performed for products in the context of medicinal product, biocidal product or medical device approval. So far, there is no evidence for any cancerogenic, mutagenic or reprotoxic effect resulting from the intended use of ethanol-based hand and surface disinfection products. An acceptable risk without relevant risk mitigation measures can be established. The classification proposal in the highest and most restrictive CLP category based on oral consumption data is not appropriate and does not account for the overall evidence of the data as well as for fundamental principles of toxicology. In view that no safety concern has been

	identified for the actual use the exclusion or substitution of ethanol will therefore represent a regrettable measure. In contrast, the substitution will pose an additional risk for user and patients due to shortcomings in infection prevention. There are no viable alternatives for ethanol due to different reasons such as unfavorable hazard profiles, lack of efficacy or material incompatibility.
Information above is confidential	
Justification for confidentiality	
Availability	Ethanol is readily available in the market due to a diverse range of formulators and active substance manufacturers. This abundance of suppliers fosters competition, further driving down costs and ensuring that a variety of ethanol-based disinfectant products are accessible to users in public health sectors, allowing compliance with hygiene standards without significant financial burden. Additionally, ethanol production is more adaptable to demand surges, allowing for quicker scaling compared to the production of propan-1-ol or propan-2-ol, which was convincingly demonstrated during the COVID-19 pandemic. This makes ethanol not only more available but also a more reliable and practical option for meeting high demand needs in critical sectors like healthcare. Outbreak situations are encountered in the medical sector - especially during winter season - and may be restricted to local or regional areas. In such a situation rapid acting disinfectants need to be available for professional and non-professional use at the point of care and without delay. Exemptions, derogation or new authorization for a very limited time period, cannot be expected to cover the demand of the health sector in such a situation if disinfectants are not commonly available on the market and from stock. Propan-1-ol and propan-2-ol are available as alternatives, but their supply situation raises potential concerns. Under the BPR Regulation only 9 (active substance/product) suppliers for propan-1-ol and 69 (active substance/product) suppliers for propan-2-ol are listed, compared to the 247 (active substance/product) suppliers for ethanol, reflecting the significantly broader availability and production base for ethanol. Conclusion Ethanol benefits from a robust and diversified supply chain within the EU, ensuring stable and reliable access even during periods of increased demand, such as the COVID-19 pandemic. This availability mitigates risks of supply shortages and enables rapid scaling to meet healthcare demands. Propan-1-ol and propan-2-ol are present in the

	market, but have a limited number of suppliers, which raises concerns, as the supply may not be sufficient to meet EU-wide demand for disinfectants, especially during a pandemic or other high-demand situations.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	The evaluation of ethanol as CMR substance is predominantly based on oral consumption data and obviously not related to the reasonably expected use of an industrial chemical. Considering the history of ethanol assessment as industrial chemical and experience from RAC opinion in similar cases, such as acetaldehyde, the proposal of the BPC WG appears to be a unique decision. The decision of the BPC WG raises the question whether the purpose of the CLP Regulation is correctly reflected, and the scientific interpretation of data is appropriate. In view that no safety concern is identified for the actual use exclusion or substitution of ethanol will represent a regrettable measure. In contrast, the substitution will pose an additional risk for user and patient due to shortcomings in infection prevention. Ethanol is a cornerstone of infection control and indispensable for alcohol-based hand rubs (ABHRs) and surface disinfectants due to its superior efficacy against non-enveloped viruses. Propan-1-ol and propan-2-ol are effective against enveloped viruses but lack sufficient activity against key non-enveloped viruses. Propan-1-ol and propan-2-ol are present in the market, but have a limited number of suppliers, which raises concerns, as the supply may not be sufficient to meet EU-wide demand for disinfectants, especially during a pandemic or high-demand situations. All in all, there are no viable alternatives due to different reasons such as lack of efficacy, material incompatibility or unfavorable hazard profiles. A classification of ethanol as CMR substance is not appropriate and represents a de facto ban of ethanol as active substance in disinfection due to BPR exclusion criteria and restrictions due to downstream regulation, e.g., on worker and maternity protection. CMR classification has to be avoided, because ethanol is indispensable and must be available for professional and non-professional use in hand- and surface disinfection without any restrictions.
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Justification for confidentiality	

Other comments	Sustainability Ethanol is primarily derived from renewable resources such as biomass and agricultural residues. Therefore, ethanol supports the EU's commitment to reducing dependency on fossil fuels while promoting circular economic principles. Its renewable sources and its high biodegradability result in a low environmental footprint, minimizing environmental persistence and ensuring compliance with the EU's vision for reducing ecological harm through sustainable resource use. In contrast, propan-1-ol and propan-2-ol are petrochemical derivatives, relying on non-renewable resources. Conclusion The characteristic of ethanol ensures minimal environmental impact while maintaining high standards of infection control, supporting the EU sustainability goals including the European Green Deal as well as the European Circular Economy Action Plan.
Information above is confidential	
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References	WHO lists ethanol-formulations as essential medicines. According to WHO ethanol is indispensable and essential for preventing infections. - WHO Model Lists of Essential Medicines. The scientific community and healthcare sector have also been pushing against the reclassification, led by VAH (Association for Applied Hygiene c/o Institute for Hygiene and Public Health) and DGKH (the German Society for General and Hospital Hygiene). With the support of 35 organizations worldwide, leading hygiene experts have published a scientific article urging ECHA to approve ethanol as a virucidal active substance for use in hand antiseptics without a CMR classification. - Ethanol is indispensable for virucidal hand antisepsis: memorandum from the alcohol-based hand rub (ABHR) Task Force, WHO Collaborating Centre on Patient Safety, and the Commission for Hospital Hygiene and Infection Prevention (KRINKO), Robert Koch Institute, Berlin, Germany - PubMed & GMS GMS Hygiene and Infection Control Medical associations and expert committees urge that ethanol be approved as a virucidal active substance for use in hand antiseptics under the European Biocidal Products Regulation, without a CMR classification. - GMS GMS Hygiene and Infection Control Medical associations and expert committees urge that ethanol be approved as a virucidal active substance for use in hand antiseptics under the European Biocidal Products Regulation, without a CMR classification.

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Attachments (confidential information)	
Justification for confidential attachment	

Comment 136	2025/04/24 13:08
Country	Germany
Name of organization/institution	Finzelberg Gmbh & Co. KG
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Finzelberg GmbH & Co. KG is a manufacturer of active pharmaceutical ingredients based on botanical extracts. Finzelberg develops, optimize and offer safe and efficacious botanical products for our customers in the pharmaceutical and dietary supplement industries. During the COVID pandemic Finzelberg produced hand sanitation solution based on ethanol. This was possible due to the "General Decree authorising biocidal products containing ethanol for hygienic hand disinfection for supply to and use by consumers and professional users due to a risk to public health." Finzelberg had chosen Formula G: Ethanol 80% (v/v); • Ethanol der Mindestreinheit 96% 83,33 ml • Purified Wasser 16,67 ml Finzelberg is registered at the EUDRA GMDP database with the number: DE_RP_01_MIA_2022_0031 . For several reasons Finzelberg had chosen to produce a hand rub disinfection based on ethanol: Superior Antimicrobial Efficacy • Ethanol (70-90%) is highly effective against a broad spectrum of pathogens, including bacteria, viruses (such as SARS-CoV-2, influenza, and norovirus), and fungi. • Ethanol is the only disinfectant with effect against non-enveloped viruses. • Ethanol is recommended by the WHO as ethanol shows benefits over other disinfectants. [WHO Guidelines on Hand Hygiene in Health Care, 2009]. • EBHR acts faster than other alcohols like isopropanol or n-propanol. • The WHO opinion regarding the superior efficacy is supported by The Association for Applied

	Hygiene [VAH, Ethanol is an indispensable biocidal agent for hygienic hand disinfection] • "The effectiveness of ethanol against various adenoviruses, poliovirus, human enterovirus, echoviruses, and various coxsackieviruses is superior to that of other alcohols, such as 1-propanol and 2-propanol, and has a stronger effect. Additionally, the amounts of ethanol absorbed through hand disinfection remain below toxicologically relevant concentrations. Therefore, the proper use of ethanol-based hand disinfectants continues to be considered safe." • Also Kramer et.al evaluated ethanol used as hand rub disinfectant being more efficient than 1-propanol and 2-propanol as both do not kill non-enveloped viruses. • Ethanol absorbed through the skin during hand hygiene is similar to consumption of beverages with hidden ethanol content (below 0.5% v/v), such as apple juice or kefir. There is no risk of carcinogenicity, mutagenicity or reprotoxicity from repeated use of EBHR. Hence, the WHO Task Force strongly recommend retaining ethanol as an essential constituent in hand rubs for healthcare." [Kramer, A., Arvand, M., Christiansen, B. et al. Ethanol is indispensable for virucidal hand antisepsis: memorandum from the alcohol-based hand rub (ABHR) Task Force, WHO Collaborating Centre on Patient Safety, and the Commission for Hospital Hygiene and Infection Prevention (KRINKO), Robert Koch Institute, Berlin, Germany. Antimicrob Resist Infect Control 11, 93 (2022). https://doi.org/10.1186/s13756-022-01134-7] • Ethanol absorbed through the skin during hand hygiene is similar to consumption of beverages with hidden ethanol content (below 0.5% v/v), such as apple juice or kefir. There is no risk of carcinogenicity, mutagenicity or reprotoxicity from repeated use of EBHR. Hence, the WHO Task Force strongly recommend retaining ethanol as an essential constituent in hand rubs for healthcare." [Kramer, A., Arvand, M., Christiansen, B. et al. Ethanol is indispensable for virucidal hand antisepsis: memorandum from the alcohol-based hand rub (ABHR) Task Force, WHO Collaborating Centre on Patient Safety, and the Commission for Hospital Hygiene and Infection Prevention (KRINKO), Robert Koch Institute, Berlin, Germany. Antimicrob Resist Infect Control 11, 93 (2022). https://doi.org/10.1186/s13756-022-01134-7] 2. Safety Profile • Ethanol is less toxic and has a better skin tolerance compared to isopropanol or chlorhexidine. • It causes less skin irritation and has a lower risk of absorption through the skin, making it safer for frequent use by healthcare workers. Lower Residual Toxicity • Unlike some disinfectants (e.g., chlorhexidine, quaternary ammonium compounds), ethanol evaporates

	quickly and leaves no harmful residues. • It reduces the risk of chemical buildup on hands, which can cause skin irritation or allergic reactions. Availability and Cost • Finzelberg had sufficient amount of ethanol available and the EBHR could be produced locally on site. This would not be possible with other disinfectants like e.g. 1- or 2-propanol. • Beside all other reasons the prompt and the almost unlimited availability was the reason to produce an ethanol-based hand rub disinfectant Environmental Considerations • Ethanol-based formulations are biodegradable and less harmful to the environment than some other disinfectants, which may persist in water systems.
Product Type	1,2,4
Alternative Identity and Properties	To our knowledge and as mentioned above there are no alternatives for the replacement of ethanol as disinfectant. In particular when it comes to occupational safety it is difficult to follow safety concerns expressed for the use of ethanol as hand rub disinfectant. According to experiments on cultures of human skin, a permeability constant of 3.2 µg/h was determined for Ethanol. From this data, a possible skin uptake (flux) of 0.25 mg/cm² x h was estimated for undiluted Ethanol. Consequently, if both hands and forearms are in contact with the liquid, about 500 mg Ethanol would be dermally absorbed within 1 hour. This amount corresponds to less than 10 % of the dose which would be absorbed inhalatively if the Ethanol concentration in the air is 500 ppm. Therefore, intake through the skin is considered to be insignificant. In a study conducted by Kramer et al the outcome of the test looking at the absorption of ethanol after excessive hand disinfection revealed the overall dermal and pulmonary absorption of ethanol being below toxic levels in humans and allows the conclusion that the use of the evaluated ethanol-based hand-rubs is safe. [A. Kramer et. al, Quantity of ethanol absorption after excessive hand disinfection using three commercially available hand rubs is minimal and below toxic levels for humans; BMC Infectious Diseases 2007, 7:117] Lifetime exposure to ethanol from occupational exposure below 500 ppm does not significantly contribute to the cancer risk. Mutagenic effects were observed only at doses within the toxic range in animal studies. While reprotoxicity is linked with abuse of alcoholic beverages, there is no epidemiological evidence for this from EBHR use in healthcare facilities or from products containing ethanol in non-healthcare settings. [Kramer et al. Antimicrobial Resistance & Infection Control (2022) 11:93] "The result of

	a risk assessment shows that with careful use of alcohol-based hand disinfectants there is no toxic hazard at any time [...]” [N. Bieber: Alkoholresorption nach Händedesinfektion; Kontrollierte randomisierte verblindete klinische Studie zur Resorption von Ethanol, Propan-1-ol und Propan-2-ol sowie deren Metabolite und Schlußfolgerungen zum risk assessment, Inaugural – Dissertation]
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Based on the “General Decree authorising biocidal products containing ethanol for hygienic hand disinfection for supply to and use by consumers and professional users due to a risk to public health.” Finzelberg was able to produce and to provide ethanol-based hand rub disinfectants For Finzelberg the production of any other disinfectant was not possible due to the immediate availability of ethanol.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Within the EU, several hundred companies produce ethanol. E.g. propanol is produced by only five companies. A small number of producers poses the risk of supply risks.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	For Finzelberg only ethanol is available on short notice with almost no limitations. Within the EU, there are several hundred ethanol producers. Ethanol can also be produced by alcoholic fermentation ensuring an unlimited supply if needed.

Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol is indispensable in the healthcare sector, particularly in disinfectants, the use of medical devices, and the manufacturing of pharmaceuticals. Its antimicrobial properties are highly effective against bacteria and viruses, including non-enveloped viruses and play a crucial role in reducing nosocomial infections. During the Covid-19 pandemic, Finzelberg was able to provide an ethanol-based hand rub disinfectant as an answer to the high demand for disinfectants. Lifetime exposure to ethanol from occupational exposure below 500 ppm does not significantly contribute to the cancer risk. Mutagenic effects were observed only at doses within the toxic range in animal studies. While reprotoxicity is linked with the abuse of alcoholic beverages, there is no epidemiological evidence for this from EBHR use in healthcare facilities or from products containing ethanol in non-healthcare settings. [Kramer et al. Antimicrobial Resistance & Infection Control (2022) 11:93]
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	WHO Guidelines on Hand Hygiene in Health Care, 2009, https://www.who.int/publications/i/item/9789241597906 Verbund für Angewandte Hygiene e.V. ,Ethanol ist als biozider Wirkstoff zur hygienischen Händedesinfektion unverzichtbar, 20.10.2020 https://vah-online.de/files/download/vah-mitteilungen/VAH_Ethanol_HM_11_20_194_200.pdf Kramer, A., Arvand, M., Christiansen, B. et al. Ethanol is indispensable for virucidal hand antisepsis: memorandum from the alcohol-based hand rub (ABHR) Task Force, WHO Collaborating Centre on Patient Safety, and the Commission for Hospital Hygiene and Infection Prevention (KRINKO), Robert Koch Institute, Berlin, Germany. Antimicrob Resist Infect Control 11, 93 (2022). https://doi.org/10.1186/s13756-022-01134-7 A. Kramer

	et. al, Quantity of ethanol absorption after excessive hand disinfection using three commercially available hand rubs is minimal and below toxic levels for humans; BMC Infectious Diseases 2007, 7:117 https://bmcinfectdis.biomedcentral.com/articles/10.1186/1471-2334-7-117 Kramer et al. Antimicrobial Resistance & Infection Control (2022) 11:93 [Nora Bieber: Alkoholresorption nach Händedesinfektion; Kontrollierte randomisierte verblindete klinische Studie zur Resorption von Ethanol, Propan-1-ol und Propan-2-ol sowie deren Metabolite und Schlußfolgerungen zum risk assessment, Inaugural – Dissertation, Ernst-Moritz -Arndt-Universität Greifswald https://epub.ub.uni-greifswald.de/frontdoor/deliver/index/docId/25/file/Alkoholresorption_nach_Haendedesinfektion.pdf
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 137	2025/04/24 14:13
Country	Germany
Name of organization/institution	BÜFA Cleaning GmbH & Co. KG
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	We produce and provide a liquid, ready to use hand disinfectant, containing ethanol as an ingredient with significant microbiocidal properties and benefit. It covers a wide range of efficacy and can combat bacterias, funghis, yeasts and viruses.
Product Type	1,2,4
Alternative Identity and Properties	The outcome of an intensive research concerning appropriate substitutes is, that there is no chemical with properties suitable to replace ethanol: Propan-1-ol and Propan-2-ol

	have an efficacy gap regarding full virucidal activities. Offered volumes are not sufficient to meet the demands of producers in the EU. They are not completely virucidal. Iodine: Endocrine Disruptor for human and environment, not readily available in sufficient quantities, not fast enough for efficacy, residue formation, DBP-formation NaOCl: DBP-formation, no evaporation, corrosive, reactivity with other chemicals in product formulations. CHDG & QAC: no full virucidal activity, residues, not fast efficacy action Monochlor-amine: DBP formation, only in situ generation, not storable, Chlorocresol: skin sensitizer, Phenol as degradation product: H2O2: not fast efficacy action, no evaporation, longevity not sufficient, corrosive, not efficacious at low concentrations and ambient temperatures. Lactic Acid: not full virucidal, odor formation Phenoxyethanol: not full virucidal Peracetic acid: corrosive, reactivity with other chemicals in product formulations. Higher safety standards for workers and higher storage standards. Other disinfectant active substances are not skin friendly or act not fast enough within seconds, or do not evaporate, or do stick on the skin.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
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Economic Feasibility	CMR classification would impact the use of ethanol in biocidal products, consumer products and as an industrial chemical, too. This would bring no health benefits at all to society but massive socioeconomic disruption. The ethanol exposition from either working with ethanol in the workplace or using ethanol containing consumer products is not harmful. In comparison with the impact given by consuming alcoholic beverages, this impact is rather negligible. To our latest information the total market for ethanol in the EU is over 6 million tons per year - appr. 1.2 mt is for industrial uses, 0.79 mt in alcoholic beverages. The bulk is used for fuel. If ethanol would be classified as a CMR substance, most of this total market would be impacted severely, and in many cases the use of ethanol would have to be stopped. Effects would be seen in private households and in the industrial sector as well. It would mean a huge

	loss of many products for consumers and industry use. Handling restrictions would make the use of ethanol difficult or impossible due to practical efforts and its derived costs.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
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Justification for confidentiality	
Availability	The supply chain supporting ethanol-based disinfectants is robust and regionally integrated, with significant production and formulation activities in several states in the EU. A significant part of Ethanol is sourced from renewable feedstocks and undergoes processes such as dehydration and denaturation before formulation into biocidal products. These products are distributed through vertically integrated networks to hospitals, public institutions, and consumers, ensuring a steady supply for diverse applications. Ethanol production is well-established with stable supply chains. Alternative biocides face higher production costs, lower availability, and logistical challenges. Regulatory decisions should account for economic feasibility and continuity of supply to prevent market disruptions.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	There is no appropriate substance to be found as a substitute for ethanol. The absence of ethanol as a biocidal active substance would severely hinder the ability to maintain hygienic environments in healthcare settings. Alternative disinfectants often lack ethanol's unique combination of rapid efficacy, safety, and widespread availability. Many biocidal substances come with significant trade-offs, such as corrosive properties, environmental persistence, or safety concerns, none of which are associated with ethanol-based formulations. Ethanol is indispensable in hospitals, where disinfectants must act quickly to reduce microbial contamination while being compatible with sensitive medical equipment and safe for

	patients and staff. Its rapid evaporation minimizes exposure time, enabling efficient infection control in high-touch areas, surgical theaters, and patient rooms. Unlike some alternatives, ethanol's compatibility with diverse materials ensures it can be used without causing damage, making it an essential tool for a broad range of medical applications. Ethanol's unique combination of attributes—its effectiveness, safety, and alignment with sustainability goals—positions it as an essential component in healthcare disinfection strategies. A shift away from ethanol would not only compromise infection control standards but also require substantial changes in procurement processes and operational practices within healthcare institutions. The critical role of ethanol extends beyond practical applications to economic considerations.
Information above is confidential	
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Other comments	Ethanol fulfills requirements which no other biocidal active substance can cover in total: • High efficacy against non-enveloped viruses, which is critical for infection control. • No residues on surfaces, making it safe for food contact applications. • Rapid evaporation, ensuring convenient use in healthcare and public settings • Ethanol is one of the few substances fully virucidal and efficient against non-enveloped viruses such as noroviruses and polioviruses. • Supported by WHO recommendations and studies (e.g., Kramer et al., 2022) that highlight its superior disinfection properties. • Long shelf life of formulated products, ensuring stability and usability over time. • No toxicologically relevant residues or persistent environmental contamination. • No reported cases of skin sensitization under normal use. • Compared to alternatives, lower risk of accidental poisoning due to rapid evaporation. • No tainting of food and odorless, making it suitable for food-related applications. Ethanol is under assessment for potential classification as carcinogenic and/or toxic to reproduction. However: • There is no conclusive evidence of carcinogenicity from real-world exposure levels. • Toxicological evaluations should differentiate ingestion vs. topical and inhalation exposure. • Any classification must consider risk-based assessment rather than hazard-only classification
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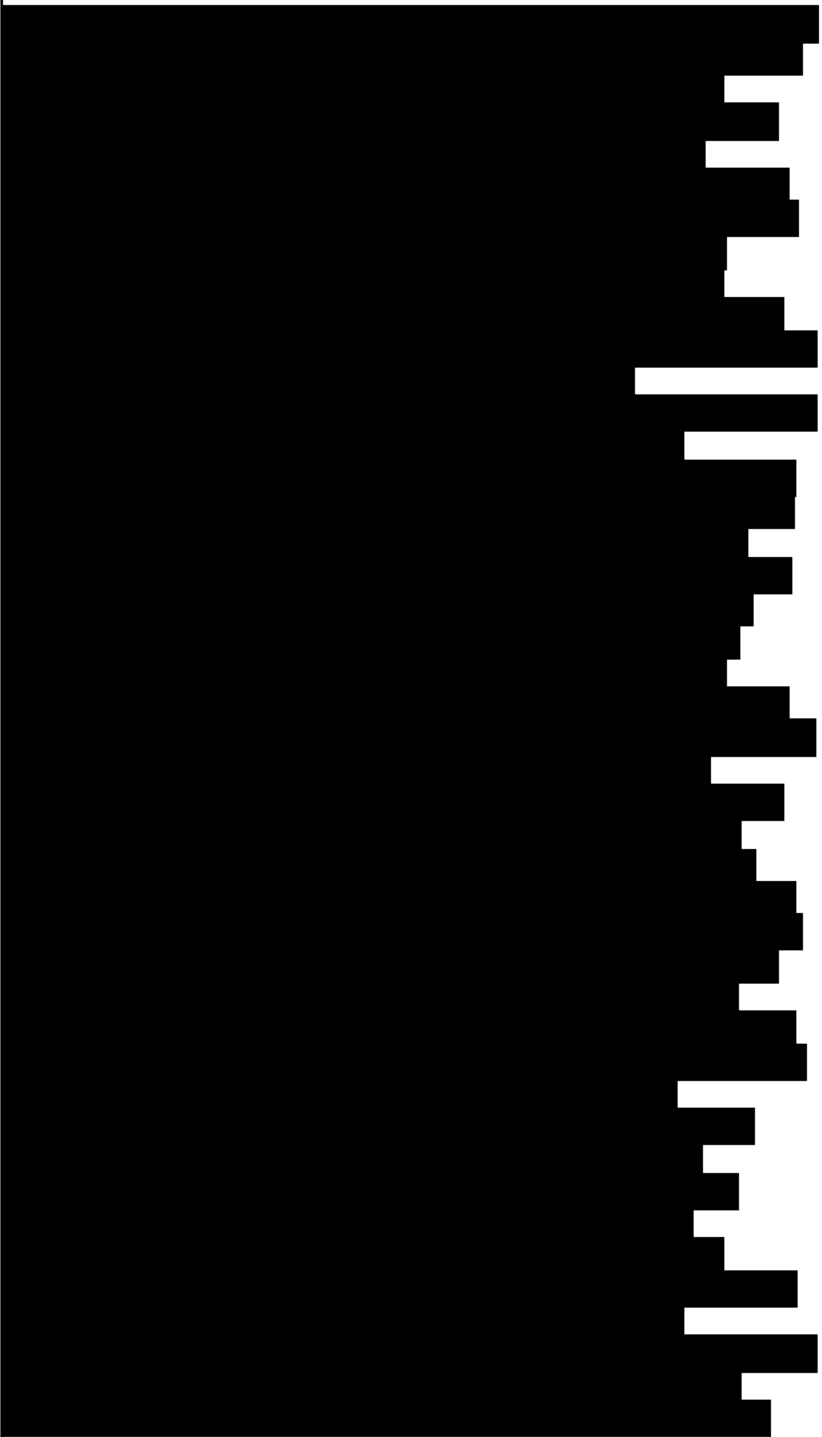
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 139	2025/04/24 14:24
Country	Netherlands
Name of organization/institution	PAUL HARTMANN BV (the Netherlands) and N.V. PAUL HARTMANN S.A. (Belgium)
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Ethanol primarily works by denaturing proteins in cell membranes, virus particles, and other cellular components, as well as solubilizing lipids and causing dehydration. Because alcohols act in a non-specific manner, there is no risk of developing resistance. Ethanol's inherent properties include a rapid and effective killing action, quick evaporation from surfaces during use, no residue left behind, long shelf life of formulated products, minimal deterioration in open packages, and no formation of disinfection byproducts or other toxicologically harmful chemicals for human health and the environment. Ethanol is naturally produced by intestinal bacteria. Fruit juices can contain up to 3 grams of ethanol per liter, with apple juice containing about 1 gram per 500 milliliters. When using ethanol-based hand disinfectants, studies show that absorption through the skin and respiratory tract is minimal, leading to only a slight increase in the naturally occurring alcohol levels in the blood. The internal ethanol levels from using hand disinfectants are comparable to those from consuming food and are within the range of non-alcoholic beverages or even lower. In contrast, the blood alcohol levels from consuming alcoholic beverages are significantly higher and are not reached through occupational or environmental exposure.

	The exposure from using disinfectants and ethanol as a chemical is not comparable to consuming alcoholic beverages, and lifetime occupational exposure remains within the standard deviation of endogenous exposure. Ethanol-based hand and surface disinfectants have been used for many years. Comprehensive safety assessments have been conducted for these products in the context of medicinal, biocidal, or medical device approval. To date, there is no evidence of any carcinogenic, mutagenic, or reprotoxic effects from the intended use of ethanol-based hand and surface disinfectants.
Product Type	1,2,4
Alternative Identity and Properties	PT1/PT2 Hand and surface disinfection with ethanol has been proven to be among the most effective measures against bacterial and viral infections. Propan-1-ol (EC: 200-746-9) and propan-2-ol (EC: 200-661-7) are also effective antimicrobial agents with significant market relevance. They are approved under the Biocidal Products Regulation (BPR) until April 30, 2029, and June 30, 2026, respectively. Several BPR authorizations for biocidal products based on propanols are available in the ECHA database. However, these products do not achieve full virucidal activity within the relevant time frame. PT2 Strong oxidizing agents like peracetic acid and hydrogen peroxide, both approved for PT2, are highly effective against a broad spectrum of pathogens, including viruses. However, they are corrosive and highly irritating, necessitating the use of Personal Protective Equipment (PPE). Quaternary Ammonium Compounds (QACs) encompass various active substances, with only some, such as ADBAC (C12-C16) and Didecyltrimethylammonium chloride (DDAC), approved for PT2. These compounds have limited efficacy, especially against non-enveloped viruses. Acids like acetic and lactic acid qualify for the simplified authorization procedure under BPR due to their low toxicity, but they have limited antiviral activity. Aldehydes, including glutaraldehyde and formaldehyde, are approved for PT2 but are candidates for substitution due to glutaraldehyde's respiratory sensitization and formaldehyde's carcinogenic properties. Biphenyl-2-ol, a phenolic compound, is approved for PT2 but has limited efficacy against viruses and is classified as a category 2 carcinogen. Phenoxyethanol has not yet received approval under BPR and thus does not qualify as a viable alternative. Active chlorine releasers are approved for PT2 but are primarily used in specific applications like swimming pools and sewage treatment. A significant drawback of active chlorine substances is the production of disinfection by-

	products, with chlorate being the main metabolite of concern.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Ethanol is a highly effective and safe active ingredient in disinfectants, crucial for preventing healthcare-associated infections and curbing the spread of antimicrobial resistance. It is appreciated for its broad-spectrum efficacy against bacteria (including mycobacteria), fungi, and both enveloped and non-enveloped viruses. Non-enveloped viruses are notably more resistant to chemical agents compared to enveloped viruses. Among the three alcohols commonly used in hand rub formulations—ethanol, propan-1-ol, and propan-2-ol—only ethanol-based formulations have demonstrated effectiveness within 30–60 seconds against non-enveloped viruses such as adenovirus, poliovirus, human enterovirus, echovirus, and coxsackievirus in quantitative suspension assays. Formulations containing propan-1-ol and propan-2-ol do not exhibit sufficient activity against non-enveloped viruses. Specifically, propan-1-ol at a 90% concentration was ineffective against coxsackievirus, poliovirus, and human enterovirus within 5 minutes. Similarly, propan-1-ol and propan-2-ol at concentrations of 80%, 90%, and 97% within 2 minutes, and at 70% and 90% within 3 minutes, failed to effectively combat poliovirus. In contrast, ethanol at concentrations of 70% or higher has proven effective in suspension tests and in vivo on hands. PT1 Sodium hypochlorite, active chlorine, QACs, acids like acetic or lactic acid, biguanide, phenols, and phenoxyethanol do not meet the criteria for use as standalone alternatives. They are mainly suitable for hand washing formulations or need to be combined with alcohol for effective application. PT2 Active substances like N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine (Diamine) (EC: 219-145-8) and Magnesium monoperoxyphthalate hexahydrate (MMPP) (EC: 279-013-0) are not yet approved under the Biocidal Products Regulation (BPR) for PT2, thus failing to meet the criteria for potential alternatives. Quaternary Ammonium Compounds (QACs) are well-known in surface disinfectants, with some approved under BPR for PT2. However, compared to ethanol, QACs have limited efficacy against gram-negative bacteria and are ineffective against non-enveloped viruses, making them unsuitable as alternatives for ethanol in surface disinfection. Oxidizing agents like hydrogen peroxide and peracetic acid

	have broad-spectrum antimicrobial activity against bacteria, fungi, enveloped and non-enveloped viruses, and spores. Both are approved under BPR for surface disinfection (PT2 and PT4). However, their use is limited to professionals due to the requirement for Personal Protective Equipment (PPE), and their application for the general public is restricted. Sodium hypochlorite and active chlorine are unstable and fail to meet the criteria as alternatives due to potential strong odor formation. Aldehydes such as glutaraldehyde and formaldehyde have broad-spectrum efficacy, including virucidal activity, but are candidates for substitution due to their harmful properties. Formaldehyde releasers are no longer supported for surface disinfection. Acids like acetic and lactic acid do not meet the criteria as alternatives due to their limited virucidal activity, potential strong odor formation, and material compatibility issues. Acid-based products generally lack rapid efficacy required in medical applications and are ineffective against non-enveloped viruses. 2-Phenoxyethanol, biphenyl-2-ol, and chlorocresol are excluded as viable alternatives to ethanol in PT2 applications due to their limited target spectrum. Unlike alcohol-based products, alternatives leave residues on treated surfaces, negatively impacting the environment and necessitating rinsing in critical areas. Conclusion Ethanol is essential for infection control and is irreplaceable in alcohol-based hand rubs (ABHRs) and surface disinfectants because of its superior effectiveness against both non-enveloped and enveloped viruses. While propan-1-ol and propan-2-ol are effective against enveloped viruses, they do not provide adequate activity against important non-enveloped viruses. There are no viable alternatives to ethanol due to various factors such as insufficient efficacy, material incompatibility, or unfavorable hazard profiles. The World Health Organization (WHO) lists ethanol-based formulations as essential medicines, highlighting their indispensable role in preventing infections. The scientific community and healthcare sector, such as Sciensano and the Belgian Society for Hospital Hygiene (BSHH) emphasize the critical role of ethanol in infection control, particularly in healthcare settings. The Belgian scientific community supports the call for ECHA to recognize ethanol's efficacy and safety, ensuring its continued use in hand antiseptics without restrictive classifications. Supported by 35 organizations worldwide, leading hygiene experts have published a scientific article urging the European Chemicals Agency (ECHA) to approve ethanol as a virucidal active substance for use in hand antiseptics without a CMR classification. In Belgium, prominent organizations have joined this advocacy.

Information above is confidential	
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Economic Feasibility	

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Hazards and Risks of the Alternative	Ethanol is classified under the harmonized classification system according to the CLP Regulation as a flammable liquid Category 2, with the hazard statement H225. Additionally, several REACH registrants self-classify ethanol as an eye irritant Category 2, with the hazard statement H319. Ethanol is currently under assessment as a biocidal active substance. The BPR Working Group concluded that it meets the exclusion criteria for carcinogenicity and reproductive toxicity, although no decision was made regarding mutagenicity. This conclusion is primarily based on data from oral consumption. However, for biocidal products, oral intake is prevented by the use of denaturants. The available human data from oral consumption do not represent a 'reasonably expected use' for ethanol as a chemical and biocidal active substance, and therefore do not align with the CLP Regulation. The 'reasonably expected use' is defined in the CLP Guidance: - Any process, including production, handling, maintenance, storage, transport or disposal. - All technical operations/manufacturing activities like e.g. spraying, filing, and sawing. - Any putative consumer

	contact through e.g. do-it-yourself or household chemicals. • All professional and non-professional uses include reasonably foreseeable accidental exposure but not abuse such as criminal or suicidal uses. Human data on adverse effects should clearly pertain to the chemical substances sector, such as occupational data and information from accident databases. Data from oral consumption is not appropriate for determining the hazard of ethanol in biocidal use, and previous assessments from various institutions support this conclusion: The International Agency for Research on Cancer (IARC) has classified alcoholic beverages, rather than ethanol itself, as carcinogenic to humans (Group 1). This classification is based on the carcinogenic risks associated with the consumption of alcoholic beverages, which contain ethanol. The OECD has evaluated ethanol, focusing on its use as an industrial chemical. They concluded that ethanol has properties indicating a hazard to human health, but these hazards are only evident at doses associated with the consumption of alcoholic beverages. In the context of its use as an industrial chemical, these hazards do not warrant further investigation, as they are unlikely to result from the manufacture and use of ethanol and ethanol-containing products. The ECHA Risk Assessment Committee (RAC) has stated that consumption data, such as from drinking or tobacco use, is not relevant for the hazard assessment of chemical substances like acetaldehyde (the main metabolite of ethanol) and nicotine. In other cases, RAC has considered only human data from environmental or occupational exposure as relevant for hazard assessment. In animal studies, adverse effects of ethanol are only observed after oral administration of very high doses designed to mimic binge drinking in humans. In rats, mice, and rabbits, a No Observed Adverse Effect Level (NOAEL) for carcinogenic, mutagenic, and reprotoxic (CMR) properties was determined above the limit dose of 1000 mg/kg body weight per day, according to the BPR dossier and REACH documentation. Under the CLP Regulation, such a chemical is considered of low toxicological concern and is typically not classified as hazardous. Assessing alternatives is reasonable if comparable data is available and assessment criteria are consistently applied. The BPC Working Group's approach to classify a chemical of low toxicological concern in the most severe category based on irrelevant data for industrial chemicals does not allow for a reliable assessment of alternatives. If comparable data related to the context of industrial chemical is applied for ethanol, ethanol would not be of concern and even show a higher level of safety compared to several other approved active substances of

the BPR Review programme for the relevant product types. Classification is a hazard-based approach and does not consider the actual risk to users from inhalation and dermal exposure. It is obvious that the route of exposure has a major impact and exposure to disinfectants is not comparable to oral consumption of alcoholic beverages. Ethanol evaporates rapidly from the skin, and dermal uptake is low. Air concentrations of ethanol at workplaces are generally expected to be well below national occupational exposure limits. Occupational exposure does not significantly increase blood ethanol concentration. Exposure up to the limits applicable in Germany and the Netherlands does not significantly contribute to cancer risk. Moreover, Dutch DECOS and the German MAK Commission concluded that blood levels are the relevant parameter for developmental and reproductive effects. According to DECOS, the maximum blood ethanol concentration after one oral drink is approximately 10-100 times higher than after inhalation of 1300 mg/m³ over 8 hours (three to five times higher than the occupational limits of 260 mg/m³ and 380 mg/m³). The German MAK Commission concluded that blood levels relevant for developmental effects will never be reached if the standard is observed. Hence, lifetime occupational exposure to ethanol via skin application or inhalation from biocidal products remains within the standard deviation of the endogenous body burden, establishing an acceptable risk for inhalation and dermal routes. Alcohol-based surface disinfectant products can usually be applied without PPE if infection protection in medical areas allows for work without gloves, as no hazard or risk is identified for the dermal route. Hazard profile of the alternatives PT1 / PT2 Propan-1-ol is already approved under the Biocidal Products Regulation (BPR), making it a viable alternative. However, it poses flammability risks (H225), is classified as causing serious eye damage (Category 1, H318), and may cause drowsiness or dizziness (H336, STOT SE 3). Due to its classification as an eye corrosive, products with concentrations above 3% may not be sold to the general public. Propan-2-ol is also approved under BPR, making it another viable alternative. Like propan-1-ol, it has flammability risks (H225), causes eye irritation (Category 2, H319), and may cause drowsiness or dizziness (H336, STOT SE 3). While propan-2-ol has a similar risk level compared to ethanol, it does not meet the efficacy requirement as a rapidly acting virucidal disinfectant PT2 Hydrogen peroxide / Peracetic acid Hydrogen peroxide is approved under the Biocidal Products Regulation (BPR), making it a viable alternative. However, it is classified as Acute Toxicity Category 4 (H302, H332) and

	Skin Corrosion Category 1A (H314). Occupational exposure limits and toxicological reference values for hydrogen peroxide are significantly lower than those for ethanol. The requirement for PPE, such as respiratory masks or room management measures (RMMs) that prevent room entry during specific uses, indicates potential concerns with peroxide use. Therefore, peroxide-based products do not represent suitable alternatives to ethanol. Additionally, the use of peroxides is limited for professional use and restricted for the general public due to PPE requirements to avoid irritant effects or skin whitening with repeated use. Hydrogen peroxide has shown carcinogenic and mutagenic properties in animal studies at very high concentrations but is not classified as such under the CLP Regulation. Aldehydes like glutaraldehyde, formaldehyde and formaldehyde releaser are concerning due to their sensitizing and carcinogenic properties. Sodium hypochlorite and active chlorine are corrosive and can form harmful byproducts, which may require rinsing in critical areas. These substances may pose risks for exothermic reactions and chlorine gas release, necessitating PPE such as gloves. Quaternary Ammonium Compounds (QACs) are classified as corrosive (e.g., skin or eye damage Category 1, H318) and pose environmental hazards. Residues remain on treated surfaces, negatively impacting the environment and requiring rinsing in critical areas as an additional step. Acids like acetic and lactic acid are corrosive, with their mode of action related to pH. Acid-based products may require PPE such as gloves if used regularly several times a day. Conclusion Ethanol-based hand and surface disinfection products have been used safely for decades. Comprehensive safety assessments have been conducted for these products in the context of medicinal, biocidal, and medical device approvals. To date, there is no evidence of any carcinogenic, mutagenic, or reprotoxic effects from the intended use of ethanol-based hand and surface disinfectants, establishing an acceptable risk without the need for additional risk mitigation measures. The proposal to classify ethanol in the highest and most restrictive CLP category based on oral consumption data is inappropriate, as it does not consider the overall evidence or fundamental principles of toxicology. Given that no safety concerns have been identified for its actual use, excluding or substituting ethanol would be a regrettable decision. Such substitution would pose additional risks to users and patients due to shortcomings in infection prevention. There are no viable alternatives to ethanol due to various factors, including unfavorable hazard profiles, lack of efficacy, or material incompatibility.

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Availability	Ethanol is widely available in the market due to a diverse range of formulators and active substance manufacturers. This abundance of suppliers fosters competition, driving down costs and ensuring that various ethanol-based disinfectant products are accessible to users in public health sectors, allowing compliance with hygiene standards without significant financial burden. Ethanol production is more adaptable to demand surges, allowing for quicker scaling compared to propan-1-ol or propan-2-ol, as demonstrated during the COVID-19 pandemic. This makes ethanol not only more available but also a more reliable and practical option for meeting high demand needs in critical sectors like healthcare. Outbreak situations, especially during the winter season, may be restricted to local or regional areas. In such scenarios, rapid-acting disinfectants need to be available for professional and non-professional use at the point of care without delay. Exemptions, derogations, or new authorizations for a limited time period cannot be expected to cover the health sector's demand if disinfectants are not commonly available on the market and from stock. While propan-1-ol and propan-2-ol are available as alternatives, their supply situation raises potential concerns. Under the BPR Regulation, only 9 suppliers for propan-1-ol and 69 suppliers for propan-2-ol are listed, compared to 247 suppliers for ethanol. This reflects the significantly broader availability and production base for ethanol. Conclusion Ethanol benefits from a robust and diversified supply chain within the EU, ensuring stable and reliable access even during periods of increased demand, such as the COVID-19 pandemic. This availability mitigates risks of supply shortages and enables rapid scaling to meet healthcare demands. Propan-1-ol and propan-2-ol are present in the market but have a limited number of suppliers, raising concerns about their ability to meet EU-wide demand for disinfectants, especially during pandemics or other high-demand situations.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	The evaluation of ethanol as a CMR substance is predominantly based on oral consumption data. This practice does neither represent the relevant exposure

	routes nor the low doses from occupational and environmental exposure and it raises questions about whether the purpose of the CLP Regulation is correctly reflected and whether the scientific interpretation of data is appropriate. Ethanol-based hand and surface disinfection products have been used safely for decades. Comprehensive safety assessments have shown no evidence of carcinogenic, mutagenic, or reprotoxic effects from the intended use of ethanol-based hand rubs and surface disinfectants. Excluding or substituting ethanol would be a regrettable measure, posing additional risks to users and patients due to shortcomings in infection prevention. Ethanol is a cornerstone of infection control and indispensable for alcohol-based hand rubs (ABHRs) and surface disinfectants due to its superior efficacy against non-enveloped viruses. Ethanol remains the most cost-effective disinfectant due to its widespread availability, ease of production, and scalability. Ethanol's characteristics ensure minimal environmental impact, supporting EU sustainability goals such as the European Green Deal and the European Circular Economy Action Plan. Overall, there are no viable alternatives due to various reasons, including lack of efficacy, material incompatibility, or unfavorable hazard profiles. Classifying ethanol as a CMR substance is inappropriate and would effectively ban its use as an active substance in disinfection due to BPR exclusion criteria and downstream regulations, such as worker and maternity protection.
Information above is confidential	
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Other comments	Other comments / Sustainability Ethanol is primarily sourced from renewable resources like biomass and agricultural residues, aligning with the EU's commitment to reducing dependency on fossil fuels and promoting circular economic principles. Its renewable origins and high biodegradability result in a low environmental footprint, minimizing environmental persistence and supporting the EU's vision for sustainable resource use and reduced ecological harm. In contrast, propan-1-ol and propan-2-ol are derived from petrochemicals, relying on non-renewable resources. Conclusion Ethanol's characteristics ensure minimal environmental impact while maintaining high standards of infection control. This supports the EU's sustainability goals, including the European Green Deal and the European Circular Economy Action Plan.

Information above is confidential	
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References	
Attachments (non-confidential information)	dgkh000495.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 138	2025/04/24 14:25
Country	Germany
Name of organization/institution	BÜFA Cleaning GmbH & Co. KG
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	We prodcue and provide a ready to use surface disinfectant, containing ethanol as an ingredient with significant microbiocidal properties and benefit. It covers a wide range or efficacy and can combat bacterias, funghis, yeasts and viruses.
Product Type	1,2,4
Alternative Identity and Properties	The outcome of an intensive research concering appropriate substitutes is, that there is no chemical with properties suitable to replace ethanol: Propan-1-ol and Propan-2-ol have an efficacy gap regarding full virucidal activities. Offered volumes are not sufficient to meet the demands of producers in the EU. They are not completely virucidal. Iodine: Endocrine Disruptor for human and environment, not readily available in sufficient quantities, not fast enough for efficacy, residue formation, DBP-formation NaOCl: DBP-formation, no evaporation, corrosive, reactivity with other chemicals in product formulations. CHDG & QAC: no full virucidal activity, residues, not fast efficacy action Monochlor-amine: DBP formation, only in situ generation,

	not storable, Chlorocresol: skin sensitizer, Phenol as degradation product: H₂O₂: not fast efficacy action, no evaporation, longevity not sufficient, corrosive, not efficacious at low concentrations and ambient temperatures. Lactic Acid: not full virucidal, odor formation Phenoxyethanol: not full virucidal Peracetic acid: corrosive, reactivity with other chemicals in product formulations. Higher safety standards for workers and higher storage standards. Other disinfectant active substances are not skin friendly or act not fast enough within seconds, or do not evaporate, or do stick on the skin.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	CMR classification would impact the use of ethanol in biocidal products, consumer products and as an industrial chemical, too. This would bring no health benefits at all to society but massive socioeconomic disruption. The ethanol exposition from either working with ethanol in the workplace or using ethanol containing consumer products is not harmful. In comparison with the impact given by consuming alcoholic beverages, this impact is rather negligible. To our latest information the total market for ethanol in the EU is over 6 million tons per year - appr. 1.2 mt is for industrial uses, 0.79 mt in alcoholic beverages. The bulk is used for fuel. If ethanol would be classified as a CMR substance, most of this total market would be impacted severely, and in many cases the use of ethanol would have to be stopped. Effects would be seen in private households and in the industrial sector as well. It would mean a huge loss of many products for consumers and industry use. Handling restrictions would make the use of ethanol difficult or impossible due to practical efforts and its derived costs.
Information above is confidential	
Justification for confidentiality	

Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	The supply chain supporting ethanol-based disinfectants is robust and regionally integrated, with significant production and formulation activities in several states in the EU. A significant part of Ethanol is sourced from renewable feedstocks and undergoes processes such as dehydration and denaturation before formulation into biocidal products. These products are distributed through vertically integrated networks to hospitals, public institutions, and consumers, ensuring a steady supply for diverse applications. Ethanol production is well-established with stable supply chains. Alternative biocides face higher production costs, lower availability, and logistical challenges. Regulatory decisions should account for economic feasibility and continuity of supply to prevent market disruptions.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	There is no appropriate substance to be found as a substitute for ethanol. The absence of ethanol as a biocidal active substance would severely hinder the ability to maintain hygienic environments in healthcare settings. Alternative disinfectants often lack ethanol's unique combination of rapid efficacy, safety, and widespread availability. Many biocidal substances come with significant trade-offs, such as corrosive properties, environmental persistence, or safety concerns, none of which are associated with ethanol-based formulations. Ethanol is indispensable in hospitals, where disinfectants must act quickly to reduce microbial contamination while being compatible with sensitive medical equipment and safe for patients and staff. Its rapid evaporation minimizes exposure time, enabling efficient infection control in high-touch areas, surgical theaters, and patient rooms. Unlike some alternatives, ethanol's compatibility with diverse materials ensures it can be used without causing damage, making it an essential tool for a broad range of medical applications. Ethanol's unique combination of attributes—its effectiveness, safety, and alignment with sustainability goals—positions it as an essential component in healthcare.

	disinfection strategies. A shift away from ethanol would not only compromise infection control standards but also require substantial changes in procurement processes and operational practices within healthcare institutions. The critical role of ethanol extends beyond practical applications to economic considerations.
Information above is confidential	
Justification for confidentiality	
Other comments	Ethanol fulfills requirements which no other biocidal active substance can cover in total: • High efficacy against non-enveloped viruses, which is critical for infection control. • No residues on surfaces, making it safe for food contact applications. • Rapid evaporation, ensuring convenient use in healthcare and public settings • Ethanol is one of the few substances fully virucidal and efficient against non-enveloped viruses such as noroviruses and polioviruses. • Supported by WHO recommendations and studies (e.g., Kramer et al., 2022) that highlight its superior disinfection properties. • Long shelf life of formulated products, ensuring stability and usability over time. • No toxicologically relevant residues or persistent environmental contamination. • No reported cases of skin sensitization under normal use. • Compared to alternatives, lower risk of accidental poisoning due to rapid evaporation. • No tainting of food and odorless, making it suitable for food-related applications. Ethanol is under assessment for potential classification as carcinogenic and/or toxic to reproduction. However: • There is no conclusive evidence of carcinogenicity from real-world exposure levels. • Toxicological evaluations should differentiate ingestion vs. topical and inhalation exposure. • Any classification must consider risk-based assessment rather than hazard-only classification In industrial and professional settings, ethanol based disinfectants are crucial for ensuring hygiene in food industry. These surfaces may be the outsides of machinery, equipment, reservoirs for water or feed in animal housing etc. Products are often wiped or sprayed onto the surface. A wiping-off or rinsing step is not necessary as no residue would remain on surface due to ethanol's volatile character. Ethanol based products offer a practical and effective option for maintaining clean workspaces, protecting workers and consumers from exposure to harmful pathogens, and ensuring compliance with occupational health and safety regulations. The 2023 EU-OSHA report highlights that

	biocides like ethanol are essential in preventing workplace outbreaks of infectious diseases, contributing to employee well-being and productivity.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
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Comment 140	2025/04/24 14:31
Country	Germany
Name of organization/institution	BÜFA Cleaning GmbH & Co. KG
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	We prodcue and provide a ready to use surface disinfectant, containing ethanol as an ingredient with significant microbiocidal properties and benefit. It covers a wide range or efficacy and can combat bacterias, funghis, yeasts and viruses
Product Type	1,2,4
Alternative Identity and Properties	The outcome of an intensive research concering appropriate substitutes is, that there is no chemical with properties suitable to replace ethanol: Propan-1-ol and Propan-2-ol have an efficacy gap regarding full virucidal activities. Offered volumes are not sufficient to meet the demands of producers in the EU. They are not completely virucidal. Iodine: Endocrine Disruptor for human and environment, not readily available in sufficient quantities, not fast enough for efficacy, residue formation, DBP-formation NaOCl: DBP-

	formation, no evaporation, corrosive, reactivity with other chemicals in product formulations. CHDG & QAC: no full virucidal activity, residues, not fast efficacy action Monochlor-amine: DBP formation, only in situ generation, not storable, Chlorocresol: skin sensitizer, Phenol as degradation product: H₂O₂: not fast efficacy action, no evaporation, longevity not sufficient, corrosive, not efficacious at low concentrations and ambient temperatures. Lactic Acid: not full virucidal, odor formation Phenoxyethanol: not full virucidal Peracetic acid: corrosive, reactivity with other chemicals in product formulations. Higher safety standards for workers and higher storage standards. Other disinfectant active substances are not skin friendly or act not fast enough within seconds, or do not evaporate, or do stick on the skin.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	CMR classification would impact the use of ethanol in biocidal products, consumer products and as an industrial chemical, too. This would bring no health benefits at all to society but massive socioeconomic disruption. The ethanol exposition from either working with ethanol in the workplace or using ethanol containing consumer products is not harmful. In comparison with the impact given by consuming alcoholic beverages, this impact is rather negligible. To our latest information the total market for ethanol in the EU is over 6 million tons per year - appr. 1.2 mt is for industrial uses, 0.79 mt in alcoholic beverages. The bulk is used for fuel. If ethanol would be classified as a CMR substance, most of this total market would be impacted severely, and in many cases the use of ethanol would have to be stopped. Effects would be seen in private households and in the industrial sector as well. It would mean a huge loss of many products for consumers and industry use. Handling restrictions would make the use of ethanol difficult or impossible due to practical efforts and its derived costs.
Information above is confidential	

Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	The supply chain supporting ethanol-based disinfectants is robust and regionally integrated, with significant production and formulation activities in several states in the EU. A significant part of Ethanol is sourced from renewable feedstocks and undergoes processes such as dehydration and denaturation before formulation into biocidal products. These products are distributed through vertically integrated networks to hospitals, public institutions, and consumers, ensuring a steady supply for diverse applications. Ethanol production is well-established with stable supply chains. Alternative biocides face higher production costs, lower availability, and logistical challenges. Regulatory decisions should account for economic feasibility and continuity of supply to prevent market disruptions.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	There is no appropriate substance to be found as a substitute for ethanol. The absence of ethanol as a biocidal active substance would severely hinder the ability to maintain hygienic environments in healthcare settings. Alternative disinfectants often lack ethanol's unique combination of rapid efficacy, safety, and widespread availability. Many biocidal substances come with significant trade-offs, such as corrosive properties, environmental persistence, or safety concerns, none of which are associated with ethanol-based formulations. Ethanol is indispensable in hospitals, where disinfectants must act quickly to reduce microbial contamination while being compatible with sensitive medical equipment and safe for patients and staff. Its rapid evaporation minimizes exposure time, enabling efficient infection control in high-touch areas, surgical theaters, and patient rooms. Unlike some alternatives, ethanol's compatibility with diverse materials ensures it can be used without causing damage, making it an essential tool for a broad range of medical applications. Ethanol's unique combination of attributes—its

	effectiveness, safety, and alignment with sustainability goals—positions it as an essential component in healthcare disinfection strategies. A shift away from ethanol would not only compromise infection control standards but also require substantial changes in procurement processes and operational practices within healthcare institutions. The critical role of ethanol extends beyond practical applications to economic considerations.
Information above is confidential	
Justification for confidentiality	
Other comments	Ethanol fulfills requirements which no other biocidal active substance can cover in total: • High efficacy against non-enveloped viruses, which is critical for infection control. • No residues on surfaces, making it safe for food contact applications. • Rapid evaporation, ensuring convenient use in healthcare and public settings • Ethanol is one of the few substances fully virucidal and efficient against non-enveloped viruses such as noroviruses and polioviruses. • Supported by WHO recommendations and studies (e.g., Kramer et al., 2022) that highlight its superior disinfection properties. • Long shelf life of formulated products, ensuring stability and usability over time. • No toxicologically relevant residues or persistent environmental contamination. • No reported cases of skin sensitization under normal use. • Compared to alternatives, lower risk of accidental poisoning due to rapid evaporation. • No tainting of food and odorless, making it suitable for food-related applications. Ethanol is under assessment for potential classification as carcinogenic and/or toxic to reproduction. However: • There is no conclusive evidence of carcinogenicity from real-world exposure levels. • Toxicological evaluations should differentiate ingestion vs. topical and inhalation exposure. • Any classification must consider risk-based assessment rather than hazard-only classification Ethanol-based surface disinfectants are indispensable tools for effective hygiene and infection control. Their rapid action, broad-spectrum efficacy, and residue-free properties make them suitable for numerous high-touch surfaces in various environments. Ethanol-based disinfectants play a vital role in maintaining hygiene in high traffic public areas. These products are used to clean frequently touched surfaces such as tables, chairs, door handles, and floors in restaurants, schools, gyms, and offices. In these settings, the risk of cross-contamination is high due to constant human

	interaction. Ethanol's rapid action and broad-spectrum efficacy ensure quick disinfection, reducing the transmission of bacteria, viruses, and fungi. Its quick evaporation minimizes downtime, enabling seamless operations in busy environments without leaving harmful residues that could compromise safety.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 141	2025/04/24 14:38
Country	Germany
Name of organization/institution	BÜFA Chemikalien GmbH & Co. KG
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	We are a trader of ethanol as a biocidal active substance. Our customers produce and provide a liquid, ready to use hand disinfectant, containing ethanol as an ingredient with significant microbiocidal properties and benefit. It covers a wide range of efficacy and can combat bacteria, fungi, yeasts and viruses.
Product Type	1,2,4
Alternative Identity and Properties	The outcome of an intensive research concerning appropriate substitutes is, that there is no chemical with properties suitable to replace ethanol: Propan-1-ol and Propan-2-ol have an efficacy gap regarding full virucidal activities. Offered volumes are not sufficient to meet the

	demands of producers in the EU. They are not completely virucidal. Iodine: Endocrine Disruptor for human and environment, not readily available in sufficient quantities, not fast enough for efficacy, residue formation, DBP-formation NaOCl: DBP-formation, no evaporation, corrosive, reactivity with other chemicals in product formulations. CHDG & QAC: no full virucidal activity, residues, not fast efficacy action Monochlor-amine: DBP formation, only in situ generation, not storable, Chlorocresol: skin sensitizer, Phenol as degradation product: H2O2: not fast efficacy action, no evaporation, longevity not sufficient, corrosive, not efficacious at low concentrations and ambient temperatures. Lactic Acid: not full virucidal, odor formation Phenoxyethanol: not full virucidal Peracetic acid: corrosive, reactivity with other chemicals in product formulations. Higher safety standards for workers and higher storage standards. Other disinfectant active substances are not skin friendly or act not fast enough within seconds, or do not evaporate, or do stick on the skin.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	CMR classification would impact the use of ethanol in biocidal products, consumer products and as an industrial chemical, too. This would bring no health benefits at all to society but massive socioeconomic disruption. The ethanol exposition from either working with ethanol in the workplace or using ethanol containing consumer products is not harmful. In comparison with the impact given by consuming alcoholic beverages, this impact is rather negligible. To our latest information the total market for ethanol in the EU is over 6 million tons per year - appr. 1.2 mt is for industrial uses, 0.79 mt in alcoholic beverages. The bulk is used for fuel. If ethanol would be classified as a CMR substance, most of this total market would be impacted severely, and in many cases the use of ethanol would have to be stopped. Effects would be seen in private households and in the industrial sector as well. It would mean a huge loss of many products for consumers and industry use.

	Handling restrictions would make the use of ethanol difficult or impossible due to practical efforts and its derived costs.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	The supply chain supporting ethanol-based disinfectants is robust and regionally integrated, with significant production and formulation activities in several states in the EU. A significant part of Ethanol is sourced from renewable feedstocks and undergoes processes such as dehydration and denaturation before formulation into biocidal products. These products are distributed through vertically integrated networks to hospitals, public institutions, and consumers, ensuring a steady supply for diverse applications. Ethanol production is well-established with stable supply chains. Alternative biocides face higher production costs, lower availability, and logistical challenges. Regulatory decisions should account for economic feasibility and continuity of supply to prevent market disruptions.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	There is no appropriate substance to be found as a substitute for ethanol. The absence of ethanol as a biocidal active substance would severely hinder the ability to maintain hygienic environments in healthcare settings. Alternative disinfectants often lack ethanol's unique combination of rapid efficacy, safety, and widespread availability. Many biocidal substances come with significant trade-offs, such as corrosive properties, environmental persistence, or safety concerns, none of which are associated with ethanol-based formulations. Ethanol is indispensable in hospitals, where disinfectants must act quickly to reduce microbial contamination while being compatible with sensitive medical equipment and safe for patients and staff. Its rapid evaporation minimizes exposure

	time, enabling efficient infection control in high-touch areas, surgical theaters, and patient rooms. Unlike some alternatives, ethanol's compatibility with diverse materials ensures it can be used without causing damage, making it an essential tool for a broad range of medical applications. Ethanol's unique combination of attributes—its effectiveness, safety, and alignment with sustainability goals—positions it as an essential component in healthcare disinfection strategies. A shift away from ethanol would not only compromise infection control standards but also require substantial changes in procurement processes and operational practices within healthcare institutions. The critical role of ethanol extends beyond practical applications to economic considerations.
Information above is confidential	
Justification for confidentiality	
Other comments	Ethanol fulfills requirements which no other biocidal active substance can cover in total: • High efficacy against non-enveloped viruses, which is critical for infection control. • No residues on surfaces, making it safe for food contact applications. • Rapid evaporation, ensuring convenient use in healthcare and public settings • Ethanol is one of the few substances fully virucidal and efficient against non-enveloped viruses such as noroviruses and polioviruses. • Supported by WHO recommendations and studies (e.g., Kramer et al., 2022) that highlight its superior disinfection properties. • Long shelf life of formulated products, ensuring stability and usability over time. • No toxicologically relevant residues or persistent environmental contamination. • No reported cases of skin sensitization under normal use. • Compared to alternatives, lower risk of accidental poisoning due to rapid evaporation. • No tainting of food and odorless, making it suitable for food-related applications. Ethanol is under assessment for potential classification as carcinogenic and/or toxic to reproduction. However: • There is no conclusive evidence of carcinogenicity from real-world exposure levels. • Toxicological evaluations should differentiate ingestion vs. topical and inhalation exposure. • Any classification must consider risk-based assessment rather than hazard-only classification
Information above is confidential	
Justification for confidentiality	

References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 142	2025/04/24 14:41
Country	Germany
Name of organization/institution	BÜFA Chemikalien GmbH & Co. KG
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	We are a trader of ethanol as a biocidal active substance. Our customers produce and provide a ready to use surface disinfectant, containing ethanol as an ingredient with significant microbiocidal properties and benefit. It covers a wide range of efficacy and can combat bacteria, fungi, yeasts and viruses.
Product Type	1,2,4
Alternative Identity and Properties	The outcome of an intensive research concerning appropriate substitutes is, that there is no chemical with properties suitable to replace ethanol: Propan-1-ol and Propan-2-ol have an efficacy gap regarding full virucidal activities. Offered volumes are not sufficient to meet the demands of producers in the EU. They are not completely virucidal. Iodine: Endocrine Disruptor for human and environment, not readily available in sufficient quantities, not fast enough for efficacy, residue formation, DBP-formation NaOCl: DBP-formation, no evaporation, corrosive, reactivity with other chemicals in product formulations. CHDG & QAC: no full virucidal activity, residues, not fast efficacy action Monochlor-amine: DBP formation, only in situ generation, not storable, Chlorocresol: skin sensitizer, Phenol as degradation product: H2O2: not fast efficacy action, no evaporation, longevity not sufficient, corrosive, not

	efficacious at low concentrations and ambient temperatures. Lactic Acid: not full virucidal, odor formation Phenoxyethanol: not full virucidal Peracetic acid: corrosive, reactivity with other chemicals in product formulations. Higher safety standards for workers and higher storage standards. Other disinfectant active substances are not skin friendly or act not fast enough within seconds, or do not evaporate, or do stick on the skin.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	CMR classification would impact the use of ethanol in biocidal products, consumer products and as an industrial chemical, too. This would bring no health benefits at all to society but massive socioeconomic disruption. The ethanol exposition from either working with ethanol in the workplace or using ethanol containing consumer products is not harmful. In comparison with the impact given by consuming alcoholic beverages, this impact is rather negligible. To our latest information the total market for ethanol in the EU is over 6 million tons per year - appr. 1.2 mt is for industrial uses, 0.79 mt in alcoholic beverages. The bulk is used for fuel. If ethanol would be classified as a CMR substance, most of this total market would be impacted severely, and in many cases the use of ethanol would have to be stopped. Effects would be seen in private households and in the industrial sector as well. It would mean a huge loss of many products for consumers and industry use. Handling restrictions would make the use of ethanol difficult or impossible due to practical efforts and its derived costs.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	

Information above is confidential	
Justification for confidentiality	
Availability	The supply chain supporting ethanol-based disinfectants is robust and regionally integrated, with significant production and formulation activities in several states in the EU. A significant part of Ethanol is sourced from renewable feedstocks and undergoes processes such as dehydration and denaturation before formulation into biocidal products. These products are distributed through vertically integrated networks to hospitals, public institutions, and consumers, ensuring a steady supply for diverse applications. Ethanol production is well-established with stable supply chains. Alternative biocides face higher production costs, lower availability, and logistical challenges. Regulatory decisions should account for economic feasibility and continuity of supply to prevent market disruptions.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	There is no appropriate substance to be found as a substitute for ethanol. The absence of ethanol as a biocidal active substance would severely hinder the ability to maintain hygienic environments in healthcare settings. Alternative disinfectants often lack ethanol's unique combination of rapid efficacy, safety, and widespread availability. Many biocidal substances come with significant trade-offs, such as corrosive properties, environmental persistence, or safety concerns, none of which are associated with ethanol-based formulations. Ethanol is indispensable in hospitals, where disinfectants must act quickly to reduce microbial contamination while being compatible with sensitive medical equipment and safe for patients and staff. Its rapid evaporation minimizes exposure time, enabling efficient infection control in high-touch areas, surgical theaters, and patient rooms. Unlike some alternatives, ethanol's compatibility with diverse materials ensures it can be used without causing damage, making it an essential tool for a broad range of medical applications. Ethanol's unique combination of attributes—its effectiveness, safety, and alignment with sustainability goals—positions it as an essential component in healthcare disinfection strategies. A shift away from ethanol would not only compromise infection control standards but also require substantial changes in procurement processes and operational practices.

	within healthcare institutions. The critical role of ethanol extends beyond practical applications to economic considerations.
Information above is confidential	
Justification for confidentiality	
Other comments	Ethanol fulfills requirements which no other biocidal active substance can cover in total: • High efficacy against non-enveloped viruses, which is critical for infection control. • No residues on surfaces, making it safe for food contact applications. • Rapid evaporation, ensuring convenient use in healthcare and public settings • Ethanol is one of the few substances fully virucidal and efficient against non-enveloped viruses such as noroviruses and polioviruses. • Supported by WHO recommendations and studies (e.g., Kramer et al., 2022) that highlight its superior disinfection properties. • Long shelf life of formulated products, ensuring stability and usability over time. • No toxicologically relevant residues or persistent environmental contamination. • No reported cases of skin sensitization under normal use. • Compared to alternatives, lower risk of accidental poisoning due to rapid evaporation. • No tainting of food and odorless, making it suitable for food-related applications. Ethanol is under assessment for potential classification as carcinogenic and/or toxic to reproduction. However: • There is no conclusive evidence of carcinogenicity from real-world exposure levels. • Toxicological evaluations should differentiate ingestion vs. topical and inhalation exposure. • Any classification must consider risk-based assessment rather than hazard-only classification Ethanol-based surface disinfectants are indispensable tools for effective hygiene and infection control. Their rapid action, broad-spectrum efficacy, and residue-free properties make them suitable for numerous high-touch surfaces in various environments. Ethanol-based disinfectants play a vital role in maintaining hygiene in high traffic public areas. These products are used to clean frequently touched surfaces such as tables, chairs, door handles, and floors in restaurants, schools, gyms, and offices. In these settings, the risk of cross-contamination is high due to constant human interaction. Ethanol's rapid action and broad-spectrum efficacy ensure quick disinfection, reducing the transmission of bacteria, viruses, and fungi. Its quick evaporation minimizes downtime, enabling seamless operations in busy

	environments without leaving harmful residues that could compromise safety.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 143	2025/04/24 14:45
Country	Germany
Name of organization/institution	BÜFA Chemikalien GmbH & Co. KG
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	We are a trader of ethanol as a biocidal active substance. Our customers produce and provide a ready to use surface disinfectant, containing ethanol as an ingredient with significant microbiocidal properties and benefit. It covers a wide range of efficacy and can combat bacterias, funghis, yeasts and viruses.
Product Type	1,2,4
Alternative Identity and Properties	The outcome of an intensive research concerning appropriate substitutes is, that there is no chemical with properties suitable to replace ethanol: Propan-1-ol and Propan-2-ol have an efficacy gap regarding full virucidal activities. Offered volumes are not sufficient to meet the demands of producers in the EU. They are not completely virucidal. Iodine: Endocrine Disruptor for human and environment, not readily available in sufficient quantities, not fast enough for efficacy, residue formation, DBP-formation NaOCl: DBP-

	formation, no evaporation, corrosive, reactivity with other chemicals in product formulations. CHDG & QAC: no full virucidal activity, residues, not fast efficacy action Monochlor-amine: DBP formation, only in situ generation, not storable, Chlorocresol: skin sensitizer, Phenol as degradation product: H₂O₂: not fast efficacy action, no evaporation, longevity not sufficient, corrosive, not efficacious at low concentrations and ambient temperatures. Lactic Acid: not full virucidal, odor formation Phenoxyethanol: not full virucidal Peracetic acid: corrosive, reactivity with other chemicals in product formulations. Higher safety standards for workers and higher storage standards. Other disinfectant active substances are not skin friendly or act not fast enough within seconds, or do not evaporate, or do stick on the skin.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	CMR classification would impact the use of ethanol in biocidal products, consumer products and as an industrial chemical, too. This would bring no health benefits at all to society but massive socioeconomic disruption. The ethanol exposition from either working with ethanol in the workplace or using ethanol containing consumer products is not harmful. In comparison with the impact given by consuming alcoholic beverages, this impact is rather negligible. To our latest information the total market for ethanol in the EU is over 6 million tons per year - appr. 1.2 mt is for industrial uses, 0.79 mt in alcoholic beverages. The bulk is used for fuel. If ethanol would be classified as a CMR substance, most of this total market would be impacted severely, and in many cases the use of ethanol would have to be stopped. Effects would be seen in private households and in the industrial sector as well. It would mean a huge loss of many products for consumers and industry use. Handling restrictions would make the use of ethanol difficult or impossible due to practical efforts and its derived costs.
Information above is confidential	

Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	The supply chain supporting ethanol-based disinfectants is robust and regionally integrated, with significant production and formulation activities in several states in the EU. A significant part of Ethanol is sourced from renewable feedstocks and undergoes processes such as dehydration and denaturation before formulation into biocidal products. These products are distributed through vertically integrated networks to hospitals, public institutions, and consumers, ensuring a steady supply for diverse applications. Ethanol production is well-established with stable supply chains. Alternative biocides face higher production costs, lower availability, and logistical challenges. Regulatory decisions should account for economic feasibility and continuity of supply to prevent market disruptions.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	There is no appropriate substance to be found as a substitute for ethanol. The absence of ethanol as a biocidal active substance would severely hinder the ability to maintain hygienic environments in healthcare settings. Alternative disinfectants often lack ethanol's unique combination of rapid efficacy, safety, and widespread availability. Many biocidal substances come with significant trade-offs, such as corrosive properties, environmental persistence, or safety concerns, none of which are associated with ethanol-based formulations. Ethanol is indispensable in hospitals, where disinfectants must act quickly to reduce microbial contamination while being compatible with sensitive medical equipment and safe for patients and staff. Its rapid evaporation minimizes exposure time, enabling efficient infection control in high-touch areas, surgical theaters, and patient rooms. Unlike some alternatives, ethanol's compatibility with diverse materials ensures it can be used without causing damage, making it an essential tool for a broad range of medical applications. Ethanol's unique combination of attributes—its effectiveness, safety, and

	alignment with sustainability goals—positions it as an essential component in healthcare disinfection strategies. A shift away from ethanol would not only compromise infection control standards but also require substantial changes in procurement processes and operational practices within healthcare institutions. The critical role of ethanol extends beyond practical applications to economic considerations.
Information above is confidential	
Justification for confidentiality	
Other comments	Ethanol fulfills requirements which no other biocidal active substance can cover in total: • High efficacy against non-enveloped viruses, which is critical for infection control. • No residues on surfaces, making it safe for food contact applications. • Rapid evaporation, ensuring convenient use in healthcare and public settings • Ethanol is one of the few substances fully virucidal and efficient against non-enveloped viruses such as noroviruses and polioviruses. • Supported by WHO recommendations and studies (e.g., Kramer et al., 2022) that highlight its superior disinfection properties. • Long shelf life of formulated products, ensuring stability and usability over time. • No toxicologically relevant residues or persistent environmental contamination. • No reported cases of skin sensitization under normal use. • Compared to alternatives, lower risk of accidental poisoning due to rapid evaporation. • No tainting of food and odorless, making it suitable for food-related applications. Ethanol is under assessment for potential classification as carcinogenic and/or toxic to reproduction. However: • There is no conclusive evidence of carcinogenicity from real-world exposure levels. • Toxicological evaluations should differentiate ingestion vs. topical and inhalation exposure. • Any classification must consider risk-based assessment rather than hazard-only classification In industrial and professional settings, ethanol based disinfectants are crucial for ensuring hygiene in food industry. These surfaces may be the outsides of machinery, equipment, reservoirs for water or feed in animal housing etc. Products are often wiped or sprayed onto the surface. A wiping-off or rinsing step is not necessary as no residue would remain on surface due to ethanol's volatile character. Ethanol based products offer a practical and effective option for maintaining clean workspaces, protecting workers and consumers from exposure to harmful pathogens, and

	ensuring compliance with occupational health and safety regulations. The 2023 EU-OSHA report highlights that biocides like ethanol are essential in preventing workplace outbreaks of infectious diseases, contributing to employee well-being and productivity.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 144	2025/04/24 14:46
Country	Germany
Name of organization/institution	Bundesärztekammer / German Medical Association
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Die Bundesärztekammer ist die Spitzenorganisation der ärztlichen Selbstverwaltung in Deutschland; sie vertritt als Arbeitsgemeinschaft der 17 deutschen Ärztekammern die berufspolitischen Interessen der ca. 570.000 Ärztinnen und Ärzte. Ärztinnen und Ärzte sowie andere Mitarbeitende in Arztpraxen und Krankenhäusern verwenden ethanolhaltige Desinfektionsmittel insbesondere zur hygienischen und chirurgischen Handdesinfektion, sowie zur Desinfektion von Arbeitsflächen und -geräten. Ethanol hat eine nachgewiesene viruzide, bakterizide und fungizide Wirkung. Die Verwendung ethanolhaltiger Desinfektionsmittel dient dem Schutz von Patientinnen und Patientinnen, sowie der Berufstätigen. Gesundheitseinrichtungen stellen auch Besucherinnen und Besuchern Handdesinfektionsmittel zur Verfügung, zu deren Schutz sowie zum Patientenschutz.

Product Type	1,2,4
Alternative Identity and Properties	Unsere Kommentierung bezieht sich auf die bekannten alternativen Wirkstoffe 1-Propanol (auch n-Propanol) und 2-Propanol (auch: Isopropanol). Bei einer Einwirkungszeit von 30-60 Sekunden, welches in klinischer Umgebung eine realistische Anwendungsdauer darstellt, sind ethanolhaltige Desinfektionsmittel gegen unbehüllte Viren (Adenoviren, Humane Enteroviren, Polioviren, Humane Papillomaviren u.a.) wirksamer als 1- oder 2-Isopropanol. Gegen Bakterien und behüllte Viren ist die Wirksamkeit der drei genannten Wirkstoffe vergleichbar. Schätzungen zufolge sind unbehüllte, leicht über Hautkontakt übertragbare Viren europaweit für knapp 400 Mio. Infektionen jährlich verantwortlich, größtenteils durch Rhinoviren, Rotaviren und Papillomaviren.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Technisch gesehen wäre eine Umstellung auf nicht ethanolhaltige Desinfektionsmittel in der Gesundheitsversorgung möglich.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Die mit einer Umstellung auf 1- und 2-Isopropanol verbundenen Kosten sind uns nicht bekannt. Sie dürften aber aufgrund der Tatsache, dass Ethanol, anders als 1- oder 2-Propanol, als Nebenprodukt industrieller Prozesse anfällt und somit nicht gesondert hergestellt werden muss, sowie aufgrund der erheblich geringeren Zahl der Bezugsquellen höher liegen.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Eine Umstellung auf 1- oder 2-Isopropanol-basierte Desinfektionsmittel birgt aufgrund der geringeren Wirksamkeit der Alternativen gegen unbehüllte Viren (s.o. Abschnitt 1) ein höheres Risiko für im Gesundheitswesen Tätige, an einer durch diese verursachten Infektion zu erkranken, und diese an weitere Personen, insbesondere

	andere Patienten, weiterzugeben. Darüber hinaus führt der krankheitsbedingte Ausfall von Beschäftigten im Gesundheitswesen zu einer Verschlechterung der Versorgungssituation von Patienten. Das Gesundheitssystem insgesamt kann bei einem Verzicht auf ethanolhaltige Desinfektionsmittel weniger wirksam auf Infektionsausbrüche reagieren: Dies gilt zunächst für Erreger, gegen die Ethanol eine überlegene Wirksamkeit gegenüber anderen Wirkstoffen hat. Aber auch bei Infektionen durch Erreger, gegen die Ethanol gleichermaßen wirksam ist wie 1- oder 2-Propanol, könnte der Wegfall von Ethanol zu Engpässen bei den übrigen Desinfektionsmitteln führen, insbesondere bei einem sprunghaften Anstieg des Bedarfs an Desinfektionsmitteln wie zu Beginn der SARS-CoV-2 Pandemie. Es ist zu befürchten, dass die wenigen Hersteller nicht-ethanolhaltiger Desinfektionsmittel nicht in der Lage wären, diesen Bedarf schnell zu decken.
Information above is confidential	
Justification for confidentiality	
Availability	Nach unserer Kenntnis wird 1-Propanol von drei Herstellern geliefert, und 2-Propanol von fünf Herstellern, die teilweise außerhalb Europas produzieren. Die Zahl der Hersteller und Lieferanten von Ethanol liegt laut Artikel 95-Liste der ECHA (Stand 06.03.2025) bei 737 (Hersteller oder Händler) in der EU. Der Ausfall einzelner Hersteller oder Unterbrechungen von Lieferketten könnten bei Ethanol daher wesentlich leichter kompensiert werden. Im Falle eines plötzlichen Anstiegs des Bedarfs könnten die Produktionskapazitäten von Ethanol voraussichtlich wesentlich schneller hochgefahren werden.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Zusammenfassend lässt sich sagen, dass die nachteiligen Folgen eines Verzichts auf ethanolhaltige Desinfektionsmittel eventuelle positive Effekte bei weitem überwiegen. Dies gilt auch dann, wenn die Auswirkungen auf Patient/innen und die öffentliche Gesundheit außer Acht gelassen würden, und allein die Gefährdung der Beschäftigten im Gesundheitswesen betrachtet würde, da auch sie durch ethanolhaltige Desinfektionsmittel wirksamer geschützt werden als durch Alternativen. Eine Gefährdung durch die Aufnahme von Ethanol über die Haut oder durch

	Einatmung von Dämpfen ist unter realistischen Anwendungsbedingungen auch bei häufiger Verwendung nicht gegeben. Eine Entscheidung, die sich auf die allgemeine Verfügbarkeit ethanolhaltiger Desinfektionsmittel auswirkt, muss unbedingt auch die tatsächlichen Anwendungsbedingungen berücksichtigen, und nicht allein inhärente Eigenschaften der Substanz Ethanol.
Information above is confidential	
Justification for confidentiality	
Other comments	Die Aufnahme von Ethanol in den Organismus über Hautkontakt oder über das Einatmen des bei der Handdesinfektion verdampfenden Ethanols ist marginal. Studien haben ergeben, dass auch nach 20facher hygienischer Handdesinfektion binnen 30 Minuten oder 10facher chirurgischer Handdesinfektion binnen 80 Minuten der Ethanolwert im Blut unterhalb toxischer Werte liegt. Da eine derart häufige Exposition im klinischen Alltag sehr selten ist, dürften die in der Realität aufgenommenen Ethanolwerte niedriger liegen. Die Menge des über die Haut oder durch Einatmung in realistischen Szenarien aufgenommenen Ethanols liegt um ein Vielfaches unterhalb der oral in Form von Genussalkohol aufgenommenen Mengen, aber auch unterhalb der Mengen, die beim Genuss von als alkoholfrei geltenden Getränken wie Fruchtsaft, Kefir oder alkoholfreiem Bier aufgenommen werden. Personen, die die vorgenannten Getränke konsumieren, werden daher Ethanol auch bei einem Verzicht auf die Verwendung in Desinfektionsmitteln weiter in vergleichsweise größerem Umfang aufnehmen. Ferner zeigen Studien, dass die Erhöhung des Blutalkoholspiegels nach Verwendung 1- oder 2-Propanol-haltiger Desinfektionsmittel 65mal höher liegt als bei Verwendung eines ethanolhaltigen Desinfektionsmittels.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	

Justification for confidential attachment	

Comment 145	2025/04/24 15:42
Country	Germany
Name of organization/institution	Bundesärztekammer / German Medical Association
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Die Bundesärztekammer ist die Spitzenorganisation der ärztlichen Selbstverwaltung in Deutschland; sie vertritt als Arbeitsgemeinschaft der 17 deutschen Ärztekammern die berufspolitischen Interessen der ca. 570.000 Ärztinnen und Ärzte. Ärztinnen und Ärzte sowie andere Mitarbeitende in Arztpraxen und Krankenhäusern verwenden ethanolhaltige Desinfektionsmittel insbesondere zur hygienischen und chirurgischen Handdesinfektion, sowie zur Desinfektion von Arbeitsflächen und -geräten. Ethanol hat eine nachgewiesene viruzide, bakterizide und fungizide Wirkung. Die Verwendung ethanolhaltiger Desinfektionsmittel dient dem Schutz von Patientinnen und Patientinnen, sowie der Berufstätigen. Gesundheitseinrichtungen stellen auch Besucherinnen und Besuchern Handdesinfektionsmittel zur Verfügung, zu deren Schutz sowie zum Patientenschutz.
Product Type	1,2,4
Alternative Identity and Properties	Unsere Kommentierung bezieht sich auf die bekannten alternativen Wirkstoffe 1-Propanol (auch n-Propanol) und 2-Propanol (auch: Isopropanol). Bei einer Einwirkungszeit von 30-60 Sekunden, welches in klinischer Umgebung eine realistische Anwendungsdauer darstellt, sind ethanolhaltige Desinfektionsmittel gegen unbehüllte Viren (Adenoviren, Humane Enteroviren, Polioviren, Humane Papillomaviren u.a.) wirksamer als 1- oder 2-Isopropanol. Gegen Bakterien und behüllte Viren ist die Wirksamkeit der drei genannten Wirkstoffe vergleichbar. Schätzungen zufolge sind unbehüllte, leicht über Hautkontakt übertragbare Viren europaweit für knapp 400 Mio. Infektionen jährlich verantwortlich, größtenteils durch Rhinoviren, Rotaviren und Papillomaviren.

Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Technisch gesehen wäre eine Umstellung auf nicht ethanolhaltige Desinfektionsmittel in der Gesundheitsversorgung möglich.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Die mit einer Umstellung auf 1- und 2-Isopropanol verbundenen Kosten sind uns nicht bekannt. Sie dürften aber aufgrund der Tatsache, dass Ethanol, anders als 1- oder 2-Propanol, als Nebenprodukt industrieller Prozesse anfällt und somit nicht gesondert hergestellt werden muss, sowie aufgrund der erheblich geringeren Zahl der Bezugsquellen höher liegen.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Eine Umstellung auf 1- oder 2-Isopropanol-basierte Desinfektionsmittel birgt aufgrund der geringeren Wirksamkeit der Alternativen gegen unbehüllte Viren (s.o. Abschnitt 1) ein höheres Risiko für im Gesundheitswesen Tätige, an einer durch diese verursachten Infektion zu erkranken, und diese an weitere Personen, insbesondere andere Patienten, weiterzugeben. Darüber hinaus führt der krankheitsbedingte Ausfall von Beschäftigten im Gesundheitswesen zu einer Verschlechterung der Versorgungssituation von Patienten. Das Gesundheitssystem insgesamt kann bei einem Verzicht auf ethanolhaltige Desinfektionsmittel weniger wirksam auf Infektionsausbrüche reagieren: Dies gilt zunächst für Erreger, gegen die Ethanol eine überlegene Wirksamkeit gegenüber anderen Wirkstoffen hat. Aber auch bei Infektionen durch Erreger, gegen die Ethanol gleichermaßen wirksam ist wie 1- oder 2-Propanol, könnte der Wegfall von Ethanol zu Engpässen bei den übrigen Desinfektionsmitteln führen, insbesondere bei einem sprunghaften Anstieg des Bedarfs an Desinfektionsmitteln wie zu Beginn der SARS-CoV-2 Pandemie. Es ist zu befürchten, dass die wenigen Hersteller nicht-ethanolhaltiger Desinfektionsmittel nicht in der Lage wären, diesen Bedarf schnell zu decken.

Information above is confidential	
Justification for confidentiality	
Availability	Nach unserer Kenntnis wird 1-Propanol von drei Herstellern geliefert, und 2-Propanol von fünf Herstellern, die teilweise außerhalb Europas produzieren. Die Zahl der Hersteller und Lieferanten von Ethanol liegt laut Artikel 95-Liste der ECHA (Stand 06.03.2025) bei 737 (Hersteller oder Händler) in der EU. Der Ausfall einzelner Hersteller oder Unterbrechungen von Lieferketten könnten bei Ethanol daher wesentlich leichter kompensiert werden. Im Falle eines plötzlichen Anstiegs des Bedarfs könnten die Produktionskapazitäten von Ethanol voraussichtlich wesentlich schneller hochgefahren werden.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Zusammenfassend lässt sich sagen, dass die nachteiligen Folgen eines Verzichts auf ethanolhaltige Desinfektionsmittel eventuelle positive Effekte bei weitem überwiegen. Dies gilt auch dann, wenn die Auswirkungen auf Patient/innen und die öffentliche Gesundheit außer Acht gelassen würden, und allein die Gefährdung der Beschäftigten im Gesundheitswesen betrachtet würde, da auch sie durch ethanolhaltige Desinfektionsmittel wirksamer geschützt werden als durch Alternativen. Eine Gefährdung durch die Aufnahme von Ethanol über die Haut oder durch Einatmung von Dämpfen ist unter realistischen Anwendungsbedingungen auch bei häufiger Verwendung nicht gegeben. Eine Entscheidung, die sich auf die allgemeine Verfügbarkeit ethanolhaltiger Desinfektionsmittel auswirkt, muss unbedingt auch die tatsächlichen Anwendungsbedingungen berücksichtigen, und nicht allein inhärente Eigenschaften der Substanz Ethanol.
Information above is confidential	
Justification for confidentiality	
Other comments	Die Aufnahme von Ethanol in den Organismus über Hautkontakt oder über das Einatmen des bei der Handdesinfektion verdampfenden Ethanols ist marginal. Studien haben ergeben, dass auch nach 20facher hygienischer Handdesinfektion binnen 30 Minuten oder

	10facher chirurgischer Handdesinfektion binnen 80 Minuten der Ethanolwert im Blut unterhalb toxischer Werte liegt. Da eine derart häufige Exposition im klinischen Alltag sehr selten ist, dürften die in der Realität aufgenommenen Ethanolwerte niedriger liegen. Die Menge des über die Haut oder durch Einatmung in realistischen Szenarien aufgenommenen Ethanols liegt um ein Vielfaches unterhalb der oral in Form von Genussalkohol aufgenommenen Mengen, aber auch unterhalb der Mengen, die beim Genuss von als alkoholfrei geltenden Getränken wie Fruchtsaft, Kefir oder alkoholfreiem Bier aufgenommen werden. Personen, die die vorgenannten Getränke konsumieren, werden daher Ethanol auch bei einem Verzicht auf die Verwendung in Desinfektionsmitteln weiter in vergleichsweise größerem Umfang aufnehmen. Ferner zeigen Studien, dass die Erhöhung des Blutalkoholspiegels nach Verwendung 1- oder 2-Propanol-haltiger Desinfektionsmittel 65mal höher liegt als bei Verwendung eines ethanolhaltigen Desinfektionsmittels.
Information above is confidential	
Justification for confidentiality	
References	Kramer et al. 2024, https://pubmed.ncbi.nlm.nih.gov/39224501/; Exner et al. 2020, https://vah-online.de/files/download/vah-mitteilungen/VAH_Ethanol_ZT_6_20_354_359_en.pdf; Kramer et al. 2007, https://pubmed.ncbi.nlm.nih.gov/17927841/.
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 146	2025/04/24 16:55
Country	Austria
Name of organization/institution	Food Industries Association of Austria

I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	As the Food Industries Association of Austria, we view a classification of ethanol as carcinogenic or toxic to reproduction with great concern. This would mean that the use of ethanol as a disinfectant, despite its superior effectiveness, would no longer be permitted or would be subject to very strict regulations. With regard to food and feed production, a ban of ethanol or disinfectants containing ethanol would mean that standard hygiene concepts could no longer be implemented, which would mean an increase in microbial risks. This would have serious consequences for food hygiene and food safety, which manufacturers must guarantee. In food production ethanol is used in pure form (e.g. cutting machines, removal of protein residues) or as a component for cleaning and/or disinfection purposes (e.g. filling of processed products, surface disinfection) and for personal hygiene. It is widely used and welcome as a hand sanitizer. There is no reasonable alternative in sight, in particular when handling food. Especially when it comes to sensible and rapid processes in connection with food, whether in production, in mass catering or food retail. When ethanol is used for disinfection purposes, it is always denatured - along the entire food and feed chain. Therefore, oral intake - the only exposure route that would justify a CMR-classification - is not taking place. Classifying ethanol as carcinogenic or toxic to reproduction would hit the food and beverage industry, the largest processing industry in the EU, particularly hard. Ethanol is not only unrivalled when it comes to hygiene concepts. In food production, it is also a natural component of food and widely used as a raw material or ingredient, for example in the production of vinegar, food flavourings or alcoholic beverages. Beyond that it is even used to produce food grade packaging. It is true that chemicals legislation does not apply to foodstuffs intended as end products for the final consumer (e.g. alcoholic beverages). However, raw materials, intermediate products and products that are not intended for the final consumer, as well as the manufacturing process itself, are fully covered by the provisions and legal consequences of the CLP Regulation (protection of employees working with CMR substances). If, as a result of a harmonised classification, ethanol is to be labelled as a hazardous substance as 'carcinogenic' and 'toxic for reproduction', ethanol can no longer be used in the manufacturing process of consumer products, even if the substance is no longer

	present in the end product. This is because in practice, even the discussion of possible carcinogenic or reprotoxic properties of a substance used in consumer products or in the production chain would trigger customer rejection. A harmonised classification of ethanol in accordance with the CLP Regulation would ultimately mean that many foods and their ingredients could no longer be produced in the EU, or only under the strictest conditions.
Product Type	1,2,4
Alternative Identity and Properties	Alternatives include iso-propanol, hydrogen peroxide, peracetic acid, n-propanol, quaternary ammonium compounds and peracetic acid. But in fact, there is no suitable substitute to ethanol, especially in the food sector. Alternatives that require rinsing with water are no adequate substitute in food production. In most cases, alternative disinfectants leave behind residues that can not be removed. They do not have a complete virucidal effect (1-propanol and 2-propanol) and are not good for dermal use, because they irritate the skin (hydrogen peroxide) and leave your hands sticky. Some are even corrosive (peracetic acid) and none of them is working as fast as ethanol, which is acting in seconds. Often iso-propanol is mentioned as useful alternative. But it can not be used in food production because of its bad smell and bad taste. Ethanol is even naturally present in food and is ideal for various types of use in food production. Moreover it is skin-friendly and volatile and leaves no traces or residues on food contact surfaces after disinfection.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Alternative disinfectants to ethanol are not authorized to be used in food and feed production, when it comes to food law. From a technical point of view, the alternatives have inferior properties to ethanol. In most cases, non-removable residues are caused by the use of alternative disinfectants. In the entire food sector, there are hardly any substitutes for concepts to combat mould or disinfect surfaces, cutting machines, tanks, pipes, filling systems and dispensing systems used for food and beverages (food processing, retail, restaurants, bars). Especially because the transported, processed or stored food and beverages could be harmed by other substances. There is no substitute with the same efficacy against non-enveloped viruses and in food and feed production. A successful fight against pandemics

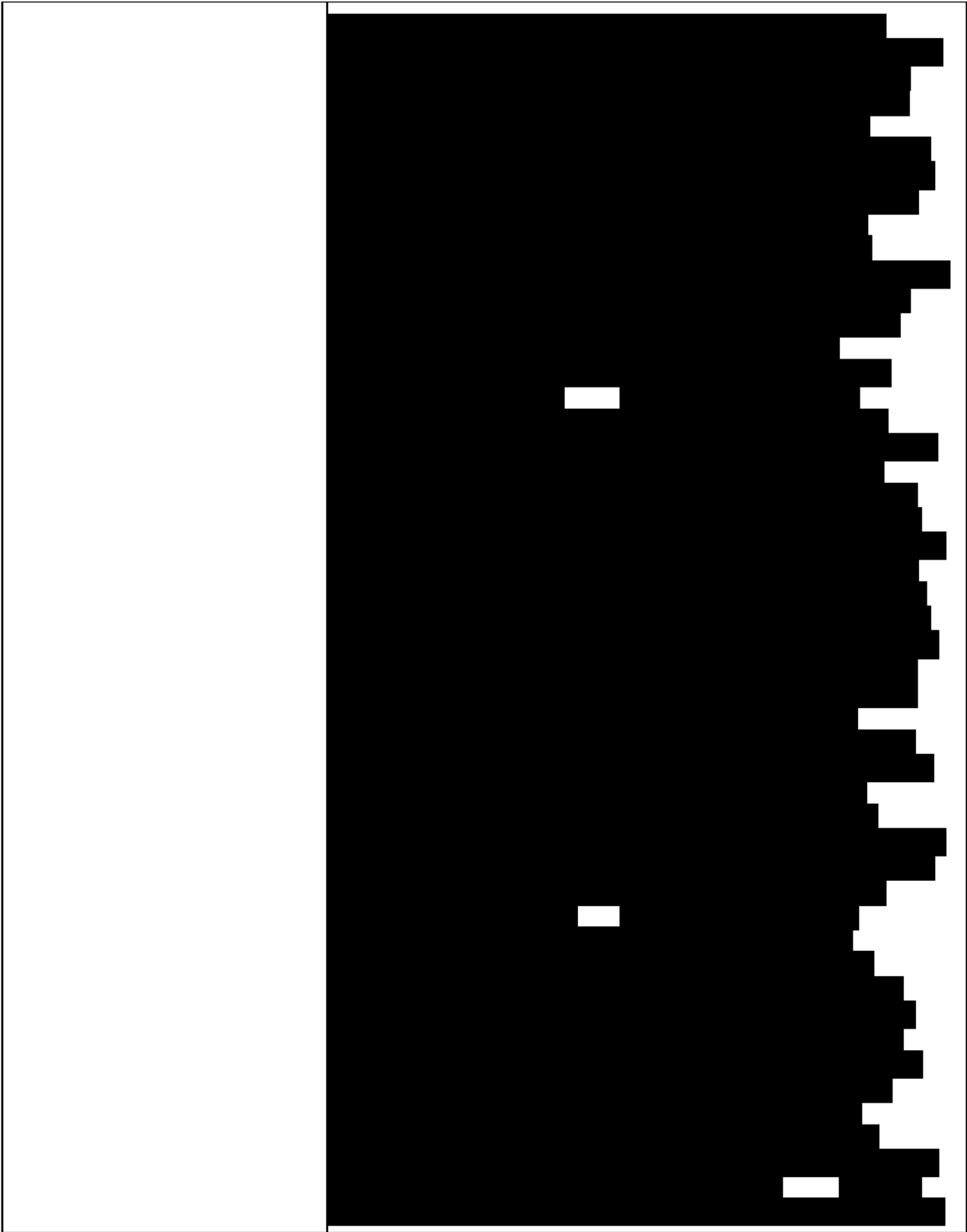
	with undeveloped viruses such as Covid-19 is hardly conceivable without the use of ethanol.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Ethanol is relatively cheap compared to other substances and highly available. It is easy to produce – even in large quantities - and is obtained from renewable raw materials (fermentation alcohol or ethanol from agricultural raw materials). It is also readily biodegradable. Replacing ethanol with other substances would require a complete reorganization of the production processes and the plants would have to be converted. Hygiene concepts would have to be rethought and reorganized. This means a high use of resources and additional costs without added value.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	A classification of ethanol as carcinogenic or toxic to reproduction would have serious consequences for food hygiene and food safety. Alternatives that require rinsing with water are no adequate substitute in food production. In most cases, alternative disinfectants leave behind residues that can not be removed. They do not have a complete virucidal effect and are not good for dermal use, because they irritate the skin and leave your hands sticky. Some are even corrosive and none of them is working as fast as ethanol, which is acting in seconds. Apart from this, odour and taste are further important factors in food production. In the entire food sector, there are hardly any substitutes for concepts to combat mould or disinfect surfaces, cutting machines, tanks, pipes, filling systems and dispensing systems used for food and beverages (food processing, retail, restaurants, bars). Besides, there are no alternatives to ethanol for cleaning and disinfecting machines and systems in the production of baby food and organic food. Compared to other substances, ethanol is unrivalled in its properties and is the only substance that is effective against non-enveloped viruses. It is simply incomprehensible to ban ethanol from a large number of applications just because a misuse of oral intake would justify a CMR classification. When ethanol is used for disinfection purposes, it is always denatured along the entire food and feed chain. This means that there is no risk whatsoever.

Information above is confidential	
Justification for confidentiality	
Availability	Ethanol is produced from renewable raw materials (agricultural crops), while other alcohols are produced by the chemical industry. The production of ethanol can be easily increased in a short space of time - even within the EU. This is particularly important in the event of pandemic outbreaks such as the coronavirus pandemic. Other alcohols such as iso-propanol cannot be produced in such large quantities as ethanol. Increasing production requires investments that cost time and money. In any case, ethanol production will fall drastically if ethanol is categorized as carcinogenic or toxic to reproduction. As a result, there is a serious risk that there will be a shortage of disinfectants on the market.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	In conclusion, there is no suitable alternative for ethanol used in food and feed production. Ethanol clearly has better properties than alternative substances in every respect. To name just a few of the many advantages of ethanol: efficacy against non-enveloped viruses, complete virucidal effect, skin-friendly, no residues, non-sticky, non-corrosive, acts within seconds, no rinsing with water required, effective against noroviruses, effective against mould, no bad taste, no odour, rapid evaporation, long storage time, biodegradable. As the Food Industries Association of Austria, we fear that the classification of ethanol as carcinogenic or toxic to reproduction would lead to a ban on biocidal products containing ethanol and thus jeopardize the standards of food hygiene and food safety that manufacturers are required to guarantee. In case ethanol is authorized for commercial use, customer concerns will lead to a loss of acceptance of its use in food and feed production. This is because in practice, even the discussion of possible carcinogenic or reprotoxic properties of a substance used in consumer products or in the production chain would trigger customer rejection. A rigid adherence to the automatisms provided for in chemicals legislation does not make sense in this specific case. It would jeopardize current hygiene concepts and mean that many foods and their ingredients could no longer be produced in the EU or only under the strictest conditions. This is why we plead for

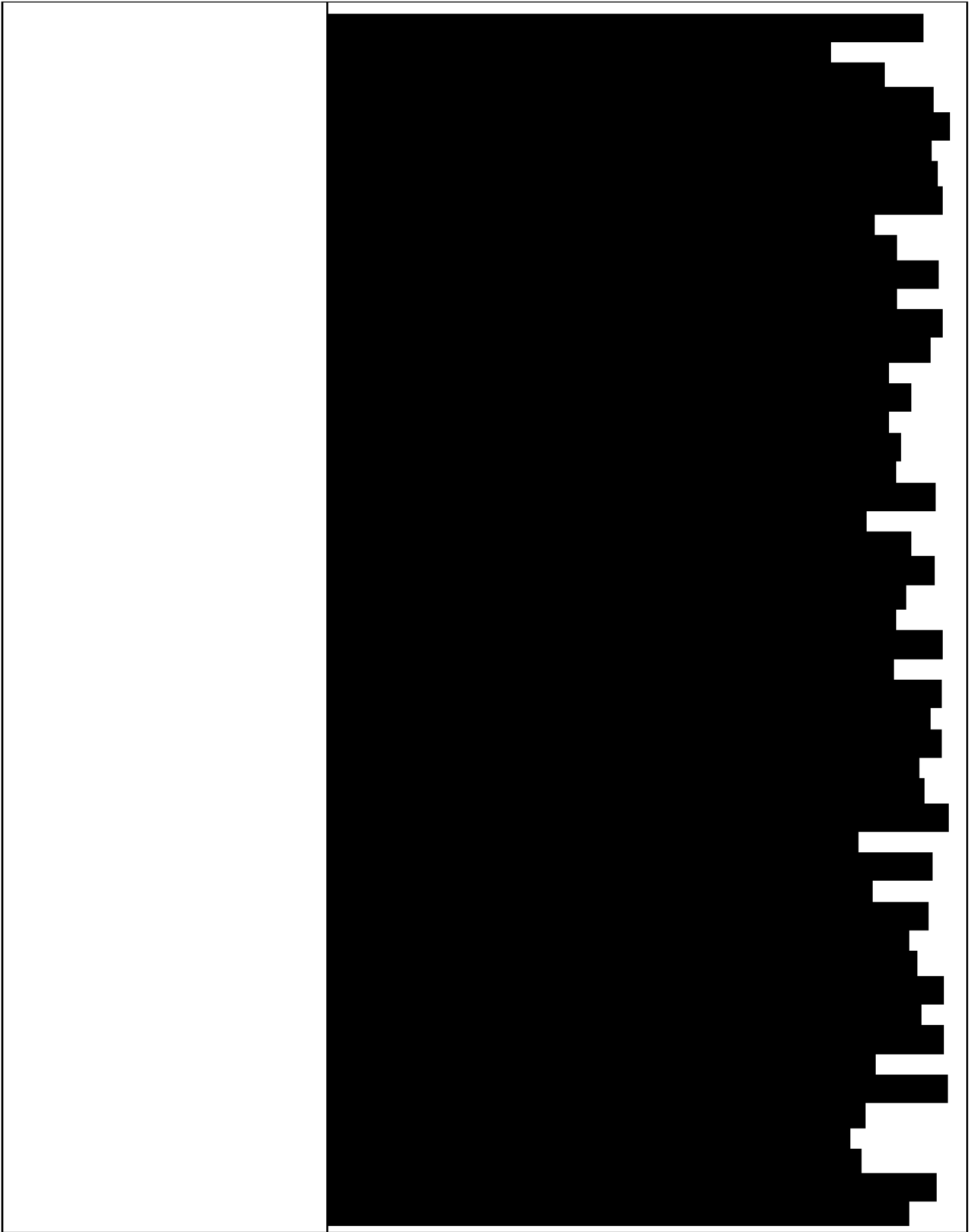
	either discarding the underlying database, which shows a carcinogenic effect only with oral ethanol intake, which is being ruled out with denatured ethanol, or for rejecting the harmonized classification of ethanol in accordance with the CLP Regulation and to provide for a risk-based assessment instead of a purely hazard-based one.
Information above is confidential	
Justification for confidentiality	
Other comments	The data on which the impending classification of ethanol as a CMR substance is based only show a carcinogenic effect when ethanol is taken orally. The exposure routes relevant for technical applications, inhalation and dermal, do not pose a risk. The assessment of chemicals in the BPR procedure is not risk-based, but purely hazard-based. The planned classification of ethanol as a CMR substance (toxic to reproduction and carcinogenic) is therefore also based on data from oral alcohol abuse, but not on the relevant exposure during occupational or intended use (e.g. dermal or inhalation in small quantities). There is a lack of scientifically reliable evidence that ethanol has a toxic or carcinogenic effect on reproduction in occupational use.
Information above is confidential	
Justification for confidentiality	
References	Bessonneau V, Clement M, Thomas O. Can intensive use of alcohol-based hand rubs lead to passive alcoholization? International journal of environmental research and public health 2010 Jul 30;7(8):3038–3050. doi: 10.3390/ijerph7083038
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 147	2025/04/24 17:04
Country	France

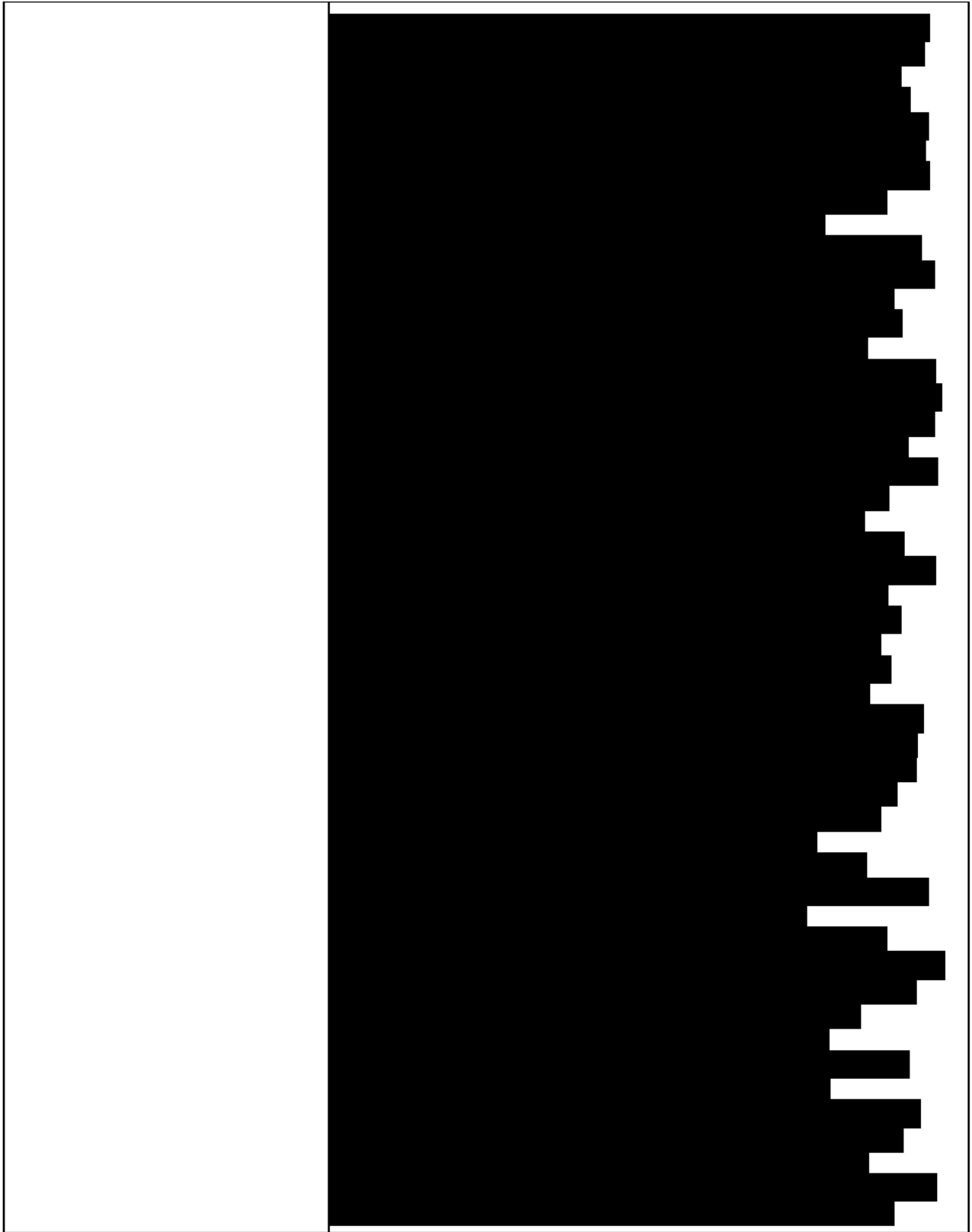
Name of organization/institution	[REDACTED]
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	Ethanol is widely utilized as a disinfectant in various applications due to its unique set of properties. In biocidal products, it serves multiple purposes including human hygiene, small surface disinfection, and disinfection in food and feed areas. For human hygiene (PT 01), ethanol-based disinfectants are employed for hand disinfection without rinsing and as skin antiseptics in medical and hygiene-sensitive environments. These include intensive care units, infection departments, and home care, among others. In private and public health areas (PT 02), ethanol is used for small surface disinfection through spraying, pouring, and wiping in healthcare institutions, laboratories, and veterinary practices. In the food and feed area (PT 04), it is used for small surface disinfection in the food processing industry. Despite several proposed alternatives such as isopropanol, n-propanol, quaternary ammonium compounds, chlorine-based oxidants, hydrogen peroxide, and physical methods, none can match ethanol's effectiveness, quick action, skin compatibility, and safety for food-contact surfaces. Ethanol's long history of safe use, broad-spectrum antimicrobial activity, and versatility make it an indispensable disinfectant in various critical applications. The comments made hereafter are made for PT1, PT2 and PT4.
Product Type	1,2,4
Alternative Identity and Properties	[REDACTED]
Information above is confidential	[REDACTED]
Justification for confidentiality	[REDACTED]

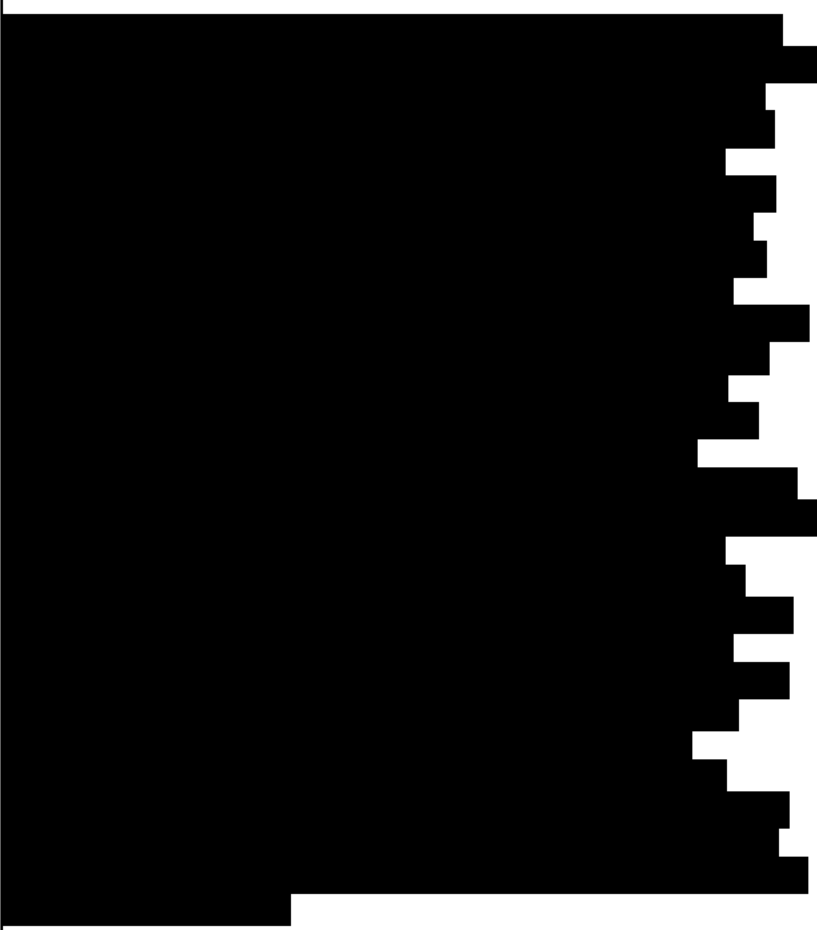
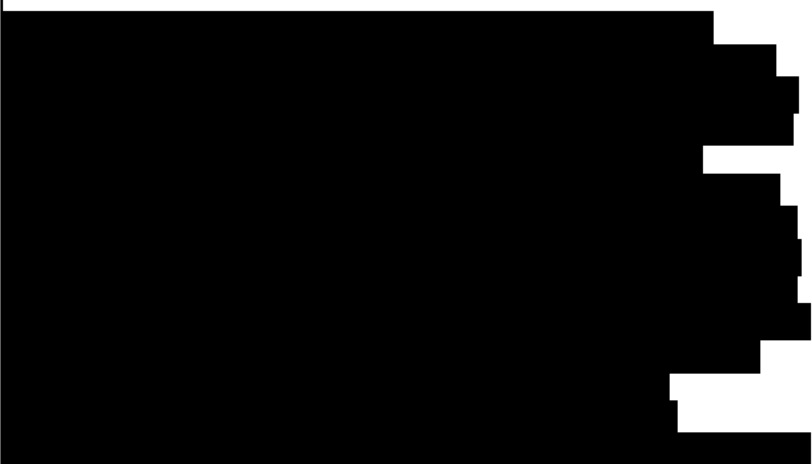


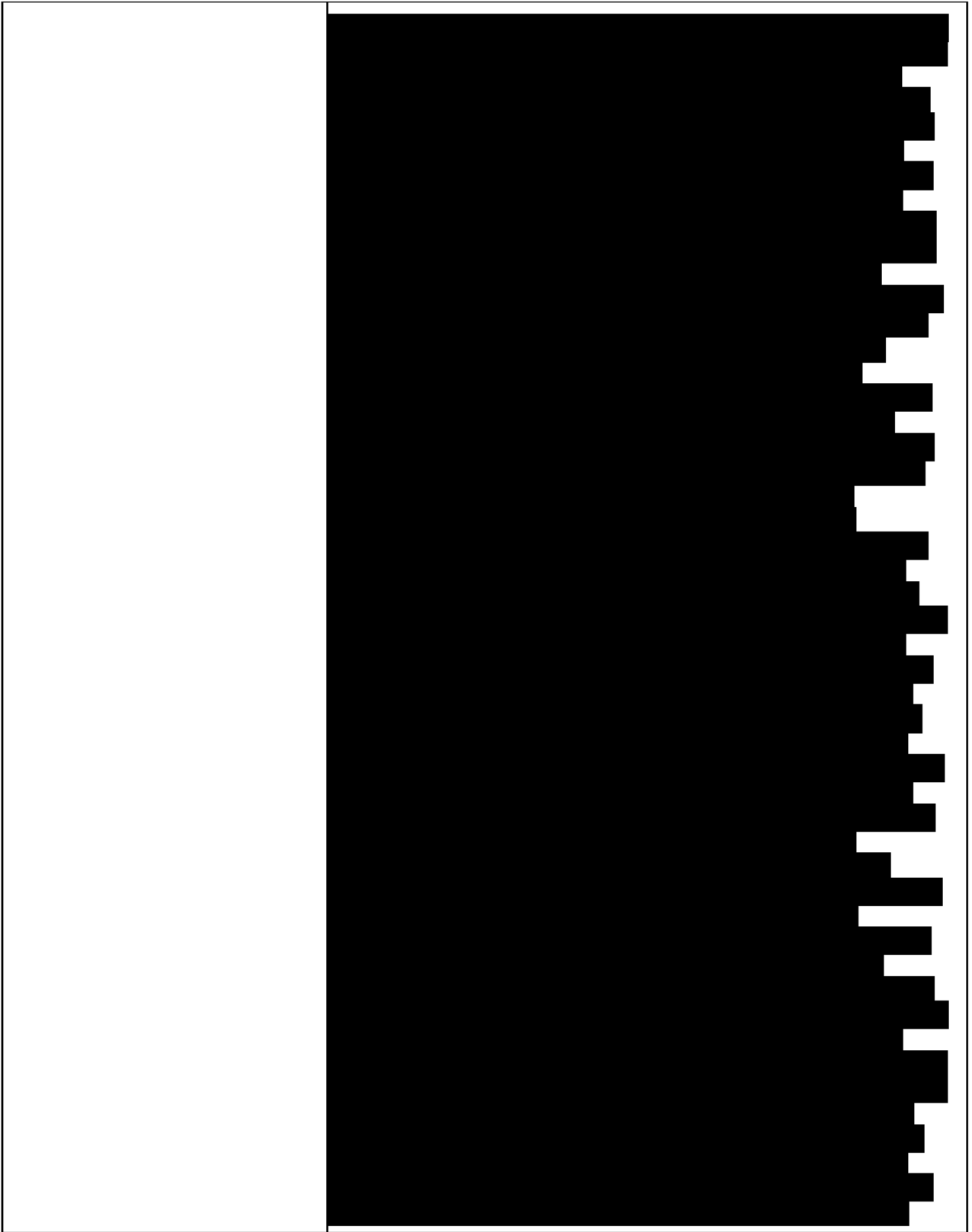
	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	

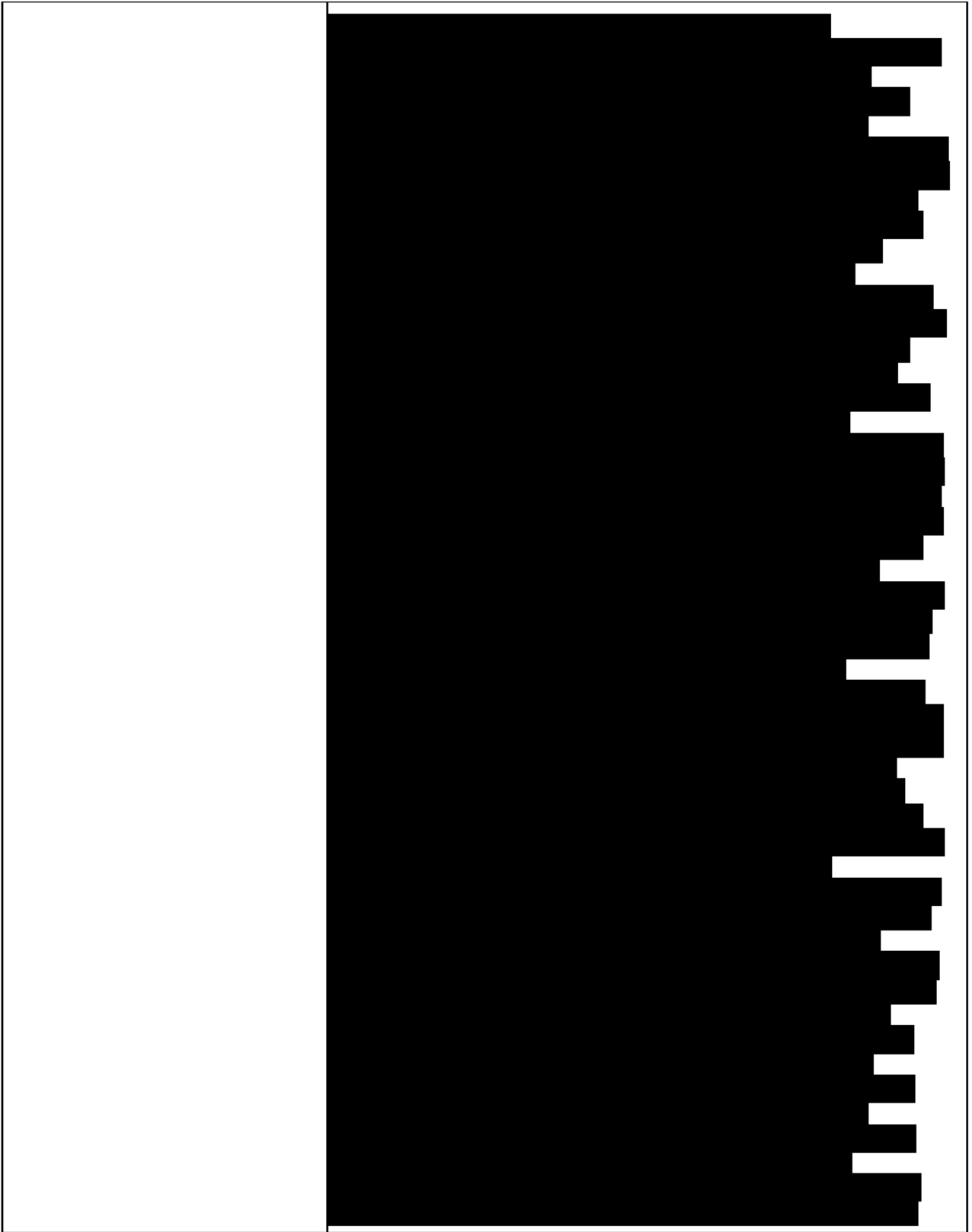


Economic Feasibility	
Information above is confidential	
Justification for confidentiality	

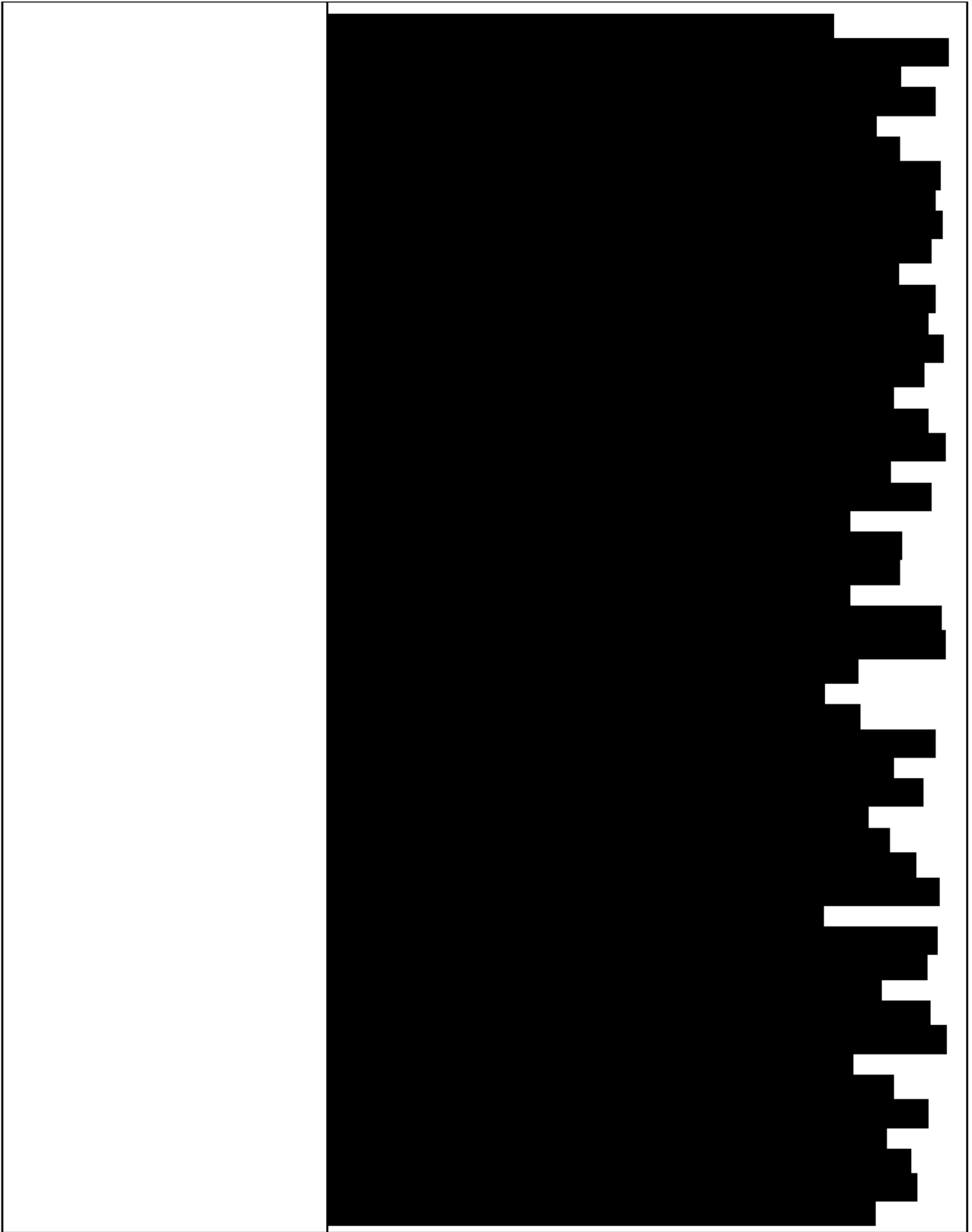


	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	



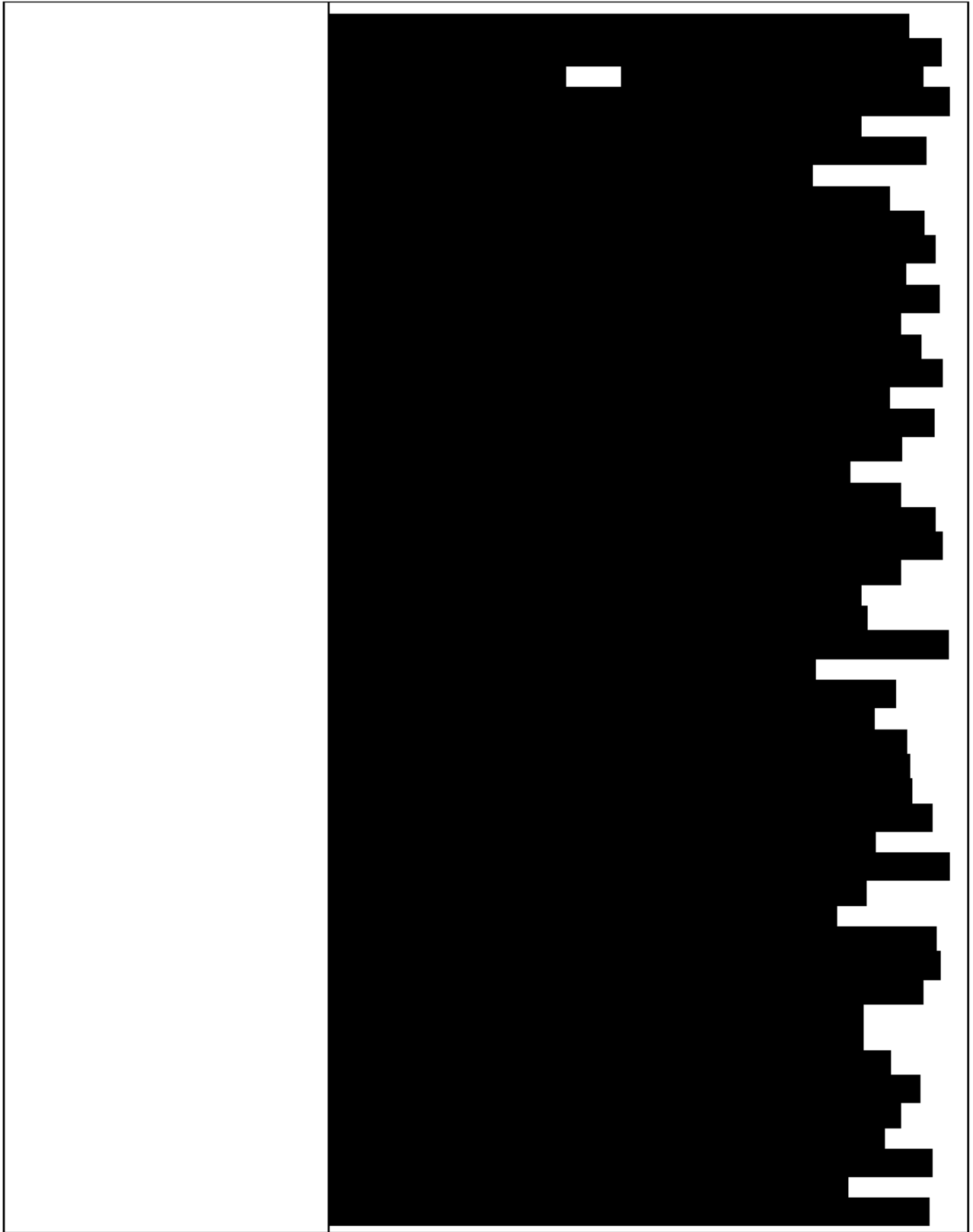


Availability	
Information above is confidential	
Justification for confidentiality	



	
Conclusion on suitability and availability of the alternative	After extensive analysis, no alternative to ethanol has been found that is both technically and economically viable, available at scale, and equally safe. Ethanol is unique in delivering rapid, broad-spectrum disinfection (including against non-enveloped viruses) without residue or rinsing—essential for hand and food-contact hygiene. Technically, alternatives fall short in efficacy, compatibility, or practicality. Economically, ethanol is cost-effective, supported by existing infrastructure, and widely used by European industry. Replacing it would generate high reformulation costs, supply instability, and burden public health systems. Regarding safety, ethanol’s risk in biocidal use is extremely low, with no evidence of harm from dermal or inhalation exposure in billions of uses. In contrast, proposed substitutes can be more hazardous (corrosive, toxic, environmentally harmful), offering no clear safety benefit. Critically, ethanol is abundantly available from renewable and petrochemical sources, with scalable production proven during the COVID-19 crisis. No other substance has this reliability or flexibility. Ethanol is therefore irreplaceable in PT1, PT2, and PT4 applications. Its continued use is not only justified but essential to protect

	public health and ensure effective hygiene across healthcare, household, and food sectors. The derogation conditions of BPR Article 5(2) are fully met: removing ethanol would cause a disproportionate negative impact on society and eliminate a vital health protection tool. For this reason, ethanol must remain approved as an active biocidal substance in the EU.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	



	
References	• A.I.S.E. Webinar (3 April 2025) – “Ethanol and the biocidal process” (Industry presentation slides) – Key data on ethanol’s uses, efficacy, and lack of alternatives. • - Kramer et al. (2023) – “Ethanol is indispensable for virucidal hand antisepsis and without toxic risks in daily use”, Journal of Hospital Infection (Open Access) – Toxicological evaluation and efficacy comparison of ethanol vs propanols. • - ECHA (2025) – Public Consultation on ethanol as a candidate for substitution (PT1, 2, 4) – Consultation background and criteria (Ethanol listed due to potential Carc. 1B/Repr. 1B. • - ECHA/Commission COVID-19 response (2020) – Statements by ECHA’s Director on disinfectant shortages and need to ensure supply of ethanol, 1-propanol, 2-propanolspecchemonline.com; example of industry scale-up (Dow producing 15 tonnes/day of bio-ethanol sanitiser). • - European Centre for Disease Control (ECDC) data via A.I.S.E. – Impact of inadequate hygiene: 90,000 EU deaths/year from healthcare infections; 420,000 global deaths from food-borne illness – highlighting need for effective disinfectants (ethanol preferred). • - WHO Guidelines on Hand Hygiene – Ethanol-based hand rubs classified as essential medicine (WHO List of Essential Medicines) and recommended as the gold standard for routine antisepsis. • - Safety Data – Hazard comparison: e.g. Benzalkonium chloride classified H302, H314, H400

	(harmful if swallowed, causes burns, aquatic toxic vs. ethanol (no such hazards in use; flammability managed). • A.I.S.E. Key Messages (2025) – Industry stance on ethanol: safe for environment and no viable alternative; warning that unwarranted classification would lead to a ban with no substitute. • Chemistry World (2023) – “Public health put at risk by mooted EU classification of ethanol...” – Experts warn of “undesirable substitutes” if ethanol use is curtailed
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 148	2025/04/24 17:42
Country	Germany
Name of organization/institution	German Paint and Coatings Association (VdL)
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	We are aware that this consultation is about ethanol as candidate for substitution in the active substance approval process for PTs 1,2, and 4 under the BPR and not about the CLH classification. However, since the process under the BPR has advanced without a published RAC opinion or a CLH dossier, the decision taken in the BPC is expected to have an impact on the CLH process. Hence, we would like to highlight that a decision in the BPC may have consequences that go way beyond biocidal products and treated articles. Ethanol is for instance the most important solvent for flexographic inks, used for instance on (food)packaging. It is known that excessive oral consumption of ethanol is harmful to the human health. However, it is can easily be demonstrated there is no risk for workers, printers or the end consumer due to the use of ethanol in inks. There is also no risk arising from residual ethanol (as retained solvent) in printed food contact material. In fact, switching

	to alternative solvents would in most cases be less favourable from a consumer safety aspect. Furthermore, it has to be kept in mind that industrial applications (such as the use as solvent in inks and coatings), rely on denatured alcohol. Hence, the oral exposure to significant amounts can be excluded.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	see "general informations" and "other comments"

Information above is confidential	
Justification for confidentiality	
Other comments	Depending on the classification, the consequences for ethanol as a proven and safe biocidal active substance could be very problematic and could even lead to a ban on its use. In addition, negative consequences beyond biocidal legislation are expected, as self-classification of manufacturers would affect the ethanol supply chains of the entire chemical industry. The assessment of the reproductive toxicity of ethanol is based on experience from the misuse of alcoholic beverages, i.e. exclusively on oral intake. When used as a chemical, this is not relevant and does not play a role in occupational hazards, so these data are not suitable for classification as an industrial chemical or in consumer products. Typically, ethanol is used in the chemical industry in denatured form to prevent oral uptake. Inclusion of the exposure route (oral vs. dermal & inhalation) for the hazard classification and risk assessment is therefore essential, as the classification proposal would have the consequences shown without achieving an improvement in occupational health and safety and human health.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 149	2025/04/24 18:28
Country	Belgium
Name of organization/institution	Federation of Veterinarians of Europe (FVE)

I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Ethanol is commonly used as a surface disinfectant in veterinary medical settings. Although its potential effects on the health of both veterinarians and animals should be thoroughly assessed, the critical importance of accessible and effective disinfectants - especially in preparedness for outbreaks of highly contagious diseases - must be acknowledged.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	

Conclusion on suitability and availability of the alternative	The FVE supports initiatives to identify safer alternatives that reduce health risks for both humans and animals. At the same time, we underline the indispensable role of surface disinfectants in veterinary practice, especially in the context of highly contagious diseases. Ethanol must remain a backup option in the event of production or supply disruptions of other products.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 150	2025/04/24 18:28
Country	Belgium
Name of organization/institution	Federation of Veterinarians of Europe (FVE)
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Ethanol is frequently used as a surface disinfectant in the food industry. While its potential impact on the health of food industry workers and potentially consumers through cross contamination should be taken into account, these concerns must be weighed against the ongoing need for effective disinfection to ensure food safety.

Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	The FVE supports the development and adoption of safer alternatives to ethanol to better protect both workers and the public. However, it is essential that these alternatives remain accessible and available throughout Europe. Where other options are unavailable for example due to chain disruptions, ethanol must remain a viable option to safeguard public health and food safety.
Information above is confidential	
Justification for confidentiality	

Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 151	2025/04/24 18:27
Country	Belgium
Name of organization/institution	Federation of Veterinarians of Europe (FVE)
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Ethanol is widely used as a hand disinfectant, including in veterinary medicine. While its potential health impact on users—particularly veterinarians—should be considered, the essential need for continuous access to effective hand disinfectants, particularly in crisis situations, cannot be overstated. Given ethanol's ease of production, it must remain a viable option when supply chains for other alternatives are disrupted.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	

Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	The FVE supports efforts to identify and promote safer alternatives to ethanol that minimize health risks. However, we also stress the importance of ensuring continuous availability of effective hand disinfectants on the market at all times.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	

Attachments (confidential information)	
Justification for confidential attachment	

Comment 152	2025/04/24 18:53
Country	France
Name of organization/institution	CRISTAL UNION
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Cristal Union is a leading agro-industrial group in the sugar, alcohol and bioethanol sectors. It brings together more than 9,000 sugar beet growers and employs over 2,000 people at 13 sites in France. It produces almost 600,000 m3 of ethanol from sugar beet, but also from wheat and industrial waste or residues, making it one of Europe's leading players. The ethanol produced by the group is used in a wide range of sectors, including biofuels, spirits, perfumes and cosmetics, chemicals, detergents and pharmaceuticals. Cristal Union wishes to provide its comments to ECHA underlining the unique use of ethanol and stress that a classification of ethanol as carcinogenic or toxic to reproduction would be detrimental to many biocidal products, create a lack of alternatives and have critical consequences for public health and various economic sectors.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	

Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol as a biocidal active substance has no alternative that is both economically competitive, of renewable origin and effective.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	Position paper ethanol classification 10042025.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 153	2025/04/25 14:07
Country	Germany
Name of organization/institution	German Social Insurance European Representation (DSV)
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	
Product Type	1,2,4
Alternative Identity and Properties	We agree with the conclusion presented in the 'Analysis of Alternatives' (AoA) published by EPPA on February 20, 2025, as attached to the present consultation, that ethanol is irreplaceable for PT1 regarding occupational health and safety of healthcare professionals.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	We agree with the conclusion presented in the 'Analysis of Alternatives' (AoA) published by EPPA on February 20, 2025, as attached to the present consultation, that ethanol is irreplaceable for PT1 regarding occupational health and safety of healthcare professionals.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	We agree with the conclusion presented in the 'Analysis of Alternatives' (AoA) published by EPPA on February 20, 2025, as attached to the present consultation, that ethanol is irreplaceable for PT1 regarding occupational health and safety of healthcare professionals.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	We agree with the conclusion presented in the 'Analysis of Alternatives' (AoA) published by EPPA on February 20,

	2025, as attached to the present consultation, that ethanol is irreplaceable for PT1 regarding occupational health and safety of healthcare professionals.
Information above is confidential	
Justification for confidentiality	
Availability	We agree with the conclusion presented in the 'Analysis of Alternatives' (AoA) published by EPPA on February 20, 2025, as attached to the present consultation, that ethanol is irreplaceable for PT1 regarding occupational health and safety of healthcare professionals.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	The use of ethanol regarding occupational health and safety of healthcare professionals is essential and irreplaceable. For more information, please consult the attached document.
Information above is confidential	
Justification for confidentiality	
Other comments	We agree with the conclusion presented in the 'Analysis of Alternatives' (AoA) published by EPPA on February 20, 2025, as attached to the present consultation, that ethanol is irreplaceable for PT1 regarding occupational health and safety of healthcare professionals.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	Comments from the German Social Insurance on ethanol PT1 and PT2.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 154	2025/04/25 14:08
Country	Germany
Name of organization/institution	German Social Insurance European Representation (DSV)
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	
Product Type	1,2,4
Alternative Identity and Properties	We agree with the conclusion presented in the 'Analysis of Alternatives' (AoA) published by EPPA on February 20, 2025, as attached to the present consultation, that ethanol is irreplaceable for PT2 regarding occupational health and safety of healthcare professionals.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	We agree with the conclusion presented in the 'Analysis of Alternatives' (AoA) published by EPPA on February 20, 2025, as attached to the present consultation, that ethanol is irreplaceable for PT2 regarding occupational health and safety of healthcare professionals.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	We agree with the conclusion presented in the 'Analysis of Alternatives' (AoA) published by EPPA on February 20, 2025, as attached to the present consultation, that ethanol is irreplaceable for PT2 regarding occupational health and safety of healthcare professionals.
Information above is confidential	
Justification for confidentiality	

Hazards and Risks of the Alternative	We agree with the conclusion presented in the 'Analysis of Alternatives' (AoA) published by EPPA on February 20, 2025, as attached to the present consultation, that ethanol is irreplaceable for PT2 regarding occupational health and safety of healthcare professionals.
Information above is confidential	
Justification for confidentiality	
Availability	We agree with the conclusion presented in the 'Analysis of Alternatives' (AoA) published by EPPA on February 20, 2025, as attached to the present consultation, that ethanol is irreplaceable for PT2 regarding occupational health and safety of healthcare professionals.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	The use of ethanol regarding occupational health and safety of healthcare professionals is essential and irreplaceable. For more information, please consult the attached document.
Information above is confidential	
Justification for confidentiality	
Other comments	We agree with the conclusion presented in the 'Analysis of Alternatives' (AoA) published by EPPA on February 20, 2025, as attached to the present consultation, that ethanol is irreplaceable for PT2 regarding occupational health and safety of healthcare professionals.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	Comments from the German Social Insurance on ethanol PT1 and PT2.pdf
Attachments (confidential information)	

Justification for confidential attachment	

Comment 155	2025/04/25 14:09
Country	Germany
Name of organization/institution	German Social Insurance European Representation (DSV)
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	
Product Type	1,2,4
Alternative Identity and Properties	We agree with the conclusion presented in the 'Analysis of Alternatives' (AoA) published by EPPA on February 20, 2025, that no suitable disinfectants exist to replace ethanol in the food and feed sector.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	We agree with the conclusion presented in the 'Analysis of Alternatives' (AoA) published by EPPA on February 20, 2025, that no suitable disinfectants exist to replace ethanol in the food and feed sector.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	We agree with the conclusion presented in the 'Analysis of Alternatives' (AoA) published by EPPA on February 20, 2025, that no suitable disinfectants exist to replace ethanol in the food and feed sector.
Information above is confidential	
Justification for confidentiality	

Hazards and Risks of the Alternative	We agree with the conclusion presented in the 'Analysis of Alternatives' (AoA) published by EPPA on February 20, 2025, that no suitable disinfectants exist to replace ethanol in the food and feed sector.
Information above is confidential	
Justification for confidentiality	
Availability	We agree with the conclusion presented in the 'Analysis of Alternatives' (AoA) published by EPPA on February 20, 2025, that no suitable disinfectants exist to replace ethanol in the food and feed sector.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	We agree with the conclusion presented in the 'Analysis of Alternatives' (AoA) published by EPPA on February 20, 2025, that there are no suitable disinfectants to replace ethanol completely in the food and feed sector. To be more precise, the usage of ethanol is mandatory in most areas of the food and feed sector. Due to its properties, ethanol evaporates quickly, leaving no traces of the disinfectant and the bacterial and virucidal effect is unequalled so that it can be used as a disinfectant in food and feed production areas where product hygiene is necessary. As an example, ethanol is used to disinfect tools with direct product contact as well as working equipment like gloves or shoes or for surface disinfection. Isopropanol is not applicable in these cases (refer to the EPPA report). Especially in hygiene-sensitive areas, ethanol is mandatory for personal disinfection and surface disinfection. However, in some food and feed sectors, isopropanol is also used for personal and surface disinfection and hydrogen peroxide to disinfect machines when necessary (e.g. manufacturing and packaging of sausage products, production of chicken feed) – ethanol can't be used here because of its explosion hazard.
Information above is confidential	
Justification for confidentiality	
Other comments	We agree with the conclusion presented in the 'Analysis of Alternatives' (AoA) published by EPPA on February 20,

	2025, that no suitable disinfectants exist to replace ethanol in the food and feed sector.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 156	2025/04/25 15:15
Country	Austria
Name of organization/institution	Food Industries Association of Austria
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	As the Food Industries Association of Austria, we view a classification of ethanol as carcinogenic or toxic to reproduction with great concern. This would mean that the use of ethanol as a disinfectant, despite its superior effectiveness, would no longer be permitted or would be subject to very strict regulations. With regard to food and feed production, a ban of ethanol or disinfectants containing ethanol would mean that standard hygiene concepts could no longer be implemented, which would mean an increase in microbial risks. This would have serious consequences for food hygiene and food safety, which manufacturers must guarantee. In food production ethanol is used in pure form (e.g. cutting machines, removal of protein residues) or as a component for cleaning and/or disinfection purposes (e.g. filling of processed products, surface disinfection) as well as for personal hygiene. It is widely used and welcome as a hand sanitizer. There is no reasonable alternative in sight, in particular when handling food. Especially when it comes

	to sensible and rapid processes in connection with food, whether in production, in mass catering or food retail. When ethanol is used for disinfection purposes, it is always denatured - along the entire food and feed chain. Therefore, oral intake - the only exposure route that would justify a CMR-classification - is not taking place. Classifying ethanol as carcinogenic or toxic to reproduction would hit the food and beverage industry, the largest processing industry in the EU, particularly hard. Ethanol is not only unrivalled when it comes to hygiene concepts. In food production, it is also a natural component of food and widely used as a raw material or ingredient, for example in the production of vinegar, food flavourings or alcoholic beverages. Beyond that it is even used to produce food grade packaging. It is true that chemicals legislation does not apply to foodstuffs intended as end products for the final consumer (e.g. alcoholic beverages). However, raw materials, intermediate products and products that are not intended for the final consumer, as well as the manufacturing process itself, are fully covered by the provisions and legal consequences of the CLP Regulation (protection of employees working with CMR substances). If, as a result of a harmonized classification, ethanol is to be labelled as a hazardous substance as 'carcinogenic' and 'toxic for reproduction', ethanol can no longer be used in the manufacturing process of consumer products, even if the substance is no longer present in the end product. This is because in practice, even the discussion of possible carcinogenic or reprotoxic properties of a substance used in consumer products or in the production chain would trigger customer rejection. A harmonized classification of ethanol in accordance with the CLP Regulation would ultimately mean that many foods and their ingredients could no longer be produced in the EU, or only under the strictest conditions.
Product Type	1,2,4
Alternative Identity and Properties	Alternatives to ethanol include iso-propanol and quaternary ammonium compounds. But in fact, there is no suitable substitute to ethanol for personal hygiene, e.g. for hand sanitizers, especially in the food sector (along the entire food chain). Alternatives that require rinsing with water are no adequate substitute in food production. In most cases, alternative disinfectants and hand rubs leave behind residues that can not be removed. They do not have a complete virucidal effect (1-propanol and 2-propanol) are not good for dermal use and leave hands sticky. None of them is working as fast as ethanol, which is acting in seconds. Often iso-propanol is mentioned as useful

	alternative. But it can not be used in food production because it would contaminate food with its bad smell and bad taste. Ethanol is instead even naturally present in food and is ideal for various types of use in food production. Moreover it is skin-friendly and volatile and leaves no traces or residues after disinfection.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	From a technical point of view, the alternatives have inferior properties to ethanol. In most cases, non-removable residues are caused by the use of alternative disinfectants. But in fact, there is no suitable substitute to ethanol for (hand) disinfection, especially in the food sector. Alternatives that require rinsing with water are no adequate substitute in food production. In most cases, alternative disinfectants leave behind residues that can not be removed. They do not have a complete virucidal effect are not suitable for use on the skin and leave hands sticky. None of them is working as fast as ethanol, which is acting in seconds. Often iso-propanol is mentioned as useful alternative. But it can not be used in food production because of its bad smell and bad taste. Ethanol is even naturally present in food and is ideal for various types of use in food production. Moreover it is skin-friendly and volatile and leaves no traces or residues on food contact surfaces after disinfection. There is no substitute with the same efficacy against non-enveloped viruses. A successful fight against pandemics with undeveloped viruses such as Covid-19 is hardly conceivable without the use of ethanol.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Ethanol is relatively cheap compared to other substances and highly available. It is easy to produce – even in large quantities - and is obtained from renewable raw materials (fermentation alcohol or ethanol from agricultural raw materials). It is also readily biodegradable. Replacing ethanol with other substances would require a reorganization of the production processes. Hygiene concepts would have to be rethought and reorganized. This means a high use of resources and additional costs without added value.

Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Not using ethanol for personal hygiene would have serious consequences for food hygiene and food safety. Ethanol in hand sanitizers is used in the entire food chain, where personal hygiene plays a highly important role. Alternatives that require rinsing with water are not an adequate substitute in the context of food. In most cases, alternative disinfectants leave behind residues that can not be removed. They do not have a complete virucidal effect (noroviruses, rhinoviruses, hepatitis viruses,..), are not good for dermal use and leave hands sticky. Besides, none of them is working as fast as ethanol, which is acting in seconds. Apart from this, odour and taste are further important factors when dealing with food and beverages (food processing, retail, restaurants, bars). Compared to other substances, ethanol is unrivalled in its properties and is the only substance that is effective against non-enveloped viruses. As a matter of fact, ethanol in hand rubs has the least risk to all types of users. It is simply incomprehensible to ban ethanol from a large number of applications just because a misuse of oral intake would justify a CMR classification. When ethanol is used for personal hygiene, it is always denatured along the entire food and feed chain. This means that there is no risk whatsoever.
Information above is confidential	
Justification for confidentiality	
Availability	Ethanol is produced from renewable raw materials (agricultural crops), while other alcohols are produced by the chemical industry. The production of ethanol can be easily increased in a short space of time - even within the EU. This is particularly important in the event of pandemic outbreaks such as the coronavirus pandemic. Other alcohols such as iso-propanol cannot be produced in such large quantities as ethanol. Increasing production requires investments that cost time and money. In any case, ethanol production will fall drastically if ethanol is categorized as carcinogenic or toxic to reproduction. As a result, there is a serious risk that there will be a shortage of disinfectants on the market.
Information above is confidential	

Justification for confidentiality	
Conclusion on suitability and availability of the alternative	In conclusion, there is no suitable alternative for ethanol used for personal hygiene in food and feed production. Ethanol clearly has better properties than alternative substances in every respect. To name just a few of the many advantages of ethanol: efficacy against non-enveloped viruses, complete virucidal effect, skin-friendly, no residues, non-sticky, acts within seconds, no rinsing with water required, effective against noroviruses, no bad taste, no odour, rapid evaporation, long storage time, biodegradable. As the Food Industries Association of Austria, we fear that the classification of ethanol as carcinogenic or toxic to reproduction would lead to a ban on biocidal products containing ethanol and thus jeopardize the standards of food hygiene and food safety that manufacturers are required to guarantee. In case ethanol is authorized for commercial use, customer concerns will lead to a loss of acceptance of its use in food and feed production. In practice, the mere discussion of possible carcinogenic or reprotoxic properties of a substance used in connection with consumer products along the food chain would lead to rejection by the customer. A rigid adherence to the automatisms provided for in chemicals legislation does not make sense in this specific case. It would jeopardize current hygiene concepts and mean that many foods and their ingredients could no longer be produced in the EU or only under the strictest conditions. This is why we plead for either discarding the underlying database, which shows a carcinogenic effect only with oral ethanol intake, which is being ruled out with denatured ethanol, or for rejecting the harmonized classification of ethanol in accordance with the CLP Regulation and to provide for a risk-based assessment instead of a purely hazard-based one.
Information above is confidential	
Justification for confidentiality	
Other comments	The data on which the impending classification of ethanol as a CMR substance is based only show a carcinogenic effect when ethanol is taken orally. The exposure routes relevant for technical applications, inhalation and dermal, do not pose a risk. The assessment of chemicals in the BPR procedure is not risk-based, but purely hazard-based. The planned classification of ethanol as a CMR substance (toxic to reproduction and carcinogenic) is therefore also based on

	data from oral alcohol abuse, but not on the relevant exposure during occupational or intended use (e.g. dermal or inhalation in small quantities). There is a lack of scientifically reliable evidence that ethanol has a toxic or carcinogenic effect on reproduction in occupational use.
Information above is confidential	
Justification for confidentiality	
References	Vincent Bessonneau, Michel Clément, Olivier Thomas; Can Intensive Use of Alcohol-Based Hand Rubs Lead to Passive Alcoholization? Int J Environ Res Public Health. 2010 Jul 30;7(8):3038–3050. doi: 10.3390/ijerph7083038 World Health Organization Model List of Essential Medicines – 23rd List, 2023. The selection and use of essential medicines 2023. Executive Summary of the report of the 24th WHO Expert Committee on Selection and Use of Essential Medicines; WHO core list 15.1 and 15.2: Web Annex A.
Attachments (non-confidential information)	WHO-MHP-HPS-EML-2023.01-eng.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 157	2025/04/25 15:23
Country	Germany
Name of organization/institution	VKE-Kosmetikverband
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	From the perspective of the cosmetics industry, both technical, economic, and public health aspects clearly speak against the classification of ethanol as a hazardous substance. Ethanol is a proven, widely used active ingredient in cosmetic and hygiene products, particularly in human hygiene (PT1), surface disinfection (PT2), and food processing (PT4).

Product Type	1,2,4
Alternative Identity and Properties	Ethanol is highly effective against bacteria, viruses, and fungi, is well tolerated by the skin, evaporates quickly, and can be safely used in a wide range of formulations. Currently, there are no equivalent alternatives that offer the same level of antimicrobial efficacy, formulation flexibility, and skin compatibility. Substitution is therefore not practicable and would significantly impair the effectiveness of many products.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	As written above, ethanol is highly effective against bacteria, viruses, and fungi, is well tolerated by the skin, evaporates quickly, and can be safely used in a wide range of formulations. Currently, there are no equivalent alternatives that offer the same level of antimicrobial efficacy, formulation flexibility, and skin compatibility. Substitution is therefore not practicable and would significantly impair the effectiveness of many products.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Reclassifying ethanol would trigger extensive, costly, and logistically overwhelming changes across the entire supply chain: new packaging solutions, comprehensive updates to safety data sheets, additional storage and transport regulations, and time-consuming (re)authorisation processes would become mandatory. Small and medium-sized enterprises in particular could face existential threats due to the scale of the required adaptations. Even more critical is the fact that for many proven uses, particularly in the areas of hygiene and disinfection, there are currently no equivalent substitutes. The few alternatives available are plagued by major disadvantages, such as reduced efficacy, poor skin compatibility, significantly higher costs, or negative environmental effects. As a result, the availability of safe and effective hygiene solutions for everyday use could be drastically curtailed, with severe consequences for public health and even economic resilience.
Information above is confidential	

Justification for confidentiality	
Hazards and Risks of the Alternative	Substitute substances would either not be available, be significantly more expensive, and often pose greater ecological concerns. Substitution is therefore neither economically nor ecologically viable.
Information above is confidential	
Justification for confidentiality	
Availability	The international availability of ethanol is secure. Substitute substances would either not be available, be significantly more expensive, or pose greater ecological concerns. Substitution is therefore neither economically nor ecologically viable.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol is indispensable for numerous cosmetic and hygiene products. There is currently no technically or economically viable alternative. Reclassifying ethanol would be disproportionate and jeopardise the principles of a risk-based regulation. The VKE-Kosmetikverband strongly opposes the classification of ethanol as a hazardous substance.
Information above is confidential	
Justification for confidentiality	
Other comments	Reclassification would not bring any recognisable benefits for health, the environment or the economy, on the contrary: an important, well-tolerated and biodegradable ingredient in disinfectants, cosmetics and cleaning products would be lost.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	

Attachments (confidential information)	
Justification for confidential attachment	

Comment 158	2025/04/25 15:27
Country	United Kingdom
Name of organization/institution	BioPhorum
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	BioPhorum material of concern team welcomes the opportunity to provide input on the potential inclusion of Ethanol as a candidate for substitution. As a key stakeholder in the biomanufacturing and pharmaceutical industries, we wish to highlight several critical points regarding the use of ethanol and the potential impact of any potential restrictions. Ethanol is extensively utilized in various applications within our industry, including: • Human hygiene biocidal products (PT01): Ethanol is used as a hand sanitiser in both office and cleanroom environments, safeguarding personnel and product quality. Although not as critical, changes to this would still necessitate some validation and regulatory approval work. • Private area and public health area disinfectant (PT02): Ethanol has proven efficacy in maintaining sterile/ clean manufacturing boundaries. Ethanol serves as a sanitiser for surfaces and facilities, providing a reliable means of maintaining hygiene standards in both general and controlled environments used to manufacture essential drug substances and drug products. Changes here would also require substantial validation work and regulatory updates. Although the following points are not part of the current consultation, the team is highlighting them to ensure reviewers have a comprehensive understanding, and these have been attached in the supporting document: • Preservative (PT06): Ethanol is employed as a biocidal agent and used as component in preservative solutions in certain key biopharmaceutical manufacturing equipment e.g. TFF modules and chromatography resins and membranes, ensuring the microbial integrity and stability of these

	essential components. Any changes to this would necessitate extensive validation work and significant regulatory updates. •Manufacturing Solvent: Ethanol (including denatured Ethanol) is utilized in the manufacturing of small and large molecules production processes. If changed would require significant development, validation and requalification work. • Material Solvent: Ethanol is a critical component used in analytical test utilised in multiple compendial and non-compendial product testing which if changed would require substantial test method validation and regulatory work/updates. • Extraction solution: Ethanol is used as standardized extraction solution in migration and extractables studies • Ethanol is used as a solvent and processing aid for the manufacturing of porous membranes for filtration and chromatography products
Product Type	1,2,4
Alternative Identity and Properties	Ethanol's Role and Efficacy: Ethanol is widely recognized for its proven efficacy in maintaining hygiene standards. It serves as a reliable hand sanitizer in both office and cleanroom environments, safeguarding personnel and product quality. Validation and Regulatory Considerations: Any changes to the use of ethanol as a hand sanitizer would necessitate some validation work and regulatory updates. This includes ensuring that alternative sanitizers meet the same stringent standards for efficacy and safety. Potential Alternatives and Considerations: • Material Compatibility: Alternatives to ethanol must be compatible with the skin and materials used in cleanroom environments. Compatibility issues can affect the effectiveness and safety of sanitizers, potentially leading to skin irritation or inadequate hygiene. • Regulatory Compliance: Switching to a new hand sanitizer would require updates to manufacturing licenses, labels, and audits to comply with regulatory standards. • The Need for Diverse Disinfectants, Addressing Potential Resistance: Considering potential restrictions on ethanol, it is crucial to consider alternative disinfectants to ensure continued efficacy. Relying on limited alternatives could lead to the emergence of resistant strains, compromising our ability to maintain effective disinfection protocols. • Facility Adaptations: Significant costs may be associated with adapting facilities to accommodate new sanitizers, including ensuring compatibility with existing materials and equipment. Examples of Alternatives for Hand Sanitizers: 1. Isopropyl Alcohol and N-Propanol: o Examples: Isopropyl Alcohol (Isopropanol), N-Propanol. o Efficacy: Both isopropyl

	alcohol and n-propanol are effective disinfectants with broad-spectrum antimicrobial activity. Isopropyl alcohol is slightly more bactericidal than ethanol, while n-propanol is also used in healthcare settings for its disinfectant properties (7) (8) o Considerations: These alcohols are commonly used in combination with other disinfectants to enhance efficacy. They are effective at concentrations of 60-90% and are compatible with many materials used in cleanroom environments. They work by denaturing proteins and disrupting cell membranes, leading to cell death (7) (8) 2. Benzalkonium Chloride: • Efficacy: Effective against a broad spectrum of microorganisms, including bacteria and fungi • Considerations: Benzalkonium chloride is less harsh on the skin compared to alcohol-based sanitizers and is suitable for frequent use (9). Key Considerations for Alternatives: • Efficacy and Safety: Any alternative must provide the same level of efficacy in maintaining hygiene standards without compromising safety. • Long-Term Viability: The long-term stability and effectiveness of alternative sanitizers must be considered to ensure they meet the rigorous demands of cleanroom environments. • Cost Implications: The financial impact of transitioning to a new hand sanitizer, including validation, regulatory updates, and facility adaptations, must be carefully evaluated.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Validation and Regulatory Considerations: Any changes to the use of ethanol as a hand sanitizer would necessitate some validation work and regulatory updates. This includes ensuring that alternative sanitizers meet the same stringent standards for efficacy and safety. Potential Considerations: • Efficacy and Safety: Any alternative must provide the same level of efficacy in maintaining hygiene standards without compromising safety. • Long-Term Viability: The long-term stability and effectiveness of alternative sanitizers must be considered to ensure they meet the rigorous demands of cleanroom environments. • Cost Implications: The financial impact of transitioning to a new hand sanitizer, including validation, regulatory updates, and facility adaptations, must be carefully evaluated. • Material Compatibility: Alternatives to ethanol must be compatible with the skin and materials used in cleanroom environments. Compatibility issues can affect the effectiveness and safety of sanitizers, potentially leading to

	skin irritation or inadequate hygiene. • Regulatory Compliance: Switching to a new hand sanitizer would require updates to manufacturing licenses, labels, and audits to comply with regulatory standards. • The Need for Diverse Disinfectants, Addressing Potential Resistance: Considering potential restrictions on ethanol, it is crucial to consider alternative disinfectants to ensure continued efficacy. Relying on limited alternatives could lead to the emergence of resistant strains, compromising our ability to maintain effective disinfection protocols. • Facility Adaptations: Significant costs may be associated with adapting facilities to accommodate new sanitizers, including ensuring compatibility with existing materials and equipment.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	The proposed legislation could negatively impact European citizens and the economy. Currently, it is unclear to what extent this may be as all use cases and n-1 to n-3 of the supply chains are not easily assessed or understood. Based on the use of Ethanol so widely in the industry as a sanitiser and solvent. To provide an overview, the biomanufacturing industry sector in Europe in 2024 is estimated to have produced approximately 1.5 billion units of biologic drugs. This includes a wide range of biologics such as monoclonal antibodies, vaccines, and biosimilars, reflecting the growing demand and advancements in biomanufacturing technologies. In 2024, the economic value of biologic drugs to the European economy was substantial. The biomanufacturing industry, including biologics, contributed approximately €311 billion to the economy. This value reflects the significant role biologics play in healthcare, driven by advancements in biotechnology and the increasing demand for innovative treatments. BioPhorum members believe that the proposed changes could pose a significant risk to patient safety. There is substantial concern about the impact these changes could have due to the availability of alternatives to bridge this gap. As a result, patients may not receive doses of lifesaving medications, including treatments such as Preventive and Therapeutic Biologics, Metabolic and Hormonal Biologics, Immunotherapy and Targeted Therapy, Advanced Cellular and Genetic Therapies, and other essential drugs that are required to be reassessed by regulatory agencies

Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Ethanol, as described in this document, presents a relatively low risk profile compared to other common alternatives. While ethanol can be dangerous if ingested, it is generally less harmful than the alternatives highlighted here. This makes ethanol a safer choice, offering effective results with a reduced risk of severe health consequences.
Information above is confidential	
Justification for confidentiality	
Availability	There is a real limitation in alternatives with a lower risk profile than ethanol. Additionally, the current demand for alternative products is low.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	In conclusion, while we understand the need to evaluate the substitution of certain substances, we urge the consultation authority to consider the substantial impact on our industry. Ethanol is a critical component in the microbial control strategies for our processes, and its substitution would pose significant challenges in terms of regulatory compliance, supply chain stability, and cost. We recommend a thorough assessment of the implications and the exploration of feasible alternatives that do not compromise the integrity and functionality of our products.
Information above is confidential	
Justification for confidentiality	
Other comments	Ethanol's compatibility with various materials is well-established, and it is crucial for maintaining the integrity and functionality of Biologic products. For instance, benzyl alcohol, a potential alternative, is not compatible with several materials an example of this can be seen in Table 1: Materials that are not compatible with 2% benzyl alcohol in the document attached. This incompatibility poses significant challenges in terms of material compatibility and

	stability. Key challenges when developing alternatives to consider include: • Regulatory Impact: The regulatory impact of substituting ethanol is substantial and could affect the availability of essential drug products in the market due to timeline requirements (additional information provided below) • Supply Chain Disruptions: The qualification of alternatives would require extensive work, potentially leading to supply chain disruptions and impacting the availability of substitute materials for drug product manufacturing, e.g. essential chromatography columns • Cost Implications: Developing and validating alternatives would incur substantial costs, including facility changes, compatibility upgrades, quality document updates, manufacturing licenses, labels, and audits. European and U.S. Regulatory Provisions Any changes to registered drug manufacturing must be approved by healthcare regulatory authorities. These could lead to a significant increase in change approval submissions, posing a risk of supply chain disruptions for critical drugs. Industry experts predict that the volume of filings and license updates to regulatory agencies, such as the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA), would be substantial and could have a knock-on impact on approvals for newer drugs. This is based on the fact that there are numerous EMA-licensed drugs and medical devices could be affected by any changes Number of Registered Products • Europe: The European Medicines Agency (EMA) oversees 2,145 medicinal products authorized for use in the EU (3). • USA: The U.S. Food and Drug Administration (FDA) manages the registration of numerous drugs and medical devices, with over 19,000 FDA-licensed drugs and more than 6,000 FDA medical devices, not including products currently in development or those licensed since 2018 (4).
Information above is confidential	
Justification for confidentiality	
References	See the attached document
Attachments (non-confidential information)	22nd April 2025 Ethanol response to ECHA - ECHA.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 159	2025/04/25 15:27
Country	United Kingdom
Name of organization/institution	BioPhorum
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	BioPhorum material of concern team welcomes the opportunity to provide input on the potential inclusion of Ethanol as a candidate for substitution. As a key stakeholder in the biomanufacturing and pharmaceutical industries, we wish to highlight several critical points regarding the use of ethanol and the potential impact of any potential restrictions. Ethanol is extensively utilized in various applications within our industry, including: • Private area and public health area disinfectant (PT02): Ethanol has proven efficacy in maintaining sterile/ clean manufacturing boundaries. Ethanol serves as a sanitiser for surfaces and facilities, providing a reliable means of maintaining hygiene standards in both general and controlled environments used to manufacture essential drug substances and drug products. Changes here would also require substantial validation work and regulatory updates. • Human hygiene biocidal products (PT01): Ethanol is used as a hand sanitiser in both office and cleanroom environments, safeguarding personnel and product quality. Although not as critical, changes to this would still necessitate some validation and regulatory approval work. Although the following points are not part of the current consultation, the team is highlighting them to ensure reviewers have a comprehensive understanding, and these have been attached in the supporting document: • Preservative (PT06): Ethanol is employed as a biocidal agent and used as component in preservative solutions in certain key biopharmaceutical manufacturing equipment e.g. TFF modules and chromatography resins and membranes, ensuring the microbial integrity and stability of these essential components. Any changes to this would necessitate extensive validation work and significant regulatory updates. • Manufacturing Solvent: Ethanol (including denatured Ethanol) is utilized in the manufacturing of small and large molecules production processes. If changed would require significant

	development, validation and requalification work. • Material Solvent: Ethanol is a critical component used in analytical test utilised in multiple compendial and non-compendial product testing which if changed would require substantial test method validation and regulatory work/updates. • Extraction solution: Ethanol is used as a standardized extraction solution in migration and extractables studies • Ethanol is used as a solvent and processing aid for the manufacturing of porous membranes for filtration and chromatography products
Product Type	1,2,4
Alternative Identity and Properties	Ethanol's Role and Efficacy: Ethanol is widely recognized for its proven efficacy in maintaining sterile and clean manufacturing boundaries. It serves as a reliable sanitizer for surfaces and facilities, ensuring hygiene standards in both general and controlled environments where essential drug substances and products are manufactured. Validation and Regulatory Considerations: Any changes to the use of ethanol in this capacity would necessitate substantial validation work and significant regulatory updates. This includes ensuring that alternative disinfectants meet the same stringent standards for efficacy and safety. Potential Alternatives and Considerations: 1.Material Compatibility: Alternatives to ethanol must be compatible with the materials used in manufacturing environments and finished goods. Compatibility issues can affect the effectiveness and safety of disinfectants. This may include either not effectively maintaining sterility of clean manufacturing value or lead to damage of the finished good or residuals left. 2.Regulatory Compliance: Switching to a new disinfectant would require updates to manufacturing licenses, labels, and audits to comply with regulatory standards. 3.Facility Adaptations: Significant costs may be associated with adapting facilities to accommodate new disinfectants, including ensuring compatibility with existing materials and equipment. Examples of Alternatives for the BioPharma Industry: Isopropyl Alcohol and N-Propanol: Examples: Isopropyl Alcohol (Isopropanol), N-Propanol. Efficacy: Both isopropyl alcohol and n-propanol are effective disinfectants with broad-spectrum antimicrobial activity. Isopropyl alcohol is slightly more bactericidal than ethanol, while n-propanol is also used in healthcare settings for its disinfectant properties. Considerations: These alcohols are commonly used in combination with other disinfectants to enhance efficacy. They are effective at concentrations of 60-90% and are compatible with many materials used in cleanroom environments. Quaternary Ammonium Compounds (QACs):

	Examples: Cetrimide, Benzalkonium Chloride. Efficacy: Effective against a broad spectrum of microorganisms, including bacteria and fungi. Considerations: QACs interact with cell membranes, leading to cytoplasm leakage and coagulation . Phenolic Disinfectants: Examples: Vesphene III, LpH III . Efficacy: Effective against bacteria, fungi, and viruses. Considerations: Phenolic disinfectants are suitable for hard, non-porous surfaces. Hydrogen Peroxide: Efficacy: Broad-spectrum activity against bacteria, fungi, and viruses. Considerations: Hydrogen peroxide is a strong oxidizing agent and can be used in various concentrations for different applications. Peracetic Acid: Efficacy: Effective against bacteria, fungi, and spores. Considerations: Peracetic acid is a potent disinfectant and is often used in combination with hydrogen peroxide . Chlorine-Based Disinfectants: Examples: Sodium hypochlorite. Efficacy: Effective against a wide range of microorganisms, including bacteria, fungi, and viruses. Considerations: Chlorine-based disinfectants are commonly used for surface disinfection.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Key Considerations for Alternatives: 1.Efficacy and Safety: Any alternative must provide the same level of efficacy in maintaining hygiene standards without compromising safety. 2.Long-Term Viability: The long-term stability and effectiveness of alternative disinfectants must be considered to ensure they meet the rigorous demands of manufacturing environments. 3.Material compatibility: The lower (chemical) compatibility of alternative sanitizers to certain materials, specifically the strong oxidizers, might limit their application. Alternatives to ethanol must be compatible with the materials used in manufacturing environments and finished goods. Compatibility issues can affect the effectiveness and safety of disinfectants. This may include either not effectively maintaining sterility of clean manufacturing value or lead to damage of the finished good or residuals left. 4.Regulatory Compliance: Switching to a new disinfectant would require updates to manufacturing licenses, labels, and audits to comply with regulatory standards. 5.Facility Adaptations: Significant costs may be associated with adapting facilities to accommodate new disinfectants, including ensuring compatibility with existing materials and equipment. 6.Cost Implications: The financial impact of transitioning to a new disinfectant, including validation, regulatory

Information above is confidential	
Justification for confidentiality	
Economic Feasibility	The proposed legislation could negatively impact European citizens and the economy. Currently, it is unclear to what extent this may be as all use cases and n-1 to n-3 of the supply chains are not easily assessed or understood. Based on the use of Ethanol so widely in the industry as a sanitiser and solvent. To provide an overview, the biomanufacturing industry sector in Europe in 2024 is estimated to have produced approximately 1.5 billion units of biologic drugs. This includes a wide range of biologics such as monoclonal antibodies, vaccines, and biosimilars, reflecting the growing demand and advancements in biomanufacturing technologies. In 2024, the economic value of biologic drugs to the European economy was substantial. The biomanufacturing industry, including biologics, contributed approximately €311 billion to the economy. This value reflects the significant role biologics play in healthcare, driven by advancements in biotechnology and the increasing demand for innovative treatments. BioPhorum members believe that the proposed changes could pose a significant risk to patient safety. There is substantial concern about the impact these changes could have due to the availability of alternatives to bridge this gap. As a result, patients may not receive doses of lifesaving medications, including treatments such as Preventive and Therapeutic Biologics, Metabolic and Hormonal Biologics, Immunotherapy and Targeted Therapy, Advanced Cellular and Genetic Therapies, and other essential drugs that are required to be reassessed by regulatory agencies
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Key Considerations for Alternatives: 1.Efficacy and Safety: Any alternative must provide the same level of efficacy in maintaining hygiene standards without compromising safety. 2.Long-Term Viability: The long-term stability and effectiveness of alternative disinfectants must be considered to ensure they meet the rigorous demands of manufacturing environments. 3.Material compatibility: The lower (chemical) compatibility of alternative sanitizers to certain materials, specifically the strong oxidizers, might limit their application. Alternatives to ethanol must be compatible with the materials used in manufacturing environments and

	finished goods. Compatibility issues can affect the effectiveness and safety of disinfectants. This may include either not effectively maintaining sterility of clean manufacturing value or lead to damage of the finished good or residuals left. 4.Regulatory Compliance: Switching to a new disinfectant would require updates to manufacturing licenses, labels, and audits to comply with regulatory standards. 5.Facility Adaptations: Significant costs may be associated with adapting facilities to accommodate new disinfectants, including ensuring compatibility with existing materials and equipment. 6.Cost Implications: The financial impact of transitioning to a new disinfectant, including validation, regulatory updates, and facility adaptations, must be carefully evaluated.
Information above is confidential	
Justification for confidentiality	
Availability	There is a real limitation in alternatives with a lower risk profile than ethanol. Additionally, the current demand for alternative products is low.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	In conclusion, while we understand the need to evaluate the substitution of certain substances, we urge the consultation authority to consider the substantial impact on our industry. Ethanol is a critical component in the microbial control strategies for our processes, and its substitution would pose significant challenges in terms of regulatory compliance, supply chain stability, and cost. We recommend a thorough assessment of the implications and the exploration of feasible alternatives that do not compromise the integrity and functionality of our products.
Information above is confidential	
Justification for confidentiality	
Other comments	Ethanol's compatibility with various materials is well-established, and it is crucial for maintaining the integrity and functionality of Biologic products. For instance, benzyl alcohol, a potential alternative, is not compatible with several materials an example of this can be seen in Table 1:

	Materials that are not compatible with 2% benzyl alcohol in the document attached. This incompatibility poses significant challenges in terms of material compatibility and stability. Key challenges when developing alternatives to consider include: • Regulatory Impact: The regulatory impact of substituting ethanol is substantial and could affect the availability of essential drug products in the market due to timeline requirements (additional information provided below) • Supply Chain Disruptions: The qualification of alternatives would require extensive work, potentially leading to supply chain disruptions and impacting the availability of substitute materials for drug product manufacturing, e.g. essential chromatography columns • Cost Implications: Developing and validating alternatives would incur substantial costs, including facility changes, compatibility upgrades, quality document updates, manufacturing licenses, labels, and audits. European and U.S. Regulatory Provisions Any changes to registered drug manufacturing must be approved by healthcare regulatory authorities. These could lead to a significant increase in change approval submissions, posing a risk of supply chain disruptions for critical drugs. Industry experts predict that the volume of filings and license updates to regulatory agencies, such as the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA), would be substantial and could have a knock-on impact on approvals for newer drugs. This is based on the fact that there are numerous EMA-licensed drugs and medical devices could be affected by any changes Number of Registered Products • Europe: The European Medicines Agency (EMA) oversees 2,145 medicinal products authorized for use in the EU (3). • USA: The U.S. Food and Drug Administration (FDA) manages the registration of numerous drugs and medical devices, with over 19,000 FDA-licensed drugs and more than 6,000 FDA medical devices, not including products currently in development or those licensed since 2018 (4).
Information above is confidential	
Justification for confidentiality	
References	Please see document attached
Attachments (non-confidential information)	22nd April 2025 Ethanol response to ECHA - ECHA.pdf
Attachments (confidential information)	

Justification for confidential attachment	

Comment 160	2025/04/25 15:46
Country	Germany
Name of organization/institution	Merck KGaA
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Ethanol is used as an active ingredient in many types of biocidal products (PT) as a disinfectant in the production of pharmaceuticals, cosmetics, and medical devices to provide safe products. Due to its broad applications, excellent material compatibility, and ease of technical use, ethanol is essential and difficult to replace. It exhibits broad antimicrobial properties and is effective against bacteria, viruses (including non-enveloped viruses), and fungi. Ethanol acts quickly and has a non-specific mode of action, which minimizes the risk of developing microbial resistance. The comprehensive analysis of alternatives (provided in the attachment to the public consultation) shows that ethanol offers an unique combination of comprehensive antimicrobial efficacy, rapid action, and good compatibility, which is essential for the strict requirements of the pharmaceutical and chemical industries. Numerous validated disinfection and cleaning processes for surfaces, materials, and equipment in GMP drug manufacturing include ethanol. Replacing ethanol would necessarily require a complex, time-consuming, and costly revalidation of these processes. The validation standards are also based on the context of ethanol usage. Furthermore, in many cases especially in the pharmaceutical area, cleaning and disinfection with ethanol is part of the operating license. Ethanol is also used in validated disinfection and cleaning methods for analytical instruments and cannot be replaced for existing equipment. The feasibility of substitution depends on conducting new validation tests to ensure that the alternative preserves the essential chemical properties and functionality of ethanol and maintains its effectiveness in specific applications and uses without introducing unintended or adverse consequences. Moreover, ethanol-containing biocidal PTs are used by employees in processing

	facilities as hand sanitizers (without direct skin contact; disinfecting gloves) to prevent contamination of pharmaceuticals, cosmetics, and medical devices and to ensure corporate hygiene. Merck KGaA, Darmstadt Germany as a significant European chemical and pharmaceutical company, is dependent on the availability of ethanol as a biocide and disinfectant. This availability is crucial to ensure the smooth operation of our business, guarantee the safety of our employees, and enable the production of pharmaceuticals within the EU. In general, good workplace hygiene is particularly crucial during pandemics to protect employees in critical infrastructures from non-enveloped viruses. The case of the Covid-19 pandemic has highlighted the necessity of ethanol-based disinfectants for critical infrastructures. Ethanol is not only used as an active ingredient in biocidal products but also as a solvent in other biocidal products, such as insect repellents. Consequently, a large number of biocidal products could be indirectly affected and thus lose their approval. Under the BPR, ethanol remains essential for applications in human hygiene, such as hand and skin disinfection, as well as in its use as a surface disinfectant and therefore cannot be eliminated. Furthermore, there is a risk that the cascading effects of the BPR on other EU legislations may restrict other uses of ethanol in general and specifically in the pharmaceutical context. All regulatory conclusions must ensure that there are no compromises in safety and efficacy. The benefit/risk assessments of available alternatives regarding worker exposure and sustainability suggest that these solutions would represent regrettable substitutions. From a chemical and regulatory perspective, ethanol is superior due to: - Faster biodegradability (lower persistence in soil/water) - Rapid and efficient efficacy against bacteria, viruses (including non-enveloped viruses), and fungi - Lower VOC reactivity (less impact on air pollution) - Quick and residue-free evaporation of surfaces during application - More sustainable production (bioethanol vs. petrochemical IPA) - High resilience in the supply chain due to a variety of regional manufacturers throughout the EEA. For industries seeking more environmentally friendly solvents, safer disinfectants, and reduced regulatory burdens, ethanol is the preferred choice over isopropanol. Overall, the use of ethanol, particularly in the context of the pharmaceutical sector's requirements, is neither hazardous for workers (as it is not absorbed or used in sufficient quantities to be harmful through inhalation) nor replaceable. We would like to emphasize and clarify that ethanol has had safe applications for a long time and only high oral abuse leads to reproductive or carcinogenic

	effects. Therefore, the potency of ethanol should be taken into account under the CLP. Furthermore, the BPR should only apply a new or stricter classification after the case has been discussed and approved at the RAC. It is crucial that a risk-based approach is followed under the BPR in this case to ensure the proper handling and regulation of ethanol.
Product Type	1,2,4
Alternative Identity and Properties	Propan-1-ol shows some effectiveness against bacteria and fungi; however, it has limited virucidal activity, particularly against non-enveloped viruses. This limitation makes it less suitable for the comprehensive disinfection requirements in the pharmaceutical industry and certain areas of the chemical industry, such as membrane manufacturing, where protection against all types of microbes and viruses is crucial. Although propan-1-ol is approved as a biocidal active substance, its applications are limited significantly restricting its flexibility and usability. Propan-2-ol is effective against many pathogens but has similar limitations as propan-1-ol, especially regarding its effectiveness against non-enveloped viruses. While propan-2-ol is widely used, the need for additional products to achieve complete disinfection significantly reduce its economic attractiveness compared to ethanol, making it less suitable for frequent surface disinfection. A restriction of Ethanol would make a complete disinfection not possible. The supply situation of isopropanol presents significant challenges compared to ethanol. Isopropanol has a less widespread production and a less integrated supply chain, which can lead to potential shortages in availability, especially during times of high demand. Additionally, the higher production costs for isopropanol further restrict its availability. Other alternatives do not demonstrate the necessary broad efficacy against the entire spectrum of pathogens required for PT2 applications, which limits their suitability for these diverse environments.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Ethanol is used in a variety of disinfectants that are suitable for surface disinfection in various environments, including GMP manufacturing of pharmaceuticals and other validated productions. The technical feasibility of using ethanol is high, as it easily mixes with water and other organic compounds, facilitating its application. Additionally, numerous "ready-to-use" formulations (liquids, pre-soaked

	wipes, etc.) are commercially available. Ethanol combines excellent compatibility with various materials with residue-free evaporation. Ethanol is a very fast and reliably effective disinfectant, leading to the inactivation of microorganisms on surfaces in a very short time (seconds to minutes). The properties of ethanol precisely meet our needs, as they provide high technical applicability, versatile formulations, excellent material compatibility, and fast, reliable disinfection that are essential for the requirements in GMP manufacturing and other validated productions.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Ethanol proves to be the most economical option for PT2 applications due to lower production costs, broad availability, and robust supply chains within the EU, leading to high cost-effectiveness while contributing to the EU's sustainability goals. Its broad spectrum of activity, rapid effectiveness, and adaptability position ethanol as the leading choice for surface disinfection in various environments. The alternatives (including propan-1-ol and propan-2-ol) are less economically favorable and have limited effectiveness against non-enveloped viruses. Given these factors, ethanol remains the most practical and cost-effective option for PT2 surface disinfection, ensuring effective infection control. We endorse the Analysis of Alternatives for use of ethanol for PT2 Section 6.1.6: Ethanol benefits from a robust and diversified supply chain with over 240 suppliers in the EU, ensuring reliability even during high demand. Alternative substances like isopropanol have significantly fewer suppliers, raising concerns about their ability to meet EU-wide demand, especially during crises. Ethanol's established supply chain and adaptability to demand surges make it a more reliable option for critical sectors like healthcare. The research, qualification, supply, and implementation factors for substituting ethanol would impose an economic burden on industrial resources. Investing in more critical and less effective alternatives to ethanol would further tighten resource constraints without providing any additional benefits for workers.
Information above is confidential	
Justification for confidentiality	

Hazards and Risks of the Alternative	Ethanol has a well-established safety record and is classified by the FDA as "Generally Recognized as Safe" (GRAS). In contrast, isopropanol is subject to significantly stricter restrictions in food and pharmaceutical applications. The assessment of CMR endpoints and a subsequent decision by the European Commission regarding this endpoint would lead to an official statement on the CMR properties of ethanol for biocidal applications. This official position on the CMR properties could influence the opinion-forming process of RAC and thus impair the currently announced harmonized classification process from the Greek authorities. It is crucial that decisions regarding classifications are made by the RAC and not prematurely influenced by the BPR. Although CMR properties are considered a non-threshold endpoint for carcinogenic and reproductive toxic effects, significant differences in potency are observed during among the assessment of various substances. The concentration tested mimic the human abuse and is therefore about ten times higher than usual. Ethanol would never be classified as non-toxic according to standard testing guidelines. A CMR classification in the biocidal sector would transfer to all sectors and would need to be considered by all users of ethanol during their self-classification. The available data on the oral intake route of ethanol do not represent a reasonably expected use of ethanol as a chemical substance in the described applications as a surface disinfectant and the associated potential exposures. Exposure to ethanol through dermal application or inhalation of ethanol, the two potential exposure routes from the production or use of biocidal products, does not lead to critical ethanol concentrations in the human body that are known to cause cancer and/or have adverse reproductive effects. Due to the rapid vaporization of ethanol, dermal uptake is low. Additionally, occupational inhalation does not result in a significant increase in blood ethanol concentrations and can be further reduced through technical measures. Current workplace exposure limits for ethanol significantly contribute to reducing worker exposure in the workplace. Moreover, these limits provide an effective measure of safety and ensure that the health of workers is protected. These points further support the requested risk-based approach in the case of classification.
Information above is confidential	
Justification for confidentiality	

Availability	Ethanol is widely available in the European Economic Area and is offered by a variety of manufacturers and suppliers, ensuring availability and mitigating supply shortages. The supply chain for ethanol-based disinfectants is well integrated, supporting efficiency and compliance with strict EU regulations. Furthermore, ethanol can be produced from renewable sources (e.g., corn, sugarcane, or cellulosic biomass), making it more environmentally friendly. In contrast, isopropanol is derived from petrochemical substances that rely on the extraction of fossil fuels, thus not aligning with Europe's sustainable development goals.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol is crucial in pharmaceutical manufacturing and the chemical industry, serving as both a disinfectant and an ingredient in pharmaceutical products. Classifying ethanol as a CMR substance would contradict the objectives of the BPR and CLP, which aim to enhance human health, leading to a decline in hygiene and healthcare standards. A potential ban on ethanol due to this classification could severely impact research, development, and the production of pharmaceuticals and medical devices, disrupting validated GMP manufacturing processes and creating cascading effects across related regulations like REACH. Such a classification would be disproportionate, focusing solely on the risks associated with oral intake, while ignoring its safe and effective use on skin and surfaces. The search for alternatives has revealed no suitable, economical substitutes for ethanol that fulfill the technical and operational needs for PT2 disinfectants. Ethanol is cost-effective and readily available, making it the industry standard. Alternatives like isopropanol could diminish disinfection efficacy, increase costs, and heighten contamination risks, leading to regrettable substitutions. Thus, ethanol is essential for disinfection in public and industrial settings due to its unique properties and the absence of viable alternatives. Eliminating ethanol as a biocidal active substance would jeopardize hygiene and safety standards and erode trust in pharmaceutical supply chains. Therefore, it is vital to recognize ethanol's role in disinfection strategies within the pharmaceutical sector and advocate for its continued availability. We endorse the preliminary analysis included in the public consultation appendices, particularly Section 3.3.1 of PT 2, which discusses the primary use of ethanol in the pharmaceutical

	sectors under the Biocidal Products Regulation. Additionally, there are applications in PT1 for hand disinfection and worker protection.
Information above is confidential	
Justification for confidentiality	
Other comments	Ethanol is essential both in pharmaceutical manufacturing and in the chemical industry, serving not only as a disinfectant but also being used at the level of pharmaceutical products. The classification of ethanol as a CMR substance would fundamentally miss the purpose of the BPR and CLP, which is to improve human health. Instead, it would lead to a significant deterioration in hygiene and healthcare. A potential ban on ethanol due to its classification as a CMR substance under the BPR would harm research and development as well as the manufacturing of pharmaceuticals and medical devices, along with the validated GMP manufacturing processes, resulting in cascading consequences in overlapping frameworks (e.g., REACH). Such a classification would be disproportionate and inappropriate, as it would be based solely on the risk of oral ethanol intake, despite its safe and effective application on skin and surfaces. The analysis of alternatives has shown that there are currently no suitable and economical alternatives to ethanol that meet the technical and operational requirements for PT2 disinfectants. Ethanol is cost-effective and readily available, making it the preferred choice in the industry. The use of alternatives such as isopropanol could not only reduce disinfection efficiency but also lead to higher costs and an increased risk of contamination, representing a regrettable substitution. The analysis concludes that ethanol remains indispensable for disinfection in public and industrial environments due to its unique properties and the lack of suitable alternatives. The loss of ethanol as a biocidal active substance would not only endanger hygiene and safety standards but also undermine trust in pharmaceutical supply. It is therefore essential to consider ethanol as an essential component of disinfection strategies in the pharmaceutical industry and to support the need for its continued availability. We support the preliminary analysis already included in the appendices of the public consultation. In particular, Section 3.3.1 of PT 2, "The EU Disinfectants Industry," addresses the primary use of ethanol for pharmaceutical sectors covered by the Biocidal Products Regulation. In some cases, we also have

	applications as PT1 for hand disinfection and worker protection.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 161	2025/04/25 15:48
Country	France
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	We use ethanol as the biocidal active substance of our PT1 disinfectants, and also as a co-formulant for some of our detergent and cosmetic products.
Product Type	1,2,4
Alternative Identity and Properties	See the detailed document attached (IV - Attachments).
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	See the detailed document attached (IV - Attachments).
Information above is confidential	

Justification for confidentiality	
Economic Feasibility	See the detailed document attached (IV - Attachments).
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	See the detailed document attached (IV - Attachments).
Information above is confidential	
Justification for confidentiality	
Availability	See the detailed document attached (IV - Attachments).
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	See the detailed document attached (IV - Attachments).
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 162	2025/04/25 15:59
Country	Germany
Name of organization/institution	EFFAT (European Federation of Food, Agriculture and Tourism Trade Unions)
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	EFFAT is the European Federation of Food, Agriculture and Tourism Trade Unions, also representing domestic workers. As a European Trade Union Federation representing 121 national trade unions from 40 European countries, EFFAT defends the interests of more than 2.6 million members and 25 million workers towards the European Institutions, European employers' associations and transnational companies.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	

Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	We recommend that ECHA conducts a comprehensive risk assessment taking into consideration the risks for the workforce producing ethanol when considering the classification of ethanol and in this assessment evaluate the potential economic consequences, including effects on employment levels and job quality.
Information above is confidential	
Justification for confidentiality	
Other comments	Ethanol is crucial as an disinfectant for infection prevention; it is of paramount interest for human health in effective infection protection; and the ethanol production has of course an important economic dimension for the production industry. EFFAT is concerned that any potential reclassification of ethanol could negatively affect the sugar and starch manufacturers, the agricultural sector and the employment levels in these sectors. Ethanol production is a big economic factor in the sugar and starch sectors. Those sectors provide direct and indirect employment for thousands of workers throughout Europe. While EFFAT clearly defends the need to reduce reliance on hazardous substances, we urge ECHA to carefully consider the potential adverse effects on workers in the sugar and starch production sectors. Classifying ethanol as “reproductive toxic” or “carcinogenic” would create public health risks in areas where no alternatives exist, lead to unjustified product restrictions and with it economic losses. Moreover, as ethanol is produced through the fermentation of agricultural products like sugar beet, wheat and corn, its production contributes significantly to: - Rural development - Agriculture and - Environmental goals A balanced approach that prioritizes both public health, environmental safety and workers' health and safety and employment is essential.
Information above is confidential	

Justification for confidentiality	
References	
Attachments (non-confidential information)	Ethanol EFFAT input.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 163	2025/04/25 15:58
Country	Belgium
Name of organization/institution	Cosmetics Europe
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Cosmetics Europe is the association representing the cosmetics and personal care industry in Europe. Our membership includes 29 national associations from EU/EEA countries, 30 active and supporting multinationals, as well as a network of 9000 SMEs, for a market value of €96 billion. Cosmetics Europe wishes to stress the significant implications of classifying ethanol as a Carcinogenic, Mutagenic, and/ or Reproductive toxicant (CMR) substance and urges a comprehensive review of the balance between negative and positive consequences of CMR classification of ethanol, particularly concerning its downstream uses in the cosmetics sector. This document outlines the potential disruptions, lack of consumer benefit, additional regulatory burdens, and strategic considerations for EU policymakers and the European Chemicals Agency (ECHA). Ethanol used in cosmetic products is denatured, i.e. unfit for consumption. By that alone, a consumer risk of (regular or excessive) oral consumption is negated and any CMR property assigned to ethanol as pure chemical substance, based on oral intake, would not be relevant to cosmetic use. Cosmetics Europe believes that it's crucial to detach the hazard classification of ethanol (harmonized classification

	under the CLP) from its ongoing evaluation as a biocidal active substance.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Lack of Suitable Alternatives Ethanol serves multiple functions in cosmetics that cannot be easily replaced by a single ingredient: •Solubilizing Properties: Ethanol dissolves various cosmetic ingredients and enhances product performance. •Volatile Properties: It contributes to consumer experience by providing freshness and reducing stickiness. •Antimicrobial Activity: Ethanol's inherent antimicrobial properties allow less use of preservatives and contribute to disinfecting functionality of products

Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	Cosmetics Europe_Ethanol Classification Policy Paper March 2025.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 164	2025/04/25 16:01
Country	Germany
Name of organization/institution	German Bioethanol Industry Association
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	

Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Substituting ethanol as a biocidal active ingredient would have fatal consequences for healthcare: no known substitute has the broad virucidal spectrum of activity and all the substitutes under consideration have a higher toxicity profile than ethanol. Accordingly, the increased use of disinfectants with a weaker effect would lead to higher microbial resistance, with corresponding far-reaching negative health consequences. In addition, possible alternatives to ethanol are not available in the required quantities either in the short or long term and would also be significantly more expensive than ethanol.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	

References	
Attachments (non-confidential information)	Statement of the BDBe_Consultations on Potential Candidates for Ethanol-Substitution.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 165	2025/04/25 16:08
Country	Belgium
Name of organization/institution	AIBI Aisbl
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	AIBI is representing the Large bakeries at EU level. Our sector is producing over 30 million tons bakery products, which are a staple food / basis of the EU diet. Bread manufacturing being based on a fermentation process (by <i>Saccharomyces</i> yeast and/or sourdough), ethanol is a natural constituent of the bread process since bread-making exists (actually almost since the origin of mankind). It evaporates during the baking process but contributes to tastes and flavours. In addition to this, ethanol is commonly used in various aspects of the bakery manufacturing as a carrier of various ingredients or for technical purpose (e.g. surface treatment of the food with preservation purpose). Ethanol is also largely used as a technical agent in bakery plants and workshops for the disinfection of surfaces, equipments (see separate input on PT4) and personal hygiene, in particular for hand disinfection. The use of ethanol / ethanol-based hand rubs (denaturated ethanol) offers inequivalent functionalities and versatility, in particular though their wide efficiency spectrum and self-drying/evaporating properties. The use of ethanol indeed avoids the need to dry disinfected hands with non-sterile clothes or materials. It also provides efficient personal hygiene support throughout the facilities (e.g. at logistic level).

Product Type	1,2,4
Alternative Identity and Properties	Although other disinfectants are used in the large bakery sector (e.g. peracid solutions and active chloride compounds) for other purposes, none of them is used in hand rubs. Ethanol-based rubs avoid need for basins/water and drying that are not available / suitable in many places of the facilities and allow more frequent and efficient hand hygiene.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	To our knowledge, no other volatile compound provides the same disinfectant properties as ethanol, including the absence of residues after drying, which could be undesirable in our food production context.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	The economic feasibility of substitution might appear as relatively irrelevant question since it would have to compare with an alternative offering equivalent properties; which is not the case. Ethanol is an efficient and cost-effective product.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	We would like to question the relevance of the hazards pre-identified for ethanol versus the relevant route of exposure associated with hand rubs/hand hygiene. As far as we understand from the pre-evaluation, the identified hazards are related to the ingestion of ethanol in excessive quantities, not to topical exposure or even inhalation (at least not as it could result from the use of hand rubs). It would be nonsense to deprive the industry/users from one of the most efficient disinfectants while the hazard identified is entirely irrelevant to the risk pattern of this use. As pointed out we did not identify any alternative that would match the properties of ethanol. If one would consider peracetic or chlorine-based products as alternative (though they are not really), it is obvious that they would bear at

	least for the first corrosiveness and for the second, inhalation, toxicity properties that would make them riskier than the use of ethanol. The lack of efficiency of the alternative against some viruses, etc. is also a risk that needs to be considered.
Information above is confidential	
Justification for confidentiality	
Availability	Ethanol is largely and easily available. It is a natural product deriving from bioeconomy/industrial fermentation. The production of renewable ethanol is deriving from agricultural carbohydrates. The EU renewable ethanol industry is a strategic sector for Europe, with a significant role in tackling climate change and bolstering food and feed security.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol is a key hygiene support for the bakery industry, which ranks as the third largest food production sector in Europe. We do not identify any alternative that would match the properties of ethanol. Questioning the use of ethanol as PT1 and raising its substitution, seems to be based on a purely hazard-based approach that we see to be entirely irrelevant to the pattern of use and risk in hand rubs / PT1. The Draghi and Niinistö reports (and deriving strategies putted forward by the EU Commission) have pointed to the urgent need to work on preparedness and EU autonomy. This BPR procedure that would result in depriving the industry (and citizens) from a pivotal disinfectant seems to be at complete odd with this reality, both from the EU production point of view and safety/preparedness to sanitary crisis.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	

References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 166	2025/04/25 16:17
Country	Belgium
Name of organization/institution	AIBI Aisbl
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	AIBI is representing the Large bakeries at EU level. Our sector is producing over 30 million tons bakery products, which are a staple food / basis of the EU diet. Bread manufacturing being based on a fermentation process (by <i>Saccharomyces</i> yeast and/or sourdough), ethanol is a natural constituent of the bread process since bread-making exists (actually almost since the origin of mankind). It evaporates during the baking process but contributes to tastes and flavours. In addition to this, ethanol is commonly used in various aspects of the bakery manufacturing as a carrier of various ingredients or for technical purpose (e.g. surface treatment of the food with preservation purpose). Ethanol is also largely used as a technical agent in bakery plants and workshops for the disinfection of surfaces, equipments and for personal hygiene (see separate input on PT1). Ethanol is used for disinfecting surfaces and equipment over the whole bakery process: from the setting-up of dough and handling of ingredients over the separate kneading and other production processes and baking up to the handling of fresh bakery wares (this concerns both packed and unpacked products for delivery to large retail, convenience stores, and Hotels/restaurant/food facilities). The use of ethanol / ethanol-based solutions offers inequivalent functionalities and versatility, in particular

	though their wide efficiency spectrum and self-drying/evaporating properties, and absence of residues.
Product Type	1,2,4
Alternative Identity and Properties	The manufacturing of bakery products involves a succession of production and downtime periods, which are necessary for deep cleaning of the machines and production lines. During these downtimes operators are cleaning the parts of the production lines that are not accessible during production. Depending upon the part and purposes, a range of cleaning/hygienisation solutions are used and levels of maintenance procedures. They each have their own characteristics and purpose and are not exchangeable. Though the use of more aggressive and/or corrosive substances might be required ad hoc or periodically in the maintenance cycle, they cannot substitute to the use of ethanol for regular cleaning since they require complex washing and rinsing processes. Ethanol is the solution of choice for efficient standard cleaning, as it evaporates with no undesired residues. The special cleaning products include other alcohols, like iso-propanol (2-propanol) and 1-propanol, peracid solutions, sodium hypochlorite solutions and quaternary ammonium compounds (QAV). All of these cleaning agents have serious drawbacks (undesired residues in/on food, corrosiveness, not suitable for surface in contact with food, or with plastic materials, etc.) and ethanol is by far the most versatile and effective cleaning agent. It is to be noted that safety considerations/HACCP and/or important customer (e.g. food trade) explicitly ban the use of some of these special cleaning solutions for safety reasons. Propanol solutions, though less aggressive, are less volatile and may lead to undesired residues which may transfer to food products (chemical smell/taste). Their toxicity (topical and respiratory) is higher than ethanol.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	The alternative cleaning agents are specialised tools used during the complex and thorough cleaning process during downtime of machines and production lines. Due to residues and use limitations of these agents (e.g. corrosion, undesired residues), all surfaces and machines must be rinsed after the specialised agents are used. This is only possible during long downtime of the machines. To our knowledge, no other volatile compound provides the same disinfectant properties as ethanol, including the absence of

	residues after drying, which could be undesirable in our food production context.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	The economic feasibility of substitution might appear as relatively irrelevant question since it would have to compare with an alternative offering equivalent properties, which is not the case. Ethanol is an efficient and cost-effective product.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	We would like to question the relevance of the hazards pre-identified for ethanol versus the relevant route of exposure associated with surface and production lines cleaning. As far as we understand from the pre-evaluation, the identified hazards are related to the ingestion of ethanol in excessive quantities, not to topical exposure or even inhalation (at least not as it could result from the use on surfaces). As pointed out we did not identify any alternative that would match the properties of ethanol. If one would consider peracetic or chlorine-based products as alternative (though they are not really), it is obvious that they would bear at least for the first corrosiveness and for the second, inhalation, toxicity properties that would make them riskier than the use of ethanol. Propanol solutions require a rinsing process after use, since they leave undesired residues spoiling taste and smell of the product. This alone makes these substances unfit for everyday cleaning in bakeries. The lack of/lower efficiency of the alternatives against some viruses, etc. is also a risk that needs to be considered. The use of ethanol is highly relevant to the cleaning of food contact surfaces in production workshops. It would be nonsense to deprive the industry/users from one of the most efficient disinfectants while the hazard identified is entirely irrelevant to the risk pattern of this use. It is also to be noted that banning ethanol is anticipated to trigger negative behavioral reactions from the workforce in production facilities and increase difficulty at work; this will erode the will of workers to effectively clean surfaces and machines (additional burden of rinsing and need to wear protective equipment with lowered effectiveness). In turn this will trigger lowering of the food manufacturing safety.

Information above is confidential	
Justification for confidentiality	
Availability	Ethanol is largely and easily available. It is a natural product deriving from bioeconomy/industrial fermentation. The production of renewable ethanol is deriving from agricultural carbohydrates. The EU renewable ethanol industry is a strategic sector for Europe, with a significant role in tackling climate change and bolstering food and feed security.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol is a key hygiene support for the bakery industry, which ranks as the third largest food production sector in Europe. It is highly efficient and versatile. We do not identify any alternative that would match the properties of ethanol. Questioning the use of ethanol as PT4 and raising its substitution, seems to be based on a purely hazard-based approach that we see to be entirely irrelevant to the pattern of use and risk in surface cleaning / PT4. Besides the technical limitations and lack of alternative described above, a ban of ethanol disinfectant would generate an economic burden linked to the fact that the cleaning processes would be less efficient/require longer downtime of production lines and negatively impact on workforce conditions. All this also bears a significant food safety risk. The Draghi and Niinistö reports (and deriving strategies putted forward by the EU Commission) have pointed to the urgent need to work on preparedness and EU autonomy. This BPR procedure that would result in depriving the industry (and citizens) from a pivotal disinfectant seems to be at complete odd with this reality, both from the EU production point of view and safety/preparedness to sanitary crisis.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	

Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 167	2025/04/25 16:43
Country	Germany
Name of organization/institution	[REDACTED]
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	We are a medium-sized cosmetics company based in Germany. We sell decorative and skin care cosmetics.
Product Type	1,2,4
Alternative Identity and Properties	[REDACTED]
Information above is confidential	[REDACTED]

Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	There are no alternatives with comparable safety, efficacy and technical properties to Ethanol. Raw materials that do not have such good dermal compatibility could be used in cosmetic products as alternatives. This would be a disadvantage for the consumers.
Information above is confidential	
Justification for confidentiality	
Other comments	

Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 168	2025/04/25 18:23
Country	France
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	Information regarding our contribution is located in the enclosed file.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	

Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	To conclude, as company, we acknowledge that ban of Ethanol would ultimately have a significant impact in terms of competitiveness, especially compared to non-European countries. Competitiveness has been set to be improved at the European scale recently and we deeply support this strategy. Yet, it is very obvious that ban of Ethanol would clearly negatively impact European competitiveness.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	Consultations on Potential Candidates for Substitution - Ethanol.pdf
Attachments (confidential information)	

Justification for confidential attachment	

Comment 169	2025/04/26 00:22
Country	Germany
Name of organization/institution	The joint commission "Virus Disinfection" of the German Association for the Control of Viral Diseases (DVV) and the German Society of Viruses (GfV)
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	The German Association for the Control of Viral Diseases was established in the 1950s with the objective of combatting polio: In September 1953, Leading Medical Officers of the Federal German States and Free Cities met in Hamburg. The following three tasks were identified as priorities: 1. Researching the polio disease, 2. Finding effective and safe means of combating it, and 3. Helping those suffering from the consequences of the polio disease. Consequently, the German Association for the Control of Viral Diseases (DVV) was founded on 31 August 1954 in Berlin. It was established as an interdisciplinary instrument for doctors and scientists in practice, clinics, research institutes, and health authorities. The initiative is endorsed by the Federal Ministry of Health, the health ministries of the federal states, and supported by scientific societies, and socially committed foundations and organisations. The DVV's initial focus was on combating poliomyelitis in Germany. As the disease was brought closer to eradication and major advances in the fight against other viral diseases became apparent thanks to the development and consistent use of new vaccines, the association's activities were expanded accordingly. This was reflected in its name in 1972, and in 1977 the association adopted its current name. The Commission for Virus Disinfection is a key component of the public health service, providing vital information to federal states. It is now a joint commission of the DVV and the German Society of Viruses (GfV). The key topic of this commission is therefore the disinfection against viral diseases.
Product Type	1,2,4

Alternative Identity and Properties	Ethanol is the only active ingredient that has been proven to be effective against non-enveloped viruses. It is also a key ingredient in highly effective hand sanitiser formulations. Ethanol-based formulations (typically at a concentration of around 80% w/w) are fast-acting bactericidal, yeasticidal, and completely virucidal agents that have been specially optimised for hand hygiene. For example, Ethanol plus phosphoric acid is even active against the resistant Hepatitis E virus (published by Prof. Steimmann who is a member of the DVV/GfV virus disinfection commission: Hepatitis E virus is highly resistant to alcohol-based disinfectants Behrendt, Patrick et al. Journal of Hepatology, Volume 76, Issue 5, 1062 - 1069 https://www.journal-of-hepatology.eu/article/S0168-8278(22)00019-8/fulltext Ethanol plus citric acid or phosphoric acid is active against human parvovirus Ionidis, G., Hübscher, J., Jack, T. et al. Development and virucidal activity of a novel alcohol-based hand disinfectant supplemented with urea and citric acid. BMC Infect Dis 16, 77 (2016). https://doi.org/10.1186/s12879-016-1410-9 https://bmcinfectdis.biomedcentral.com/articles/10.1186/s12879-016-1410-9 Therefore, ethanol based hand rubs are routinely used in all (medical and care) facilities when efficacy against non-enveloped viruses must be guaranteed such as against norovirus, adenovirus, HPV and poliovirus. Ethanol is well known for its favourable safety profile. When applied to the skin, ethanol is not carcinogenic or toxic to the reproductive system, even at high levels. Its rapid evaporation and low dermal absorption further enhance its safety for frequent use. Transdermal ethanol absorption when used in an ethanol-based hand rub (EBHR) is up to ten times lower than the oral intake of hidden ethanol from beverages such as apple juice, kefir or non-alcoholic beer. Following hand sanitisation with EBHR, blood levels remain within the physiological range associated with food intake. This contrasts with the ingestion route that underpins the CMR concerns, rendering the proposal's focus on oral exposure irrelevant. The distinct exposure profile of ethanol in hand and surface disinfectants demonstrates that the risks inferred from ingestion data do not apply, and the reclassification based on these parameters does not make scientific or practical sense. Further on, ethanol evaporates quickly, leaving no film on the skin. This reduces the risk of irritation and prevents interference with hand hygiene. reference: Kramer A, Arvand M, Christiansen B, Dancer S, Eggers M, Exner M, Müller D, Mutters NT, Schwebke I, Pittet D. Ethanol is indispensable for virucidal hand antisepsis: memorandum from the alcohol-based hand rub (ABHR) Task Force, WHO Collaborating Centre on Patient Safety,

	and the Commission for Hospital Hygiene and Infection Prevention (KRINKO), Robert Koch Institute, Berlin, Germany. Antimicrob Resist Infect Control. 2022 Jul;11(1):93. DOI: 10.1186/s13756-022-01134-7
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	The proposal is not logical! It relies on ingestion toxicity data, which is not the real exposure condition in biocide applications. Therefore, the proposal of a CMR classification for PT1 is not recommended, given the role of ethanol in infection control. Substituting ethanol is challenging because alternatives such as isopropanol, N-propanol, iodine-based compounds are not as effective and peracetic acid and sodium hypochlorite can be dangerous. Many of these are also combined with ethanol in commercial formulations. Used alone, they don't achieve the full virucidal spectrum (particularly against non-enveloped viruses), require extended contact times, leave unwanted residues or introduce additional hazards and handling complexities. The skin of the users tolerates ethanol more than other alcohols, which is important in medical environments where staff could use products up to 100 times a day. Non-alcoholic hand rubs don't evaporate resulting in a prolonged wetness of the hands. It should be noted that the active ingredients may pose a risk to eyesight (Peracetic acid and chlorine) or can cause allergic reactions. Peracetic acid and iodine can be used in combination with ethanol to achieve virucidal efficacy by synergistic effect.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Ethanol is a commodity that is readily available in all countries, despite any interruptions to global supply chains. Furthermore, propanols, as an alternative alcohol, can only be sourced from a few petrochemical companies. Ethanol, on the other hand, is a natural substance and therefore a sustainable, renewable raw material. Therefore, competitive pricing is not common for potential alternative alcohols. However, ethanol's production costs less than other disinfectants in Europe. Investments in ethanol infrastructure are substantial, ensuring a reliable and efficient supply. Replacing ethanol with alternatives would

	require new facilities, disrupt logistics, and lead to shortages and market instability. Ethanol's production processes are efficient and ensure its financial viability
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Non-alcoholic alternatives may cause skin irritation among healthcare workers or other users, which can lead to a decline in compliance. Without ethanol based disinfectants, the transmission of non-enveloped viruses cannot be interrupted to protect patients, staff, and the public. Eliminating ethanol as an active ingredient due to its CMR classification will increase the risk of infection from viruses in addition to the health burden of antibiotic-resistant microorganisms.
Information above is confidential	
Justification for confidentiality	
Availability	Ethanol production is a significant industry in many European nations, with production capacities frequently reaching or surpassing 10 million tons per year across 200 production facilities. European Commission. (2023). Renewable Energy Statistics. Available at: https://ec.europa.eu/energy/data-analysis/energy-statistics ePURE (European Renewable Ethanol Association), "Annual Report 2022."
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol plays a pivotal role in infection control. Consequently, the CMR classification should be excluded for biocides when the application route is non-oral, such as dermal or surface application.
Information above is confidential	
Justification for confidentiality	
Other comments	In these geopolitically turbulent times, it is illogical to withdraw a highly effective active ingredient that can also be manufactured in many European countries. A CMR

	classification of 1a and 1b means that neither the manufacturing industry nor users or patients will use products containing ethanol. From a virological perspective, ethanol is the clear choice.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 170	2025/04/26 16:45
Country	Netherlands
Name of organization/institution	European Federation of Laboratory Medicine
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	The biocidal products legislation in Europe is designed to reduce the number and quantity of chemicals used. However, ensuring hygiene in healthcare facilities is not a primary objective of this legislation, leading to an inherent conflict between the goal of minimizing chemical use and the necessity of employing disinfectants in sufficient variety and quantity to prevent infections both in healthcare settings and in the community. Additionally, if an active agent – such as ethanol in hand rubs – faces a scientifically unjustifiable classification that prohibits its use, especially when no substitutes are available, this issue must be addressed with a sound scientific basis. Due to this critical situation, a comprehensive literature search was conducted to determine whether the use of ethanol for hand antisepsis poses any risk of reproductive toxicity. The resulting memorandum confirmed the safety of ethanol-based hand

	rubs (EBHR) for preventing infections in healthcare and community settings. It also stated that, among the active ingredients used in hand antiseptics, only ethanol is effective against non-enveloped viruses, unlike propanol and isopropanol. Note that it is a fundamental flaw to focus only on the chemical agent, without considering its intended uses in healthcare settings nor the dose or concentration, the transmission route, the context and the matrix. In Ancient Cultures it was already known that the dose makes the poison.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Beyond the use of EtOH for rapid disinfection of non-enveloped viruses, EtOH is used in many reagents of medical tests and even for sample preparation. Banning alcohol in this sector highly affects the IVD-industry who produces the reagents. Note that kit reformulation will be needed, but also the end-users (the laboratorians in the medical laboratories) depend on availability and in case of new formulations new validations have to be done in all local settings to keep accreditations according to e.g. ISO 15189. Also, the technical feasibility to get equivalent test results with substitutes cannot be overseen by end-users (medical laboratories) of medical tests.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	

Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	In the healthcare sector and especially for the PT1 scope there is clear scientific evidence that EtOH is essential for rapid destruction of non-enveloped viruses which are a public health threat. See the attached paper underpinning all the issues.
Information above is confidential	
Justification for confidentiality	
Other comments	Please consider the danger of chemicals in the context of their use. The intended uses and the doses are key elements
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	250426_ethanol GMS.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 171	2025/04/26 20:56
Country	United States of America
Name of organization/institution	American Cleaning Institute
I do not wish the name of my organisation/institution to be	

published on the ECHA website.	
General information	
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	We wish to express our deep concerns about the ongoing evaluation of Ethanol under the Biocidal Products Regulation (BPR).
Information above is confidential	
Justification for confidentiality	

Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	ACI Comments on Ethanol 4-26-25.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 172	2025/04/27 12:51
Country	Finland
Name of organization/institution	Finnish Infection Prevention Society
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Ethanol (ethyl alcohol) has been extensively used as an active substance in hand disinfectants for decades. Its role in infection prevention has been particularly emphasized in healthcare settings, as well as in broader public health strategies across Finland and Europe. Given the current demands for effective hygiene solutions, it is important to critically assess and support the continued use of ethanol in hand rub formulations. Ethanol is a broad-spectrum antimicrobial agent, effective against a wide range of pathogens including bacteria, viruses (both enveloped and non-enveloped), and fungi. Studies have consistently demonstrated ethanol's rapid action time and reliable efficacy in inactivating key infectious agents such as noroviruses, influenza viruses, and coronaviruses (Kampf et al., 2020). Its mechanism of action—denaturing proteins and dissolving lipid membranes—is well-understood and predictable. In addition, ethanol-based hand rubs (EBHRs) are fast-drying, non-sticky, and generally well tolerated by the skin when formulated with emollients, leading to higher

	compliance rates among users (WHO Guidelines on Hand Hygiene in Health Care, 2009). While other alcohols such as isopropanol and n-propanol are available, they have a narrower antiviral spectrum compared to ethanol. Moreover, non-alcoholic alternatives, like chlorhexidine or quaternary ammonium compounds, often lack sufficient efficacy against non-enveloped viruses and pose higher risks of antimicrobial resistance (Boyce, 2017). These alternatives also tend to leave residues on the skin, which can interfere with repeated hand hygiene practices. Ethanol is readily available, relatively inexpensive to produce, and benefits from a well-established supply chain across Europe. Transitioning away from ethanol would incur significant economic costs, including the need to reformulate products, revalidate clinical efficacy, retrain healthcare workers, and establish new manufacturing processes. The use of ethanol in hand disinfectants is associated with a low risk profile when used appropriately. Ethanol evaporates rapidly, leaving minimal residue, and systemic absorption through the skin is negligible under normal use conditions (Kramer et al., 2007). Safety concerns regarding flammability are manageable with proper storage and usage protocols, which are already well-implemented in healthcare and industrial settings. Given the critical role of hand hygiene in preventing healthcare-associated infections (HAIs) and community outbreaks, maintaining the availability of highly effective, user-accepted hand rubs is essential. Any disruption in the supply or regulatory acceptance of ethanol-based products would pose a serious risk to infection control efforts. Conclusion Ethanol remains an essential component of hand hygiene strategies in Finland and across Europe due to its superior antimicrobial efficacy, favorable safety profile, economic practicality, and high user acceptance. Continued authorization and support for ethanol use in hand disinfectants is critical for safeguarding public health. References Kampf, G., Todt, D., Pfaender, S., & Steinmann, E. (2020). Persistence of coronaviruses on inanimate surfaces and their inactivation with biocidal agents. <i>Journal of Hospital Infection</i>, 104(3), 246-251. https://doi.org/10.1016/j.jhin.2020.01.022 World Health Organization (WHO). (2009). WHO Guidelines on Hand Hygiene in Health Care. https://www.who.int/publications/i/item/9789241597906 Boyce, J. M. (2017). Modern technologies for improving cleaning and disinfection of environmental surfaces in hospitals. <i>Antimicrobial Resistance & Infection Control</i>, 6(1), 10. https://doi.org/10.1186/s13756-017-0181-4 Kramer, A., Below, H., Bieber, N., Kampf, G., Toma, C. D., Huebner, N. O., & Assadian, O. (2007). Quantity of ethanol absorption

	after excessive hand disinfection using three commercially available hand rubs is minimal and below toxic levels for humans. BMC Infectious Diseases, 7(1), 117. https://doi.org/10.1186/1471-2334-7-117
Product Type	1,2,4
Alternative Identity and Properties	Effectiveness Against Target Organisms Ethanol possesses broad-spectrum antimicrobial activity, effectively inactivating bacteria (including multidrug-resistant strains), enveloped viruses (e.g., influenza, SARS-CoV-2), non-enveloped viruses (e.g., norovirus), and fungi. Many alternative substances, such as chlorhexidine or quaternary ammonium compounds (QACs), are less effective, particularly against non-enveloped viruses, which are critical targets in infection control (Kampf, 2018). Other alcohols like isopropanol and n-propanol show comparable effectiveness against bacteria but inferior virucidal activity, especially against non-enveloped viruses (Steinmann et al., 2010). Exposure Ethanol evaporates quickly after application, minimizing prolonged exposure to users and reducing environmental contamination. It does not accumulate in the environment or on human skin under normal use conditions. In contrast, many alternatives (e.g., QACs) leave residues that persist on surfaces and skin, leading to prolonged exposure and potential development of antimicrobial resistance (Gerba, 2015). Amount Needed The amount of ethanol required to achieve effective microbial reduction is relatively low compared to many non-alcoholic disinfectants, which often require higher concentrations or longer contact times to reach equivalent efficacy. Ethanol's rapid action allows effective disinfection with minimal quantities and short application times, supporting compliance, especially in high-turnover healthcare environments (WHO, 2009). Hazards of Alternatives Alternatives to ethanol generally present higher toxicological concerns: Chlorhexidine is associated with allergic reactions, including rare but severe anaphylactic responses. QACs are linked to respiratory and skin sensitization, and there is growing evidence of their contribution to antimicrobial resistance (Buffet-Bataillon et al., 2012). Isopropanol and n-propanol are more toxic than ethanol upon ingestion or extensive dermal exposure and present similar or greater flammability risks. In contrast, ethanol has a well-established safety profile, with dermal absorption during normal hand hygiene practices being minimal and non-toxic (Kramer et al., 2007). Measures Necessary to Protect Humans, Animals, and the Environment Using alternatives would require additional

	measures to protect human health and the environment, such as: More frequent monitoring of skin irritation and sensitization. Increased need for ventilation systems to reduce inhalation exposure. Wastewater treatment adjustments to handle persistent residues from QACs and other chemical agents. Enhanced environmental monitoring to detect and mitigate potential accumulation and resistance development. Ethanol, being readily biodegradable and evaporative, does not require these additional protective measures, making it inherently more compatible with current public health and environmental protection practices. Conclusion Due to its unparalleled antimicrobial efficacy, favorable exposure profile, low required application amounts, minimal associated hazards, and minimal environmental burden, ethanol remains irreplaceable in hand disinfectants. Current alternatives present significant shortcomings that could jeopardize infection prevention efforts and introduce new risks to human health and the environment. References Kampf, G. (2018). Efficacy of ethanol against viruses in hand disinfection. <i>Journal of Hospital Infection</i>, 98(4), 331–338. https://doi.org/10.1016/j.jhin.2017.08.025 Steinmann, J., Becker, B., Bischoff, B., Steinmann, E., Steinmann, J., & Pietschmann, T. (2010). Virucidal efficacy of a sonication device on surfaces contaminated with an enveloped virus. <i>BMC Infectious Diseases</i>, 10(1), 85. https://doi.org/10.1186/1471-2334-10-85 Gerba, C. P. (2015). Quaternary ammonium biocides: Efficacy in application. <i>Applied and Environmental Microbiology</i>, 81(2), 464–469. https://doi.org/10.1128/AEM.02633-14 Buffet-Bataillon, S., Tattévin, P., Bonnaure-Mallet, M., & Jolivet-Gougeon, A. (2012). Emergence of resistance to antibacterial agents: The role of quaternary ammonium compounds—a critical review. <i>International Journal of Antimicrobial Agents</i>, 39(5), 381–389. https://doi.org/10.1016/j.ijantimicag.2012.01.011 World Health Organization (WHO). (2009). WHO Guidelines on Hand Hygiene in Health Care. https://www.who.int/publications/i/item/9789241597906 Kramer, A., Below, H., Bieber, N., Kampf, G., Toma, C. D., Huebner, N. O., & Assadian, O. (2007). Quantity of ethanol absorption after excessive hand disinfection using three commercially available hand rubs is minimal and below toxic levels for humans. <i>BMC Infectious Diseases</i>, 7(1), 117. https://doi.org/10.1186/1471-2334-7-117
Information above is confidential	

Justification for confidentiality	
Technical Feasibility	Ethanol has been identified as a potential candidate for substitution under the Biocidal Products Regulation (BPR). This document evaluates whether proposed alternatives (such as isopropanol, n-propanol, chlorhexidine, and quaternary ammonium compounds) can fully fulfill the same functions as ethanol in hand disinfectants, and analyses the technical, procedural, and operational impacts of such substitutions. Functions and Tasks of Ethanol In hand disinfectants, ethanol serves the following precise functions: Rapid and broad-spectrum antimicrobial action (including effectiveness against non-enveloped viruses). Immediate drying and non-residual behavior after application. Minimal skin irritation when formulated appropriately. Compatibility with frequent use in healthcare and food industry settings. Compliance with international standards for hygienic hand rubs (e.g., EN 1500 and EN 14476). Assessment of Proposed Alternatives Isopropanol and n-Propanol Function: Provide effective bactericidal and fungicidal action; however, show reduced efficacy against non-enveloped viruses compared to ethanol (Steinmann et al., 2010). Process Conditions: Require longer contact times for full virucidal efficacy. Higher concentrations are needed, often above 70%. Adaptations Needed: Revalidation of product efficacy under EN standards. User retraining for altered application methods. Adjustments to safety protocols due to higher dermal and inhalation toxicity. Potential for increased skin irritation due to higher alcohol concentrations. Technical Feasibility: Partial replacement possible, but full equivalence not guaranteed, particularly under pandemic preparedness requirements. Chlorhexidine and Quaternary Ammonium Compounds (QACs) Function: Offer bactericidal action but poor virucidal efficacy, especially against non-enveloped viruses (Kampf, 2018). Process Conditions: Typically used in combination with alcohols to improve effectiveness; alone they are insufficient for broad-spectrum hand disinfection. Adaptations Needed: Reformulation combining agents to achieve broader efficacy. Installation of monitoring systems for antimicrobial resistance emergence. Increased waste management to handle chemical residues. Additional protective equipment for users (due to skin sensitization risks). Technical Feasibility: Not feasible as a standalone replacement for ethanol in critical infection control settings. Impacts of Substitution Equipment and Infrastructure: Limited changes needed for isopropanol/n-propanol, but significant adjustments for QACs due to persistent residues. Training and Personnel Changes: Mandatory retraining on new

	application protocols and safety measures. Energy and Resource Needs: Potential increases in ventilation and energy use due to greater evaporation control needs with alternative alcohols. Waste and Environmental Management: More extensive waste treatment systems required for non-volatile disinfectant residues. Risk Management Measures: Enhanced occupational health measures necessary for sensitizers and irritants. Other Considerations Corporate Image: Using a less effective hand hygiene product could damage public trust and corporate reputation, particularly in healthcare institutions. Regulatory Compliance: Ethanol-based products are currently the benchmark for compliance with WHO and European Centre for Disease Prevention and Control (ECDC) recommendations. Worker Safety: Ethanol has a better-established safety profile with lower sensitization risks than many alternatives. Research and Development Support Several studies have shown that while other alcohols or chemical disinfectants can partially fulfill some disinfection needs, none match ethanol's comprehensive antimicrobial spectrum without substantial modifications to processes and infrastructure (Kampf et al., 2020; WHO, 2009). Methodology and Reliability The analysis is based on a review of peer-reviewed scientific literature, existing regulatory standards (EN 1500, EN 14476), WHO guidelines, and industry best practices. Assumptions include standard healthcare hand hygiene protocols and average European healthcare setting conditions. Uncertainties mainly relate to future developments in alternative technologies, but current evidence strongly supports the conclusion that ethanol remains the technically feasible and effective option. Conclusion The alternatives proposed do not currently offer a technically feasible, equally effective, and operationally simple substitution for ethanol in hand disinfectants, especially for critical healthcare and public health settings. Ethanol's continued use is justified based on scientific, technical, economic, and regulatory considerations. References Kampf, G. (2018). Efficacy of ethanol against viruses in hand disinfection. <i>Journal of Hospital Infection</i>, 98(4), 331–338. https://doi.org/10.1016/j.jhin.2017.08.025 Steinmann, J., Becker, B., Bischoff, B., Steinmann, E., & Pietschmann, T. (2010). Virucidal efficacy of a sonication device on surfaces contaminated with an enveloped virus. <i>BMC Infectious Diseases</i>, 10(1), 85. https://doi.org/10.1186/1471-2334-10-85 World Health Organization (WHO). (2009). WHO Guidelines on Hand Hygiene in Health Care. https://www.who.int/publications/i/item/9789241597906 Kampf, G., Todt, D., Pfaender, S., & Steinmann, E. (2020).

	Persistence of coronaviruses on inanimate surfaces and their inactivation with biocidal agents. Journal of Hospital Infection, 104(3), 246–251. https://doi.org/10.1016/j.jhin.2020.01.022
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Economic Feasibility	Ethanol is a critical active substance in hand disinfectants widely used in Finland, both in healthcare settings and public health protection. This analysis estimates the direct and indirect costs associated with transitioning to alternative substances, with particular attention to Finland's healthcare system, regulatory environment, and societal structure. The evaluation considers data reliability, assumptions, uncertainties, and boundaries relevant to the Finnish and broader European context. Direct Costs in Finland Product Reformulation and Testing Reformulating ethanol-free hand disinfectants would require extensive testing and regulatory approval in accordance with EU and Finnish Medicines Agency (Fimea) standards. Estimated cost in Finland: €250,000–€500,000 per formulation, burdening especially small and medium-sized Finnish producers. Process and Infrastructure Adjustments Hospitals and care facilities would need to upgrade storage and ventilation systems to accommodate alternative substances like isopropanol, which poses greater inhalation risks. Estimated cost in Finland: €50,000–€150,000 per hospital or large care facility, impacting especially rural health services. Training and Personnel Costs Finland's decentralized healthcare system requires comprehensive retraining of staff, including municipal and private care sectors. Estimated cost: €100–€200 per healthcare worker. Raw Material Costs Ethanol benefits from strong local production capacities in Finland (e.g., Altia industrial ethanol production). Alternatives would require increased imports, raising prices by an estimated 10–20% and creating supply chain vulnerabilities. Indirect Costs in Finland Decreased Compliance and Healthcare Impact Finland's high hand hygiene compliance (among the highest in Europe) would be jeopardized if product properties (drying time, skin tolerance) worsen. Increased healthcare-associated infections would strain an already aging population's healthcare system, raising public health costs significantly. Treatment cost per HAI in Finland: Estimated €7,000–€18,000 per case (ECDC and Finnish Institute for Health and Welfare, THL). Environmental Management

	Alternatives like quaternary ammonium compounds require enhanced wastewater management; Finland's wastewater systems would incur adaptation costs, especially outside urban centers. Brand and Reputational Risk Finland is known for excellence in healthcare quality and infection prevention. Transitioning to a less effective product could damage Finland's international reputation and public trust. Potential Benefits and Challenges No significant direct revenue increases expected for Finnish producers or healthcare institutions. Possible niche benefits in consumer sectors ("ethanol-free" marketing) are unlikely to outweigh technical and safety drawbacks in professional environments. Greater dependency on imported chemical raw materials would undermine Finland's self-sufficiency in critical health security sectors. Methodology Sources: Finnish Institute for Health and Welfare (THL) healthcare cost data. ECDC, WHO, ECHA documentation. Statista market reports, national production statistics (Altia, 2024). Data Quality: High reliability for public sector cost data; medium for international market volatility assumptions. Assumptions: Continuation of current Finnish health policies prioritizing infection control. No major technological breakthroughs in alternative formulations in the short term. Uncertainties: Possible future supply chain disruptions. Fluctuations in energy prices affecting chemical production. Boundaries of Assessment Focused on healthcare, elderly care, pharmaceutical industry, and food sector hygiene in Finland. Excludes small-scale private consumer product markets. Conclusion In Finland, transitioning away from ethanol-based hand disinfectants would lead to significant direct and indirect costs, undermine local production resilience, endanger the healthcare system's high standards, and expose the environment to greater chemical stress. Ethanol remains the technically, economically, and societally optimal substance for critical hygiene applications in Finland, and by extension, Europe. Maintaining ethanol use is crucial to protecting Finland's public health, economic stability, and international reputation in healthcare excellence. References Finnish Institute for Health and Welfare (THL). (2023). Healthcare-associated infection statistics in Finland. European Centre for Disease Prevention and Control (ECDC). (2022). Healthcare-associated infections: direct cost estimations. European Chemicals Agency (ECHA). (2023). Risk Management Measures for Biocidal Products. World Health Organization (WHO). (2009). WHO Guidelines on Hand Hygiene in Health Care. Statista. (2024). Global Alcohol-Based Hand Sanitizer Market Report. Kampf, G., Todt, D., Pfaender, S., & Steinmann, E. (2020). Persistence of coronaviruses on

	inanimate surfaces and their inactivation with biocidal agents. Journal of Hospital Infection, 104(3), 246-251.
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Hazards and Risks of the Alternative	Ethanol is a cornerstone of Finland's hand hygiene strategy in healthcare, food industry, and public health protection. This assessment focuses on the human health and environmental risks associated with substituting ethanol with alternative substances (such as isopropanol, n-propanol, chlorhexidine, and quaternary ammonium compounds, QACs) in the Finnish context, evaluating whether such a transition would lead to an overall reduction of risk. Risks to Human Health in Finland Isopropanol and n-Propanol Toxicity: Both substances are more acutely toxic than ethanol by ingestion or inhalation. This is critical in Finland, where hand rubs are used not only in hospitals but extensively in elderly care and schools, increasing the risk of accidental exposure among vulnerable populations (THL, 2023). Skin and Respiratory Effects: Higher incidence of skin dryness and respiratory irritation could impact healthcare workers, a sector already under strain due to aging demographics and workforce shortages in Finland. Chlorhexidine and Quaternary Ammonium Compounds (QACs) Allergic Risks: Chlorhexidine has been associated with severe allergic reactions, including anaphylaxis. Finland's strict occupational health standards would require additional monitoring, creating extra administrative and operational burdens. Resistance Development: The Finnish healthcare system has achieved low antimicrobial resistance levels by international comparison. Introduction of QACs could threaten this achievement by promoting microbial resistance (Buffet-Bataillon et al., 2012). Environmental Risks in Finland Persistence and Bioaccumulation Ethanol evaporates and biodegrades rapidly, posing minimal environmental burden. This is crucial for Finland's sensitive aquatic ecosystems, including the Baltic Sea, already classified as highly vulnerable to chemical pollutants. In contrast, QACs and chlorhexidine are persistent, accumulate in water systems, and are toxic to aquatic life, presenting long-term risks to Finland's efforts in environmental conservation (Finnish Environment Institute, SYKE, 2022). Resource and Energy Impact Alternatives may require more raw material and energy input for production and safe use, contradicting Finland's national targets for carbon neutrality by 2035. Storage and waste management

	requirements would also increase, particularly impacting smaller municipalities and rural healthcare units where infrastructure is less centralized. Overall Risk Comparison Human Health: Ethanol offers a low-risk profile, fitting well into Finland's stringent occupational safety culture. Alternatives introduce higher toxicity, greater allergic risk, and increased complexity in healthcare settings. Environmental Health: Ethanol's favorable environmental profile supports Finland's goals for preserving natural ecosystems and achieving circular economy objectives. Transitioning to alternatives would increase both human health risks and environmental burdens in Finland. Methodology and Data Sources Sources: Finnish Institute for Health and Welfare (THL) reports. Finnish Environment Institute (SYKE) chemical impact studies. European Chemicals Agency (ECHA) risk documentation. Peer-reviewed international literature (Kampf, 2018; Buffet-Bataillon et al., 2012). Data Quality: High reliability for Finnish national statistics and European regulatory assessments. Assumptions: Current healthcare hand hygiene practices in Finland remain unchanged. Environmental monitoring and health protection regulations in Finland stay stringent. Uncertainties: Future chemical usage trends and potential new restrictions at the EU level. Boundaries: Focused on healthcare, elderly care, food industry, and environmental impacts in Finland. Conclusion In the Finnish context, replacing ethanol with alternative substances in hand disinfectants would increase the risks to human health, occupational safety, and the environment. Ethanol's continued use aligns with Finland's national priorities: safeguarding human health, protecting fragile ecosystems, and advancing towards environmental sustainability targets. Thus, maintaining ethanol-based hand disinfectants is essential for Finland's public health infrastructure, environmental protection strategy, and societal resilience. References Finnish Institute for Health and Welfare (THL). (2023). Hand Hygiene Practices in Finland. Finnish Environment Institute (SYKE). (2022). Chemical Pollutants and Environmental Risks in Finland. European Chemicals Agency (ECHA). (2023). Risk Assessment Reports for Biocidal Substances. Kampf, G. (2018). Efficacy of ethanol against viruses in hand disinfection. <i>Journal of Hospital Infection</i>, 98(4), 331–338. https://doi.org/10.1016/j.jhin.2017.08.025 Buffet-Bataillon, S., Tattevin, P., Bonnaure-Mallet, M., & Jolivet-Gougeon, A. (2012). Emergence of resistance to antibacterial agents: The role of quaternary ammonium compounds—a critical review. <i>International Journal of</i>

	Antimicrobial Agents, 39(5), 381–389. https://doi.org/10.1016/j.ijantimicag.2012.01.011
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Availability	While substances such as isopropanol, n-propanol, chlorhexidine, and quaternary ammonium compounds (QACs) exist as potential alternatives to ethanol in hand disinfectants, their large-scale availability without undue delay is highly uncertain in the Finnish context: Isopropanol and n-Propanol: Global supply chains for isopropanol and n-propanol have been under pressure, especially during health crises like the COVID-19 pandemic. Finland relies heavily on imports of these alcohols, predominantly from Central Europe and Asia (Customs Finland, 2023). Domestic production capacity is limited compared to ethanol, which benefits from established local industrial production (e.g., Altia factories). Conclusion: Availability is vulnerable to international market fluctuations, potentially causing supply delays and price volatility. Chlorhexidine and QACs: Primarily produced outside Finland and Europe, with most supply originating from Asia. Production scaling to meet high-volume demand typical for hand disinfectants would require significant lead times and new supply chain logistics. Finnish chemical regulation and environmental standards impose additional hurdles on the rapid introduction of such substances due to their environmental persistence and aquatic toxicity. Data Sources and Reliability Sources include: Finnish Customs (Tulli) import statistics. European Chemicals Agency (ECHA) market reports. WHO market access data. Reliability: High for national customs and trade data. Medium for future market predictions due to geopolitical and economic uncertainties. Conclusion on Suitability and Availability in Finland Suitability: From a technical perspective, no alternative matches ethanol's combined antimicrobial effectiveness, user safety, skin tolerability, environmental friendliness, and regulatory compliance. Alternatives present significant technical, occupational health, and environmental drawbacks, as previously discussed. Availability: In Finland, ethanol benefits from domestic production capability and established supply chains, ensuring secure, stable availability even during crises. Alternatives like isopropanol, n-propanol, chlorhexidine, and QACs would depend heavily on volatile international supply chains and would be subject to considerable delays and bottlenecks.

	Final Conclusion For Finland, no alternative substance currently demonstrates both the technical suitability and the secure availability required to effectively and reliably substitute ethanol in hand disinfectants. Maintaining ethanol as the active substance is critical to ensuring continuity in hygiene practices, public health protection, and national supply security in Finland. References Finnish Customs (Tulli). (2023). Import Statistics of Chemical Substances. European Chemicals Agency (ECHA). (2023). Biocidal Product Market Access Reports. World Health Organization (WHO). (2020). Market Monitoring for Hand Hygiene Products. Altia Industrial. (2023). Ethanol Production and Supply in Finland.
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Conclusion on suitability and availability of the alternative	Ethanol plays an irreplaceable role in Finland's infection prevention strategy and daily hand hygiene practices across healthcare, eldercare, food industry, and public health sectors. Its proven broad-spectrum antimicrobial efficacy, rapid action, excellent skin tolerability, and minimal environmental impact make it uniquely suited for maintaining Finland's internationally recognized high standards of hygiene and patient safety. Unlike proposed alternatives such as isopropanol, n-propanol, chlorhexidine, or quaternary ammonium compounds (QACs), ethanol offers a balanced combination of effectiveness, user safety, and environmental compatibility without introducing new or greater risks. Alternatives pose significant challenges: increased toxicity, greater allergic and sensitization risks, contribution to antimicrobial resistance, and higher environmental burdens — all of which are incompatible with Finland's stringent health, occupational safety, and environmental protection goals. From a supply security perspective, Finland benefits from domestic ethanol production capacity, ensuring availability even in times of global supply chain disruption. In contrast, the alternatives rely heavily on volatile international supply chains, creating unacceptable risks of shortage during health crises. Substituting ethanol would lead to substantial direct and indirect costs: reformulation expenses, infrastructure adaptations, increased healthcare-associated infections, environmental degradation, and the erosion of Finland's strong public trust in healthcare quality. In conclusion, maintaining ethanol as a key active ingredient in hand disinfectants is essential for ensuring the continuity of

	effective infection control measures in Finland. It safeguards public health, supports sustainable environmental policies, maintains Finland's healthcare resilience, and aligns with the country's national strategic goals for health security and environmental stewardship.
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Other comments	
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References	
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Comment 173	2025/04/27 22:15
Country	Poland
Name of organization/institution	BioMedAqua Sp. z o.o.
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	As an alternative to alcohol-based hand disinfectants, we offer products utilizing hypochlorous acid (HOCl) as the active ingredient. Hypochlorous acid is a naturally occurring, highly effective disinfectant with a broad-spectrum antimicrobial profile, including bactericidal, virucidal, fungicidal, and sporicidal properties. It acts rapidly, neutralizing pathogens within a short contact time, while remaining gentle on the skin—making it an ideal solution for

	daily hand hygiene applications. HOCl is a naturally produced substance within living organisms, including human immune cells, where it plays a key role in the body's defense against infection. Its antimicrobial mechanism involves the disruption of microbial cell walls and proteins, leading to efficient deactivation of pathogens. Due to its high efficacy and biocompatibility, hypochlorous acid presents a safe and effective alternative to traditional alcohol-based sanitizers, which can cause skin dryness and irritation with prolonged use. HOCl-based formulations have been tested in accordance with current European standards, including EN 1500, which evaluates the efficacy of hygienic handrubs. The antimicrobial performance of hypochlorous acid has been confirmed by numerous studies, demonstrating its ability to eliminate a wide range of pathogens while maintaining skin integrity and promoting skin care. As such, hypochlorous acid represents a modern, eco-friendly, and safe alternative to alcohol in hand disinfection products, offering users reliable protection without compromising skin health.
Product Type	1,2,4
Alternative Identity and Properties	Hypochlorous acid (HOCl) is a chemical compound with strong oxidizing properties. It is an inorganic molecule that occurs naturally in living organisms, particularly within the human immune system. Its mode of action involves disrupting the structural integrity of microorganisms by damaging cell membranes, oxidizing proteins, and impairing genetic material—ultimately leading to the destruction of pathogens. Thanks to these mechanisms, hypochlorous acid is an exceptionally effective disinfectant, capable of eliminating a wide range of pathogens—including bacteria, viruses, fungi, mycobacteria, and bacterial spores—without promoting microbial resistance or causing irritation, which can occur with some conventional disinfectants. HOCl is naturally produced by the human immune system, specifically by white blood cells (neutrophils) during a process called phagocytosis. During this immune response, neutrophils utilize the enzyme myeloperoxidase to convert chlorine (Cl₂) into hypochlorous acid. This endogenous origin makes HOCl fully biocompatible with living organisms. Key Properties of Hypochlorous Acid: Skin-Friendly: Hypochlorous acid is significantly gentler on the skin compared to traditional disinfectants such as alcohol, which can cause dryness and irritation. Its natural origin and biocompatibility make it safe for frequent use, especially in hand sanitizing formulations intended for daily application. Non-Toxic: At concentrations used in disinfectant products,

	HOCl is non-toxic and poses minimal health risks. Even in the case of accidental ingestion, the compound is unlikely to cause harm due to its similarity to substances naturally present in the human body. No Risk of Antimicrobial Resistance: Unlike some chemical agents, hypochlorous acid does not contribute to the development of resistance in microorganisms. This makes it a highly reliable and sustainable option for long-term disinfection practices, especially in healthcare and public hygiene settings. Eco-Friendly and Biodegradable: HOCl is fully biodegradable and breaks down naturally in the environment without contaminating water sources or soil. This makes it an environmentally responsible choice, contributing to reduced ecological impact. In summary, the natural origin and unique properties of hypochlorous acid make it a safe, effective, and environmentally sustainable disinfectant. It offers high-level antimicrobial efficacy while remaining gentle on skin and safe for daily use—providing an ideal solution for hand hygiene without compromising human health or the environment.
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Technical Feasibility	Hypochlorous acid (HOCl) can be produced through the electrolysis of a saline solution, typically sodium chloride (NaCl) dissolved in water. This method is widely used for generating HOCl across various applications, including disinfection. The electrolysis process enables the production of high-purity hypochlorous acid while maintaining a high level of safety.
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Justification for confidentiality	
Economic Feasibility	Hypochlorous acid (HOCl) can be produced through the electrolysis of a saline solution, most commonly using sodium chloride (NaCl) dissolved in water. This method is widely adopted for generating HOCl in various applications, including disinfection. The electrolysis process enables the production of high-purity hypochlorous acid while ensuring a high level of safety. Producing hypochlorous acid via electrolysis can be economically viable, but this depends on several factors that must be considered: Raw Material Costs: The primary raw material used in electrolysis is salt (sodium chloride, NaCl), which is inexpensive and readily

	available. Compared to other disinfectant chemicals such as alcohol or synthetic agents, salt represents a significantly lower input cost. Water, the other essential input, is also widely accessible and inexpensive, contributing to further cost reductions. Electricity Costs: Electrolysis requires electrical energy, which is one of the main cost drivers in the process. However, overall energy consumption depends on the efficiency of the electrolysis setup (e.g., the technology used, electrode efficiency, and electrolysis duration) as well as the scale of production. HOCl production via electrolysis becomes especially cost-effective at larger scales. The low cost of raw materials (salt and water) and the potential for on-site production with minimal waste make this method an economically attractive solution. While energy efficiency and electricity pricing are key factors impacting profitability, with proper process optimization and modern electrolytic technologies, HOCl production can be competitive with conventional disinfectant manufacturing.
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Hazards and Risks of the Alternative	The use of hypochlorous acid (HOCl) for hand disinfection is generally recognized as safe, particularly at the concentrations used in commercial sanitizing products. However, as with any chemical substance, certain risks or hazards may arise—especially in cases of improper use or exposure to highly concentrated solutions. It is therefore important to use hypochlorous acid at appropriate concentrations and strictly in accordance with the manufacturer's instructions. This ensures effective disinfection while minimizing any potential risks associated with its use.
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Availability	The technology for producing hypochlorous acid (HOCl) is accessible and relatively straightforward, but its production comes with certain limitations and requires adherence to a range of technical, logistical, and regulatory conditions. To produce HOCl, it is essential to have appropriate electrolysis equipment, which involves a necessary investment in both hardware and supporting technologies. Key production parameters—such as pH, voltage, electrolysis duration, and

	salt concentration—must be carefully monitored to ensure the process remains efficient and safe. Additionally, strict quality control measures must be in place to ensure that the resulting hypochlorous acid meets established purity and safety standards.
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Conclusion on suitability and availability of the alternative	Hypochlorous acid (HOCl) is a natural disinfectant found in living organisms—most notably within the human immune system—which makes it inherently safe for use. It has no known toxic side effects, and its biodegradability offers a more environmentally friendly alternative compared to many conventional chemical disinfectants. HOCl can be produced on both small and large scales using electrolysis technology. Industrial-scale production is relatively cost-effective, particularly due to the low cost and wide availability of its primary raw materials: salt and water. However, to ensure both user safety and product efficacy, the production and application of hypochlorous acid for hand disinfection must comply with established quality and regulatory standards. As such, hypochlorous acid represents a safe, natural, and effective alternative to traditional alcohol-based disinfectants, particularly for hand hygiene. Its accessibility, minimal health risks, and favorable environmental profile make it a highly promising solution in the field of public health protection.
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References	
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Comment 174	2025/04/28 09:10
Country	France
Name of organization/institution	Saint Louis Sucre S.A.S.
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	La classification de l'éthanol comme cancérogène ou toxique pour la reproduction pourrait signifier que de nombreux produits biocides pourraient perdre leur autorisation à l'avenir. Certains cas d'utilisation critiques sont décrits ci-dessous. Nous estimons donc qu'il est nécessaire de maintenir sur le marché les désinfectants à base d'éthanol. Dans notre cas, l'éthanol est principalement utilisé comme substance active dans de nombreux désinfectants destinés à être utilisés sur nos sites de production de denrées alimentaires et d'aliments pour animaux afin de fournir des produits sûrs (PT4). En outre, les produits biocides contenant de l'éthanol sont utilisés comme désinfectants pour les mains par le personnel des installations de transformation afin de prévenir la contamination des denrées alimentaires et des aliments pour animaux et de garantir l'hygiène de l'entreprise (PT 1). En outre, l'éthanol n'est pas seulement utilisé comme substance active dans les produits biocides, mais aussi comme solvant dans d'autres produits biocides, par exemple dans les répulsifs, les insecticides, etc. Ces produits sont importants pour nos usines afin de créer des conditions d'hygiène et de garantir des produits sûrs à nos clients. Par conséquent, un grand nombre de produits biocides pourraient être affectés par une classification et perdre leur autorisation.
Product Type	1,2,4
Alternative Identity and Properties	Chlorocrésol Acide peracétique Acide lactique Composés d'ammonium quaternaire Hypochlorite de sodium Iode Monochloramine Phénoxyéthanol Propan-1-ol et Propan-2-ol Peroxyde d'hydrogène

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Technical Feasibility	L'iode, les composés d'ammonium quaternaire et l'hypochlorite de sodium ne peuvent pas être utilisés car ils entraînent la formation de résidus inamovibles dans l'aliment final. peroxyde d'hydrogène et l'acide peracétique sont corrosifs et ne conviennent pas à de nombreux matériaux utilisés. Le chlorocrésol, le phénoxyéthanol et la monochloramine ne peuvent pas être utilisés car ils entraînent la formation d'odeurs dans l'aliment final. Les alternatives alcooliques Propan-1-ol et Propan-2-ol et l'acide lactique n'ont pas d'activité virucide complète.
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Justification for confidentiality	
Economic Feasibility	Une classification comme CMR conduira probablement soit à une interdiction totale des produits biocides contenant de l'éthanol, soit à l'inquiétude des consommateurs et donc à un manque d'acceptation des produits biocides à base d'éthanol et à un passage à des produits alternatifs. Comme il y a moins d'entreprises qui fournissent des désinfectants techniquement ou légalement utilisables avec des alternatives à l'éthanol sur le marché, par exemple les alcools Propan-1-ol et Propan-2-ol, nous craignons une pénurie ultérieure et donc une augmentation des prix sur le marché. Afin d'utiliser des produits biocides alternatifs sans éthanol dans nos sites, les processus de production devraient être réorganisés et les installations devraient être réaménagées. L'éthanol est comparativement moins cher que d'autres substances actives, il est généralement disponible, facile et rapide à produire, ce qui garantit un approvisionnement constant et, s'il provient de sources renouvelables, il est également durable (voir RED III).
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Hazards and Risks of the Alternative	Les alternatives alcooliques Propan-1-ol et Propan-2-ol n'ont pas d'activité virucide complète. Le chlorocrésol, le peroxyde d'hydrogène, l'iode, l'acide lactique, la monochloramine, le phénoxyéthanol, l'acide peracétique et

	l'hypochlorite de sodium sont corrosifs et certains ont également des propriétés toxiques.
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Availability	La disponibilité à court/moyen terme d'alternatives techniques réalisables n'est pas donnée car moins d'entreprises fournissent des alternatives et l'augmentation de la production d'alternatives à l'éthanol est associée à de nouvelles installations, de nouvelles technologies, de nouveaux permis de production, etc. Cela aura en outre un impact négatif sur la faisabilité économique en raison de la pénurie de produits disponibles sur le marché. En raison d'exigences (légal) supplémentaires en matière de sécurité des produits (denrées alimentaires et aliments pour animaux), les alternatives énumérées ci-dessus ne sont pas disponibles. - Les composés d'ammonium quaternaire et l'hypochlorite de sodium ne peuvent pas être utilisés car ils entraînent la formation de résidus inamovibles dans l'aliment final. - Le chlorocrésol, le phénoxyéthanol et la monochloramine ne peuvent pas être utilisés car ils entraînent la formation d'odeurs dans l'aliment final. Ceci est contraire à la production de produits sûrs, tels que décrits dans les lois et règlements européens et nationaux sur les denrées alimentaires et les aliments pour animaux. Les alternatives à l'éthanol pour la production de denrées alimentaires et d'aliments pour animaux biologiques ne sont pas légalement approuvées.
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Conclusion on suitability and availability of the alternative	Les conséquences d'une interdiction de l'éthanol seront extrêmement graves. Une bonne hygiène sur le lieu de travail est essentielle, en particulier pendant les pandémies, pour protéger les employés des infrastructures critiques contre les virus non développés. La pandémie de Covid-19 a démontré la nécessité des désinfectants à base d'éthanol pour la survie des infrastructures critiques. L'absence de désinfectants à base de cette substance active puissante et bien tolérée mettra en péril la sécurité de la production alimentaire, des travailleurs et du grand public. Il n'existe pas de substance active biocide de substitution aussi efficace sur le site de production de denrées alimentaires et d'aliments pour animaux (PT4 et PT1).

Information above is confidential	
Justification for confidentiality	
Other comments	Les études sur l'utilisation de l'éthanol montrent que l'éthanol s'évapore rapidement. L'inhalation professionnelle n'entraîne pas d'augmentation significative de la concentration d'éthanol dans le sang. Les concentrations atmosphériques d'éthanol sur les lieux de travail où il est utilisé sont généralement bien inférieures (6 à 20 fois) aux limites nationales d'exposition professionnelle sur une période de huit heures. Voir Bessonneau V, Clement M, Thomas O. Can intensive use of alcohol-based hand rubs lead to passive alcoholization ? International journal of environmental research and public health 2010 ; 7 : 3038-50. La combinaison de toutes les propriétés inhérentes à la substance n'est donnée que par l'éthanol : action rapide, virucide complet, pas de résidus, évaporation rapide, longue durée de stockage, pas de transfert ou d'altération des aliments, inodore, pas de sous-produits de désinfection ou de produits de dégradation (écotoxicologiques) pertinents. Un autre fait important est le manque d'efficacité de toutes les alternatives possibles à l'éthanol pour les virus non enveloppés. Cela signifie qu'il n'est pas possible de prévenir la propagation de maladies par des virus non enveloppés comme la polio, la noro, etc. Voir la liste principale de l'OMS 15.1 et 15.2 : Web Annexe A. Liste modèle des médicaments essentiels de l'Organisation mondiale de la santé - 23e liste, 2023. In : La sélection et l'utilisation de médicaments essentiels 2023 : Résumé du rapport du 24e Comité d'experts de l'OMS sur la sélection et l'utilisation des médicaments essentiels, 24 - 28 avril 2023. Genève : Organisation mondiale de la santé ; 2023 (WHO/MHP/HPS/EML/2023.02). Lien entre le processus de biocides et d'autres secteurs : L'évaluation des critères CMR et une décision ultérieure de la Commission européenne sur ces critères aboutiraient à une déclaration officielle sur les propriétés CMR de l'éthanol pour les utilisations biocides. Ces informations disponibles devront être prises en compte par tous les utilisateurs d'éthanol lors de leur auto-classification. Ainsi, une classification dans le secteur des biocides s'appliquerait à tous les secteurs. En outre, cette position officielle sur les propriétés CMR pourrait influencer le processus de formation d'opinion des autres comités CLP et donc affecter le processus de classification harmonisée actuellement en cours. Par exemple, les directives sur la santé et la sécurité des travailleurs, y compris la directive sur les travailleuses

	enceintes, stipulent que les employeurs doivent évaluer tous les risques liés à la sécurité et à la santé des travailleuses (enceintes, allaitantes, adolescentes) et décider des mesures de prévention et de protection à prendre. Une de ces mesures pourrait être l'interdiction pour les travailleuses (enceintes, allaitantes, adolescentes) d'utiliser de l'éthanol classé comme cancérigène ou reprotoxique.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 175	2025/04/28 09:15
Country	Belgium
Name of organization/institution	Raffinerie Tirlemontois
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	La classification de l'éthanol comme cancérigène ou toxique pour la reproduction pourrait signifier que de nombreux produits biocides pourraient perdre leur autorisation à l'avenir. Certains cas d'utilisation critiques sont décrits ci-dessous. Nous estimons donc qu'il est nécessaire de maintenir sur le marché les désinfectants à base d'éthanol. Dans notre cas, l'éthanol est principalement utilisé comme substance active dans de nombreux désinfectants destinés à être utilisés sur nos sites de production de denrées alimentaires et d'aliments pour animaux afin de fournir des produits sûrs (PT4). En outre, les produits biocides contenant de l'éthanol sont utilisés comme désinfectants pour les mains par le personnel des installations de

	transformation afin de prévenir la contamination des denrées alimentaires et des aliments pour animaux et de garantir l'hygiène de l'entreprise (PT 1). En outre, l'éthanol n'est pas seulement utilisé comme substance active dans les produits biocides, mais aussi comme solvant dans d'autres produits biocides, par exemple dans les répulsifs, les insecticides, etc. Ces produits sont importants pour nos usines afin de créer des conditions d'hygiène et de garantir des produits sûrs à nos clients. Par conséquent, un grand nombre de produits biocides pourraient être affectés par une classification et perdre leur autorisation.
Product Type	1,2,4
Alternative Identity and Properties	Chlorocrésol Peroxyde d'hydrogène Iode Acide lactique Monochloramine Phénoxyéthanol Propan-1-ol et Propan-2-ol Acide peracétique Composés d'ammonium quaternaire Hypochlorite de sodium
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	L'iode, les composés d'ammonium quaternaire et l'hypochlorite de sodium ne peuvent pas être utilisés car ils entraînent la formation de résidus inamovibles dans l'aliment final. peroxyde d'hydrogène et l'acide peracétique sont corrosifs et ne conviennent pas à de nombreux matériaux utilisés. Le chlorocrésol, le phénoxyéthanol et la monochloramine ne peuvent pas être utilisés car ils entraînent la formation d'odeurs dans l'aliment final. Les alternatives alcooliques Propan-1-ol et Propan-2-ol et l'acide lactique n'ont pas d'activité virucide complète.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Une classification comme CMR conduira probablement soit à une interdiction totale des produits biocides contenant de l'éthanol, soit à l'inquiétude des consommateurs et donc à un manque d'acceptation des produits biocides à base d'éthanol et à un passage à des produits alternatifs. Comme il y a moins d'entreprises qui fournissent des désinfectants techniquement ou légalement utilisables avec des alternatives à l'éthanol sur le marché, par exemple les alcools Propan-1-ol et Propan-2-ol, nous craignons une pénurie ultérieure et donc une augmentation des prix sur le

	marché. Afin d'utiliser des produits biocides alternatifs sans éthanol dans nos sites, les processus de production devraient être réorganisés et les installations devraient être réaménagées. L'éthanol est comparativement moins cher que d'autres substances actives, il est généralement disponible, facile et rapide à produire, ce qui garantit un approvisionnement constant et, s'il provient de sources renouvelables, il est également durable (voir RED III).
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Les alternatives alcooliques Propan-1-ol et Propan-2-ol n'ont pas d'activité virucide complète. Le chlorocrésol, le peroxyde d'hydrogène, l'iode, l'acide lactique, la monochloramine, le phénoxyéthanol, l'acide peracétique et l'hypochlorite de sodium sont corrosifs et certains ont également des propriétés toxiques.
Information above is confidential	
Justification for confidentiality	
Availability	La disponibilité à court/moyen terme d'alternatives techniques réalisables n'est pas donnée car moins d'entreprises fournissent des alternatives et l'augmentation de la production d'alternatives à l'éthanol est associée à de nouvelles installations, de nouvelles technologies, de nouveaux permis de production, etc. Cela aura en outre un impact négatif sur la faisabilité économique en raison de la pénurie de produits disponibles sur le marché. En raison d'exigences (légales) supplémentaires en matière de sécurité des produits (denrées alimentaires et aliments pour animaux), les alternatives énumérées ci-dessus ne sont pas disponibles. - Les composés d'ammonium quaternaire et l'hypochlorite de sodium ne peuvent pas être utilisés car ils entraînent la formation de résidus inamovibles dans l'aliment final. - Le chlorocrésol, le phénoxyéthanol et la monochloramine ne peuvent pas être utilisés car ils entraînent la formation d'odeurs dans l'aliment final. Ceci est contraire à la production de produits sûrs, tels que décrits dans les lois et règlements européens et nationaux sur les denrées alimentaires et les aliments pour animaux. Les alternatives à l'éthanol pour la production de denrées alimentaires et d'aliments pour animaux biologiques ne sont pas légalement approuvées.

Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Les conséquences d'une interdiction de l'éthanol seront extrêmement graves. Une bonne hygiène sur le lieu de travail est essentielle, en particulier pendant les pandémies, pour protéger les employés des infrastructures critiques contre les virus non développés. La pandémie de Covid-19 a démontré la nécessité des désinfectants à base d'éthanol pour la survie des infrastructures critiques. L'absence de désinfectants à base de cette substance active puissante et bien tolérée mettra en péril la sécurité de la production alimentaire, des travailleurs et du grand public. Il n'existe pas de substance active biocide de substitution aussi efficace sur le site de production de denrées alimentaires et d'aliments pour animaux (PT4 et PT1).
Information above is confidential	
Justification for confidentiality	
Other comments	Les études sur l'utilisation de l'éthanol montrent que l'éthanol s'évapore rapidement. L'inhalation professionnelle n'entraîne pas d'augmentation significative de la concentration d'éthanol dans le sang. Les concentrations atmosphériques d'éthanol sur les lieux de travail où il est utilisé sont généralement bien inférieures (6 à 20 fois) aux limites nationales d'exposition professionnelle sur une période de huit heures. Voir Bessonneau V, Clement M, Thomas O. Can intensive use of alcohol-based hand rubs lead to passive alcoholization ? International journal of environmental research and public health 2010 ; 7 : 3038-50. La combinaison de toutes les propriétés inhérentes à la substance n'est donnée que par l'éthanol : action rapide, virucide complet, pas de résidus, évaporation rapide, longue durée de stockage, pas de transfert ou d'altération des aliments, inodore, pas de sous-produits de désinfection ou de produits de dégradation (écotoxicologiques) pertinents. Un autre fait important est le manque d'efficacité de toutes les alternatives possibles à l'éthanol pour les virus non enveloppés. Cela signifie qu'il n'est pas possible de prévenir la propagation de maladies par des virus non enveloppés comme la polio, la noro, etc. Voir la liste principale de l'OMS 15.1 et 15.2 : Web Annexe A. Liste modèle des médicaments essentiels de l'Organisation mondiale de la santé - 23e liste, 2023. In : La sélection et l'utilisation de médicaments essentiels 2023 : Résumé du rapport du 24e

	Comité d'experts de l'OMS sur la sélection et l'utilisation des médicaments essentiels, 24 - 28 avril 2023. Genève : Organisation mondiale de la santé ; 2023 (WHO/MHP/HPS/EML/2023.02). Lien entre le processus de biocides et d'autres secteurs : L'évaluation des critères CMR et une décision ultérieure de la Commission européenne sur ces critères aboutiraient à une déclaration officielle sur les propriétés CMR de l'éthanol pour les utilisations biocides. Ces informations disponibles devront être prises en compte par tous les utilisateurs d'éthanol lors de leur auto-classification. Ainsi, une classification dans le secteur des biocides s'appliquerait à tous les secteurs. En outre, cette position officielle sur les propriétés CMR pourrait influencer le processus de formation d'opinion des autres comités CLP et donc affecter le processus de classification harmonisée actuellement en cours. Par exemple, les directives sur la santé et la sécurité des travailleurs, y compris la directive sur les travailleuses enceintes, stipulent que les employeurs doivent évaluer tous les risques liés à la sécurité et à la santé des travailleuses (enceintes, allaitantes, adolescentes) et décider des mesures de prévention et de protection à prendre. Une de ces mesures pourrait être l'interdiction pour les travailleuses (enceintes, allaitantes, adolescentes) d'utiliser de l'éthanol classé comme cancérigène ou reprotoxique.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 176	2025/04/28 10:20
Country	Finland
Name of organization/institution	Suomen infektiolääkärit ry (Finnish Infectious Disease Physicians Association)

I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	The Finnish Infectious Disease Physicians Association is a non-profit organization focused on the continuing education of infectious disease specialists and physicians in training. The association was founded on February 8, 1996, and has approximately 180 members. Membership is open to specialists in internal medicine or pediatrics who are specialized or specializing in infectious diseases, as well as physicians in training who are directly qualifying as infectious disease specialists.
Product Type	1,2,4
Alternative Identity and Properties	Ethanol at 80% w/w concentration is uniquely effective against hydrophilic non-enveloped viruses, such as enteroviruses, and is the preferred active substance in handrubs. Several non-enveloped viruses have been detected on hands and for which transmission via hands has led to nosocomial infections and outbreaks. If there is an infection due to one of these viruses, only hand antiseptics based on ethanol 95% or with reduced ethanol content and synergistic additives can be used to interrupt potential transmission. Other substances like isopropanol, chlorine-based agents, oxidants, and peracetic acid (PAA) are either ineffective or have negative toxicological effects, making them unsuitable for handrub formulations. Ethanol is the reference alcohol for the EN 17430 test standard due to its efficacy and widespread use in virucidal handrubs. PAA, while effective in vitro, is corrosive and irritating, causing significant health issues upon exposure.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	There are currently no biocidal products approved as PT1 which exhibit virucidal activity. Using handrubs with active substances other than ethanol may be suitable in specific situations, but it requires managing various disinfectants, which increases the risk of incorrect use due to differing handling instructions, and safety regulations.
Information above is confidential	

Justification for confidentiality	
Economic Feasibility	The substitution of ethanol with other active substances, is likely to increase production costs for manufacturers, consumers, and governments in Europe.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Some alternative substances risk developing resistance or tolerance in target organisms. No resistance has been reported for ethanol. Some alternative substances, such as chlorine-based disinfectants are unstable and sensitive to temperature changes, and users may not know when to discard them due to insufficient information on stability after opening. Ethanol-based handrubs (EBHR) have favorable stability properties if stored correctly. Alternative active substances with in-vitro virucidal activity have more adverse toxicity profile. The frequency of use in everyday clinical practice (several dozens or even over hundred uses every day) has to be taken in a consideration.
Information above is confidential	
Justification for confidentiality	
Availability	Ethanol is produced at a much larger scale in Europe than propanols or other alternative substances.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Hand hygiene is crucial for infection prevention, with alcohol-based handrubs (ABHR) being the gold standard due to ethanol's virucidal effect. At the 2023 ICPIC conference, experts agreed that repeated use of ethanol-based handrubs poses no carcinogenic, mutagenic, or reproductive toxicity risks. Ethanol is superior to other substances like propanols in terms of activity spectrum, skin tolerability, and toxicity. Despite concerns raised by ECHA/BPC about ethanol's classification as a biocidal substance, ethanol remains essential and irreplaceable for handrubs.
Information above is confidential	

Justification for confidentiality	
Other comments	A ban of ethanol for biocidal production and/or a restriction of use in Europe due to CMR classification would have a (negative) impact on the availability of effective ABHR handrubs in global crisis situations in Europe and other parts of the world. This ban or restriction could potentially lead to an increase in healthcare-associated infections, a decline in patient safety, and a deterioration in the occupational safety of healthcare personnel.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 177	2025/04/28 12:09
Country	Germany
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	AlmaWin is a manufacturer of detergents, and cleaning agents, providing proprietary and contract manufacturing for consumer markets. A key principle of our formulation strategy is the use of sustainable raw materials, of which ethanol is one of the most important. Obtained from natural, renewable resources, ethanol is used in more than 200 of our products due to its effectiveness, versatility, and environmental compatibility.
Product Type	1,2,4

Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	AlmaWin is strongly critical of the proposed reclassification and is calling on the regulatory authorities to revise the proposed reclassification. Ethanol is a safe, essential, and irreplaceable raw material in ecological detergents and cleaning products. Its regulation must reflect real-world application and corresponding exposure scenarios, ensuring the availability of safe, effective, and environmentally responsible products for consumer markets.
Information above is confidential	
Justification for confidentiality	

Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	ECHA Consultation Ethanol AW position paper.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 178	2025/04/28 12:13
Country	Germany
Name of organization/institution	AlmaWin Reinigungskonzentrate GmbH
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	AlmaWin is a manufacturer of detergents, and cleaning agents, providing proprietary and contract manufacturing for consumer markets. A key principle of our formulation strategy is the use of sustainable raw materials, of which ethanol is one of the most important. Obtained from natural, renewable resources, ethanol is used in more than 200 of our products due to its effectiveness, versatility, and environmental compatibility.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	

Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	AlmaWin is strongly critical of the proposed reclassification and is calling on the regulatory authorities to revise the proposed reclassification. Ethanol is a safe, essential, and irreplaceable raw material in ecological detergents and cleaning products. Its regulation must reflect real-world application and corresponding exposure scenarios, ensuring the availability of safe, effective, and environmentally responsible products for consumer markets.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	

Attachments (non-confidential information)	ECHA Consultation Ethanol AW position paper.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 179	2025/04/28 12:14
Country	Germany
Name of organization/institution	AlmaWin Reinigungskonzentrate GmbH
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	AlmaWin is a manufacturer of detergents, and cleaning agents, providing proprietary and contract manufacturing for consumer markets. A key principle of our formulation strategy is the use of sustainable raw materials, of which ethanol is one of the most important. Obtained from natural, renewable resources, ethanol is used in more than 200 of our products due to its effectiveness, versatility, and environmental compatibility.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	

Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	AlmaWin is strongly critical of the proposed reclassification and is calling on the regulatory authorities to revise the proposed reclassification. Ethanol is a safe, essential, and irreplaceable raw material in ecological detergents and cleaning products. Its regulation must reflect real-world application and corresponding exposure scenarios, ensuring the availability of safe, effective, and environmentally responsible products for consumer markets.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	ECHA Consultation Ethanol AW position paper.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 180	2025/04/28 12:15
Country	Germany
Name of organization/institution	AlmaWin Reinigungskonzentrate GmbH
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	AlmaWin is a manufacturer of detergents, and cleaning agents, providing proprietary and contract manufacturing for consumer markets. A key principle of our formulation strategy is the use of sustainable raw materials, of which ethanol is one of the most important. Obtained from natural, renewable resources, ethanol is used in more than 200 of our products due to its effectiveness, versatility, and environmental compatibility.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	

Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	AlmaWin is strongly critical of the proposed reclassification and is calling on the regulatory authorities to revise the proposed reclassification. Ethanol is a safe, essential, and irreplaceable raw material in ecological detergents and cleaning products. Its regulation must reflect real-world application and corresponding exposure scenarios, ensuring the availability of safe, effective, and environmentally responsible products for consumer markets.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	ECHA Consultation Ethanol AW position paper.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 181	2025/04/28 12:16
Country	Germany

Name of organization/institution	Remsgold Chemie
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Remsgold Chemie is a manufacturer of detergents, cleaning agents and disinfectants, providing proprietary and contract manufacturing for both professional and consumer markets. A key principle of our formulation strategy is the use of sustainable raw materials, of which ethanol is one of the most important. Obtained from natural, renewable resources, ethanol is used in more than 200 of our products due to its effectiveness, versatility, and environmental compatibility.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	

Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Remsgold Chemie is strongly critical of the proposed reclassification and is calling on the regulatory authorities to revise the proposed reclassification. Ethanol is a safe, essential, and irreplaceable raw material in ecological detergents and cleaning products. Its regulation must reflect real-world application and corresponding exposure scenarios, ensuring the availability of safe, effective, and environmentally responsible products for both professional and consumer markets.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	ECHA Consultation Ethanol RG position paper.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 182	2025/04/28 12:17
Country	Germany
Name of organization/institution	Remsgold Chemie
I do not wish the name of my organisation/institution to be published on the ECHA website.	

General information	Remsgold Chemie is a manufacturer of detergents, cleaning agents and disinfectants, providing proprietary and contract manufacturing for both professional and consumer markets. A key principle of our formulation strategy is the use of sustainable raw materials, of which ethanol is one of the most important. Obtained from natural, renewable resources, ethanol is used in more than 200 of our products due to its effectiveness, versatility, and environmental compatibility.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	

Conclusion on suitability and availability of the alternative	Remsgold Chemie is strongly critical of the proposed reclassification and is calling on the regulatory authorities to revise the proposed reclassification. Ethanol is a safe, essential, and irreplaceable raw material in ecological detergents and cleaning products. Its regulation must reflect real-world application and corresponding exposure scenarios, ensuring the availability of safe, effective, and environmentally responsible products for both professional and consumer markets.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	ECHA Consultation Ethanol RG position paper.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 184	2025/04/28 12:17
Country	France
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	Ethanol-based hand disinfectants are widely used in hospitals, healthcare centers, the food industry, and by the general public. These products are indispensable for infection prevention, particularly during health crises such

	as the COVID-19 pandemic. Ethanol enables fast, effective, and safe hand hygiene practices.
Product Type	1,2,4
Alternative Identity and Properties	- Ethanol is fully virucidal, including non-enveloped viruses (e.g., norovirus, poliovirus). - Propanols and QACs are less effective and more irritating; QACs pose sensitization and endocrine risks. - Ethanol evaporates cleanly, no systemic accumulation under typical dermal use.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	- Ethanol-based hand rubs require no rinsing and are compatible with current dispenser systems. - Substitution would require full reformulation, new procedures, and incompatible contact requirements.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	- Substitution implies high costs: formulation, validation (EN 1500, 14476), training, and equipment redesign. - SMEs may not withstand the burden.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	- Ethanol is safe, well-tolerated, low systemic exposure. - Alternatives: irritants (propanols), sensitizers (QACs), or corrosives (acids).
Information above is confidential	
Justification for confidentiality	
Availability	- Ethanol is produced in large scale across the EU, scalable during crises. - Alternatives face limited supply chains and cost volatility.
Information above is confidential	

Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol is indispensable for PT1: no equivalent in safety, efficacy, availability, and technical integration.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 183	2025/04/28 12:18
Country	Germany
Name of organization/institution	Remsgold Chemie
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Remsgold Chemie is a manufacturer of detergents, cleaning agents and disinfectants, providing proprietary and contract manufacturing for both professional and consumer markets. A key principle of our formulation strategy is the use of sustainable raw materials, of which ethanol is one of the most important. Obtained from natural, renewable resources, ethanol is used in more than 200 of our products

	due to its effectiveness, versatility, and environmental compatibility.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Remsgold Chemie is strongly critical of the proposed reclassification and is calling on the regulatory authorities to revise the proposed reclassification. Ethanol is a safe, essential, and irreplaceable raw material in ecological detergents and cleaning products. Its regulation must reflect real-world application and corresponding exposure scenarios, ensuring the availability of safe, effective, and environmentally responsible products for both professional and consumer markets.

Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	ECHA Consultation Ethanol RG position paper.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 185	2025/04/28 12:19
Country	France
Name of organization/institution	KEMIX
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Ethanol-based surface disinfectants are commonly used in hospitals, transportation, educational facilities, and workplaces. They allow for fast, effective disinfection without rinsing, particularly in high-touch and sensitive areas.
Product Type	1,2,4
Alternative Identity and Properties	- Ethanol ensures effective disinfection in clean and soiled conditions. - QACs are less effective in soiling; - NaOCl and peracetic acid are corrosive, leave residues.
Information above is confidential	

Justification for confidentiality	
Technical Feasibility	- Ethanol enables quick application and drying with no residue. - Substitutes may corrode surfaces and are incompatible with rapid disinfection workflows
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	- Major impact across sectors (healthcare, public buildings, transport) requiring new protocols and retraining. - Infrastructure adaptation is costly
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	- Ethanol: non-corrosive, biodegradable, safe for repeated use. - Others: DBP formation, environmental persistence, increased health risks.
Information above is confidential	
Justification for confidentiality	
Availability	- Ethanol is reliable and easy to produce at scale. - Alternatives have short shelf lives or constrained logistics.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol is superior in PT2 for technical, operational, and safety performance. No equivalent alternatives.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	

Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 186	2025/04/28 12:20
Country	France
Name of organization/institution	KEMIX
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Ethanol is widely used in the food and beverage industry to disinfect surfaces in direct or indirect contact with food, such as worktops, conveyor belts, and tools. It is recognized for its safety, speed of action, and compatibility with HACCP procedures.
Product Type	1,2,4
Alternative Identity and Properties	- Ethanol is food-safe, requires no rinsing, and does not alter organoleptic properties. - Alternatives (peracetic acid, H2O2): corrosive, require rinsing, alter food or equipment
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	- Compatible with existing industrial lines (CIP/SIP, manual sprays). - Substitution implies major HACCP changes, equipment overhaul.
Information above is confidential	

Justification for confidentiality	
Economic Feasibility	• Downtime, requalification, and supply chain adjustments create excessive costs. • SMEs particularly impacted.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	• Ethanol: odorless, non-corrosive, safe in food environments. • Others: toxic residues, odor, increased poisoning risk.
Information above is confidential	
Justification for confidentiality	
Availability	• Ethanol is widely produced with food-grade variants. • Alternatives less stable, with restrictive regulations.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	In PT4, ethanol offers unmatched food safety compatibility, operational efficiency, and user safety.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	

Justification for confidential attachment	

Comment 187	2025/04/28 12:22
Country	Germany
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	

Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	

Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	There are currently no viable alternatives to ethanol. Due to their lower efficacy against viruses, propan-1-ol and propan-2-ol are not suitable. Ethanol, as a biocidal active substance, is essential for human hygiene disinfectants in healthcare, public institutions and domestic environment. A CMR classification would have a serious impact on the manufacture and the application of important hand disinfectant products. Ethanol is effective, safe, readily sustainably available and therefore indispensable. Due to higher production costs for propanols and no sustainable raw materials as well as the dependence on external supply chains, ethanol is the most economically feasible option. Considering all the legislations that would be affected by a CMR classification, this could have far-reaching consequences for EU industry and the supply of the population, not only limited to biocidal products, but also with regard to medical devices, pharmaceuticals, cosmetic products, industrial chemicals, etc. The legal monitoring at the global level would certainly be a challenge.
Information above is confidential	
Justification for confidentiality	

Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 188	2025/04/28 12:22
Country	France
Name of organization/institution	France Culinaire
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Ethanol-based hand disinfectants are widely used in hospitals, healthcare centers, the food industry, and by the general public. These products are indispensable for infection prevention, particularly during health crises such as the COVID-19 pandemic. Ethanol enables fast, effective, and safe hand hygiene practices.
Product Type	1,2,4

Alternative Identity and Properties	- Ethanol is fully virucidal, including non-enveloped viruses (e.g., norovirus, poliovirus). - Propanols and QACs are less effective and more irritating; QACs pose sensitization and endocrine risks. - Ethanol evaporates cleanly, no systemic accumulation under typical dermal use.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	- Ethanol-based hand rubs require no rinsing and are compatible with current dispenser systems. - Substitution would require full reformulation, new procedures, and incompatible contact requirements.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	- Substitution implies high costs: formulation, validation (EN 1500, 14476), training, and equipment redesign. - SMEs may not withstand the burden.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	- Ethanol is safe, well-tolerated, low systemic exposure. - Alternatives: irritants (propanols), sensitizers (QACs), or corrosives (acids).
Information above is confidential	
Justification for confidentiality	
Availability	- Ethanol is produced in large scale across the EU, scalable during crises. - Alternatives face limited supply chains and cost volatility.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol is indispensable for PT1: no equivalent in safety, efficacy, availability, and technical integration.

Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 189	2025/04/28 12:24
Country	France
Name of organization/institution	France Culinaire
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Ethanol-based surface disinfectants are commonly used in hospitals, transportation, educational facilities, and workplaces. They allow for fast, effective disinfection without rinsing, particularly in high-touch and sensitive areas.
Product Type	1,2,4
Alternative Identity and Properties	- Ethanol ensures effective disinfection in clean and soiled conditions. - QACs are less effective in soiling; - NaOCl and peracetic acid are corrosive, leave residues.
Information above is confidential	

Justification for confidentiality	
Technical Feasibility	- Ethanol enables quick application and drying with no residue. - Substitutes may corrode surfaces and are incompatible with rapid disinfection workflows
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	- Major impact across sectors (healthcare, public buildings, transport) requiring new protocols and retraining. - Infrastructure adaptation is costly.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	- Ethanol: non-corrosive, biodegradable, safe for repeated use. - Others: DBP formation, environmental persistence, increased health risks.
Information above is confidential	
Justification for confidentiality	
Availability	- Ethanol is reliable and easy to produce at scale. - Alternatives have short shelf lives or constrained logistics.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol is superior in PT2 for technical, operational, and safety performance. No equivalent alternatives.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	

Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 190	2025/04/28 12:25
Country	France
Name of organization/institution	France Culinaire
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Ethanol is widely used in the food and beverage industry to disinfect surfaces in direct or indirect contact with food, such as worktops, conveyor belts, and tools. It is recognized for its safety, speed of action, and compatibility with HACCP procedures.
Product Type	1,2,4
Alternative Identity and Properties	- Ethanol is food-safe, requires no rinsing, and does not alter organoleptic properties. - Alternatives (peracetic acid, H2O2): corrosive, require rinsing, alter food or equipment.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	- Compatible with existing industrial lines (CIP/SIP, manual sprays). - Substitution implies major HACCP changes, equipment overhaul.
Information above is confidential	

Justification for confidentiality	
Economic Feasibility	• Downtime, requalification, and supply chain adjustments create excessive costs. • SMEs particularly impacted.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	• Ethanol: odorless, non-corrosive, safe in food environments. • Others: toxic residues, odor, increased poisoning risk.
Information above is confidential	
Justification for confidentiality	
Availability	• Ethanol is widely produced with food-grade variants. • Alternatives less stable, with restrictive regulations.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	In PT4, ethanol offers unmatched food safety compatibility, operational efficiency, and user safety.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	

Justification for confidential attachment	

Comment 191	2025/04/28 12:47
Country	France
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	Ethanol is crucial to our activity sector : as the biocidal active substance of disinfectants but also as co-formulant for detergent products.
Product Type	1,2,4
Alternative Identity and Properties	See the detailed document attached (IV. Attachments)
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	See the detailed document attached (IV. Attachments)
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	See the detailed document attached (IV. Attachments)
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	See the detailed document attached (IV. Attachments)
Information above is confidential	

Justification for confidentiality	
Availability	See the detailed document attached (IV. Attachments)
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	See the detailed document attached (IV. Attachments)
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 192	2025/04/28 13:19
Country	Netherlands
Name of organization/institution	European Society of Clinical Microbiology and Infectious Diseases
I do not wish the name of my organisation/institution to be published on the ECHA website.	

General information	On behalf of the European Society for Clinical Microbiology and Infectious Diseases (ESCMID), we are writing to express our full support for the position presented by the VAH submission (ECHA submission data: Ethanol, 64-17-5, 200-578-6; reference number: 9b9ee290-503d-480b-8c61-2ac65ae4487c) regarding the use of ethanol-based hand rubs (EBHR) in healthcare and community settings, as well as the importance of not classifying ethanol as a substance with carcinogenic, mutagenic, or reprotoxic (CMR) properties in the context of hand hygiene and surface disinfection.
Product Type	1,2,4
Alternative Identity and Properties	There are no real alternatives to ethanol for hand disinfection which have been studied with widescale oral intake to base the side-effects upon.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Alcohol based hand-disinfection has become THE standard of care in hospitals, nursing homes and other healthcare facilities all over the world. There are no substitute with comparable effectiveness and applicability in practice.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Alcohol-based hand disinfection has been proven cost-effective.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Alternatives to ethanol carry a similar risk. For example iso-propyl alcohol can be used for skindisinfection but the risks associated with oral ingestion is not known.
Information above is confidential	
Justification for confidentiality	
Availability	not relevant

Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	The role of ethanol as a skin-disinfectants in modern healthcare is critical to deliver safe care, saving numerous lives of our patients every year. The ongoing discussions about the safety of the cutaneous applications cause unnecessary concern and uncertainty. The proven benefits are in no way to be comarred with the theoretical risks of the cutaneous application. As a worldwide leading scientific society representing experts in clinical microbiology, infectious diseases and infection control, ESCMID and its committee EUCIC stand by the conclusion that ethanol-based hand rubs remain an indispensable tool for controlling the spread of infectious diseases and safeguarding public health. We support the VAH's call for ethanol to be approved as an active substance for biocidal products under the appropriate classification, without the application of CMR concerns. We urge ECHA and relevant stakeholders to consider the critical evidence presented and to support the continued safe and effective use of ethanol-based hand rubs as an essential part of global infection prevention efforts.
Information above is confidential	
Justification for confidentiality	
Other comments	Hand hygiene remains a cornerstone of infection prevention and control, recognized globally by health authorities and experts as essential for safeguarding patient safety. EBHR are the gold standard for effective hand disinfection, demonstrating broad-spectrum virucidal activity and proven efficacy in reducing healthcare-associated infections. The ESCMID and its associated initiatives such as the EUCIC, strongly advocates for the continued use of ethanol in hand hygiene practices. Scientific evidence confirms that repeated use of ethanol-based hand rubs does not pose a risk of carcinogenicity, mutagenicity, or reproductive toxicity when used as intended. This consensus is supported by recent expert discussions and extensive research, which affirm that ethanol's safety profile remains robust under proper application. Global and national infection prevention campaigns, including those promoted by ESCMID and EUCIC, emphasize the importance of access to and compliance with alcohol-based hand hygiene products. These products are listed as essential supplies in international frameworks for infection control, including the

	WHO's strategies for 2024–2030. While ethanol's classification as a carcinogen, mutagen, or reproductive toxin may be justified when intended for oral ingestion, such classifications are not applicable to its use as a biocidal active substance in hand rubs and surface disinfectants. When used as intended, ethanol should be approved as an active substance for PT1 without CMR classification. We also wish to emphasize that the classification of ethanol as a CMR substance in this context is inconsistent with other global regulatory standards. In no other jurisdiction or regulatory framework is ethanol, when used as intended in hand rubs and disinfectants, subject to such a classification. The ongoing discussions and opinions from bodies such as ECHA/BPC regarding ethanol's CMR properties have caused unnecessary concern and uncertainty. Such classifications threaten to undermine the fundamental role of hand hygiene in infection prevention, which is vital for patient safety. It is crucial to recognize that these classifications do not reflect the safety of ethanol when used appropriately in hand rubs. ESCMID strongly agrees with the VAH Society's assertion that the current discussion around ethanol's potential classification as a CMR substance for use in biocidal products could lead to unnecessary fear and confusion, undermining critical infection control measures globally threatening patient safety in healthcare. Such a classification would have serious consequences, but not only for healthcare settings but also for public health efforts in the face of emerging infectious threats, including zoonotic diseases and pandemics. This would be particularly damaging in scenarios where vaccines are not yet available, and hand hygiene remains one of the most effective non-pharmaceutical interventions. To provide one example regarding the impact of the threats we are facing: The current estimate of annual deaths which are directly attributed to infections caused by antibiotic-resistant bacteria in the EU/European Economic Area (EEA) is 35,000. Approximately 70% of these infections are healthcare-associated, occurring in settings such as hospitals and long-term care facilities. Hand alcohol is an essential component of the prevention of spread of microorganisms in these settings. Without effective interventions, annual deaths in Europe due to AMR are expected to rise to 390,000 by 2050. Globally, AMR is projected to cause up to 10 million deaths per year by 2050, surpassing the current mortality rates of cancer and diabetes. AMR incurs an estimated €11.7 billion annually in the EU/EEA due to increased healthcare costs and productivity losses. The theoretical carcinogenic effect of cutaneous use of ethanol is totally out

	of balance with the proven benefits in healthcare settings and banning it would cause serious harm.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	ESMCID_EUCIC statement.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 193	2025/04/28 13:24
Country	Germany
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	

Justification for confidentiality	[REDACTED]
Technical Feasibility	[REDACTED]
Information above is confidential	[REDACTED]
Justification for confidentiality	[REDACTED]
Economic Feasibility	[REDACTED]
Information above is confidential	[REDACTED]
Justification for confidentiality	[REDACTED]

Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	There are currently no viable alternatives to ethanol. Due to their lower efficacy against viruses, propan-1-ol and propan-2-ol are not suitable. Ethanol, as a biocidal active substance, is essential for surface disinfectants in healthcare, public institutions and domestic environment. A CMR classification would have a serious impact on the manufacture and the application of important surface disinfectant products. Ethanol is effective, safe, readily and sustainably available and therefore indispensable. Due to higher production costs for propanols and no sustainable raw materials as well as the dependence on external supply chains, ethanol is the most economically feasible option. Considering all the legislations that would be affected by a CMR classification, this could have far-reaching consequences for EU industry and the supply of the

	population, not only limited to biocidal products, but also with regard to medical devices, pharmaceuticals, cosmetic products, industrial chemicals, etc. The legal monitoring at the global level would certainly be a challenge.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 194	2025/04/28 13:32
Country	Germany
Name of organization/institution	

I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	

Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	

Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	There are currently no viable alternatives to ethanol. Due to their lower efficacy against viruses, propan-1-ol and propan-2-ol are not suitable. Ethanol, as a biocidal active substance, is essential for surface disinfectants in healthcare, public institutions and domestic environment. A CMR classification would have a serious impact on the manufacture and the application of important surface disinfectant products. Ethanol is effective, safe, readily and sustainably available and therefore indispensable. Due to higher production costs for propanols and no sustainable raw materials as well as the dependence on external supply chains, ethanol is the most economically feasible option. Considering all the legislations that would be affected by a CMR classification, this could have far-reaching consequences for EU industry and the supply of the population, not only limited to biocidal products, but also with regard to medical devices, pharmaceuticals, cosmetic products, industrial chemicals, etc. The legal monitoring at the global level would certainly be a challenge.
Information above is confidential	
Justification for confidentiality	
Other comments	

Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

	cause cases of infection diseases. This is why disinfectants against non-enveloped viruses are needed in medical facilities, laboratories and community facilities. As not all patients are treated in hospitals, disinfectants against these viruses must also be available to the public. Ethanol works in a very short time - hand disinfectants shall work in 60 seconds, maximum 120 seconds. Hands must be dry after the exposure time, as gloves often have to be put on after sanitising. Alcohol-based products are the only way to ensure that hands are really dry after the exposure time. If the hands are still wet, skin damage will occur. For occupational health and safety reasons, it is not permitted to put gloves on damp hands.
Product Type	1,2,4
Alternative Identity and Properties	There are no alternative active substances. Rare or for special purposes used products containing chlorine or iodine compounds or peracetic acid (see disinfectant list of the Robert Koch-Institute [1]) are not suitable for routine use for many reasons. Hand disinfection has to be done 100 - 250 times per shift in medical facilities (until 400 times/day in Intensive care units). No other product is known that can be used so frequently on the skin without damaging the skin or the entire organism.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	In my experience, only products containing ethanol can fulfil these requirements. I worked in Mongolia as a WHO consultant many years ago. At that time, alcohol-based products were not available there and hand disinfection was carried out using chlorine products. Aqueous products such as these chlorine products only dry very slowly on the skin. Such products are completely unsuitable for everyday clinical use, as there is no time for disinfection followed by a long drying phase. In addition, compliance is poor due to the odour. The same applies to other aqueous products containing halogens such as iodine. In addition, the skin is discoloured. Due to the toxicological properties, it is also not possible to apply non-alcoholic products with the necessary frequency in everyday clinical practice (100 -250x/shift). A recent publication shows that ethanol is the best tolerated alcohol in hand disinfectants [2].
Information above is confidential	

Justification for confidentiality	
Economic Feasibility	no information
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	In my experience, only products containing ethanol can fulfil these requirements. I worked in Mongolia as a WHO consultant many years ago. At that time, alcohol-based products were not available there and hand disinfection was carried out using chlorine products. Aqueous products such as these chlorine products only dry very slowly on the skin. Such products are completely unsuitable for everyday clinical use, as there is no time for disinfection followed by a long drying phase. In addition, compliance is poor due to the odour. The same applies to other aqueous products containing halogens such as iodine. In addition, the skin is discoloured. Due to the toxicological properties, it is also not possible to apply non-alcoholic products with the necessary frequency in everyday clinical practice (100 -250x/shift). A recent publication shows that ethanol is the best tolerated alcohol in hand disinfectants [2].
Information above is confidential	
Justification for confidentiality	
Availability	Other active ingredients would have to be available in very pure quality in order not to cause additional damage to the skin. However, there are no known active ingredients that are toxicologically safe for the required frequency of application.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Hand disinfection is the most important measure for breaking chains of infection. If products containing ethanol are not available, the spread of dangerous non-enveloped viruses cannot be prevented [3].
Information above is confidential	
Justification for confidentiality	

Other comments	Products containing ethanol can currently be produced quickly, even in emergencies. During the Covid 19 pandemic, the orders/ general ruling issued by the national authorities for biocides in many European countries have made it possible to manage the disinfectants deficiency. At that time, no other active ingredient was available that could be made available quickly enough in sufficient quantities for hand disinfection.
Information above is confidential	
Justification for confidentiality	
References	1. Liste der vom Robert Koch-Institut geprüften und anerkannten Desinfektionsmittel und -verfahren https://www.rki.de/DE/Themen/Infektionskrankheiten/Krankenhaushygiene/Desinfektionsmittelliste/Desinfektionsmittel-und-verfahren/Downloads/BGBl_60_2017_Desinfektionsmittelliste.pdf?__blob=publicationFile&v=1 2. Gina, M et al. (2025). The effect of alcohol-based virucidal hand sanitizers on skin barrier function: A randomized experimental study. Contact Dermatitis, in press. DOI: 10.1111/cod.14808 3. Kramer A, Arvand M, Christiansen B, Dancer S, Eggers M, Exner M, Müller D, Mutters NT, Schwebke I, Pittet D. Ethanol is indispensable for virucidal hand antisepsis: memorandum from the alcohol-based hand rub (ABHR) Task Force, WHO Collaborating Centre on Patient Safety, and the Commission for Hospital Hygiene and Infection Prevention (KRINKO), Robert Koch Institute, Berlin, Germany. Antimicrob Resist Infect Control. 2022 Jul 6;11(1):93. doi: 10.1186/s13756-022-01134-7. PMID: 35794648; PMCID: PMC9257567.
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 196	2025/04/28 13:58
Country	Germany

Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	

Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	

Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	There are currently no viable alternatives to ethanol. Due to their lower efficacy against viruses, propan-1-ol and propan-2-ol are not suitable. Ethanol, as a biocidal active substance, is essential for surface disinfectants in healthcare, public institutions and domestic environment. A CMR classification would have a serious impact on the manufacture and the application of important surface disinfectant products. Ethanol is effective, safe, readily and sustainably available and therefore indispensable. Due to higher production costs for propanols and no sustainable raw materials as well as the dependence on external supply chains, ethanol is the most economically feasible option. Considering all the legislations that would be affected by a CMR classification, this could have far-reaching consequences for EU industry and the supply of the population, not only limited to biocidal products, but also with regard to medical devices, pharmaceuticals, cosmetic products, industrial chemicals, etc. The legal monitoring at the global level would certainly be a challenge.
Information above is confidential	
Justification for confidentiality	
Other comments	

Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 197	2025/04/28 14:29
Country	Germany
Name of organization/institution	Arethia Services Germany GmbH & Co. KG
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Arethia represents an international group of companies operating within the flavour & fragrance industry. The group's entities focus on high-quality products and tailor-made solutions. With over 250 employees worldwide and production and innovation facilities in Europe, the Middle East and Asia, our end-market divisions serve customers from different industries in over 70 countries. We are not directly involved in the production of biocidal products. However, biocides such as the listed product types affect ultimately everyone due to their use e.g. in the health sector and food industry. Moreover, our company will be

	affected due to its connection to the food industry via production of food flavours. A lack of high quality products than will maintain and improve hygiene in the food sector will harm the food and beverage industry and therefore also influence our direct customers. Moreover, ethanol is a very important solvent in the flavour industry, which is often used for the extraction of plant materials (e.g. vanilla, cocoa) in order to make their key ingredients usable in a large variety of products, that could not otherwise be produced. We want to contribute to this discussion already at this point, as we think the outcome for biocide applications will also influence other industry sectors in the long-term, e.g. by paving the way for the harmonised classification including CMR properties, which will not only affect biocides and flavours, but also a number of other industry sectors that rely on organic solvents, and for which ethanol might not be easily replacable, thus resulting in lower product quality and increased prices when the substance needs to be replaced as companies cannot fulfil requirements that would be needed for handling CMR substances (e.g. different forms of fuel, paints, personal care products). Even companies not directly involved in the marketing of biocides will be negatively influenced by the anticipated changes.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	

Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	To our knowledge there exists no suitable alternative for ethanol in biocidal products, including the universally relevant health sector and the food industry. The same applies to its use as solvent in many industry areas, including the flavour industry and other areas. We think that a CMR classification of ethanol cannot be justified from a scientific view, therefore making a substitution not only immensely difficult, but also unnecessary. A removal of ethanol and an EU wide CMR classification would negatively affect all of EU industry, but also end-users, as safety in the health and food sectors, as well as general hygiene in many public areas, heavily depends on the use of effective biocides.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	https://www.egms.de/static/en/journals/dgkh/2024-19/dgkh000495.shtml https://pubmed.ncbi.nlm.nih.gov/35794648/
Attachments (non-confidential information)	250428 Arethia Ethanol Consultation.pdf
Attachments (confidential information)	

Justification for confidential attachment	

Comment 198	2025/04/28 14:31
Country	Germany
Name of organization/institution	Pharma Deutschland e.V.
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Pharma Deutschland is a full-service association of pharmaceutical companies in Germany. Besides medicines manufacturers, the membership is also comprised of pharmacists, lawyers, publishing houses and agencies, as well as market research and opinion research institutions. Pharma Deutschland member companies contribute enormously to the securing of the supply of medicines in Germany. For example, they produce nearly 80 per cent of the prescription-free medicines sold in pharmacies and almost two thirds of the prescription medicines as well as a major part of the substance-based medical devices, providing patients with products that are both effective and safe. Pharma Deutschland advocates for secure and responsible self-medication through professional medical and pharmaceutical advice. Therefore, Pharma Deutschland strongly supports the statutory protection of the owner-operated pharmacy as primary institution for distribution. Member companies of Pharma Deutschland use various products containing ethanol in different concentrations as ethanol-based hand rubs (EBHRs) and surface disinfectants. Applications are in manufacturing, research and laboratory areas for medicinal products, medical devices, food supplements, dietetics, cosmetics, biocides and in hygiene and social areas for employees. Also, it is known for its safe use in various products with direct exposure to the human skin (e.g. medicinal products like hand disinfectants in occupational settings, cosmetics like hairsprays or mouthwashes, pharmaceutical preparations, and many household products). Due to its strong germicidal properties, ethanol is an important key in the prevention of infections. Ethanol is uniquely virucidal and highly effective against non-enveloped viruses, including polioviruses. It is also one of the few alcohols that demonstrate efficacy

against noroviruses. Ethanol is widely used in disinfectants and is important in the production of medicinal products and medical devices, food supplements, dietetics, cosmetics, biocides. It serves as an extractant, solvent, preservative, process and cleaning agent and in laboratory analysis. In this context, we would like to refer you to the publication of VAH (Verbund für Angewandte Hygiene e.V.) entitled 'Ethanol is indispensable as a biocidal agent for hygienic hand disinfection'. In particular, Table 1 highlights the effectiveness of ethanol, 2-propanol, and 1-propanol solutions from suspension tests against various non-enveloped viruses. This clearly shows the superiority of ethanol in terms of efficacy against non-enveloped viruses. [1], [2]. Ethanol is also included in the WHO list of essential medicines (eEML - Electronic Essential Medicines List). This inclusion underscores ethanol's crucial role in healthcare worldwide, highlighting its effectiveness and safety in various medical applications. As mentioned by Kramer et. al in Medical associations and expert committees urge that ethanol be approved as a virucidal active substance for use in hand antiseptics under the European Biocidal Products Regulation, without a CMR classification - PubMed [3]. Currently, there is no epidemiological evidence indicating ethanol toxicity in workers who handle ethanol-containing products in the healthcare sector. It is important to note that ethanol is absorbed through the skin only to a very limited extent and is inhaled in minimal quantities [3, 4]. Therefore, we recommend taking the route of exposure into account when determining the classification. There are several hundred ethanol manufacturers within the European Union. It is important to note that ethanol can be produced using relatively simple manufacturing processes, which becomes crucial during situations such as pandemic crises. For instance, during the COVID-19 crisis, it was possible to supply public health services with significant quantities of ethanol-based hand rubs (EBHR) to mitigate the risk of virus transmission. From an ecological perspective, a significant advantage of ethanol in various applications is its complete biodegradability. Additionally, ethanol can be effortlessly removed from extracts through distillation, allowing to produce nearly ethanol-free liquid extracts. These two attributes are unique to ethanol. Ethanol: Substance Information - ECHA <https://echa.europa.eu/de/substance-information/-/substanceinfo/100.000.526> EC / List no.: 200-578-6 CAS no.: 64-17-5 Mol. formula: C₂H₆O Material Safety Data Sheet: Ethanol 100% 01_0-000064-17-5-000000_1_1_51.PDF Propan-2-ol - Substance Information - ECHA <https://www.echa.europa.eu/de/substance->

	information/-/substanceinfo/100.000.601 EC / List no.: 200-661-7 CAS no.: 67-63-0 Mol. formula: C₃H₈O Material Safety Data Sheet: Isopropanol https://www.gischem.de/download/01_0-000067-63-0-000000_1_1_88.PDF Propan-1-ol - Substance Information - ECHA https://www.echa.europa.eu/de/substance-information/-/substanceinfo/100.000.679 EC / List no.: 200-746-9 CAS no.: 71-23-8 Mol. formula: C₃H₈O Material Safety Data Sheet: 1-Propanol 01_0-000071-23-8-000000_1_1_104.PDF The current occupational exposure limit (OEL) specified in TRGS 900 and set by the MAK (Maximum Allowable Concentration) Commission is 380 mg/m³. Adhering to this limit ensures that employees are not exposed to any acute or chronic health risks. A thorough assessment of the workplace environment must be conducted to verify compliance. [1] VAH e.V. Ethanol ist als biozider Wirkstoff zur hygienischen Händedesinfektion unverzichtbar, VAH_Ethanol_HM_11_20_194_200.pdf, in Hygiene & Medizin, Volume 45, 11/2020) [2] Persistence of coronaviruses on inanimate surfaces and their inactivation with biocidal agents G. Kampf a, *, D. Todt b, S. Pfaender b, E. Steinmann b. , G. Kampf et al. / Journal of Hospital Infection 104 (2020) 246e251, DOI: 10.1016/j.jhin.2020.01.022; https://www.journalofhospitalinfection.com/article/S0195-6701(20)30046-3/fulltext [3] Kramer A, Pittet D, Exner M, Wendt C. Medical associations and expert committees urge that ethanol be approved as a virucidal active substance for use in hand antiseptics under the European Biocidal Products Regulation, without a CMR classification. GMS Hyg Infect Control. 2024 Aug 21;19:Doc40. doi: 10.3205/dgkh000495. PMID: 39224501; PMCID: PMC11367556. [4] Ethanol is indispensable for virucidal hand antisepsis and without toxic risks in daily use. GMS Hyg Infect Control, Axel Kramer, Hicham Benkhail, Christian Jäkel, Paula Zwicker 1 2023, Jan 23:18:Doc02. doi: 10.3205/dgkh000428. eCollection 2023. https://pmc.ncbi.nlm.nih.gov/articles/PMC9978451/
Product Type	1,2,4
Alternative Identity and Properties	To our knowledge and as mentioned before there are no alternatives for the replacement of ethanol as disinfectant. Ethanol is an important key in the prevention of infections, due to: • Strong germicidal properties, • uniquely virucidal, • highly effective against non-enveloped viruses, including polioviruses, • efficacy against noroviruses, • its availability (several hundred ethanol manufacturers within the European Union), •

	evaporates totally, • neglectable skin-irritating properties [4]. • dry without toxic residues. Common substances for disinfection purposes aren't an alternative as mentioned below, because only ethanol fulfils all of the above-mentioned criteria. Possible Substances for disinfection purposes: Propan-1-ol & Propan-2-ol • not fully virucidal efficient • not readily available in sufficient quantities • higher risk of accidental poisoning • sustainable production is limited Iodine • Endocrine Disruptor for human and environment • not readily available in sufficient quantities • no fast enough for efficacy • residue formation • DBP (Di-Butyl Phthalate) – formation • need for water for rinsing or drying with towel • low stability. Peracetic acid • corrosive • longevity not sufficient • reactivity with other chemicals in product formulations • higher safety standards for workers and higher storage standards • higher risk of accidental poisoning • low stability NaOCl • DBP-formation • no evaporation • longevity not sufficient • corrosive • reactivity with other chemicals in product formulations • higher risk of accidental poisoning • low stability. CHDG & QAC • no full virucidal activity • residues • no fast efficacy action • low activity Gram-negative bacteria, Fungi, Mycobacteria, non-enveloped viruses • cationic structure, they may cause inactivation or precipitation with anionic chemicals like soaps/ detergents • need for water for rinsing or drying with towel. Monochloramine • DBP formation, only in situ generation, not storable. • need for water for rinsing or drying with towel Chlorocresol • skin sensitizer • Phenol as degradation product: • Higher risk of accidental poisoning • https://echa.europa.eu/documents/10162/de108693-1d4f-abfe-818e-9cea812ab4c2 : Mutagenicity: Concern unresolved; restriction proposed (p. 9). Low activity to <i>Pseudomonas aeruginosa</i>. Need for water for rinsing or drying with towel. H2O2 • Micro lesions on skin • no fast efficacy action • no evaporation, longevity not sufficient, corrosive, not efficacious at low concentrations and ambient temperatures. Higher safety standards for workers and higher storage standards. Higher risk of accidental poisoning. Low stability. Lactic Acid • not full virucidal • odor formation • low stability. Phenoxyethanol • not full virucidal • higher risk of accidental poisoning • known to cause allergic-type reactions on the skin • need for water for rinsing or drying with towel.

Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Not applicable - as mentioned before there are no alternatives for the replacement of ethanol as disinfectant.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Not applicable - as mentioned before there are no alternatives for the replacement of ethanol as disinfectant. Furthermore, it would have a significant impact on public health systems. Ethanol can be produced synthetically via direct or indirect ethylene hydration (e.g., petroleum-derived ethanol) as well as by fermentation of biomass. Ethanol is a renewable active material because it is produced from biomass. As during the pandemic crisis successfully experienced, ethanol was despite global shortages of hand rubs available, because it can easily be produced locally. As for example medicinal product manufacturer, beverage distilleries and industrial ethanol plants provided big amounts of ethanol for the production of EBHR during Covid -19 pandemic. From an ecological perspective, a significant advantage of ethanol in various applications is its complete biodegradability.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Not applicable - as mentioned before there are no alternatives, that have a more favourable safety profile and the same efficacy for the replacement of ethanol as disinfectant.
Information above is confidential	
Justification for confidentiality	
Availability	Not applicable - as mentioned before, there are no alternatives in sufficient amounts currently available for the replacement of ethanol as disinfectant. Currently, there are several hundred manufacturers producing ethanol, whereas the number of isopropanol manufacturers remains very

	limited. Additionally, ethanol is the only disinfectant that can be derived from renewable resources, requiring no petrochemical processes for its production. From an ecological standpoint, ethanol offers a significant advantage due to its complete biodegradability across all aforementioned applications. Beyond its environmentally friendly nature, ethanol can be easily removed from extracts through distillation, allowing for the production of nearly ethanol-free liquid extracts—both of which are unique properties of ethanol. Ethanol can be produced synthetically via direct or indirect ethylene hydration (e.g., petroleum-derived ethanol) as well as by fermentation of biomass. Ethanol is a renewable active material because it is produced from biomass and unlimited available (e.g. potential capacities from biofuel production) on short notice in times of crisis. As during the pandemic crisis successfully experienced, ethanol was despite global shortages of hand rubs available, because it can easily be produced locally. As for example medicinal product manufacturer, beverage distilleries and industrial ethanol plants provided big amounts of ethanol for the production of EBHR during Covid-19 pandemia.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	If ethanol is classified as a CMR substance, it will no longer be available for use by the general public, effectively amounting to a full ban. Such a ban would have severe consequences, especially during outbreaks and pandemics involving non-enveloped viruses. There is currently no alternative biocidal active substance that offers the same efficacy against non-enveloped viruses. A lack of approval would result in a shortage of sufficient equivalent substitutes. In the event of an outbreak caused by a non-enveloped virus, ethanol remains indispensable for effective disease control. Classifying ethanol as a CMR substance will also have a negative impact on the subsequent classification in the context of CLH-evaluation (CLP Regulation) and therefore also on the use of ethanol in the manufacture of medicinal products, medical devices, food supplements, dietetics, cosmetics. If ethanol would be classified as a category 1 CMR substance, this would have far-reaching consequences for the manufacture of medicinal products, medical devices, food supplements, dietetics, and cosmetics due to the associated health and safety concerns: Disinfectants containing ethanol could no longer be used

	broadly, Pregnant and breastfeeding women and young adults would no longer be able to work in the manufacture of medicinal products, medical devices food supplements, dietetics, and cosmetics, Tremendous additional measures in connection with occupational health and safety that would have to be observed or applied, e.g. substitution as well as technical, organisational, and personal measures. This would jeopardise availability of medicinal products, medical devices food supplements, dietetics, and cosmetics patient care in the European Union. Given these factors, we strongly recommend maintaining the current classification of ethanol, which already provide adequate public health protection.
Information above is confidential	
Justification for confidentiality	
Other comments	Ethanol is indispensable in the healthcare sector, particularly in disinfectants, the use of medical devices, and the manufacturing of pharmaceuticals. Its antimicrobial properties are highly effective against bacteria and viruses, especially against the more virulent non-enveloped viruses (e.g. poliovirus and rotavirus) and play a crucial role in reducing nosocomial infections. Throughout the Covid-19 pandemic, ethanol played a crucial role in swiftly and effectively interrupting infection chains. The high demand for disinfectants was successfully met due to the widespread availability of ethanol. As a candidate for substitution ethanol will no longer be available for use by the general public. The discussed classification is de facto equivalent with a full ban. The implications of an ethanol ban will be significantly serious. During outbreaks and pandemics involving non-enveloped viruses, the absence of disinfectant hand rubs that contain this effective and well-tolerated active ingredient will compromise the safety of patients, nursing home residents, staff, and the general public. There is no substitute biocidal active substance with equal efficacy against non-enveloped viruses. In case of non-approval shortage of sufficient equivalent alternatives needs to be considered as it is impossible to fight against non-enveloped viruses in case of an outbreak without ethanol. Further, switching to alternatives will require an increase of production capacities associated with tremendous costs and effort (new facilities, new technologies, new production permits and hurdles from authorities and NGOs).

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Justification for confidentiality	
References	[1] VAH e.V. Ethanol ist als biozider Wirkstoff zur hygienischen Händedesinfektion unverzichtbar, VAH_Ethanol_HM_11_20_194_200.pdf, in Hygiene & Medizin, Volume 45, 11/2020) [2] Persistence of coronaviruses on inanimate surfaces and their inactivation with biocidal agents G. Kampf a, *, D. Todt b, S. Pfaender b, E. Steinmann b. , G. Kampf et al. / Journal of Hospital Infection 104 (2020) 246e251, DOI: 10.1016/j.jhin.2020.01.022; https://www.journalofhospitalinfection.com/article/S0195-6701(20)30046-3/fulltext [3] Kramer A, Pittet D, Exner M, Wendt C. Medical associations and expert committees urge that ethanol be approved as a virucidal active substance for use in hand antiseptics under the European Biocidal Products Regulation, without a CMR classification. GMS Hyg Infect Control. 2024 Aug 21;19:Doc40. doi: 10.3205/dgkh000495. PMID: 39224501; PMCID: PMC11367556. [4] Ethanol is indispensable for virucidal hand antisepsis and without toxic risks in daily use. GMS Hyg Infect Control, Axel Kramer, Hicham Benkhail, Christian Jäkel, Paula Zwicker 1 2023, Jan 23:18:Doc02. doi: 10.3205/dgkh000428. eCollection 2023. https://pmc.ncbi.nlm.nih.gov/articles/PMC9978451/
Attachments (non-confidential information)	ECHA EtOH_Konsultation_final_BPR.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 199	2025/04/28 14:38
Country	Germany
Name of organization/institution	Pharma Deutschland e.V.
I do not wish the name of my organisation/institution to be	

published on the ECHA website.	
General information	Pharma Deutschland is a full-service association of pharmaceutical companies in Germany. Besides medicines manufacturers, the membership is also comprised of pharmacists, lawyers, publishing houses and agencies, as well as market research and opinion research institutions. Pharma Deutschland member companies contribute enormously to the securing of the supply of medicines in Germany. For example, they produce nearly 80 per cent of the prescription-free medicines sold in pharmacies and almost two thirds of the prescription medicines as well as a major part of the substance-based medical devices, providing patients with products that are both effective and safe. Pharma Deutschland advocates for secure and responsible self-medication through professional medical and pharmaceutical advice. Therefore, Pharma Deutschland strongly supports the statutory protection of the owner-operated pharmacy as primary institution for distribution. Member companies of Pharma Deutschland use various products containing ethanol in different concentrations as ethanol-based hand rubs (EBHRs) and surface disinfectants. Applications are in manufacturing, research and laboratory areas for medicinal products, medical devices, food supplements, dietetics, cosmetics, biocides and in hygiene and social areas for employees. Also, it is known for its safe use in various products with direct exposure to the human skin (e.g. medicinal products like hand disinfectants in occupational settings, cosmetics like hairsprays or mouthwashes, pharmaceutical preparations, and many household products). Due to its strong germicidal properties, ethanol is an important key in the prevention of infections. Ethanol is uniquely virucidal and highly effective against non-enveloped viruses, including polioviruses. It is also one of the few alcohols that demonstrate efficacy against noroviruses. Ethanol is widely used in disinfectants and is important in the production of medicinal products and medical devices, food supplements, dietetics, cosmetics, biocides. It serves as an extractant, solvent, preservative, process and cleaning agent and in laboratory analysis. In this context, we would like to refer you to the publication of VAH (Verbund für Angewandte Hygiene e.V.) entitled 'Ethanol is indispensable as a biocidal agent for hygienic hand disinfection'. In particular, Table 1 highlights the effectiveness of ethanol, 2-propanol, and 1-propanol solutions from suspension tests against various non-enveloped viruses. This clearly shows the superiority of ethanol in terms of efficacy against non-enveloped viruses.

[1], [2]. Ethanol is also included in the WHO list of essential medicines (eEML - Electronic Essential Medicines List). This inclusion underscores ethanol's crucial role in healthcare worldwide, highlighting its effectiveness and safety in various medical applications. As mentioned by Kramer et. al in Medical associations and expert committees urge that ethanol be approved as a virucidal active substance for use in hand antiseptics under the European Biocidal Products Regulation, without a CMR classification - PubMed [3]. Currently, there is no epidemiological evidence indicating ethanol toxicity in workers who handle ethanol-containing products in the healthcare sector. It is important to note that ethanol is absorbed through the skin only to a very limited extent and is inhaled in minimal quantities [3, 4]. Therefore, we recommend taking the route of exposure into account when determining the classification. There are several hundred ethanol manufacturers within the European Union. It is important to note that ethanol can be produced using relatively simple manufacturing processes, which becomes crucial during situations such as pandemic crises. For instance, during the COVID-19 crisis, it was possible to supply public health services with significant quantities of ethanol-based hand rubs (EBHR) to mitigate the risk of virus transmission. From an ecological perspective, a significant advantage of ethanol in various applications is its complete biodegradability. Additionally, ethanol can be effortlessly removed from extracts through distillation, allowing to produce nearly ethanol-free liquid extracts. These two attributes are unique to ethanol. Ethanol: Substance Information - ECHA
<https://echa.europa.eu/de/substance-information/-/substanceinfo/100.000.526> EC / List no.: 200-578-6 CAS no.: 64-17-5 Mol. formula: C₂H₆O Material Safety Data Sheet: Ethanol 100% 01_0-000064-17-5-000000_1_1_51.PDF Propan-2-ol - Substance Information - ECHA <https://www.echa.europa.eu/de/substance-information/-/substanceinfo/100.000.601> EC / List no.: 200-661-7 CAS no.: 67-63-0 Mol. formula: C₃H₈O Material Safety Data Sheet: Isopropanol https://www.gischem.de/download/01_0-000067-63-0-000000_1_1_88.PDF Propan-1-ol - Substance Information - ECHA <https://www.echa.europa.eu/de/substance-information/-/substanceinfo/100.000.679> EC / List no.: 200-746-9 CAS no.: 71-23-8 Mol. formula: C₃H₈O Material Safety Data Sheet: 1-Propanol 01_0-000071-23-8-000000_1_1_104.PDF The current occupational exposure limit (OEL) specified in TRGS 900 and set by the MAK (Maximum Allowable Concentration) Commission is 380 mg/m³. Adhering to this limit ensures that employees are

	not exposed to any acute or chronic health risks. A thorough assessment of the workplace environment must be conducted to verify compliance. [1] VAH e.V. Ethanol ist als biozider Wirkstoff zur hygienischen Händedesinfektion unverzichtbar, VAH_Ethanol_HM_11_20_194_200.pdf, in Hygiene & Medizin, Volume 45, 11/2020) [2] Persistence of coronaviruses on inanimate surfaces and their inactivation with biocidal agents G. Kampf a, *, D. Todt b, S. Pfaender b, E. Steinmann b. , G. Kampf et al. / Journal of Hospital Infection 104 (2020) 246e251, DOI: 10.1016/j.jhin.2020.01.022; https://www.journalofhospitalinfection.com/article/S0195-6701(20)30046-3/fulltext [3] Kramer A, Pittet D, Exner M, Wendt C. Medical associations and expert committees urge that ethanol be approved as a virucidal active substance for use in hand antiseptics under the European Biocidal Products Regulation, without a CMR classification. GMS Hyg Infect Control. 2024 Aug 21;19:Doc40. doi: 10.3205/dgkh000495. PMID: 39224501; PMCID: PMC11367556. [4] Ethanol is indispensable for virucidal hand antisepsis and without toxic risks in daily use. GMS Hyg Infect Control, Axel Kramer, Hicham Benkhail, Christian Jäkel, Paula Zwicker 1 2023, Jan 23:18:Doc02. doi: 10.3205/dgkh000428. eCollection 2023. https://pmc.ncbi.nlm.nih.gov/articles/PMC9978451/
Product Type	1,2,4
Alternative Identity and Properties	To our knowledge and as mentioned before there are no alternatives for the replacement of ethanol as disinfectant. Ethanol is an important key in the prevention of infections, due to: • Strong germicidal properties, • uniquely virucidal, • highly effective against non-enveloped viruses, including polioviruses, • efficacy against noroviruses, • its availability (several hundred ethanol manufacturers within the European Union), • evaporates totally, • neglectable skin-irritating properties [4]. • dry without toxic residues. Common substances for disinfection purposes aren't an alternative as mentioned below, because only ethanol fulfils all of the above-mentioned criteria. Possible Substances for disinfection purposes Propan-1-ol & Propan-2-ol • not fully virucidal efficient • not readily available in sufficient quantities • higher risk of accidental poisoning • sustainable production is limited Iodine • Endocrine Disruptor for human and environment • not readily available in sufficient quantities • no fast enough for efficacy • residue formation • DBP (Di-Butyl Phthalate) – formation • need for water for

	rinsing or drying with towel • low stability. Peracetic acid • corrosive • longevity not sufficient • reactivity with other chemicals in product formulations • higher safety standards for workers and higher storage standards • higher risk of accidental poisoning • low stability NaOCl • DBP-formation • no evaporation • longevity not sufficient • corrosive • reactivity with other chemicals in product formulations • higher risk of accidental poisoning • low stability. CHDG & QAC • no full virucidal activity • residues • no fast efficacy action • low activity Gram-negative bacteria, Fungi, Mycobacteria, non-enveloped viruses • cationic structure, they may cause inactivation or precipitation with anionic chemicals like soaps/ detergents • need for water for rinsing or drying with towel. Monochloramine • DBP formation, only in situ generation, not storable. • need for water for rinsing or drying with towel Chlorocresol • skin sensitizer • Phenol as degradation product: • Higher risk of accidental poisoning • https://echa.europa.eu/documents/10162/de108693-1d4f-abfe-818e-9cea812ab4c2 : Mutagenicity: Concern unresolved; restriction proposed (p. 9). Low activity to Pseudomonas aeruginosa. Need for water for rinsing or drying with towel. H2O2 • Micro lesions on skin • no fast efficacy action • no evaporation, longevity not sufficient, corrosive, not efficacious at low concentrations and ambient temperatures. Higher safety standards for workers and higher storage standards. Higher risk of accidental poisoning. Low stability. Lactic Acid • not full virucidal • odor formation • low stability. Phenoxyethanol • not full virucidal • higher risk of accidental poisoning • known to cause allergic-type reactions on the skin • need for water for rinsing or drying with towel.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Not applicable - as mentioned before there are no alternatives for the replacement of ethanol as disinfectant.
Information above is confidential	
Justification for confidentiality	

Economic Feasibility	Not applicable - as mentioned before there are no alternatives for the replacement of ethanol as disinfectant. Furthermore, it would have a significant impact on public health systems. Ethanol can be produced synthetically via direct or indirect ethylene hydration (e.g., petroleum-derived ethanol) as well as by fermentation of biomass. Ethanol is a renewable active material because it is produced from biomass. As during the pandemic crisis successfully experienced, ethanol was despite global shortages of hand rubs available, because it can easily be produced locally. As for example medicinal product manufacturer, beverage distilleries and industrial ethanol plants provided big amounts of ethanol for the production of EBHR during Covid -19 pandemia. From an ecological perspective, a significant advantage of ethanol in various applications is its complete biodegradability.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Not applicable - as mentioned before there are no alternatives, that have a more favourable safety profile and the same efficacy for the replacement of ethanol as disinfectant.
Information above is confidential	
Justification for confidentiality	
Availability	Not applicable - as mentioned before, there are no alternatives in sufficient amounts currently available for the replacement of ethanol as disinfectant. Currently, there are several hundred manufacturers producing ethanol, whereas the number of isopropanol manufacturers remains very limited. Additionally, ethanol is the only disinfectant that can be derived from renewable resources, requiring no petrochemical processes for its production. From an ecological standpoint, ethanol offers a significant advantage due to its complete biodegradability across all aforementioned applications. Beyond its environmentally friendly nature, ethanol can be easily removed from extracts through distillation, allowing for the production of nearly ethanol-free liquid extracts—both of which are unique properties of ethanol. Ethanol can be produced synthetically via direct or indirect ethylene hydration (e.g., petroleum-derived ethanol) as well as by fermentation of biomass. Ethanol is a renewable active material because it

	is produced from biomass and unlimited available (e.g. potential capacities from biofuel production) on short notice in times of crisis. As during the pandemic crisis successfully experienced, ethanol was despite global shortages of hand rubs available, because it can easily be produced locally. As for example medicinal product manufacturer, beverage distilleries and industrial ethanol plants provided big amounts of ethanol for the production of EBHR during Covid-19 pandemia.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	If ethanol is classified as a CMR substance, it will no longer be available for use by the general public, effectively amounting to a full ban. Such a ban would have severe consequences, especially during outbreaks and pandemics involving non-enveloped viruses. There is currently no alternative biocidal active substance that offers the same efficacy against non-enveloped viruses. A lack of approval would result in a shortage of sufficient equivalent substitutes. In the event of an outbreak caused by a non-enveloped virus, ethanol remains indispensable for effective disease control. Classifying ethanol as a CMR substance will also have a negative impact on the subsequent classification in the context of CLH-evaluation (CLP Regulation) and therefore also on the use of ethanol in the manufacture of medicinal products, medical devices, food supplements, dietetics, cosmetics. If ethanol would be classified as a category 1 CMR substance, this would have far-reaching consequences for the manufacture of medicinal products, medical devices, food supplements, dietetics, and cosmetics due to the associated health and safety concerns: Disinfectants containing ethanol could no longer be used broadly, Pregnant and breastfeeding women and young adults would no longer be able to work in the manufacture of medicinal products, medical devices food supplements, dietetics, and cosmetics, Tremendous additional measures in connection with occupational health and safety that would have to be observed or applied, e.g. substitution as well as technical, organisational, and personal measures. This would jeopardise availability of medicinal products, medical devices food supplements, dietetics, and cosmetics patient care in the European Union. Given these factors, we strongly recommend maintaining the current classification of ethanol, which already provide adequate public health protection.

Information above is confidential	
Justification for confidentiality	
Other comments	Ethanol is indispensable in the healthcare sector, particularly in disinfectants, the use of medical devices, and the manufacturing of pharmaceuticals. Its antimicrobial properties are highly effective against bacteria and viruses, especially against the more virulent non-enveloped viruses (e.g. poliovirus and rotavirus) and play a crucial role in reducing nosocomial infections. Throughout the Covid-19 pandemic, ethanol played a crucial role in swiftly and effectively interrupting infection chains. The high demand for disinfectants was successfully met due to the widespread availability of ethanol. As a candidate for substitution ethanol will no longer be available for use by the general public. The discussed classification is de facto equivalent with a full ban. The implications of an ethanol ban will be significantly serious. During outbreaks and pandemics involving non-enveloped viruses, the absence of disinfectant hand rubs that contain this effective and well-tolerated active ingredient will compromise the safety of patients, nursing home residents, staff, and the general public. There is no substitute biocidal active substance with equal efficacy against non-enveloped viruses. In case of non-approval shortage of sufficient equivalent alternatives needs to be considered as it is impossible to fight against non-enveloped viruses in case of an outbreak without ethanol. Further, switching to alternatives will require an increase of production capacities associated with tremendous costs and effort (new facilities, new technologies, new production permits and hurdles from authorities and NGOs).
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Justification for confidentiality	
References	[1] VAH e.V. Ethanol ist als biozider Wirkstoff zur hygienischen Händedesinfektion unverzichtbar, VAH_Ethanol_HM_11_20_194_200.pdf, in Hygiene & Medizin, Volume 45, 11/2020) [2] Persistence of coronaviruses on inanimate surfaces and their inactivation with biocidal agents G. Kampf a, *, D. Todt b, S. Pfaender b, E. Steinmann b. , G. Kampf et al. / Journal of Hospital Infection 104 (2020) 246e251, DOI: 10.1016/j.jhin.2020.01.022; https://www.journalofhospitalinfection.com/article/S0195-6701(20)30046-3/fulltext [3] Kramer A, Pittet D,

	Exner M, Wendt C. Medical associations and expert committees urge that ethanol be approved as a virucidal active substance for use in hand antiseptics under the European Biocidal Products Regulation, without a CMR classification. GMS Hyg Infect Control. 2024 Aug 21;19:Doc40. doi: 10.3205/dgkh000495. PMID: 39224501; PMCID: PMC11367556. [4] Ethanol is indispensable for virucidal hand antisepsis and without toxic risks in daily use. GMS Hyg Infect Control, Axel Kramer, Hicham Benkhail, Christian Jäkel, Paula Zwicker 1 2023, Jan 23:18:Doc02. doi: 10.3205/dgkh000428. eCollection 2023. https://pmc.ncbi.nlm.nih.gov/articles/PMC9978451/
Attachments (non-confidential information)	ECHA EtOH_Konsultation_final_BPR.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 200	2025/04/28 14:44
Country	Finland
Name of organization/institution	Hydzone Oy
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	This submission is provided to support the substitution of hazardous chemical disinfectants with a safer, sustainable alternative offered by Hydzone Oy, a provider of ozone-based disinfection technology. As a stakeholder advocating for environmentally friendly solutions, the submitter seeks to contribute to the ECHA consultation by presenting Hydzone Oy's ozone technology, which generates ozone on-site for disinfecting water, surfaces, and air across sectors like healthcare, food processing, and water treatment. The technology, implemented through CE-marked devices, aligns with REACH objectives by reducing health and environmental risks associated with chemical disinfectants. Further details on Hydzone Oy's solutions are available in Finnish at https://hydzone.com , and this submission aims to

	demonstrate the feasibility, safety, and availability of this alternative.
Product Type	1,2,4
Alternative Identity and Properties	Hydzone Oy's ozone-based disinfection technology generates ozone on-site using electrical energy to disinfect water, surfaces, and air in applications spanning healthcare, food processing, and hospitality. This chemical-free solution employs ozone, a potent oxidizing agent, which decomposes into oxygen after use, leaving no harmful residues. The technology, implemented through Hydzone Oy's devices like the Hydzonator and Hydzone WDS, delivers broad-spectrum antimicrobial action against bacteria, viruses, fungi, and spores. With CE-marked compliance to European standards, the solution ensures reliability and environmental sustainability, eliminating the need for chemical storage and reducing ecological im
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Technical Feasibility	Hydzone Oy's ozone-based disinfection technology demonstrates robust technical feasibility for replacing chemical disinfectants across diverse sectors, including healthcare, agriculture, and water treatment. The technology, powered by Hydzone Oy's devices, generates ozone at concentrations of 0.05 to 2.0 ppm, ensuring effective pathogen elimination without fostering microbial resistance. Scalable from portable units for small-scale use to industrial systems for large facilities, the solution integrates seamlessly with minimal infrastructure changes, relying solely on electricity. While a stable power supply and trained operators may be required for industrial applications, compliance with international standards like ISO and CE guarantees consistent performance.
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Justification for confidentiality	
Economic Feasibility	Hydzone Oy's ozone-based disinfection technology offers economic viability despite higher initial costs for device acquisition compared to chemical disinfectants. By generating ozonated water on-site, Hydzone Oy's devices eliminate expenses related to purchasing, transporting, and storing chemicals. The absence of chemical residues reduces

	waste management costs, and the durability of Hydzone Oy's devices minimizes maintenance expenses. Long-term savings are particularly significant in high-usage settings like water treatment plants and hospitals, where reduced reliance on chemical supplies enhances cost-effectiveness, making the technology a financially sound alternative.
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Hazards and Risks of the Alternative	Hydzone Oy's ozone-based disinfection technology presents minimal hazards and risks compared to chemical disinfectants. Ozone, generated at controlled concentrations of 0.05 to 2.0 ppm by Hydzone Oy's devices, decomposes into oxygen and water post-use, leaving no toxic residues or environmental pollutants. Built-in safety features and adherence to occupational exposure limits, such as EU guidelines, mitigate overexposure risks. Operational risks, including equipment malfunction, are low with proper maintenance and operator training. By eliminating chemical exposure, the technology significantly reduces health and environmental risks, aligning with REACH safety objectives.
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Availability	Hydzone Oy's ozone-based disinfection technology stands as a highly suitable and readily available alternative to hazardous chemical disinfectants. The solution, delivered through Hydzone Oy's devices, offers proven technical feasibility across healthcare, food processing, and water treatment, with scalable systems ensuring broad applicability. Economically, it provides long-term savings by eliminating chemical-related costs, despite initial investment. The technology minimizes health and environmental risks, as ozone leaves no harmful residues. Commercially available through Hydzone Oy, the solution aligns with ECHA's sustainability goals under REACH, offering a safe, effective, and eco-friendly replacement for hazardous disinfectants. Further details are accessible at https://hydzone.com .
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Conclusion on suitability and availability of the alternative	Hydzone Oy's ozone-based disinfection technology stands as a highly suitable and readily available alternative to hazardous chemical disinfectants. The solution, delivered through Hydzone Oy's devices, offers proven technical feasibility across healthcare, food processing, and water treatment, with scalable systems ensuring broad applicability. Economically, it provides long-term savings by eliminating chemical-related costs, despite initial investment. The technology minimizes health and environmental risks, as ozone leaves no harmful residues. Commercially available through Hydzone Oy, the solution aligns with ECHA's sustainability goals under REACH, offering a safe, effective, and eco-friendly replacement for hazardous disinfectants. Further details are accessible at https://hydzone.com .
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Other comments	
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Comment 201	2025/04/28 14:46
Country	Germany
Name of organization/institution	Pharma Deutschland e.V.
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published on the ECHA website.	
General information	Pharma Deutschland is a full-service association of pharmaceutical companies in Germany. Besides medicines manufacturers, the membership is also comprised of pharmacists, lawyers, publishing houses and agencies, as well as market research and opinion research institutions. Pharma Deutschland member companies contribute enormously to the securing of the supply of medicines in Germany. For example, they produce nearly 80 per cent of the prescription-free medicines sold in pharmacies and almost two thirds of the prescription medicines as well as a major part of the substance-based medical devices, providing patients with products that are both effective and safe. Pharma Deutschland advocates for secure and responsible self-medication through professional medical and pharmaceutical advice. Therefore, Pharma Deutschland strongly supports the statutory protection of the owner-operated pharmacy as primary institution for distribution. Member companies of Pharma Deutschland use various products containing ethanol in different concentrations as ethanol-based hand rubs (EBHRs) and surface disinfectants. Applications are in manufacturing, research and laboratory areas for medicinal products, medical devices, food supplements, dietetics, cosmetics, biocides and in hygiene and social areas for employees. Also, it is known for its safe use in various products with direct exposure to the human skin (e.g. medicinal products like hand disinfectants in occupational settings, cosmetics like hairsprays or mouthwashes, pharmaceutical preparations, and many household products). Due to its strong germicidal properties, ethanol is an important key in the prevention of infections. Ethanol is uniquely virucidal and highly effective against non-enveloped viruses, including polioviruses. It is also one of the few alcohols that demonstrate efficacy against noroviruses. Ethanol is widely used in disinfectants and is important in the production of medicinal products and medical devices, food supplements, dietetics, cosmetics, biocides. It serves as an extractant, solvent, preservative, process and cleaning agent and in laboratory analysis. In this context, we would like to refer you to the publication of VAH (Verbund für Angewandte Hygiene e.V.) entitled 'Ethanol is indispensable as a biocidal agent for hygienic hand disinfection'. In particular, Table 1 highlights the effectiveness of ethanol, 2-propanol, and 1-propanol solutions from suspension tests against various non-enveloped viruses. This clearly shows the superiority of ethanol in terms of efficacy against non-enveloped viruses.

[1], [2]. Ethanol is also included in the WHO list of essential medicines (eEML - Electronic Essential Medicines List). This inclusion underscores ethanol's crucial role in healthcare worldwide, highlighting its effectiveness and safety in various medical applications. As mentioned by Kramer et. al in Medical associations and expert committees urge that ethanol be approved as a virucidal active substance for use in hand antiseptics under the European Biocidal Products Regulation, without a CMR classification - PubMed [3]. Currently, there is no epidemiological evidence indicating ethanol toxicity in workers who handle ethanol-containing products in the healthcare sector. It is important to note that ethanol is absorbed through the skin only to a very limited extent and is inhaled in minimal quantities [3, 4]. Therefore, we recommend taking the route of exposure into account when determining the classification. There are several hundred ethanol manufacturers within the European Union. It is important to note that ethanol can be produced using relatively simple manufacturing processes, which becomes crucial during situations such as pandemic crises. For instance, during the COVID-19 crisis, it was possible to supply public health services with significant quantities of ethanol-based hand rubs (EBHR) to mitigate the risk of virus transmission. From an ecological perspective, a significant advantage of ethanol in various applications is its complete biodegradability. Additionally, ethanol can be effortlessly removed from extracts through distillation, allowing to produce nearly ethanol-free liquid extracts. These two attributes are unique to ethanol. Ethanol: Substance Information - ECHA
<https://echa.europa.eu/de/substance-information/-/substanceinfo/100.000.526> EC / List no.: 200-578-6 CAS no.: 64-17-5 Mol. formula: C₂H₆O Material Safety Data Sheet: Ethanol 100% 01_0-000064-17-5-000000_1_1_51.PDF Propan-2-ol - Substance Information - ECHA <https://www.echa.europa.eu/de/substance-information/-/substanceinfo/100.000.601> EC / List no.: 200-661-7 CAS no.: 67-63-0 Mol. formula: C₃H₈O Material Safety Data Sheet: Isopropanol https://www.gischem.de/download/01_0-000067-63-0-000000_1_1_88.PDF Propan-1-ol - Substance Information - ECHA <https://www.echa.europa.eu/de/substance-information/-/substanceinfo/100.000.679> EC / List no.: 200-746-9 CAS no.: 71-23-8 Mol. formula: C₃H₈O Material Safety Data Sheet: 1-Propanol 01_0-000071-23-8-000000_1_1_104.PDF The current occupational exposure limit (OEL) specified in TRGS 900 and set by the MAK (Maximum Allowable Concentration) Commission is 380 mg/m³. Adhering to this limit ensures that employees are

	not exposed to any acute or chronic health risks. A thorough assessment of the workplace environment must be conducted to verify compliance. [1] VAH e.V. Ethanol ist als biozider Wirkstoff zur hygienischen Händedesinfektion unverzichtbar, VAH_Ethanol_HM_11_20_194_200.pdf, in Hygiene & Medizin, Volume 45, 11/2020) [2] Persistence of coronaviruses on inanimate surfaces and their inactivation with biocidal agents G. Kampf a, *, D. Todt b, S. Pfaender b, E. Steinmann b. , G. Kampf et al. / Journal of Hospital Infection 104 (2020) 246e251, DOI: 10.1016/j.jhin.2020.01.022; https://www.journalofhospitalinfection.com/article/S0195-6701(20)30046-3/fulltext [3] Kramer A, Pittet D, Exner M, Wendt C. Medical associations and expert committees urge that ethanol be approved as a virucidal active substance for use in hand antiseptics under the European Biocidal Products Regulation, without a CMR classification. GMS Hyg Infect Control. 2024 Aug 21;19:Doc40. doi: 10.3205/dgkh000495. PMID: 39224501; PMCID: PMC11367556. [4] Ethanol is indispensable for virucidal hand antisepsis and without toxic risks in daily use. GMS Hyg Infect Control, Axel Kramer, Hicham Benkhail, Christian Jäkel, Paula Zwicker 1 2023, Jan 23:18:Doc02. doi: 10.3205/dgkh000428. eCollection 2023. https://pmc.ncbi.nlm.nih.gov/articles/PMC9978451/
Product Type	1,2,4
Alternative Identity and Properties	To our knowledge and as mentioned before there are no alternatives for the replacement of ethanol as disinfectant. Ethanol is an important key in the prevention of infections, due to: • Strong germicidal properties, • uniquely virucidal, • highly effective against non-enveloped viruses, including polioviruses, • efficacy against noroviruses, • its availability (several hundred ethanol manufacturers within the European Union), • evaporates totally, • neglectable skin-irritating properties [4]. • dry without toxic residues. Common substances for disinfection purposes aren't an alternative as mentioned below, because only ethanol fulfils all of the above-mentioned criteria. Possible Substances for disinfection purposes Propan-1-ol & Propan-2-ol • not fully virucidal efficient • not readily available in sufficient quantities • higher risk of accidental poisoning • sustainable production is limited Iodine • Endocrine Disruptor for human and environment • not readily available in sufficient quantities • no fast enough for efficacy • residue formation • DBP (Di-Butyl Phthalate) – formation • need for water for

	rinsing or drying with towel • low stability. Peracetic acid • corrosive • longevity not sufficient • reactivity with other chemicals in product formulations • higher safety standards for workers and higher storage standards • higher risk of accidental poisoning • low stability NaOCl • DBP-formation • no evaporation • longevity not sufficient • corrosive • reactivity with other chemicals in product formulations • higher risk of accidental poisoning • low stability. CHDG & QAC • no full virucidal activity • residues • no fast efficacy action • low activity Gram-negative bacteria, Fungi, Mycobacteria, non-enveloped viruses • cationic structure, they may cause inactivation or precipitation with anionic chemicals like soaps/ detergents • need for water for rinsing or drying with towel. Monochloramine • DBP formation, only in situ generation, not storable. • need for water for rinsing or drying with towel Chlorocresol • skin sensitizer • Phenol as degradation product: • Higher risk of accidental poisoning • https://echa.europa.eu/documents/10162/de108693-1d4f-abfe-818e-9cea812ab4c2 : Mutagenicity: Concern unresolved; restriction proposed (p. 9). Low activity to Pseudomonas aeruginosa. Need for water for rinsing or drying with towel. H2O2 • Micro lesions on skin • no fast efficacy action • no evaporation, longevity not sufficient, corrosive, not efficacious at low concentrations and ambient temperatures. Higher safety standards for workers and higher storage standards. Higher risk of accidental poisoning. Low stability. Lactic Acid • not full virucidal • odor formation • low stability. Phenoxyethanol • not full virucidal • higher risk of accidental poisoning • known to cause allergic-type reactions on the skin • need for water for rinsing or drying with towel.
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Technical Feasibility	Not applicable - as mentioned before there are no alternatives for the replacement of ethanol as disinfectant.
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Economic Feasibility	Not applicable - as mentioned before there are no alternatives for the replacement of ethanol as disinfectant. Furthermore, it would have a significant impact on public health systems. Ethanol can be produced synthetically via direct or indirect ethylene hydration (e.g., petroleum-derived ethanol) as well as by fermentation of biomass. Ethanol is a renewable active material because it is produced from biomass. As during the pandemic crisis successfully experienced, ethanol was despite global shortages of hand rubs available, because it can easily be produced locally. As for example medicinal product manufacturer, beverage distilleries and industrial ethanol plants provided big amounts of ethanol for the production of EBHR during Covid -19 pandemia. From an ecological perspective, a significant advantage of ethanol in various applications is its complete biodegradability.
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Hazards and Risks of the Alternative	Not applicable - as mentioned before there are no alternatives, that have a more favourable safety profile and the same efficacy for the replacement of ethanol as disinfectant.
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Availability	Not applicable - as mentioned before, there are no alternatives in sufficient amounts currently available for the replacement of ethanol as disinfectant. Currently, there are several hundred manufacturers producing ethanol, whereas the number of isopropanol manufacturers remains very limited. Additionally, ethanol is the only disinfectant that can be derived from renewable resources, requiring no petrochemical processes for its production. From an ecological standpoint, ethanol offers a significant advantage due to its complete biodegradability across all aforementioned applications. Beyond its environmentally friendly nature, ethanol can be easily removed from extracts through distillation, allowing for the production of nearly ethanol-free liquid extracts—both of which are unique properties of ethanol. Ethanol can be produced synthetically via direct or indirect ethylene hydration (e.g., petroleum-derived ethanol) as well as by fermentation of biomass. Ethanol is a renewable active material because it

	is produced from biomass and unlimited available (e.g. potential capacities from biofuel production) on short notice in times of crisis. As during the pandemic crisis successfully experienced, ethanol was despite global shortages of hand rubs available, because it can easily be produced locally. As for example medicinal product manufacturer, beverage distilleries and industrial ethanol plants provided big amounts of ethanol for the production of EBHR during Covid-19 pandemia.
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Justification for confidentiality	
Conclusion on suitability and availability of the alternative	If ethanol is classified as a CMR substance, it will no longer be available for use by the general public, effectively amounting to a full ban. Such a ban would have severe consequences, especially during outbreaks and pandemics involving non-enveloped viruses. There is currently no alternative biocidal active substance that offers the same efficacy against non-enveloped viruses. A lack of approval would result in a shortage of sufficient equivalent substitutes. In the event of an outbreak caused by a non-enveloped virus, ethanol remains indispensable for effective disease control. Classifying ethanol as a CMR substance will also have a negative impact on the subsequent classification in the context of CLH-evaluation (CLP Regulation) and therefore also on the use of ethanol in the manufacture of medicinal products, medical devices, food supplements, dietetics, cosmetics. If ethanol would be classified as a category 1 CMR substance, this would have far-reaching consequences for the manufacture of medicinal products, medical devices, food supplements, dietetics, and cosmetics due to the associated health and safety concerns: Disinfectants containing ethanol could no longer be used broadly, Pregnant and breastfeeding women and young adults would no longer be able to work in the manufacture of medicinal products, medical devices food supplements, dietetics, and cosmetics, Tremendous additional measures in connection with occupational health and safety that would have to be observed or applied, e.g. substitution as well as technical, organisational, and personal measures. This would jeopardise availability of medicinal products, medical devices food supplements, dietetics, and cosmetics patient care in the European Union. Given these factors, we strongly recommend maintaining the current classification of ethanol, which already provide adequate public health protection.

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Other comments	Ethanol is indispensable in the healthcare sector, particularly in disinfectants, the use of medical devices, and the manufacturing of pharmaceuticals. Its antimicrobial properties are highly effective against bacteria and viruses, especially against the more virulent non-enveloped viruses (e.g. poliovirus and rotavirus) and play a crucial role in reducing nosocomial infections. Throughout the Covid-19 pandemic, ethanol played a crucial role in swiftly and effectively interrupting infection chains. The high demand for disinfectants was successfully met due to the widespread availability of ethanol. As a candidate for substitution ethanol will no longer be available for use by the general public. The discussed classification is de facto equivalent with a full ban. The implications of an ethanol ban will be significantly serious. During outbreaks and pandemics involving non-enveloped viruses, the absence of disinfectant hand rubs that contain this effective and well-tolerated active ingredient will compromise the safety of patients, nursing home residents, staff, and the general public. There is no substitute biocidal active substance with equal efficacy against non-enveloped viruses. In case of non-approval shortage of sufficient equivalent alternatives needs to be considered as it is impossible to fight against non-enveloped viruses in case of an outbreak without ethanol. Further, switching to alternatives will require an increase of production capacities associated with tremendous costs and effort (new facilities, new technologies, new production permits and hurdles from authorities and NGOs).
Information above is confidential	
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References	[1] VAH e.V. Ethanol ist als biozider Wirkstoff zur hygienischen Händedesinfektion unverzichtbar, VAH_Ethanol_HM_11_20_194_200.pdf, in Hygiene & Medizin, Volume 45, 11/2020) [2] Persistence of coronaviruses on inanimate surfaces and their inactivation with biocidal agents G. Kampf a, *, D. Todt b, S. Pfaender b, E. Steinmann b. , G. Kampf et al. / Journal of Hospital Infection 104 (2020) 246e251, DOI: 10.1016/j.jhin.2020.01.022; https://www.journalofhospitalinfection.com/article/S0195-6701(20)30046-3/fulltext [3] Kramer A, Pittet D,

	Exner M, Wendt C. Medical associations and expert committees urge that ethanol be approved as a virucidal active substance for use in hand antiseptics under the European Biocidal Products Regulation, without a CMR classification. GMS Hyg Infect Control. 2024 Aug 21;19:Doc40. doi: 10.3205/dgkh000495. PMID: 39224501; PMCID: PMC11367556. [4] Ethanol is indispensable for virucidal hand antisepsis and without toxic risks in daily use. GMS Hyg Infect Control, Axel Kramer, Hicham Benkhail, Christian Jäkel, Paula Zwicker 1 2023, Jan 23:18:Doc02. doi: 10.3205/dgkh000428. eCollection 2023. https://pmc.ncbi.nlm.nih.gov/articles/PMC9978451/
Attachments (non-confidential information)	ECHA EtOH_Konsultation_final_BPR.pdf
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Comment 202	2025/04/28 14:47
Country	Switzerland
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	The just published Article "The Magic Molecule: Why isn't everyone carrying around a bottle of hypochlorous acid?" in the May issue 2025 of Scientific American sums it up in good lay terms, why HOCl is the best candidate for substitution of ethanol for product type 1, 2 and 4 [1]. Hypochlorous acid (HOCl) should not be confused with sodium hypochlorite (NaClO), the main active ingredient in household bleach products, even though they both involve free chlorine as the active substance. HOCl has been widely studied for its application as an efficient biocide in many different fields such as health care, food and water treatment sciences since more than 130 years. The claim of the defendants of ethanol that ethanol is indispensable because there is no alternative, especially against non-

	enveloped viruses, is simply not true. HOCl is THE alternative, not only as it is the disinfectant with the broadest spectrum eliminating all viruses and also bacteria, fungi, yeasts, spores and even prions, but also for its lack of risks associated with its use, as well as the superior economicaly and ecologically advantages over ethanol making it easily available everywhere, since it only takes table salt, water and some electricity to produce it. Details will be discussed below and full text including all references will be attached. References: [1] Schwartz, J. (2025). The Magic Molecule: Why isn't everyone carrying around a bottle of hypochlorous acid? Sci Am, 332(5), 52. https://doi.org/10.1038/scientificamerican052025-6qjd5Og5ov35x8PgwaWCHn
Product Type	1,2,4
Alternative Identity and Properties	ECHA has approved “free chlorine generated from sodium chloride by electrolysis” and “free chlrorine released from hypochlorous acid” as active substances and product authorization is currently under way. While the former describes the manufacturing (and use) of HOCl in situ, the latter refers to bottled solutions that can be bought and used everywhere. HOCl only exists in aqueous solutions and its concentration (in regard to chlorine and hypochlorite anion as the other forms of active chlorine) is dependent on pH and temperature. With its minute concentration in the approved substances, less than 0.25% of active chlorine, HOCl is not listed in Annex VI of Regulation 1272/2008/EC (CLP) and hence is not classified as hazardous. For more detailed information on risks including the environment see the ECHA assessment report “Active chlorine released from hypochlorous acid Product-type 1” [1]. HOCl formulations have been approved as a Class IIB medical device products to be used as wound antispetics [2]. This demonstrates that if HOCl can be safely used on open wounds directly, it will also not harm intact skin. References: [1] ECHA. (2020). Assessment Report Active Chlorine Released from Hypochlorous Acid. Accessed 18.04.2025. Link: https://kleegmbh.ch/media/25/7c/44/1744992228/129847_Active_chlorine_hypochlorous_acid_PT_1_final_AR_2020_public.pdf?ts=1744992228 [2] Yan, P., et al. (2021). New Clinical Applications of Electrolyzed Water: A Review. Microorganisms, 9(1). https://doi.org/10.3390/microorganisms9010136
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Technical Feasibility	While advocates of ethanol claim that ethanol is indispensable and safe as a biocidal active substance for hand disinfection [1; 2] one must stress that virucidal claims of ethanol, especially against human noroviruses, are disputed [3; 4]. Even though inhalation and dermal adsorption of ethanol might not pose a risk of carcinogenicity, mutagenicity or reprotoxicity from repeated use, it is false to claim that ethanol-based biocides are safe. There is a rising concern of intentional ingestion [5; 6], as well as paediatric ingestion of ethanol-based hand sanitisers [7]. Hypochlorous acid has a much broader biocidal spectrum than ethanol due to its strong oxidizing power [8; 9]. HOCl also eliminates spores of <i>Clostridium difficile</i> and <i>Bacillus anthracis</i> from skin, where ethanol showed no effects [10]. Bedbaths with HOCl showed an impressive log reduction of -13 of <i>C. diff</i> spores on groins in this study. HOCl is also more effective than other chlorine-based sanitizers and does not induce viable but nonculturable (VBNC) cells [11]. References: [1] Kampf, G., et al. (2021). Ethanol is indispensable and safe as a biocidal active substance for hand disinfection. <i>J Hosp Infect</i>, 108, 205-206. https://doi.org/10.1016/j.jhin.2020.11.013 [2] Kramer, A., et al. (2022). Ethanol is indispensable for virucidal hand antisepsis: memorandum from the alcohol-based hand rub (ABHR) Task Force, WHO Collaborating Centre on Patient Safety, and the Commission for Hospital Hygiene and Infection Prevention (KRINKO), Robert Koch Institute, Berlin, Germany. <i>Antimicrob Resist Infect Control</i>, 11(1), 93. https://doi.org/10.1186/s13756-022-01134-7 [3] Wieselmann, N. (2024, 07.01.2025). Alcohol-Based Hand Sanitizers Ineffective Against Norovirus: Effective Alternatives and Infection Control Strategies. Accessed 21.04.2025. Link: https://www.infectioncontrolday.com/view/alcohol-based-hand-sanitizers-ineffective-against-norovirus-effective-alternatives-infection-control-strategies [4] Vogel, L. (2011). Hand sanitizers may increase norovirus risk. <i>CMAJ</i>, 183(12), E799-800. https://doi.org/10.1503/cmaj.109-3922 [5] El-Hussein, M., et al. (2024). The Rising Concern of Ethanol Intoxication from Easy Access to Hand Sanitizers: A Case Report. <i>Am J Case Rep</i>, 25, e943318. https://doi.org/10.12659/AJCR.943318 [6] Gormley, N. J., et al. (2012). The rising incidence of intentional ingestion of ethanol-containing hand sanitizers. <i>Crit Care Med</i>, 40(1), 290-294. https://doi.org/10.1097/CCM.0b013e31822f09c0 [7] Hanna, S., et al. (2021). Morbidity in the COVID-19 era:

	Ethanol intoxication secondary to hand sanitiser ingestion. J Paediatr Child Health, 57(5), 741-742. https://doi.org/10.1111/jpc.15017 [8] Zhao, L., et al. (2021). Recent advances on research of electrolyzed water and its applications. Current Opinion in Food Science, 41, 180-188. https://doi.org/https://doi.org/10.1016/j.cofs.2021.03.004 [9] Wigginton, K. R., et al. (2012). Virus inactivation mechanisms: impact of disinfectants on virus function and structural integrity. Environ Sci Technol, 46(21), 12069-12078. https://doi.org/10.1021/es3029473 [10] Nerandzic, M. M., et al. (2013). Novel strategies for enhanced removal of persistent Bacillus anthracis surrogates and Clostridium difficile spores from skin. PLoS One, 8(7), e68706. https://doi.org/10.1371/journal.pone.0068706 [11] Ogunniyi, A. D., et al. (2019). Comparative antibacterial activities of neutral electrolyzed oxidizing water and other chlorine-based sanitizers. Sci Rep, 9(1), 19955. https://doi.org/10.1038/s41598-019-56248-7
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Economic Feasibility	The World Health Organization published the “Guide to local production: WHO-recommended handrub formulations” in 2010 for low-income countries, “since it is a less expensive alternative to commercially available preparations and can be produced locally” [1]. But local production of these formulations has drawbacks: you need a well-ventilated room, trained staff to handle the dangerous ingredients (ethanol 96%, hydrogen peroxide 3%) and consider the salary of it. Commercially available bottled hypochlorous acid usually costs less than ethanol products, especially considering formulations containing humectants or emollients. With a better safety profile, and potential applicability across many healthcare uses, HOCl provides an attractive and potentially cost-efficient alternative to sodium hypochlorite in low resource settings [2]. But HOCl can also be produced on site (ECHA approved as “free chlorine generated from sodium chloride by electrolysis”). While a generator to produce HOCl in situ is an initial investment, it pays off quickly, because you only need sodium chloride (NaCl - which certainly is cheaper than ethanol), water and electricity. There is no handling of dangerous products and no special trained staff needed to run the generator. Especially health care facilities can profit from on site generated HOCl. You can not only use the produce for hand

	and skin disinfection, but also for surface and water disinfection, as well as a wound cleanser. Most generators, while producing HOCl at the anode, also generate a diluted sodium hydroxide solution at the cathode, which is an excellent degreaser and like HOCl non-toxic. References: [1] Guide to local production: WHO-recommended handrub formulations. (2010). Accessed 21.04.2025. Link: https://www.who.int/publications/i/item/WHO-IER-PSP-2010.5 [2] Gon, G., et al. (2022). A Better Disinfectant for Low-Resourced Hospitals? A Multi-Period Cluster Randomised Trial Comparing Hypochlorous Acid with Sodium Hypochlorite in Nigerian Hospitals: The EWASH Trial. <i>Microorganisms</i>, 10(5). https://doi.org/10.3390/microorganisms10050910
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	As mentioned above (see section 2), to state that ethanol is a safe biocidal active substance is unjustified. Vapor from alcohol-based hand sanitizers can also compromise the filtration performance of surgical masks and N95 respirators [1]. Ethanol-based disinfectant sprays pose a further risk given the elevated production of volatile chemicals and nano-sized particles, resulting in large deposited doses in the tracheobronchial and pulmonary regions of the respiratory system [2]. On the other hand, hypochlorous acid in a concentration as for the ECHA approved active substances, does not pose any risks, even if you would swallow or drink it. Experiments in mice actually showed that drinking up to 20 ppm of HOCl has the potential to improve or prevent glucose tolerance and memory decline by altering gut microbiota [3]. Another advantage of HOCl over ethanol are the many ways you can use it: wash, rinse, wipe, spray, mist and fog. Misting and fogging is even possible in the presence of people, as inhaling microaerosolized hypochlorous acid (HOCl) as an intervention in the prevention and treatment of respiratory virus infections has been shown to have beneficial effects [4-7]. References: [1] He, W., et al. (2021). Filtration Performance Degradation of In-Use Masks by Vapors from Alcohol-Based Hand Sanitizers and the Mitigation Solutions. <i>Glob Chall</i>, 5(9), 2100015. https://doi.org/10.1002/gch2.202100015 [2] Jiang, J., et al. (2021). Ethanol-based disinfectant sprays drive rapid changes in the chemical composition of indoor air in residential buildings. <i>J Hazard Mater Lett</i>, 2, 100042.

	https://doi.org/10.1016/j.hazl.2021.100042 [3] Watanabe, K., et al. (2024). Highly purified hypochlorous acid water facilitates glucose metabolism and memory formation in type 2 diabetic mice associated with altered-gut microbiota. <i>Sci Rep</i>, 14(1), 16107. https://doi.org/10.1038/s41598-024-67129-z [4] Benedusi, M., et al. (2022). The Lesson Learned from the COVID-19 Pandemic: Can an Active Chemical Be Effective, Safe, Harmless-for-Humans and Low-Cost at a Time? Evidence on Aerosolized Hypochlorous Acid. <i>Int J Environ Res Public Health</i>, 19(20). https://doi.org/10.3390/ijerph192013163 [5] Delgado-Enciso, I., et al. (2020). Patient-Reported Health Outcomes After Treatment of COVID-19 with Nebulized and/or Intravenous Neutral Electrolyzed Saline Combined with Usual Medical Care Versus Usual Medical care alone: A Randomized, Open-Label, Controlled Trial. <i>Res Sq</i>. https://doi.org/10.21203/rs.3.rs-68403/v1 [6] Rasmussen, E. D., et al. (2022). Inhalation of Microaerosolized Hypochlorous Acid (HOCl): Biochemical, Antimicrobial, and Pathological Assessment. <i>Archives of Internal Medicine Research</i>, 5, 311-318. https://doi.org/10.26502/aimr.0111 [7] Rebollar González, D. R. C., & López, D. E. T. (2020). Super-Oxidized Solution Nebulization for the Symptomatic Treatment of Airway Infections Including COVID-19 Cases Report. <i>International Journal of Innovative Research in Medical Science</i>, 5(08), 339 - 348. https://doi.org/10.23958/ijirms/vol05-i08/922
Information above is confidential	
Justification for confidentiality	
Availability	Hypochlorous acid can be simply produced by electrolyzing sodium chloride solutions including seawater directly. While electrode composition influences properties of the HOCl produced (e.g. stability), any material works in an emergency setting. HOCl-generators can run on solar power making them independent from the grid. Sodium chloride, which has no shelf life, can be stored with much less space usage than bottled solutions. An ultimate advantage compared to ethanol-based products, as has been shown by the wide shortages of such disinfectants during the early phase of the Covid pandemic.
Information above is confidential	
Justification for confidentiality	

Conclusion on suitability and availability of the alternative	The active substances “free chlorine generated from sodium chloride by electrolysis” and “free chlorine released from hypochlorous acid” are suitable alternatives for ethanol for PT1, PT2 and PT4, as they pose no risks, are ready available at lesser cost and lesser CO2-footprint.
Information above is confidential	
Justification for confidentiality	
Other comments	Finally, the use of hypochlorous acid benefits also the environment. It has the lowest CO2-footprint of any effective disinfectant, especially when produced on site. Ethanol manufacturing is based on distilling sugar cane, corn or other plants/fruits, competing land use for food production. On the other hand, salt is abundant with no such competing conflicts. Finally, hypochlorous acid, with its strong oxidizing power, has been shown to degrade harmful chemicals, such as fungal toxins [1-4] and cytostatics [5], making it the perfect sanitizer in food and health care. References: [1] Castro-Rios, K., et al. (2021). Physicochemical treatments for the reduction of aflatoxins and <i>Aspergillus niger</i> in corn grains (<i>Zea mays</i>). <i>J Sci Food Agric</i>, 101(9), 3707-3713. https://doi.org/10.1002/jsfa.11001 [2] Gomez-Espinosa, D., et al. (2017). Ameliorative Effects of Neutral Electrolyzed Water on Growth Performance, Biochemical Constituents, and Histopathological Changes in Turkey Poults during Aflatoxicosis. <i>Toxins (Basel)</i>, 9(3). https://doi.org/10.3390/toxins9030104 [3] Jardon-Xicotencatl, S., et al. (2015). Detoxification of Aflatoxin-Contaminated Maize by Neutral Electrolyzed Oxidizing Water. <i>Toxins (Basel)</i>, 7(10), 4294-4314. https://doi.org/10.3390/toxins7104294 [4] Xiong, K., et al. (2012). Product identification and safety evaluation of aflatoxin B1 decontaminated by electrolyzed oxidizing water. <i>J Agric Food Chem</i>, 60(38), 9770-9778. https://doi.org/10.1021/jf303478y [5] Ferreira Garcia, L., et al. (2020). Effective degradation of the antineoplastic doxorubicin by electrochemical oxidation on boron doped diamond. <i>Journal of Electroanalytical Chemistry</i>, 870, 114252. https://doi.org/https://doi.org/10.1016/j.jelechem.2020.114252
Information above is confidential	
Justification for confidentiality	

References	
Attachments (non-confidential information)	Consultations on Potential Candidates for Substitution of ethanol.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 203	2025/04/28 14:50
Country	Finland
Name of organization/institution	Finnish Institute for Health and Welfare
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	WHO recommends performing hand hygiene in healthcare, by using an alcohol-based handrub and applying the correct technique. Ethanol is used worldwide in hand rubs because it has a broad-spectrum antimicrobial efficacy (Gram-positive and Gram-negative bacteria, enveloped- and non-enveloped viruses). Ethanol works quickly, inactivating microorganisms within seconds to minutes depending on the concentration, formulation, and conditions of use. Propanol evaporates more slowly than ethanol, which is considered to be a risk for skin dryness in health care personnel's hands and it does not have as broad-spectrum of antimicrobial efficacy than ethanol. Ethanol can be used in different kinds of health care settings which makes it essential in preventing health care acquired infections. In healthcare settings ethanol is used topically in controlled quantities by the existing guidelines. To prevent oral intake, ethanol handrubs are denatured, and they have tailored formulation. In certain healthcare settings handrubs are not displayed in patient areas if, after a risk assessment, there is a risk of misuse. Finnish Institute for Health and Welfare considers that ethanol is irreplaceable for PT1 hand-rub disinfectants.
Product Type	1,2,4

Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Finnish Institute for Health and Welfare considers that ethanol is irreplaceable for PT1 hand-rub disinfectants.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	

References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 204	2025/04/28 15:01
Country	Finland
Name of organization/institution	Hydzone Oy
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	This submission is provided to support the substitution of hazardous chemical disinfectants with a safer, sustainable alternative offered by Hydzone Oy, a provider of ozone-based disinfection technology. As a stakeholder advocating for environmentally friendly solutions, the submitter seeks to contribute to the ECHA consultation by presenting Hydzone Oy's ozone technology, which generates ozone on-site for disinfecting water, surfaces, and air across sectors like healthcare, food processing, and water treatment. The technology, implemented through CE-marked devices, aligns with REACH objectives by reducing health and environmental risks associated with chemical disinfectants. Further details on Hydzone Oy's solutions are available at https://hydzone.com, and this submission aims to demonstrate the feasibility, safety, and availability of this alternative.
Product Type	1,2,4
Alternative Identity and Properties	Hydzone Oy's ozone-based disinfection technology generates ozone on-site using electrical energy to disinfect water, surfaces, and air in applications spanning healthcare, food processing, and hospitality. This chemical-free solution employs ozone, a potent oxidizing agent, which decomposes into oxygen after use, leaving no harmful residues. The

	technology, implemented through Hydzone Oy's devices like the Hydzonator and Hydzone WDS, delivers broad-spectrum antimicrobial action against bacteria, viruses, fungi, and spores. With CE-marked compliance to European standards, the solution ensures reliability and environmental sustainability, eliminating the need for chemical storage and reducing ecological impact.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Hydzone Oy's ozone-based disinfection technology demonstrates robust technical feasibility for replacing chemical disinfectants across diverse sectors, including healthcare, agriculture, and water treatment. The technology, powered by Hydzone Oy's devices, generates ozone at concentrations of 0.05 to 2.0 ppm, ensuring effective pathogen elimination without fostering microbial resistance. Scalable from portable units for small-scale use to industrial systems for large facilities, the solution integrates seamlessly with minimal infrastructure changes, relying solely on electricity. While a stable power supply and trained operators may be required for industrial applications, compliance with international standards like ISO and CE guarantees consistent performance.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Hydzone Oy's ozone-based disinfection technology offers economic viability despite higher initial costs for device acquisition compared to chemical disinfectants. By generating ozone on-site, Hydzone Oy's devices eliminate expenses related to purchasing, transporting, and storing chemicals. The absence of chemical residues reduces waste management costs, and the durability of Hydzone Oy's devices minimizes maintenance expenses. Long-term savings are particularly significant in high-usage settings like water treatment plants and hospitals, where reduced reliance on chemical supplies enhances cost-effectiveness, making the technology a financially sound alternative.
Information above is confidential	
Justification for confidentiality	

Hazards and Risks of the Alternative	Hydzone Oy's ozone-based disinfection technology presents minimal hazards and risks compared to chemical disinfectants. Ozone, generated at controlled concentrations of 0.05 to 2.0 ppm by Hydzone Oy's devices, decomposes into oxygen and water post-use, leaving no toxic residues or environmental pollutants. Built-in safety features and adherence to occupational exposure limits, such as EU guidelines, mitigate overexposure risks. Operational risks, including equipment malfunction, are low with proper maintenance and operator training. By eliminating chemical exposure, the technology significantly reduces health and environmental risks, aligning with REACH safety objectives.
Information above is confidential	
Justification for confidentiality	
Availability	Hydzone Oy's ozone-based disinfection technology stands as a highly suitable and readily available alternative to hazardous chemical disinfectants. The solution, delivered through Hydzone Oy's devices, offers proven technical feasibility across healthcare, food processing, and water treatment, with scalable systems ensuring broad applicability. Economically, it provides long-term savings by eliminating chemical-related costs, despite initial investment. The technology minimizes health and environmental risks, as ozone leaves no harmful residues. Commercially available through Hydzone Oy, the solution aligns with ECHA's sustainability goals under REACH, offering a safe, effective, and eco-friendly replacement for hazardous disinfectants. Further details are accessible at https://hydzone.com .
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Hydzone Oy's ozone-based disinfection technology stands as a highly suitable and readily available alternative to hazardous chemical disinfectants. The solution, delivered through Hydzone Oy's devices, offers proven technical feasibility across healthcare, food processing, and water treatment, with scalable systems ensuring broad applicability. Economically, it provides long-term savings by eliminating chemical-related costs, despite initial investment. The technology minimizes health and environmental risks, as ozone leaves no harmful residues. Commercially available through Hydzone Oy, the solution

	aligns with ECHA's sustainability goals under REACH, offering a safe, effective, and eco-friendly replacement for hazardous disinfectants. Further details are accessible at https://hydzone.com .
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	https://pubmed.ncbi.nlm.nih.gov/?term=ozonated+water
Attachments (non-confidential information)	efficiency.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 205	2025/04/28 15:05
Country	Finland
Name of organization/institution	Hydzone Oy
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	This submission is provided to support the substitution of hazardous chemical disinfectants with a safer, sustainable alternative offered by Hydzone Oy, a provider of ozone-based disinfection technology. As a stakeholder advocating for environmentally friendly solutions, the submitter seeks to contribute to the ECHA consultation by presenting Hydzone Oy's ozone technology, which generates ozone on-site for disinfecting water, surfaces, and air across sectors like healthcare, food processing, and water treatment. The

	technology, implemented through CE-marked devices, aligns with REACH objectives by reducing health and environmental risks associated with chemical disinfectants. Further details on Hydzone Oy's solutions are available at https://hydzone.com, and this submission aims to demonstrate the feasibility, safety, and availability of this alternative.
Product Type	1,2,4
Alternative Identity and Properties	Hydzone Oy's ozone-based disinfection technology generates ozone on-site using electrical energy to disinfect water, surfaces, and air in applications spanning healthcare, food processing, and hospitality. This chemical-free solution employs ozone, a potent oxidizing agent, which decomposes into oxygen after use, leaving no harmful residues. The technology, implemented through Hydzone Oy's devices like the Hydzonator and Hydzone WDS, delivers broad-spectrum antimicrobial action against bacteria, viruses, fungi, and spores. With CE-marked compliance to European standards, the solution ensures reliability and environmental sustainability, eliminating the need for chemical storage and reducing ecological impact.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Hydzone Oy's ozone-based disinfection technology demonstrates robust technical feasibility for replacing chemical disinfectants across diverse sectors, including healthcare, agriculture, and water treatment. The technology, powered by Hydzone Oy's devices, generates ozone at concentrations of 0.05 to 2.0 ppm, ensuring effective pathogen elimination without fostering microbial resistance. Scalable from portable units for small-scale use to industrial systems for large facilities, the solution integrates seamlessly with minimal infrastructure changes, relying solely on electricity and tap water. While a stable power supply and trained operators may be required for industrial applications, compliance with international standards like ISO and CE guarantees consistent performance.
Information above is confidential	
Justification for confidentiality	

Economic Feasibility	Hydzone Oy's ozone-based disinfection technology offers economic viability despite higher initial costs for device acquisition compared to chemical disinfectants. By generating ozone on-site, Hydzone Oy's devices eliminate expenses related to purchasing, transporting, and storing chemicals. The absence of chemical residues reduces waste management costs, and the durability of Hydzone Oy's devices minimizes maintenance expenses. Long-term savings are particularly significant in high-usage settings like water treatment plants and hospitals, where reduced reliance on chemical supplies enhances cost-effectiveness, making the technology a financially sound alternative.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Hydzone Oy's ozone-based disinfection technology presents minimal hazards and risks compared to chemical disinfectants. Ozone, generated at controlled concentrations of 0.05 to 2.0 ppm by Hydzone Oy's devices, decomposes into oxygen and water post-use, leaving no toxic residues or environmental pollutants. Built-in safety features and adherence to occupational exposure limits, such as EU guidelines, mitigate overexposure risks. Operational risks, including equipment malfunction, are low with proper maintenance and operator training. By eliminating chemical exposure, the technology significantly reduces health and environmental risks, aligning with REACH safety objectives.
Information above is confidential	
Justification for confidentiality	
Availability	Hydzone Oy's ozone-based disinfection technology stands as a highly suitable and readily available alternative to hazardous chemical disinfectants. The solution, delivered through Hydzone Oy's devices, offers proven technical feasibility across healthcare, food processing, and water treatment, with scalable systems ensuring broad applicability. Economically, it provides long-term savings by eliminating chemical-related costs, despite initial investment. The technology minimizes health and environmental risks, as ozone leaves no harmful residues. Commercially available through Hydzone Oy, the solution aligns with ECHA's sustainability goals under REACH, offering a safe, effective, and eco-friendly replacement for

	hazardous disinfectants. Further details are accessible at https://hydzone.com .
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Hydzone Oy's ozone-based disinfection technology stands as a highly suitable and readily available alternative to hazardous chemical disinfectants. The solution, delivered through Hydzone Oy's devices, offers proven technical feasibility across healthcare, food processing, and water treatment, with scalable systems ensuring broad applicability. Economically, it provides long-term savings by eliminating chemical-related costs, despite initial investment. The technology minimizes health and environmental risks, as ozone leaves no harmful residues. Commercially available through Hydzone Oy, the solution aligns with ECHA's sustainability goals under REACH, offering a safe, effective, and eco-friendly replacement for hazardous disinfectants. Further details are accessible at https://hydzone.com .
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	https://pubmed.ncbi.nlm.nih.gov/?term=ozonated+water
Attachments (non-confidential information)	efficiency.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 206	2025/04/28 15:12

Country	Germany
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	Ethanol als wichtiges Extraktionsmittel zur Herstellung von pflanzlichen Arzneimitteln und als Hilfsstoff in der homöopathischen Arzneimittelherstellung
Product Type	1,2,4
Alternative Identity and Properties	Ethanol in der Funktion als Extraktionsmittel; in den Arzneibüchern keine Alternative; Die Extraktion der gewünschten Pflanzeninhaltsstoffe ist explizit nur mit Ethanol möglich; gute Strukturen zur Kontrolle der im Markt befindlichen Arzneimittel
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	keine Substitution möglich, Arzneibücher, Zulassungen und Registrierungen enthalten Ethanol als Hilfsstoff zur Arzneimittelherstellung, keine Alternative möglich
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Wegfall des Ethanols als Hilfsstoff in der Arzneimittelherstellung bedingt Wegfall der betroffenen Fertig Arzneimittel für den Markt; Versorgung der Bevölkerung für den größten Teil der Arzneimittel nicht mehr gesichert.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	keine Substitution für die Arzneimittelherstellung vorhanden

Information above is confidential	
Justification for confidentiality	
Availability	Ethanol ist als pharmazeutischer Hilfsstoff gut und sicher verfügbar, es gibt keine Alternative
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	- Ethanol ist ein sicheres, gut überwachtes und unverzichtbares Pflanzenauszugsmittel. - Der Einsatz von Ethanol im Bereich der Herstellung von Arzneimitteln ist durch ständige gesetzliche Regulation sehr, sehr sicher. - Im Markt befindliche Arzneimittel sind durch gute Strukturen zur Kontrolle der Anwendung sicher für jeden Patienten. - Eine Einstufung von Ethanol als CMR-Stoff würde mehr als die Hälfte der momentan im Markt befindlichen Arzneimittel betreffen. Eine planbare Aussage zur Versorgung der Bevölkerung kann nicht getroffen werden.
Information above is confidential	
Justification for confidentiality	
Other comments	siehe IV Attachements
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	Ergänzende Stellungnahme zur Einstufung von Ethanol als CMR.docx
Attachments (confidential information)	
Justification for confidential attachment	

Comment 207	2025/04/28 15:18

Country	Germany
Name of organization/institution	BIONORICA SE
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	

Conclusion on suitability and availability of the alternative	Ethanol is indispensable in the healthcare sector, particularly in disinfectants, the use of medical devices, and the manufacturing of pharmaceuticals. Its antimicrobial properties are highly effective against bacteria and viruses, including non-enveloped viruses (e.g., polio), and play a crucial role in reducing nosocomial infections. During the Covid-19 pandemic, ethanol enabled the rapid and effective interruption of infection chains, and the high demand for disinfectants was met only due to the wide availability of ethanol. As a candidate for substitution Ethanol will no longer be available for use by the general public. The discussed classification is de facto equivalent with a full ban. The consequences of a ban of Ethanol will be extremely severe. Particularly in the event of outbreaks and pandemics with non-enveloped viruses, the lack of disinfectant hand rubs based on this potent and well-tolerated core active substance will harm the safety of patients, nursing home residents, staff and the general public. There is no substitute biocidal active substance with equal efficacy against non-enveloped viruses. In case of non-approval shortage of sufficient equivalent alternatives has to be mentioned. In case of an outbreak of a non-enveloped virus disease, it is not possible to fight against these without ethanol. Increase of production capacities associated with tremendous costs (New facilities, new technologies, new production permits and hurdles from authorities and NGOs). We would like to suggest that ECHA recommends to the European commission to maintain the current classification, because public health is sufficiently protected by existing legislation, e.g. occupational safety.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	

Justification for confidential attachment	

Comment 208	2025/04/28 15:43
Country	Italy
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	La Sacchetto S.p.A. produce Alcol Amido e proteine dalla lavorazione de grano tenero; L'alcol etilico di frumento si ottiene dalla trasformazione enzimatica e successiva fermentazione dell'amido da frumento tenero proveniente dalla Comunità Europea. La separazione della frazione alcolica dal liquido madre si attua tramite impianto di distillazione frazionata sotto vuoto, integrante processi di idroselezione, rettifica e demetilazione. L'alcol etilico viene commercializzato per la produzione di bevande alcoliche, antimuffa, conservante e solvente per aromi. "Il mercato dell'etanolo dell'UE può essere suddiviso in tre segmenti: combustibile, alimentare e industriale. i) Carburante: l'etanolo viene utilizzato in miscela con la benzina o come carburante alternativo. L'E10, ad esempio, è un tipo di benzina che contiene fino al 10% di etanolo e può essere utilizzato nella maggior parte dei motori a combustione interna e dei veicoli ibridi di oggi, riducendo significativamente le emissioni di gas serra dei trasporti. ii) Alimentare: l'etanolo può essere utilizzato per produrre bevande spiritose, come additivo alimentare, per l'estrazione di aromi, per la conservazione degli alimenti e la produzione di aceto bianco. iii) Industriale: l'etanolo è un componente chimico rinnovabile essenziale in vari prodotti (ad es. prodotti igienizzanti, cosmetici, prodotti farmaceutici, solventi, vernici e fluidi antigelo) per garantire l'igiene e la sicurezza, nonché una materia prima rinnovabile per la produzione di sostanze chimiche rinnovabili (ad es. bioetilene). Il bioetanolo viene prodotto nelle bioraffinerie europee fermentando gli zuccheri in alcol. Nell'UE, questi zuccheri provengono tipicamente da una varietà di fonti agricole come grano, mais, orzo, segale, triticale e barbabietola da zucchero. In Italia il bioetanolo è ottenuto principalmente da residui della produzione del vino (e.g.

	vinacce e fecce di vino) ottenendo quindi un biocarburante avanzato che contribuisce significativamente alla riduzione delle emissioni di gas effetto-serra e quindi al raggiungimento degli obiettivi UE di decarbonizzazione dei trasporti. Nel 2023, i produttori europei di etanolo rinnovabile hanno prodotto 6,44 miliardi di litri di etanolo, operando all'80% dei loro 8,05 miliardi di litri di capacità installata. L'utilizzo come biocarburante ha rappresentato l'85,9% dell'utilizzo; Altri mercati, come le applicazioni industriali e le bevande, hanno rappresentato rispettivamente il 7,6% e il 6,5%. (Nome Azienda) desidera fornire le sue osservazioni all'ECHA sottolineando l'uso insostituibile dell'etanolo e sottolineando che una classificazione dell'etanolo come cancerogeno o tossico per la riproduzione sarebbe dannosa per molti biocidi, creerebbe una mancanza di alternative e avrebbe conseguenze critiche per la salute pubblica."
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	

Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Essendo da sempre produttori di etanolo per fermentazione di prodotti di origine agricola, non individuiamo al momento alternative di processo sostenibili, in questo momento l'etanolo viene prodotto dall'amido B a valle del processo di raffinazione dell'amido A, per l'amido B al momento non vi sono prospettive di mercato valide se non quello di inviarlo alla trasformazione in alcol, il presente commento è relativo all'utilizzo di etanolo come biocida, rimaniamo in attesa di capire i risvolti futuri di questa nuova considerazione, proposta dal Regolamento UE 528/2012 in abito biocida per definire poi in modo preciso quali opzioni di mercato sostenibili potranno essere percorse.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 209	2025/04/28 16:02
Country	Germany
Name of organization/institution	Deutsche Krankenhausgesellschaft e.V.

I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	The German Hospital Federation (DKG) is the umbrella organisation of hospital operators in Germany. It represents the interests of its 28 members - 16 state associations and 12 umbrella organisations - in Germany and performs the tasks assigned to it by law. The 1,874 hospitals treat around 17 million inpatients and around 23 million outpatients every year. With an annual turnover of 141 billion euros, German hospitals are a significant economic factor in the growing healthcare market. For some years now, the DKG has been very concerned about the developments that have occurred in the EU and those that are still imminent and will have a massive impact on the care and treatment of patients in Germany. Examples include the European Medical Device Regulation (MDR) and the In Vitro Diagnostics Regulation (IVDR), which are characterised by enormous implementation problems and are therefore now to undergo changes. The planned restriction of so-called perpetual chemicals PFAS (per- and polyfluoroalkyl substances) for medical technology production should also be mentioned, which will have an enormous impact on medical care in hospitals. Even though corresponding procedures are always initiated at EU level with the best possible and ambitious goal of improving care and increasing patient safety throughout the EU, it is a matter of great regret that this is often not reflected in the results. On the contrary, the requirements often have such an exaggerated tendency that the hoped-for goals are sometimes even reversed, resulting in a deterioration of the care situation and, moreover, innovations disappearing from Europe. In this context, we also take a critical view of the current procedure for the risk classification of ethanol. Ethanol is used extensively as a hand and surface disinfectant both in hospitals and in other medical care. Adequate alternatives are practically non-existent. Classifying ethanol as a so-called CMR substance (category 2 or even category 1) will result in a de facto ban or at least an essential restriction on the use of ethanol and thus massively jeopardise patient care and also the protection of employees in medical facilities. The restrictions would be greatest if it were categorised in categories 1A and 1B. However, classification in category 2 would also mean that ethanol could no longer be used in everyday practice. There is no alternative to ethanol due to its high effectiveness. Substitution would lead to restrictions in infection protection

	(lack of protection against some non-enveloped viruses). According to the German Maternity Protection Act [Mutterschutzgesetz] (Section 11 (1) No. 1 a) , pregnant and breastfeeding women are not permitted to handle CMR substances classified as toxic for reproduction of category 1A/B or 2 or according to the additional category for effects on or via lactation. The handling of ethanol-containing disinfectants would therefore no longer be possible for pregnant and breastfeeding women after classification as a CMR substance. This could lead to employment bans in a sector characterised by a shortage of skilled workers. Similarly, according to the German Youth Protection Act [Jugendschutzgesetz], persons under the age of 18 may not be employed in work where they are exposed to the harmful effects of hazardous substances. Although exceptions are possible here, ensuring the necessary criteria are met would involve a great deal of effort and make it more difficult to employ young people, who are an important group in the care sector, for example, as part of vocational training programmes. Furthermore, in the event of classification as a CMR in category 1A or 1B, the supply of ethanol-containing disinfectants to private users would be prohibited under the German Chemicals Prohibition Ordinance [Chemikalien-Verbotsverordnung] (Section 3 (1)). Disinfectants containing ethanol could also no longer be made available to visitors in healthcare facilities.
Product Type	1,2,4
Alternative Identity and Properties	Ethanol is a widely used biocidal active ingredient with a broad spectrum of activity, particularly in disinfectants and antiseptics. It has a proven virucidal, bactericidal, fungicidal and tuberculocidal activity. Ethanol was first mentioned in the specialist literature in 1888 for the antiseptic treatment of hands. Since then, ethanol has been used alongside 2-propanol and 1-propanol as an active ingredient in hand sanitisers in many countries, usually as the only active ingredient. The WHO has maintained a list of essential medicines since 1977, which was last updated in 2023. Here, ethanol is listed under antiseptics and under alcohol-based hand sanitisers as well as in the so-called "core list" of active ingredients for basic care, which should be present as a minimum. In this respect, ethanol is recognised as an "essential medicine" and is considered to have no alternative. There are no adequate alternatives because ethanol has superior efficacy against selected clinically relevant viruses compared to other alcohols. Its unique selling point is its efficacy against some non-enveloped viruses. Ethanol is the only alcohol that is fully virucidal and

	comprehensively effective against non-enveloped viruses including enteroviruses (e.g. polioviruses) and one of the few alcoholic substances that is effective against noroviruses. Therefore, neither 2-propanol nor 1-propanol are suitable biocidal agents for hygienic hand disinfection in the context of infection prevention. The high effectiveness against non-enveloped viruses is also crucial when using ethanol as a surface disinfectant. Its ease of use, rapid evaporation and lack of residue on surfaces are also decisive advantages. In this respect, it can be clearly stated that ethanol is of essential importance in hospital hygiene due to its superior effectiveness as a disinfectant and is indispensable for protection against infection.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	There is no alternative to the use of ethanol in healthcare. As already described, other alcohols are not effective against some non-enveloped viruses. This unique feature makes ethanol indispensable for infection prevention in the healthcare sector. In the context of a possible classification under the Regulation on the supply and use of biocidal products, ethanol would be assessed as carcinogenic and/or toxic for reproduction. However, there is no conclusive evidence for carcinogenicity in the context of the routes of exposure used in healthcare (dermal application). A particularly critical aspect of the assessment procedure is that a large proportion of the data on ethanol currently available for a risk assessment comes from studies that have investigated ethanol as alcohol for drinking. When ingested orally, ethanol has a proven carcinogenic effect. However, the fact that oral intake has completely different effects than dermal application probably requires no scientific evidence. Transferring results from studies on oral ingestion to dermal application is therefore inadmissible for an evaluation of ethanol as an active ingredient in disinfectants. This approach lacks any basis and is not comprehensible. Moreover, it is particularly absurd that ethanol as alcohol in luxury foods and foodstuffs does not fall within the scope of the Biocidal Products Regulation, but the available studies on ethanol as a luxury food and foodstuff are nevertheless used for classification as a biocide and a CMR labelling is now to be obtained on this data basis, which will only have an impact on products in which ethanol is used as an active ingredient (such as disinfectants). In addition, the quantities of ethanol

	absorbed through hand disinfection are below toxicologically relevant concentrations. Last but not least, the repeated daily use of hand and surface disinfectants in medicine for decades proves that dermal application is safe. Increased cancer rates or reprotoxic effects in medical and nursing staff would have long since been noticed over this long period of time. In this respect, toxicological evaluations should differentiate between oral intake and dermal application. Any classification must consider a risk-based assessment rather than hazard-only classification.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	A possible end to the free sale of ethanol-based disinfectants is likely to lead to many manufacturers discontinuing the production of ethanol-based disinfectants. This would result in greater market concentration and thus reduced availability and greater dependence on individual manufacturers. Alternative active ingredients are currently not as widespread and are also more expensive. Scaling up production for substitutes would require massive investments in new facilities, technologies, and regulatory approvals. It can be assumed that these costs would be passed on to consumers/users and thus lead to an additional financial burden on the healthcare system. Healthcare institutions would therefore have to pay more for less effective substances.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	There is no alternative to the use of ethanol in the healthcare sector. No substitute biocidal active ingredient offers the same virucidal efficacy against non-enveloped viruses. And an increased use of weaker disinfectants may lead to higher microbial resistance. In addition, other active ingredients have a higher toxicity profile than ethanol. They also leave residues on surfaces that are undesirable in the healthcare sector. Ethanol, on the other hand, does not leave any relevant residues and there is virtually no risk of accidental poisoning due to its rapid evaporation. In addition, there are no reported cases of skin sensitisation to ethanol.

Information above is confidential	
Justification for confidentiality	
Availability	The use of ethanol is widespread. Accordingly, large production capacities are well-established and the supply chains are stable. Alternative biocidal active substances are associated with higher production costs, lower availability and logistical challenges (production almost exclusively in non-EU countries).
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Due to its superior effectiveness as a disinfectant, ethanol is of essential importance in hospital hygiene and is indispensable for the prevention of infection. It is used extensively as a hand and surface disinfectant both in hospitals and in other medical care settings. Studies and decades of use have proven the safety and effectiveness of ethanol - not least during the coronavirus pandemic. Adequate alternatives are practically non-existent. Classifying ethanol as a so-called CMR substance (category 2 or even category 1) will result in a de facto ban or at least an essential restriction on the use of ethanol and thus massively jeopardise patient care. In Germany, the current legal situation would mean that pregnant women and breastfeeding mothers would no longer be able to handle disinfectants containing ethanol if they were categorised as CMR substances. There would also be restrictions on young people in vocational training and on the distribution of disinfectants in dispensers to visitors to healthcare facilities. Although studies on oral intake show a carcinogenic and reproductive toxic effect, this has not been proven for dermal application and decades of use in the health sector show no evidence of such toxicological effects. The categorisation of ethanol must therefore be risk-based and take into account the area of application. Any regulatory decision should also consider the impact on supply.
Information above is confidential	
Justification for confidentiality	
Other comments	

Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 210	2025/04/28 16:06
Country	Germany
Name of organization/institution	Deutsche Krankenhausgesellschaft e.V.
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	The German Hospital Federation (DKG) is the umbrella organisation of hospital operators in Germany. It represents the interests of its 28 members - 16 state associations and 12 umbrella organisations - in Germany and performs the tasks assigned to it by law. The 1,874 hospitals treat around 17 million inpatients and around 23 million outpatients every year. With an annual turnover of 141 billion euros, German hospitals are a significant economic factor in the growing healthcare market. For some years now, the DKG has been very concerned about the developments that have occurred in the EU and those that are still imminent and will have a massive impact on the care and treatment of patients in Germany. Examples include the European Medical Device Regulation (MDR) and the In Vitro Diagnostics Regulation (IVDR), which are characterised by enormous implementation problems and are therefore now to undergo changes. The planned restriction of so-called perpetual chemicals PFAS (per- and polyfluoroalkyl substances) for medical technology production should also be mentioned, which will have an enormous impact on

	medical care in hospitals. Even though corresponding procedures are always initiated at EU level with the best possible and ambitious goal of improving care and increasing patient safety throughout the EU, it is a matter of great regret that this is often not reflected in the results. On the contrary, the requirements often have such an exaggerated tendency that the hoped-for goals are sometimes even reversed, resulting in a deterioration of the care situation and, moreover, innovations disappearing from Europe. In this context, we also take a critical view of the current procedure for the risk classification of ethanol. Ethanol is used extensively as a hand and surface disinfectant both in hospitals and in other medical care. Adequate alternatives are practically non-existent. Classifying ethanol as a so-called CMR substance (category 2 or even category 1) will result in a de facto ban or at least an essential restriction on the use of ethanol and thus massively jeopardise patient care and also the protection of employees in medical facilities. The restrictions would be greatest if it were categorised in categories 1A and 1B. However, classification in category 2 would also mean that ethanol could no longer be used in everyday practice. There is no alternative to ethanol due to its high effectiveness. Substitution would lead to restrictions in infection protection (lack of protection against some non-enveloped viruses). According to the German Maternity Protection Act [Mutterschutzgesetz] (Section 11 (1) No. 1 a) , pregnant and breastfeeding women are not permitted to handle CMR substances classified as toxic for reproduction of category 1A/B or 2 or according to the additional category for effects on or via lactation. The handling of ethanol-containing disinfectants would therefore no longer be possible for pregnant and breastfeeding women after classification as a CMR substance. This could lead to employment bans in a sector characterised by a shortage of skilled workers. Similarly, according to the German Youth Protection Act [Jugendschutzgesetz], persons under the age of 18 may not be employed in work where they are exposed to the harmful effects of hazardous substances. Although exceptions are possible here, ensuring the necessary criteria are met would involve a great deal of effort and make it more difficult to employ young people, who are an important group in the care sector, for example, as part of vocational training programmes. Furthermore, in the event of classification as a CMR in category 1A or 1B, the supply of ethanol-containing disinfectants to private users would be prohibited under the German Chemicals Prohibition Ordinance [Chemikalien-Verbotsverordnung] (Section 3 (1)).

	Disinfectants containing ethanol could also no longer be made available to visitors in healthcare facilities.
Product Type	1,2,4
Alternative Identity and Properties	Ethanol is a widely used biocidal active ingredient with a broad spectrum of activity, particularly in disinfectants and antiseptics. It has a proven virucidal, bactericidal, fungicidal and tuberculocidal activity. Ethanol was first mentioned in the specialist literature in 1888 for the antiseptic treatment of hands. Since then, ethanol has been used alongside 2-propanol and 1-propanol as an active ingredient in hand sanitisers in many countries, usually as the only active ingredient. The WHO has maintained a list of essential medicines since 1977, which was last updated in 2023. Here, ethanol is listed under antiseptics and under alcohol-based hand sanitisers as well as in the so-called "core list" of active ingredients for basic care, which should be present as a minimum. In this respect, ethanol is recognised as an "essential medicine" and is considered to have no alternative. There are no adequate alternatives because ethanol has superior efficacy against selected clinically relevant viruses compared to other alcohols. Its unique selling point is its efficacy against some non-enveloped viruses. Ethanol is the only alcohol that is fully virucidal and comprehensively effective against non-enveloped viruses including enteroviruses (e.g. polioviruses) and one of the few alcoholic substances that is effective against noroviruses. Therefore, neither 2-propanol nor 1-propanol are suitable biocidal agents for hygienic hand disinfection in the context of infection prevention. The high effectiveness against non-enveloped viruses is also crucial when using ethanol as a surface disinfectant. Its ease of use, rapid evaporation and lack of residue on surfaces are also decisive advantages. In this respect, it can be clearly stated that ethanol is of essential importance in hospital hygiene due to its superior effectiveness as a disinfectant and is indispensable for protection against infection.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	There is no alternative to the use of ethanol in healthcare. As already described, other alcohols are not effective against some non-enveloped viruses. This unique feature makes ethanol indispensable for infection prevention in the healthcare sector. In the context of a possible classification under the Regulation on the supply and use of biocidal

	products, ethanol would be assessed as carcinogenic and/or toxic for reproduction. However, there is no conclusive evidence for carcinogenicity in the context of the routes of exposure used in healthcare (dermal application). A particularly critical aspect of the assessment procedure is that a large proportion of the data on ethanol currently available for a risk assessment comes from studies that have investigated ethanol as alcohol for drinking. When ingested orally, ethanol has a proven carcinogenic effect. However, the fact that oral intake has completely different effects than dermal application probably requires no scientific evidence. Transferring results from studies on oral ingestion to dermal application is therefore inadmissible for an evaluation of ethanol as an active ingredient in disinfectants. This approach lacks any basis and is not comprehensible. Moreover, it is particularly absurd that ethanol as alcohol in luxury foods and foodstuffs does not fall within the scope of the Biocidal Products Regulation, but the available studies on ethanol as a luxury food and foodstuff are nevertheless used for classification as a biocide and a CMR labelling is now to be obtained on this data basis, which will only have an impact on products in which ethanol is used as an active ingredient (such as disinfectants). In addition, the quantities of ethanol absorbed through hand disinfection are below toxicologically relevant concentrations. Last but not least, the repeated daily use of hand and surface disinfectants in medicine for decades proves that dermal application is safe. Increased cancer rates or reprotoxic effects in medical and nursing staff would have long since been noticed over this long period of time. In this respect, toxicological evaluations should differentiate between oral intake and dermal application. Any classification must consider a risk-based assessment rather than hazard-only classification.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	A possible end to the free sale of ethanol-based disinfectants is likely to lead to many manufacturers discontinuing the production of ethanol-based disinfectants. This would result in greater market concentration and thus reduced availability and greater dependence on individual manufacturers. Alternative active ingredients are currently not as widespread and are also more expensive. Scaling up production for substitutes would require massive investments in new facilities, technologies, and regulatory

	approvals. It can be assumed that these costs would be passed on to consumers/users and thus lead to an additional financial burden on the healthcare system. Healthcare institutions would therefore have to pay more for less effective substances.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	There is no alternative to the use of ethanol in the healthcare sector. No substitute biocidal active ingredient offers the same virucidal efficacy against non-enveloped viruses. And an increased use of weaker disinfectants may lead to higher microbial resistance. In addition, other active ingredients have a higher toxicity profile than ethanol. They also leave residues on surfaces that are undesirable in the healthcare sector. Ethanol, on the other hand, does not leave any relevant residues and there is virtually no risk of accidental poisoning due to its rapid evaporation. In addition, there are no reported cases of skin sensitisation to ethanol.
Information above is confidential	
Justification for confidentiality	
Availability	The use of ethanol is widespread. Accordingly, large production capacities are well-established and the supply chains are stable. Alternative biocidal active substances are associated with higher production costs, lower availability and logistical challenges (production almost exclusively in non-EU countries).
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Due to its superior effectiveness as a disinfectant, ethanol is of essential importance in hospital hygiene and is indispensable for the prevention of infection. It is used extensively as a hand and surface disinfectant both in hospitals and in other medical care settings. Studies and decades of use have proven the safety and effectiveness of ethanol - not least during the coronavirus pandemic. Adequate alternatives are practically non-existent. Classifying ethanol as a so-called CMR substance (category

	2 or even category 1) will result in a de facto ban or at least an essential restriction on the use of ethanol and thus massively jeopardise patient care. In Germany, the current legal situation would mean that pregnant women and breastfeeding mothers would no longer be able to handle disinfectants containing ethanol if they were categorised as CMR substances. There would also be restrictions on young people in vocational training and on the distribution of disinfectants in dispensers to visitors to healthcare facilities. Although studies on oral intake show a carcinogenic and reproductive toxic effect, this has not been proven for dermal application and decades of use in the health sector show no evidence of such toxicological effects. The categorisation of ethanol must therefore be risk-based and take into account the area of application. Any regulatory decision should also consider the impact on supply.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 211	2025/04/28 16:15
Country	Germany
Name of organization/institution	Bundesinnungsverband des Gebäudereiniger-Handwerks
I do not wish the name of my organisation/institution to be	

published on the ECHA website.	
General information	Das Gebäudereiniger- Handwerk ist das beschäftigungsintensivste Handwerk in Deutschland und gehört bundesweit zu den zentralen Wirtschaftszweigen. Es umfasst rund 660.000 Beschäftigte, davon rund 80% weibliche Beschäftigte, in knapp 35.000 Betrieben (Stand 1. Qu. 2024). Der Bundesinnungsverband des Gebäudereiniger-Handwerks (BIV) vertritt als Spitzenvereinigung die Interessen von etwa 2.500 Innungsbetrieben gegenüber allen relevanten Behörden und Institutionen sowie der Öffentlichkeit auf nationaler und europäischer Ebene. In den rund 2.500 Innungsbetrieben des BIV sind 85 % aller Beschäftigten tätig. Das Gebäudereiniger-Handwerk ist ein Ausbildungs- und Meisterberuf. Darüber hinaus gehören branchenspezifische Fort- und Weiterbildungsmaßnahmen insbesondere für Vorarbeiter, Objektleiter, Fachkraft zur Hygienesicherung und Desinfektor zum Standard. Unsere Mitgliedsbetriebe sind in allen Bereichen des täglichen und Wirtschaftslebens als umfängliche Dienstleister tätig und führen Reinigungsarbeiten in Objekten aller Art und Größe durch. Insbesondere in hygienesensiblen Bereichen, wie beispielsweise dem Gesundheitswesen, der Lebensmittelherstellung bzw. -industrie oder der Pharmazeutischen Industrie, bieten die Handwerksbetriebe hochwertige Hygienesdienste. Zur Einhaltung der hohen Hygienestandards kommt der fach- und sachgerechten Anwendung der jeweils geeigneten, sicheren und wirksamen Reinigungs- und Desinfektionsmittel erhebliche Bedeutung bei. Die Formulierung zahlreicher in der Gebäudereinigung verwendeten Reinigungs- und Desinfektionsmittel weist dabei Ethanol als wesentlichen und wichtigen Bestandteil auf, da es sowohl desinfizierende als auch lösende Eigenschaften besitzt. Es wirkt aseptisch und kann mit einer Vielzahl anderer Wirk- und Hilfsstoffe kombiniert werden. Dank dieser Eigenschaften werden entsprechende Formulierungen heute u. a. zur Händedesinfektion und zur Flächenschnelldesinfektion eingesetzt. In der professionellen Gebäudereinigung kommen diesbezüglich insbesondere folgende Produktgruppen bei zur Anwendung: Desinfektionsmittel Ethanol besitzt eine einzigartige Virus-Wirksamkeit unter den Alkoholen, sein Alleinstellungsmerkmal ist seine Wirksamkeit gegenüber unbehüllten Viren, die von anderen Alkoholen wie 1-Propanol und 2-Propanol nicht deaktiviert werden können wie z. B.: Polioviren, Coxsackieviren, Echoviren und das Enterovirus A71. Aufgrund dieser einzigartigen

	Eigenschaften werden folgende Desinfektionsmittel in der Gebäudereinigung regelmäßig angewendet: • Flächendesinfektionsmittel: Viele Flächendesinfektionsmittel enthalten Ethanol, um Oberflächen von Keimen zu befreien. Besonders wichtig in Bereichen wie Krankenhäusern oder in der Lebensmittelindustrie. • Sprühdesinfektionsmittel: Ethanol ist ebenso ein häufiger Bestandteil in Desinfektionssprays. Die WHO listet Ethanol als unverzichtbaren Wirkstoff für antiseptische Anwendungen. • Händedesinfektionsmittel: Ethanol wird häufig in alkoholbasierten Händedesinfektionsmitteln verwendet, da es effektiv gegen Bakterien, Viren und Pilze wirkt. • Desinfizierende Oberflächenreiniger / Bodenreiniger: Ethanol kann in Reinigungsmitteln für Hartböden enthalten sein, um eine antimikrobielle Wirkung zu erzielen. • Einwegdesinfektionstücher: Diese, in einigen Bereichen von Auftraggebern als Anwendung vorgeschriebenes Arbeitsmittel, Einwegreinigungstücher enthalten Ethanol, da es eine schnelle Trocknung ermöglicht und Keime zuverlässig abtötet. Einsatzgebiete sind insbesondere Einrichtungen des Gesundheitswesens (Krankenhäuser, Kliniken, Praxen, Pflegeeinrichtungen, etc.), und unterstützen damit das Multibarrierensystem zur Einhaltung von Hygienestandards und der Verhinderung von Infektionskrankheiten, u.a. auf Basis der Vorgaben der einschlägigen Norm DIN 13063 „Krankenhausreinigung - Anforderungen an die Reinigung und desinfizierende Reinigung in Krankenhäusern und anderen medizinischen Einrichtungen“. Bei der Reinigung in der Pharmazeutischen Industrie wird die Einhaltung der höchsten hygienischen Anforderungen im Standard der Reinraumreinigung, denen die Produktionsprozesse in der pharmazeutischen Industrie unterliegen, gewährleistet. In diesem Bereich wird in der professionellen Reinigung und Desinfektion deshalb Ethanol vor allem wegen seiner sehr guten Wirksamkeit und Rückstandsfreiheit eingesetzt: Bei der Anwendung verdampft Ethanol und bleibt daher nicht wie andere Wirkstoffe als unerwünschter Rückstand auf der Haut oder auf Oberflächen zurück. Diese Eigenschaft ist für die reinigende Desinfektion von Oberflächen im Produktionsumfeld unverzichtbar. Ethanol wirkt besonders bei den schwer zu inaktivierenden unbehüllten Viren. Gebäudereinigungsbetriebe sorgen in der Lebensmittelindustrie aber auch in anderen Bereichen der Lebensmittelherstellung, wie dem Lebensmittelhandwerk oder in Manufakturen, und -Zubereitung sowie Spülküchen mit ihren Reinigungs- und Desinfektionsdienstleistungen für hygienisch einwandfreie Zustände. Auf die Anwendung von

	Ethanol in Reinigungs- und Desinfektionsmitteln sind die Daten zur oralen Exposition, wie sie derzeit als Grundlage herangezogen werden, nicht übertragbar. Hier erfolgt die Exposition maximal inhalativ und dermal. Die vorhandenen oralen Daten beruhen zudem überwiegend auf der missbräuchlichen Verwendung von Ethanol-Gemischen. Für eine umfassende wissenschaftliche Beurteilung des Gefährdungspotentials eines Stoffes reichen diese daher unserer Ansicht nach nicht aus. Diesem Urteil schließt sich im Übrigen auch die BAU Berufsgenossenschaft (BG BAU) an, bei der die ganz überwiegende Mehrzahl unserer Unternehmen Mitglied sind und in Sachen Arbeits- und Gesundheitsschutz betreut werden: Laut Dr. Thorsten Reinecke, Referatsleiter Gefahrstoffe-Biostoffe bei der BG BAU besitzt Ethanol einen verbindlichen AGW (Arbeitsplatz-Grenzwert) in Höhe von 380 mg/m³, der zur Beurteilung der inhalativen Exposition an Arbeitsplätzen im Rahmen der Gefährdungsbeurteilung und zur Überprüfung der Wirksamkeit der Schutzmaßnahmen heranzuziehen ist. Weiterhin ist Ethanol in der TRGS 900 „Arbeitsplatzgrenzwerte“ mit der Bemerkung „Y“ als Stoff ausgewiesen, bei dem ein Risiko der Fruchtschädigung bei Einhaltung des Arbeitsplatzgrenzwertes nicht befürchtet zu werden braucht. Bei Ethanol handelt es sich nicht um einen hautresorptiven Stoff, weshalb beim Umgang mit Ethanol die Einhaltung des AGW für den Schutz der Gesundheit der Beschäftigten ausreichend ist. Die BG BAU hat bei Tätigkeiten mit ethanolhaltigen Reinigungsmitteln wie beispielsweise Glasreinigern zahlreiche Arbeitsplatzmessungen durchgeführt, teilweise unter Worst-Case-Bedingungen - bei sämtlichen Messungen wurde der AGW von Ethanol eingehalten.
Product Type	1,2,4
Alternative Identity and Properties	Wasserstoffperoxid (H ₂ O ₂) Chlorhaltige Desinfektionsmittel (z. B. Natriumhypochlorit) Quaternäre Ammoniumverbindungen (Quats) Aldehyde (z. B. Glutaraldehyd, Formaldehyd) Propanol
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Für die vollständige und rasche Desinfektion oder desinfizierende Reinigung eignen sich andere Inhaltsstoffe in der Regel häufig weniger gut als Ethanol. Um das ganze Spektrum ihrer Reinigungsaufträge erfüllen zu können, muss auch künftig Ethanol als Desinfektionswirkstoff zur

	Verfügung stehen. Da rund 80% der in der Reinigung tätigen Personen weiblich sind, würde ein ganz überwiegender Teil des Personals unter die Anwendung von Beschäftigungsverboten oder -einschränkungen fallen, sollte es zu der zur Diskussion stehenden Neueinstufung von Ethanol kommen. Angesichts der Tatsache, dass die Gründe für die in Frage stehende Einstufung auf Basis von Risiken bei oraler Aufnahme zum Tragen kommen, die für die Anwendung als Desinfektionsmittel vollkommen irrelevant ist, wäre diese Folge vollkommen unangemessen: Die oben aufgeführten Messungen der Berufsgenossenschaft haben keinerlei Überschreiten von Grenzwerten bei dermale oder inhalativem Kontakt gezeigt. Die Reinigungsunternehmen wären angesichts der ohnehin angespannten Personalsituation und da z.B. bei den anspruchsvollen Tätigkeiten im Gesundheitssektor oder der Reinraumreinigung auch nur entsprechend geschulte Beschäftigte eingesetzt werden können, bei den weitgehenden Einschränkungen für die Ethanolanwendung nicht der Lage, die Desinfektions- und Reinigungsaufträge zu erfüllen.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Durch die Auswirkungen auf die Auftragslage wäre mit erheblichen wirtschaftlichen Auswirkungen auf die Unternehmen der Gebäudereinigungsbranche zu rechnen. Auch muss von wirtschaftlichen Auswirkungen auf den Gesundheitssektor und andere Kundenbereiche wie die Lebensmittelwirtschaft oder Pharmazeutische Industrie ausgegangen werden, da ein verknapptes Angebot in der Regel zu höheren Preisen führt. Aufgrund der längeren Einwirkzeiten zahlreicher alternativer Wirkstoffe werden zudem Produktions- oder medizinische Abläufe verlangsamt und damit teurer.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Alternative Inhaltsstoffe benötigen in der Regel eine längere Einwirkzeit als Ethanol. Für eine vollständige Desinfektion ist eine längere Kontaktzeit erforderlich, was in manchen Situationen problematisch sein kann, wenn schnelle Desinfektion, beispielsweise in Operations- oder Ambulanzräumen, notwendig ist. Haut- und

	Augenreizungen: Alternative Inhaltsstoffe können Haut- und Augenreizungen verursachen, insbesondere bei längerer oder häufiger Exposition. Der Kontakt kann zu Hauttrockenheit, Rötungen und Irritationen führen. Bei direktem Kontakt mit den Augen kann es zu schweren Reizungen kommen. Andere Desinfektionswirkstoffe können allergische Reaktionen hervorrufen, so dass es bei prädisponierten Personen zu Hautausschlägen oder Atemproblemen kommen kann. Einige alternative Inhaltsstoffe wirken auf bestimmte Oberflächen schädigend, so dass ihre Anwendung nicht in allen Objekten bzw. für alle Einrichtungsgegenstände geeignet ist. Sie sind zum Teil stark reizend für Haut, Augen und Atemwege. Es erfordert daher einen sorgfältigen Umgang und Schutzmaßnahmen, z. B. Handschuhe und gute Belüftung. letzere ist häufig von Dienstleistern in den Liegenschaften ihrer Kunden nicht oder wenig beeinflussbar. Auch weisen sie teils einen starken, unangenehmen Geruch auf, der für viele Nutzer unangenehm sein kann. Bei wiederholtem Einsatz bestimmter Inhaltsstoffe kann es zur Resistenzbildung bei Bakterien kommen. Die Bildung von Bakterienresistenzen kann in Folge die Wirksamkeit im Kampf gegen bestimmte Keime verringern.
Information above is confidential	
Justification for confidentiality	
Availability	Ethanol ist sehr gut verfügbar, den zahlreichen Ethanolproduzenten stehen z.B. wesentlich weniger Propanolhersteller gegenüber. Die stark angestiegene Nachfrage nach Ethanol zu Beginn und im Verlauf der SARS Cov2-Pandemie hat leider eindrucksvoll gezeigt, wie schnell erhebliche Versorgungsengpässe eintreten können und eine flächendeckende Versorgung kaum mehr möglich ist. Aufgrund der hohen Verbreitung der sicheren und wirksamen Ethanolhaltigen Desinfektionsmittel wäre ein Wegfall dieses wesentlichen Arbeitsmittel für eine Vielzahl unserer Mitgliedsbetriebe schwerlich aufzufangen und mit erheblichen Problemen verbunden.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Für zahlreiche Reinigungs- und Desinfektionsaufträge der Gebäudereinigungsbetriebe sind ethanolhaltige Arbeitsmittel unverzichtbar und ein Ersatz nur schwer bis nicht

	vorstellbar. Da beim Kontakt in der Gebäudereinigung maximal mit dermalelem oder inhalativen Kontakt zu rechnen ist, der nach Begutachtung durch die Berufsgenossenschaft kein Risiko bedeutet und bei dem sämtliche Grenzwerte eingehalten werden, ist die Begründung mit Studienergebnissen, die auf oraler Aufnahme von Ethanol basieren, irrelevant. Alternativen weisen ihrerseits teilweise zahlreiche Risiken auf, die einen Ersatz des bei Anwendung zu Desinfektions- und Reinigungszwecken sicheren Stoffs Ethanol nicht sinnvoll machen. Reinigungsarbeiten würden zum Teil aufwändiger, langwieriger bzw. können Flächen nach der Anwendung weniger schnell wieder genutzt werden, z.B. für medizinische Eingriffe und Behandlungen oder auch im Rahmen von Produktionsabläufen in der Lebensmittel- oder pharmazeutischen Produktion. Da bei Neueinstufung von Ethanol erhebliche Beeinträchtigungen bei der Beschäftigung von Frauen zu befürchten wären, die rund 80% der in der Reinigung Tätigen Personen ausmachen, hätte dies nicht nur Auswirkungen auf die Reinigungsunternehmen, sondern auch auf die Beschäftigungsmöglichkeiten der Arbeitnehmerinnen, die beispielsweise bei der Krankenhausreinigung und Reinraumreinigung in der pharmazeutischen Industrie zudem hochspezialisierte Tätigkeiten durchführen, die kurzfristig nicht durch andere Mitarbeitende zu ersetzen sind.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	250428 Stellungnahme BIV.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 212	2025/04/28 16:35
Country	Germany
Name of organization/institution	Deutscher Verband der Riechstoff-Hersteller e.V. (DVRH)
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Personal hygiene products with ethanol are not only used by the fragrance industry, but in various other sectors. So far, there are no restrictions for the use of ethanol in the production of cosmetic products and fragrance.
Product Type	1,2,4
Alternative Identity and Properties	Ethanol is one of the most active substances in disinfectants that is entirely effective against non-enveloped viruses. Isopropanol and other alcohols are not as effective against several important human pathogens. Isopropanol as an alternative disinfectant to ethanol is not completely virucidal and not appropriately available in the EU, therefore being not accessible in necessary amounts. Furthermore, using this alternative there is a higher threat of incidental poisoning.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	The use of disinfectants containing active substances other than ethanol is technically feasible. Nonetheless, in scenarios where a contamination via disinfectants might occur, other active substances than ethanol are no appropriate alternative. When ethanol-based disinfectants are used, wearing protective gloves is considered unnecessary. Using alternative disinfectants like isopropanol there could be a challenge concerning regulatory compliance. Furthermore ethanol-based disinfectants leave no residues. Ethanol is particularly useful in mould control concepts because it does not require rinsing after application. Another example of its use as a disinfectant is in the cleaning of tubes and tanks, where other alcohols could contaminate the stored or transferred goods.

Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Disinfectants with ethanol are used as a standard in various sectors. Alternative disinfectants are more expensive. Ethanol can be produced easily in higher amounts which brings down its price.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Personal hygiene is of the highest importance. Disinfectants are essential to assure personal hygiene and to avoid that pathogens or other microorganisms contaminate the products. Using alternative disinfectants could also lead to possible skin damage, accidental poisoning or potential environmental contamination due to residues. Ethanol is considered as active substance in disinfectants having the lowest risks for all kinds of users. Overall the main risks with ethanol are associated with the misuse of drinking too much alcohol. However, when it comes to disinfectants of PT 1, ethanol is denatured, therefore oral consumption is improbable. The relevant ways of exposure to ethanol as disinfectant are solely dermal uptake and inhalation.
Information above is confidential	
Justification for confidentiality	
Availability	Isopropanol can not be produced in as big amounts as ethanol. There is no established or reliable supply chain for the production of alternative disinfectants. As the Corona pandemic demonstrated, production of ethanol can effortlessly be raised in a short amount of time. This is unique for active substances in disinfectants.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Disinfectants with ethanol are broadly used in various sectors. They are not only used by professionals but also by workers to protect their personal health. Personal hygiene is of very high importance in fragrance production.

	Disinfectants are essential to guarantee personal hygiene and to avoid that pathogens contaminate the products. An alternative for ethanol as a disinfectant is isopropanol. However, isopropanol can leave residues and can possibly contaminate the products and environment during the production or preparation which is undesirable. Furthermore, when isopropanol is used as an active substance, it is often mixed with ethanol. Therefore disinfectants with ethanol are the ideal option. Also, ethanol is the active substance of choice in disinfectants that is entirely effective against non-enveloped viruses. Risks with ethanol are mainly associated with drinking too much alcohol. In disinfectants, the ethanol used is denatured, therefore oral consumption is not plausible. Overall, there are no suitable alternatives for ethanol as a disinfectant because of the costs and availability, the effectiveness, residues and required following tests to ensure the absence of the alternatives.
Information above is confidential	
Justification for confidentiality	
Other comments	Regulatory challenges should be approached with a well-balanced strategy that incorporates a risk-based decision-making process. It is essential to carefully evaluate potential threats and their implications to ensure that regulations remain both effective and feasible. Striking the right balance prevents unnecessary restrictions while safeguarding compliance, safety, and ethical principles. Taking these aspects into account could lead to better, well-informed and sustainable policy choices.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 213	2025/04/28 16:38
Country	Germany
Name of organization/institution	MedicalMountains GmbH
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	The use of alcohol-based disinfectants represents a critical strategy in the prevention and control of infections, both in healthcare settings and within the broader community. Their effectiveness and reliability have been well established over many years of application. Ethanol, the key active ingredient in these disinfectants, plays an indispensable role. It is essential not only for hand and surface disinfection but also for numerous production processes, particularly in the healthcare and pharmaceutical industries. Compared to other disinfecting agents, ethanol offers several advantages: it has a relatively low hazard profile, is highly effective against a broad range of bacteria and viruses, and is both safe and biodegradable. A notable feature of ethanol is its specific and irreplaceable action against non-enveloped viruses, such as poliovirus. Its use in alcohol-based hand sanitizers has been instrumental in significantly reducing the prevalence of healthcare-associated infections. Given its critical importance, the World Health Organization (WHO) has officially designated ethanol-based hand disinfectants as essential tools for infection control- In addition, ethanol's ready availability and the flexibility to rapidly scale up production capacities, as demonstrated during the COVID-19 pandemic, underline its critical role in maintaining infection control measures. The ability to quickly interrupt transmission chains was substantially supported by the availability of ethanol, enabling manufacturers to meet the unprecedented demand for disinfectants. For hygiene and cleaning applications, only denatured ethanol is utilized to preclude the possibility of oral consumption. The toxicological data underlying the proposed classification of ethanol as potentially reprotoxic or carcinogenic predominantly originate from the (abusive) oral consumption of alcoholic beverages. In contrast, exposures via inhalation or dermal contact result in blood ethanol levels that are comparable to those arising from endogenous synthesis or dietary intake. A classification of ethanol as a CMR substance (carcinogenic, mutagenic, or

	reprotoxic) would have extensive and adverse consequences for public health protection measures and the healthcare sector as a whole. Specifically, such a classification would severely restrict the broad and essential use of ethanol-based disinfectants, as well as impact the manufacturing of critical products, including medicinal products, medical devices, and in vitro diagnostic medical devices (IVDs). Furthermore, a classification as a reproductive toxicant affecting or transmitted via lactation would, under German labor legislation, trigger employment prohibitions for women of childbearing age, leading to significant workforce challenges in key sectors.
Product Type	1,2,4
Alternative Identity and Properties	The World Health Organization (WHO) has classified ethanol-based hand disinfectants as indispensable for infection control. Similarly, Germany's Robert Koch Institute recommends the use of ethanol, citing its superior antiviral efficacy compared to propyl alcohols. The addition of other active substances—such as chlorhexidine digluconate, octenidine hydrochloride, polihexanide, quaternary ammonium compounds, ampholytes, phenol derivatives, and triclosan—does not enhance the efficacy of alcohol-based disinfectants. Instead, depending on the added substance, their inclusion may increase the risk of intolerance or promote the development of microbial resistance. Furthermore, the use of PVP iodine products is limited due to the potential for iodine absorption. Aqueous solutions based on chlorinated solvents, PVP (polyvinylpyrrolidone) iodine, or peroxides are not suitable alternatives to alcohol-based hand disinfectants in healthcare environments. Their comparatively lower antimicrobial efficacy, poorer skin tolerance, inferior spreading properties on the skin, and longer evaporation times render them unsuitable for effective infection control.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	

Economic Feasibility	The COVID-19 pandemic clearly demonstrated the capacity for rapid scale-up of disinfectant production in response to urgent public health needs. Ethanol-based disinfectants were crucial in maintaining effective infection control measures during this period. Disinfectants are frequently marketed as dual-use products under both the Biocidal Products Regulation (BPR) and the Medical Device Regulation (MDR, Regulation (EU) 2017/745). Any change to the primary active substance would trigger extensive and resource-intensive testing and approval procedures, significantly delaying market access and disrupting supply. In Germany alone, the market for hand disinfectants is valued at approximately €80 million. Importantly, all virucidal hand disinfectants currently available are ethanol-based, while the effectiveness spectrum of alternative substances remains considerably limited. The consistent implementation of infection prevention and control (IPC) measures is vital for reducing the additional burden on both the healthcare system and the wider economy caused by preventable infections. Hand and surface disinfectants, classified as risk-reducing medical devices and technologies, play a fundamental role in this context. Their continuous use demonstrably contributes to the prevention of infections. According to the Robert Koch Institute, approximately 600,000 nosocomial infections occur annually in Germany, resulting in up to 20,000 deaths. Such infections lead to prolonged hospital stays and considerable additional costs for the healthcare system. Cost-benefit analyses have shown that IPC programmes, including hand hygiene initiatives, are highly cost-effective (6). The availability and use of appropriate hand disinfectants are indispensable for the success of these programmes. These findings underline the critical importance of maintaining and strengthening preventive measures against nosocomial infections. Ethanol-based hand and surface disinfectants are key components of such measures. A reclassification of ethanol, as currently proposed, would severely undermine infection protection efforts to an unprecedented degree, posing a direct threat to patient safety and public health. In addition, compliance with hygiene protocols in healthcare settings would be significantly jeopardized. Ethanol-based disinfectants enjoy a particularly high level of acceptance among healthcare professionals, a factor critical for ensuring consistent and effective hand hygiene practices.
Information above is confidential	
Justification for confidentiality	

Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	We urgently request that the planned classification be halted immediately. Only exposure-relevant and use-appropriate data should be considered in the assessment process. The proposed classification of ethanol is primarily based on data derived from the abusive oral consumption of alcoholic beverages. This hazard-based approach does not accurately reflect actual exposure levels and usage conditions in hygienic and healthcare applications. Implementing such a classification would have severe and far-reaching consequences for the healthcare system and public health protection. Failure to do so would lead to serious consequences for the industrial health sector, significantly restricting or even prohibiting the availability and use of ethanol as a primary or auxiliary active ingredient in essential products such as hand disinfectants, surface disinfectants, and in critical production and hygiene processes. Moreover, the classification of ethanol as a CMR substance (carcinogenic, mutagenic, or reprotoxic) under the biocide and Classification, Labelling and Packaging (CLP) regulations would have massive economic and legal repercussions. It is therefore absolutely necessary that this classification process be stopped immediately to avoid jeopardizing the healthcare sector's infection prevention capabilities and economic stability.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	

Justification for confidentiality	
References	
Attachments (non-confidential information)	202504_Forderungspapier_Ethanolverfahren_EN.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 214	2025/04/28 16:40
Country	Germany
Name of organization/institution	MedicalMountains GmbH
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	The use of alcohol-based disinfectants represents a critical strategy in the prevention and control of infections, both in healthcare settings and within the broader community. Their effectiveness and reliability have been well established over many years of application. Ethanol, the key active ingredient in these disinfectants, plays an indispensable role. It is essential not only for hand and surface disinfection but also for numerous production processes, particularly in the healthcare and pharmaceutical industries. Compared to other disinfecting agents, ethanol offers several advantages: it has a relatively low hazard profile, is highly effective against a broad range of bacteria and viruses, and is both safe and biodegradable. A notable feature of ethanol is its specific and irreplaceable action against non-enveloped viruses, such as poliovirus. Its use in alcohol-based hand sanitizers has been instrumental in significantly reducing the prevalence of healthcare-associated infections. Given its critical importance, the World Health Organization (WHO) has officially designated ethanol-based hand disinfectants as essential tools for infection control- In addition, ethanol's ready availability and the flexibility to rapidly scale up production capacities, as demonstrated during the COVID-19 pandemic, underline

	its critical role in maintaining infection control measures. The ability to quickly interrupt transmission chains was substantially supported by the availability of ethanol, enabling manufacturers to meet the unprecedented demand for disinfectants. For hygiene and cleaning applications, only denatured ethanol is utilized to preclude the possibility of oral consumption. The toxicological data underlying the proposed classification of ethanol as potentially reprotoxic or carcinogenic predominantly originate from the (abusive) oral consumption of alcoholic beverages. In contrast, exposures via inhalation or dermal contact result in blood ethanol levels that are comparable to those arising from endogenous synthesis or dietary intake. A classification of ethanol as a CMR substance (carcinogenic, mutagenic, or reprotoxic) would have extensive and adverse consequences for public health protection measures and the healthcare sector as a whole. Specifically, such a classification would severely restrict the broad and essential use of ethanol-based disinfectants, as well as impact the manufacturing of critical products, including medicinal products, medical devices, and in vitro diagnostic medical devices (IVDs). Furthermore, a classification as a reproductive toxicant affecting or transmitted via lactation would, under German labor legislation, trigger employment prohibitions for women of childbearing age, leading to significant workforce challenges in key sectors.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	The COVID-19 pandemic clearly demonstrated the capacity for rapid scale-up of disinfectant production in response to urgent public health needs. Ethanol-based disinfectants were crucial in maintaining effective infection control measures during this period. Disinfectants are frequently marketed as dual-use products under both the Biocidal

	Products Regulation (BPR) and the Medical Device Regulation (MDR, Regulation (EU) 2017/745). Any change to the primary active substance would trigger extensive and resource-intensive testing and approval procedures, significantly delaying market access and disrupting supply. In Germany alone, the market for hand disinfectants is valued at approximately €80 million. Importantly, all virucidal hand disinfectants currently available are ethanol-based, while the effectiveness spectrum of alternative substances remains considerably limited. The consistent implementation of infection prevention and control (IPC) measures is vital for reducing the additional burden on both the healthcare system and the wider economy caused by preventable infections. Hand and surface disinfectants, classified as risk-reducing medical devices and technologies, play a fundamental role in this context. Their continuous use demonstrably contributes to the prevention of infections. Cost-benefit analyses have shown that IPC programmes, including hand hygiene initiatives, are highly cost-effective. The availability and use of appropriate hand disinfectants are indispensable for the success of these programmes. These findings underline the critical importance of maintaining and strengthening preventive measures against nosocomial infections. Ethanol-based hand and surface disinfectants are key components of such measures. A reclassification of ethanol, as currently proposed, would severely undermine infection protection efforts to an unprecedented degree, posing a direct threat to patient safety and public health. In addition, compliance with hygiene protocols in healthcare settings would be significantly jeopardized. Ethanol-based disinfectants enjoy a particularly high level of acceptance among healthcare professionals, a factor critical for ensuring consistent and effective hand hygiene practices. It can be foreseen that a classification of ethanol within this process will influence other areas as well. A CLH classification under the CLP regulation might be the next step. Legislations like the MDR and IVDR will be impacted, but at the same time production plants and the use within production processes. To think ahead, other supplied products will be affected by the classification. Inks and varnishes for labelling, preparation solutions for cleaning surfaces could be examples. Ethanol is the best solution for these applications because it has favourable evaporation properties.
Information above is confidential	
Justification for confidentiality	

Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	We urgently request that the planned classification be halted immediately. Only exposure-relevant and use-appropriate data should be considered in the assessment process. The proposed classification of ethanol is primarily based on data derived from the abusive oral consumption of alcoholic beverages. This hazard-based approach does not accurately reflect actual exposure levels and usage conditions in hygienic and healthcare applications. Implementing such a classification would have severe and far-reaching consequences for the healthcare system and public health protection. Failure to do so would lead to serious consequences for the industrial health sector, significantly restricting or even prohibiting the availability and use of ethanol as a primary or auxiliary active ingredient in essential products such as hand disinfectants, surface disinfectants, and in critical production and hygiene processes. Moreover, the classification of ethanol as a CMR substance (carcinogenic, mutagenic, or reprotoxic) under the biocide and Classification, Labelling and Packaging (CLP) regulations would have massive economic and legal repercussions. It is therefore absolutely necessary that this classification process be stopped immediately to avoid jeopardizing the healthcare sector's infection prevention capabilities and economic stability.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	

Justification for confidentiality	
References	
Attachments (non-confidential information)	202504_Forderungspapier_Ethanolverfahren_EN.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 215	2025/04/28 16:48
Country	Germany
Name of organization/institution	Deutscher Verband der Aromenindustrie e.V. (DVAI)
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Ethanol is a natural compound of numerous foodstuffs, it is intentionally added to certain foods, it is used as a functional compound in food and food production - furthermore ethanol is used for disinfection purposes. Regarding disinfection in the food industry, ethanol is utilized for the disinfection of surfaces and equipment (PT 4) and for personal hygiene (PT 1). Disinfection with ethanol is not only used by the food industry, but in the entire food chain and other sectors.
Product Type	1,2,4
Alternative Identity and Properties	Other alcohols, particularly isopropanol (2-propanol and 1-propanol). Also mentioned were sodium hypochlorite solutions and hydrogen peroxide solutions. Sodium hypochlorite may leave residues in food products which is not desirable. It can also only be used for disinfecting instruments or surfaces. Sodium hypochlorite is considered to have a higher risk of accidental poisoning and it does not evaporate, therefore being unsuitable for personal hygiene or workers safety. Hydrogen peroxide is an aggressive chemical which is unsuitable for many surfaces which come into contact with food. In comparison to ethanol, isopropanol is less volatile, potentially leading to residues

	which can spoil food due to the bad taste and odor left behind by isopropanol. In contrast, Ethanol completely evaporates quickly and even if traces would remain on the surfaces with food contact, they would not be considered relevant because ethanol is also a natural compound in food.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	One of the most important active components in disinfectants effective against non-enveloped viruses is ethanol. Isopropanol or other alcohols are less effective against known pathogens in certain foodstuffs. The use of other alcohols, e.g. isopropanol instead of ethanol, is technically feasible. Nevertheless, when residues might occur or the use of alternatives requires rinsing with water afterwards, other alcohols are not suitable as an alternative. As potential alternatives for surfaces and instruments there are sodium hypochlorite, sodium hydroxide and hydrogen peroxide to be mentioned. Those have very limited application possibilities and additional safety precautions are required. Ethanol is especially suitable e.g. to combat moulds because it does not have to be rinsed off afterwards. Another example for the use of ethanol as a disinfectant is the cleansing of tubes and tanks where other alcohols would contaminate the stored or transferred goods. For the food industry it is of very high importance to ensure that there are no residues in the final food products, if necessary, retests for the absence of the respective disinfectants must be carried out. Moreover, disinfectants often consist of mixtures of ethanol and alternative substances.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Disinfectants with ethanol are commonly used in the food sector. A main application is spraying or wiping surfaces with ethanol-based disinfectants. But ethanol is also used for the disinfection of dispensing systems in food production and for disinfecting filling lines or storing units and various other examples. Alternative disinfectants with other alcohols are more expensive than ethanol. Ethanol can be produced in vast amounts lowering its price.

Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	When rinsing steps with water are required after the use of other alcohols as disinfectants, new microbiological risks in the foodstuff could occur, especially for the formation of moulds and their mycotoxins which will often lead to a reduced shelf life of the food product. Additionally, using alcohols other than ethanol could possibly lead to skin damage or accidental poisoning. Furthermore, taste and odor problems could occur in the final food products when using e.g. isopropanol. Ethanol is considered as an active substance in disinfectants presenting the lowest risks for all kinds of users. The main risks with ethanol are associated with the misuse of drinking too many alcoholic beverages. When it comes to disinfectants of PT 4, ethanol is denatured and oral intake is improbable. The relevant ways of exposure to ethanol as disinfectant are inhalation and dermal uptake only.
Information above is confidential	
Justification for confidentiality	
Availability	Isopropanol and other alcohols do not have a reliable and established supply chain, therefore they cannot be produced in as big amounts as ethanol. Furthermore, ethanol is mostly produced from agricultural plants, other alcohols are produced by chemical industry. During the COVID-pandemic it was proven that ethanol production could be rapidly and easily increased. This would not be possible for the mentioned alternatives.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Disinfectants with ethanol are commonly used in the food sector. Main applications are the disinfection of surfaces by spraying/wiping and the cleaning/disinfection of tanks, tubes, equipment or machines. Alternatives for ethanol as disinfectants are other alcohols, e.g. isopropanol. However, to date isopropanol is considered to be more toxic than ethanol, it is not as effective against non-enveloped viruses as ethanol and it is less volatile, leading to residues on surfaces with food contact that spoil food due to bad odor or

	taste left behind. Risks with ethanol are mainly associated with drinking too many alcoholic beverages. In disinfectants, the ethanol used is denatured, therefore an oral poisoning is improbable. Overall, there is no suitable alternative for ethanol as an active substance in disinfectants because of the lower effectiveness, residues and resulting additional tests to ensure the absence of the alternative disinfectants. Furthermore, there is no established supply chain and therefore a reduced availability of potential alternatives for ethanol.
Information above is confidential	
Justification for confidentiality	
Other comments	In general, when addressing regulatory issues, it is crucial to adopt a risk-based decision-making process that carefully assesses potential hazards and their impact. A well-balanced approach ensures that regulations are both effective and practical, avoiding unnecessary restrictions while still maintaining safety, compliance, and ethical standards. Considering these factors leads to more informed and sustainable policy decisions.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 216	2025/04/28 16:55
Country	Belgium
Name of organization/institution	FoodDrinkEurope

I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Ethanol-based disinfectants play a crucial role in maintaining high hygiene standards and safety in the food and beverage manufacturing [food and feed area applications (PT4)], but also extensively used for personal hygiene (hand rubs; PT 1). Before any possible restriction on the use of ethanol as a biocidal active substance, it is essential that technically feasible and safe alternatives are identified and validated. As of current knowledge, ethanol's specific characteristics — efficacy against a broad range of microorganisms, regulatory acceptance, low residue levels, and compatibility with food production environments — are critical and cannot be matched by currently available substances. It is crucial that any possible restriction on the use of ethanol as a biocidal active substance, does not put food production, food safety, or food security at risk. We highlight that critical hygiene practices in food production would be compromised, potentially endangering food safety and food security across the European Union. It is also important to highlight that existing concerns regarding ethanol's health effects are primarily based on oral exposure data, which is not directly relevant to its use in biocidal applications involving dermal or respiratory exposure. No adverse health effects associated with such exposures have been observed when appropriate occupational risk management measures are applied.
Product Type	1,2,4
Alternative Identity and Properties	For any alternatives being proposed during this consultation process, we strongly highlight that disinfection with ethanol is not only used by the food processing industry, but along the whole agri food chain. Ethanol offers a unique performance. It combines broad-spectrum efficacy, rapid evaporation, low residues, and compatibility with food contact surfaces. These properties are essential to ensure safe food manufacturing and protect public health. There is currently no alternative biocidal substance that offers equivalent or better effectiveness, operational feasibility, and safety for use in food production environments. Any substitute substances being considered should not put food production, food safety, or food security at risk
Information above is confidential	

Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Based on current knowledge and practical experience from the sector, FoodDrinkEurope considers that there are no suitable and available alternatives equal or better than ethanol for its biocidal uses, particularly within PT4 (food and feed area disinfectants). Any alternative would require to have similar effectiveness to ethanol against a wide range of microorganisms, including bacteria, viruses, and fungi. It has to act and evaporate quickly, which is important in fast-paced manufacturing environments. Ethanol is the only active substance in disinfectants that is effective against non-enveloped viruses. Substances considered required need to have a broad-spectrum antimicrobial activity; rapid action; low residue; regulatory approval; non-toxic at proper use levels. So far, ethanol is perceived as active substance in disinfectants having the lowest risks for all kind of users. When it comes to disinfectants of PT 4, ethanol is denatured (oral consumption is not possible). The relevant routes of exposure for ethanol as disinfectant are dermal uptake and inhalation only. Alternatives, where they exist, either: • Fail

	to deliver the same level of disinfection performance, • Are not technically feasible at industrial scale, or • Introduce additional hazards or operational challenges that may compromise food safety or worker safety. Ethanol-based products are used with established risk mitigation measures that minimise exposure and ensure worker protection under EU occupational health and safety rules. In light of these considerations, FoodDrinkEurope concludes that ethanol should continue to be authorised for biocidal uses under the BPR, unless and until suitable, safe, and technically feasible alternatives have been identified and are available to industry without compromising food production, food safety and food security.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 217	2025/04/28 17:19
Country	Germany
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1

General information	As a manufacturer of cleaning products, cosmetic products, and disinfectants, among others, we use ethanol as an active ingredient and excipient in these product categories. Ethanol is a very important component of these products, especially our disinfectants, as it is the main active ingredient.
Product Type	1,2,4
Alternative Identity and Properties	Ethanol is one of the most important industrial solvents due to its ability to dissolve both water-soluble (hydrophilic) and fat-soluble (lipophilic) substances. Compared to other alcohols such as 1-propanol or 2-propanol, ethanol offers the following advantages: Long-standing use as a starting material: Ethanol has been used safely and effectively in various technical fields for many years without any proven risks to humans or the environment. Absorption through the skin or by inhalation – for example, in hand disinfection – is well below toxicologically relevant levels. Efficacy in disinfectants: In disinfectants, ethanol is an important active ingredient for combating microorganisms, including bacteria, fungi, and viruses. A mixture of 70% ethanol with water offers the highest antimicrobial effect. Mixtures of isopropanol/water or propanol/water cannot match the effectiveness of ethanol. Good biodegradability: Ethanol is readily biodegradable and therefore does not accumulate in the environment. Ethanol also has a low odor and is available from renewable resources.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Ethanol is characterized by its rapid and residue-free evaporation, which is due to its low molecular weight. This property is particularly advantageous for rapid surface disinfection, as ethanol evaporates quickly and leaves no residue. Isopropanol exhibits similar volatility, but isopropanol cannot compete with ethanol in terms of biocidal efficacy. Ethanol exhibits exceptional efficacy against non-enveloped viruses, which cannot be inactivated by other alcohols such as 1-propanol or 2-propanol. This property makes ethanol particularly relevant for use as a disinfectant for human hygiene and surface disinfection. Furthermore, ethanol is extremely versatile and can be effectively combined with other active ingredients such as acids and excipients such as glycerin. These combinations can improve the efficacy and skin compatibility of formulations such as hand sanitizers. In terms of safety and

	tolerability, ethanol is considered very safe, as its absorption through inhalation or skin contact, for example, in hand disinfection, is significantly below toxicologically relevant concentrations. Furthermore, ethanol does not accumulate in the environment over the long term, underscoring its environmental compatibility. Ethanol is frequently used as an active ingredient in hand disinfectants and is classified by the World Health Organization (WHO) as an essential ingredient for antiseptic applications. This international relevance makes ethanol a crucial component in disinfection and other hygiene-relevant areas.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	There is a call for a measured approach to the categorization of ethanol and for consideration of the actual risk. The harmful effects of excessive oral ingestion of ethanol are undisputed. Furthermore, ethanol has been shown to have teratogenic (fertility-damaging) effects in pregnant women and to be carcinogenic when ingested above a certain threshold dose. Given this, it is likely that the classification into CMR Category 1 (or Category 2) discussed in the biocides process will also impact the update of the harmonized classification initiated in the CLH process. However, a CMR classification under the CLP Regulation would be independent of actual exposure (whether dermal or inhalation) and would not consider the actual risk depending on the intended use. It should also be noted that denatured ethanol is used in industrial settings to manufacture disinfectants, cleaning agents, and other products. Denaturation effectively prevents oral absorption. Experts have also determined that dermal exposure is irrelevant, as ethanol is not a skin-absorbing substance. This means that ethanol cannot be absorbed through intact skin and cannot cause health damage.
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Justification for confidentiality	

Availability	Classification under the CLP Regulation would gradually lead to restrictions under the REACH Regulation for consumer products such as disinfectants, detergents, cleaning agents, and even cosmetic products, and could thus de facto result in a ban on these products containing ethanol. Manufacturers would be forced to modify formulations that have proven effective over time, which would involve considerable effort and expense. Furthermore, there are no suitable substitutes for ethanol for many formulations. Due to its aforementioned properties and its ready availability, ethanol cannot be easily and widely replaced. Against this backdrop, despite its advantageous material properties—such as its ability to dissolve both hydrophilic and lipophilic substances, its good biodegradability, and the possibility of being sustainably obtained from renewable raw materials—ethanol could be subject to a ban on use in various products, even though it has been used safely for many years. It is therefore questionable what benefit such a categorization would have for human health or the environment. On the contrary: The use of ethanol for hygienic purposes, particularly as a disinfectant—for example, in the form of biocidal products for hand disinfection—has proven successful over the long term and could be jeopardized by such a classification. This could have negative impacts on human health, particularly in emergencies such as a pandemic, where pathogens must be combated against which ethanol is effective, but 1- or 2-propanol is not.
Information above is confidential	
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Conclusion on suitability and availability of the alternative	There are no alternatives comparable to ethanol in terms of safety, efficacy and technical properties, particularly biocidal properties.
Information above is confidential	
Justification for confidentiality	
Other comments	Given the particular importance of ethanol as a biocidal active ingredient and as an ingredient in household care and cosmetic products, a balanced and pragmatic approach to regulation is required, and the benefits to human health and the environment must be assessed in advance. Before a possible CMR classification of ethanol is considered, it should first be examined whether a harmonized

	classification is even necessary, what effort and costs would be involved, and what benefits or harms such a classification would entail. A comprehensive impact assessment is absolutely necessary. It is important to consider the actual routes of exposure (oral vs. inhalation). The toxicological data used to assess the risks of ethanol are based on alcohol abuse, i.e., oral intake. The available human data are insufficient for a sound assessment, as they do not include inhalation and dermal routes of exposure. However, when used as a washing, cleaning, or disinfectant agent, the inhalation or dermal route of exposure is irrelevant, as no risk arises from these. A CMR classification would result in a general ban on all cleaning agents and other products containing ethanol. Furthermore, the socioeconomic impacts should be considered as part of the ongoing process.
Information above is confidential	
Justification for confidentiality	
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Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 218	2025/04/28 17:24
Country	Germany
Name of organization/institution	Verband deutscher Alkoholhersteller u. Verarbeiter e.V.
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	The VDAHV (Verband Deutscher Alkoholhersteller e.V.) represents producers, processors, and distributors of ethanol in Germany. The association probably has the most significant market share of industrial used ethanol in

	Germany, with eight members. Our members are mid-size family companies as well as a large chemical group. Many members have run their business for over 150 years with the natural and renewable product ethanol. A possible classification of ethanol as a CMR substance with its dramatic consequences in almost every sector that uses ethanol would jeopardise the existence of the members of VDAHV, which have over 500 direct and many more indirect employees. Therefore, the VDAHV strongly contradicts a possible classification of ethanol as a CMR substance. Especially as it will not improve but will even worsen the health and safety of the people and will create a huge additional bureaucratic burden for producers and users of ethanol.
Product Type	1,2,4
Alternative Identity and Properties	N-propanol and isopropanol are the only alternatives with comparable antimicrobial effects. However, neither chemical inactivates non-enveloped viruses. Therefore, those two alternatives are generally used in combination with ethanol to ensure the required antimicrobial effect in disinfectants used in human hygiene. No substitute biocidal active substance has equal efficiency against non-enveloped viruses. The Assessment of Alternatives by the Alcohol Task Force for all three product types in question (P1, PT2 and PT4) showed that there is, by far, no better alternative to ethanol for disinfection against non-enveloped viruses, which form a majority of the human infecting viruses, such as Polio, and entero- and noroviruses
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Ethanol is a highly effective microbicide that prevents infection even with nosocomial multiresistant microorganisms in humans and animals when applied as a disinfectant on skin and contact surfaces. Humans and most other species well tolerate it. It is produced from sustainable and renewable raw materials with a low carbon footprint, and it is available worldwide from a vast number of producers and distributors. It is the only skin-tolerated substance in humans and most animals that inactivates non-enveloped viruses. According to the Robert Koch Institute, considering the type of exposure (dermal, oral), no carcinogenicity, teratogenicity, or mutagenicity of ethanol has been described until today.

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Justification for confidentiality	
Economic Feasibility	Ethanol has long been used in hospitals and healthcare as an essential and efficient disinfectant. During the COVID-19 pandemic, ethanol was the only product available in sufficient quantities, supplied by various sources, and the only sanitiser able to combat the Coronavirus and other non-enveloped viruses and ensure the safety of patients, vulnerable populations, hospital staff, and the public. As the alternative products are only produced by a few Petrochemical giants (fewer than 12 worldwide), the price sensitivity for additional demand during the COVID-19 pandemic was tremendous. Price increases by 300 – 400 % occurred, while the ethanol price increased only by 50 -80 % and only during a short period. This is because there are many producers and suppliers in Europe (100), guaranteeing intense competition, safety of supply, and efficient healthcare. Even if there are currently no reliable estimates of the total costs, we expect the economic impact to be in the billions for the EU, especially for the cosmetics industry, where ethanol often cannot be replaced by other substances without jeopardising the quality and safety of the products.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Ethanol is less toxic than n-Propanol and Isopropanol. According to the safety data sheets, the oral LD50 in rats is much lower for the alternatives (n-Propanol 1.870 mg/kg; Isopropanol 4.570 mg/kg) than for Ethanol (7.060 mg/kg). Hence, possible accidental oral intake of n-Propanol and Isopropanol disinfectant would be much more dangerous compared to Ethanol products. However, the intention to classify Ethanol as CMR is solely based on the description of hazardous, abusive ingestion, while local topical use has been proven safe.
Information above is confidential	
Justification for confidentiality	
Availability	n-Propanol and Isopropanol are produced by fewer than 10 sources worldwide (e., Shell, Ineos, Exxon). These are

	mainly petrol giants that produce n-Propanol and Isopropanol from byproducts from petrol refinery, processing crude oil or natural gas. This also limits the total future availability and today's local sourcing. Europe's estimated annual production volumes of n-propanol and Isopropanol are 100k mt and 700k mt, respectively. In comparison, 5 million mt of Ethanol are produced in Europe annually. In Europe alone, Ethanol is available from over 100 producers. Since Ethanol is plant-based, it is available in all regions worldwide. Furthermore, future availability is secured due to renewable raw materials. During the COVID-19 pandemic, ethanol was the only product available in large volumes, efficient in reducing the risk of infection, and comparable in costs of supply. As many experts say, the next pandemic will occur sooner rather than later. It is unclear how the European population will be treated and cared for without ethanol as a sanitiser, and how the European population would accept the decision of the European Commission to ban ethanol as a CMR.
Information above is confidential	
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Conclusion on suitability and availability of the alternative	A CMR classification would have far-reaching negative consequences for hygiene, the economy and the environment. It would lead to substitution by petrochemically produced alcohols such as isopropanol or n-propanol - substances that are often more questionable from a toxicological point of view and whose ecological balance is significantly worse. Ethanol is an essential component of preventive healthcare, particularly hand disinfection. In medical facilities, it makes a decisive contribution to infection prevention. In addition, ethanol is being produced from renewable raw materials and, therefore, makes an important contribution to reducing greenhouse gas emissions. Ethanol is widely used in many basic chemicals and other applications, such as pharmaceuticals, cosmetics, homecare products, or antifreeze solvents worldwide. The recommendation for a CMR classification would put pressure on the exclusion or substitution of ethanol. The replacement products, if there are some at all, would be less healthy, more hazardous and bad for the environment because of much higher greenhouse gas emissions. Furthermore, they will prevent the use of ethanol by the general public (hand gels) and professional users (hospitals) where no suitable alternatives exist that are effective against non-enveloped viruses, as

	demonstrated by the Assessment of Alternatives. Finally, it would impact various industries beyond biocidal applications linked to cosmetic products, chemical agents at work, food-contact materials, EU Ecolabel, waste, medical devices, and general food law. Such a classification would bring no health benefit at all. Still, it would create severe health issues and would have severe socio-economic consequences for many industries that would be left with no alternative.
Information above is confidential	
Justification for confidentiality	
Other comments	The proposed classification is based on data on the abuse of alcoholic beverages. However, these are not transferable to technical and industrial applications - especially not to biocidal use. The human drinking data is not scientifically suitable for classification. Studies show that even under extreme conditions of dermal or inhalation exposure, only minimal amounts of ethanol are absorbed, which are considered harmless from a toxicological point of view. Ethanol has a comparatively low toxicity and is indispensable in numerous applications due to its unique properties. It is also important to stress that for technical or most other uses, except for drinking alcohol, denatured ethanol is supplied and used, which is not suitable for drinking and therefore not comparable to drinking alcohol. A CMR classification would have far-reaching negative consequences for hygiene, the economy and the environment. It would lead to substitution by petrochemically produced alcohols such as isopropanol or n-propanol - substances that are often more questionable from a toxicological point of view and whose ecological balance is significantly worse. The proposed classification of ethanol by the BPC would also significantly impact the ongoing CLP regulation. Therefore, the Risk Assessment Committee (RAC) under the CLP Framework, not the Biocidal Products Committee (BPC), should address the harmonised classification discussion, especially considering the complexity of the discussion around classification and its significant consequences. It is also important to mention that a classification and consequently a ban of ethanol based on a Database on the abuse of drinking alcohol would undermine the credibility of the European institutions because nobody would understand why false data justify a massive increase in bureaucracy and the ban of the most efficient sanitiser during Corona.

Information above is confidential	
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References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 219	2025/04/28 17:26
Country	Belgium
Name of organization/institution	A.I.S.E.
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	A.I.S.E. is the European association representing detergents, disinfectants and maintenance products. Ethanol is an indispensable ingredient in a broad range of household, professional and industrial products, namely in biocidal products (use as active substance in disinfectants and use as co-formulant in insecticides and repellents) and in cleaning products such as hand dish washing liquids, laundry detergents and surface cleaners, where it is used for its solvent properties. Ethanol shows a unique combination of rapid, broad-spectrum antimicrobial activity and a favorable exposure profile in PT1 (Human hygiene biocidal products Hygienic and surgical hand disinfection by hand rubbing without rinsing), PT2 (Private area and public health area disinfectant) and PT4 (Food and feed area disinfectant) formulations that are unmatched by available alternatives. It has a broad-spectrum efficacy against bacteria, fungi, and both enveloped and non-enveloped viruses, and this within very short contact times. Its use in biocidal applications, whether as a hand disinfectant or a surface disinfectant—is essential for maintaining public

	health, particularly in high-risk environments. Reclassification that compromises these applications would jeopardize effective infection control and could lead to significant safety and supply challenges. In fact, ethanol is critical for human health and safety. More than 3.5 million cases of Health Acquired Infections (HAI) are estimated to occur in the EU/EEA each year, leading to more than 90 thousand deaths. Ethanol is endorsed by the WHO. It is known to be the most effective substance in the fight against HAIs and the only substance effective against viruses like polio. Ethanol is a vital ingredient in various cleaning and household products, such as surface disinfectants and skin repellents. Restaurants use ethanol-based products to prevent the spread of salmonella, ensuring food safety and public health. It is also a skin repellent essential since vector borne diseases are rising due to climate change in Europe. In many use cases, substitutes are either non-existent or less effective: - o In terms of HAIs, there is no alternative for fighting polio and other non-enveloped viruses. - o No other substance matches ethanol's efficacy, skin tolerability and safety profile for point-of-care hand hygiene. Other substances are known to dry and irritate the skin. The absence of an effective substitute could lead to increased infection rates and higher healthcare costs (Hand sanitizers in hospitals are used by nurses between 60 to 100 times per day, and insect repellents are applied to the skin). - o The absence of an effective substitute could lead to increased infection rates and higher healthcare costs. A recent study found that ethanol at a 70% concentration had a stronger effect on coronaviruses, with a contact time of just one minute, compared to 0.06% sodium hypochlorite. Ethanol was critical in combating COVID-19: it was widely available and cost-effective, unlike propanol and other alternatives. Industry was able to ramp up production and meet government requirements. In a world of geopolitical uncertainty and climate related disasters, ethanol-based hand disinfectants are a key tool in preventing the spread of disease in war torn and disaster areas, refugee camps and during rural outbreaks of deadly viruses such as Ebola when water and proper handwashing is inaccessible. Ethanol is safe for the environment: it mainly comes from renewable sources, it is fully biodegradable compared to its alternatives, it leaves no residue on surfaces, it evaporates quickly, and it is generally more sustainable than other options. When used as a co-formulant in insecticides and repellents, ethanol presents unique solvency properties, helps control viscosity and is highly compatible with the other formulation's ingredients. Conclusion Ethanol's

	reclassification means a de facto ban and would have massive consequences not only on European industry, but also on society as a whole, while not bringing any benefit to human health or the environment. Even with derogations, the availability of ethanol will be severely restricted due to local regulations. Authorities will have to face a host of (unintended) consequences including a change in infection patterns as well as higher costs. A.I.S.E believes that the proposed reclassification of ethanol is based on very flawed assumptions: it considers the effects of the substance after oral intake of high doses, in other words utilising data on the adverse effects of (excessive) drinking of alcoholic beverages. This is not based on the typical uses of ethanol in biocidal products. It also does not take into account mitigation strategies used in industry to provide safe products, such as denaturation of ethanol to prevent drinking of ethanol-containing products. The uptake of ethanol after skin contact or inhalation is negligible and better comparable to the intake of ethanol in non-alcoholic products such as apple juice, where ethanol occurs naturally. A.I.S.E. calls on the European authorities to recognise the essential role of ethanol. Ethanol should remain classified based on its real-world, biocidal use, rather than being inaccurately compared to alcohol consumption. Recognising ethanol's essential role in infection control and public health is vital for maintaining effective and safe disinfecting practices. Specifically, A.I.S.E. calls on ECHA to take realistic exposure routes into consideration. Risk assessments should distinguish between ingestion and dermal/inhalation exposures to avoid unnecessary restrictions and de facto bans. It is crucial to consider realistic exposure scenarios to ensure that regulations are based on accurate and relevant data. Finally, A.I.S.E. calls on the European Commission to fully assess the consequences of reclassifying ethanol on public health, healthcare costs and economic stability. A thorough impact assessment will provide a clear understanding of the potential ramifications and help guide informed decisions. The European Commission can demonstrate its commitment to simplifying legislation and supporting EU competitiveness by avoiding an unjustified reclassification that does not positively impact EU citizens, while negatively impacting EU industry. Supporting European competitiveness is essential for fostering innovation and economic growth.
Product Type	1,2,4
Alternative Identity and Properties	There is no substitute biocidal active substance with similar time-effective profile against non-enveloped viruses

	such as norovirus, enteroviruses, and adenoviruses, but also enveloped viruses such as SARS-COV-2: ethanol effectively inactivates a wide range of pathogens within seconds, reducing contact times and product usage, which streamlines workflow in critical settings like hospitals. • In addition, there is no alternative that matches ethanol's skin tolerability - potential alternatives such as propanols evaporate less quickly than ethanol, thus prolonging dermal exposure, which makes them unsuitable for use in premises such as healthcare where hand disinfection is required at a very high frequency. It is also important to underline that some alternatives already carry classification/labelling such as for example Propanols - EUH066 'Repeated exposure may cause skin dryness or cracking'. • Ethanol-based hand sanitisers are indispensable in infection prevention and control both in hospitals and citizens' daily lives. • The WHO has recognised the importance of these products through their inclusion in the Essential Medicines List. • Limiting the use of ethanol-based hand sanitisers would put public health at risk. • According to the World Health Organisation (WHO), hand hygiene campaigns promoting the use of Ethanol-based hand sanitisers have halved the number of health care-associated infections (HCAIs) in Europe in the last decade. However, these infections still cause over 4.3 million cases of HCAIs in the European Union and European Economic Area (EU/EEA), with 37,000 attributable deaths, 16 million extra days of hospital stay and contributes to between 90,000 and 110,000 deaths each year. If Ethanol were to be classified as a CMR, Ethanol-based sanitisers could not be used in hospitals, which would reverse this improvement, possibly doubling the current rate of HCAIs. • No substitute matches ethanol's efficacy against non-enveloped viruses like Adenovirus, Enterovirus, and Norovirus, which are not vaccine preventable. With the rise of viruses such as Norovirus, which causes millions of cases of gastroenteritis, and the return of Poliovirus, it is crucial for Europe to keep strong preventive measures in place to limit the spread of these viruses. Ethanol-based hand rubs have no equal in their ability to fight these viruses effectively and remain essential for preventing infections.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	

Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	The conclusion is provided in the boxes above and in the attachment.
Information above is confidential	
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Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	2025-04-28 A.I.S.E. Comments to Public Consultation ethanol - attachment.pdf
Attachments (confidential information)	

Justification for confidential attachment	

Comment 220	2025/04/28 17:29
Country	Belgium
Name of organization/institution	A.I.S.E.
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	A.I.S.E. is the European association representing detergents, disinfectants and maintenance products. Ethanol is an indispensable ingredient in a broad range of household, professional and industrial products, namely in biocidal products (use as active substance in disinfectants and use as co-formulant in insecticides and repellents) and in cleaning products such as hand dish washing liquids, laundry detergents and surface cleaners, where it is used for its solvent properties. Ethanol shows a unique combination of rapid, broad-spectrum antimicrobial activity and a favorable exposure profile in PT1 (Human hygiene biocidal products Hygienic and surgical hand disinfection by hand rubbing without rinsing), PT2 (Private area and public health area disinfectant) and PT4 (Food and feed area disinfectant) formulations that are unmatched by available alternatives. It has a broad-spectrum efficacy against bacteria, fungi, and both enveloped and non-enveloped viruses, and this within very short contact times. Its use in biocidal applications, whether as a hand disinfectant or a surface disinfectant—is essential for maintaining public health, particularly in high-risk environments. Reclassification that compromises these applications would jeopardize effective infection control and could lead to significant safety and supply challenges. In fact, ethanol is critical for human health and safety. More than 3.5 million cases of Health Acquired Infections (HAI) are estimated to occur in the EU/EEA each year, leading to more than 90 thousand deaths. Ethanol is endorsed by the WHO. It is known to be the most effective substance in the fight against HAIs and the only substance effective against viruses like polio. Ethanol is a vital ingredient in various cleaning and household products, such as surface disinfectants and skin repellents. Restaurants use ethanol-

	based products to prevent the spread of salmonella, ensuring food safety and public health. It is also a skin repellent essential since vector borne diseases are rising due to climate change in Europe. In many use cases, substitutes are either non-existent or less effective: - o In terms of HAIs, there is no alternative for fighting polio and other non-enveloped viruses. - o No other substance matches ethanol's efficacy, skin tolerability and safety profile for point-of-care hand hygiene. Other substances are known to dry and irritate the skin. The absence of an effective substitute could lead to increased infection rates and higher healthcare costs (Hand sanitizers in hospitals are used by nurses between 60 to 100 times per day, and insect repellents are applied to the skin). - o The absence of an effective substitute could lead to increased infection rates and higher healthcare costs. A recent study found that ethanol at a 70% concentration had a stronger effect on coronaviruses, with a contact time of just one minute, compared to 0.06% sodium hypochlorite. Ethanol was critical in combating COVID-19: it was widely available and cost-effective, unlike propanol and other alternatives. Industry was able to ramp up production and meet government requirements. In a world of geopolitical uncertainty and climate related disasters, ethanol-based hand disinfectants are a key tool in preventing the spread of disease in war torn and disaster areas, refugee camps and during rural outbreaks of deadly viruses such as Ebola when water and proper handwashing is inaccessible. Ethanol is safe for the environment: it mainly comes from renewable sources, it is fully biodegradable compared to its alternatives, it leaves no residue on surfaces, it evaporates quickly, and it is generally more sustainable than other options. When used as a co-formulant in insecticides and repellents, ethanol presents unique solvency properties, helps control viscosity and is highly compatible with the other formulation's ingredients. Conclusion Ethanol's reclassification means a de facto ban and would have massive consequences not only on European industry, but also on society as a whole, while not bringing any benefit to human health or the environment. Even with derogations, the availability of ethanol will be severely restricted due to local regulations. Authorities will have to face a host of (unintended) consequences including a change in infection patterns as well as higher costs. A.I.S.E believes that the proposed reclassification of ethanol is based on very flawed assumptions: it considers the effects of the substance after oral intake of high doses, in other words utilising data on the adverse effects of (excessive) drinking of alcoholic beverages. This is not based on the typical uses of ethanol

	in biocidal products. It also does not take into account mitigation strategies used in industry to provide safe products, such as denaturation of ethanol to prevent drinking of ethanol-containing products. The uptake of ethanol after skin contact or inhalation is negligible and better comparable to the intake of ethanol in non-alcoholic products such as apple juice, where ethanol occurs naturally. A.I.S.E. calls on the European authorities to recognise the essential role of ethanol. Ethanol should remain classified based on its real-world, biocidal use, rather than being inaccurately compared to alcohol consumption. Recognising ethanol's essential role in infection control and public health is vital for maintaining effective and safe disinfecting practices. Specifically, A.I.S.E. calls on ECHA to take realistic exposure routes into consideration. Risk assessments should distinguish between ingestion and dermal/inhalation exposures to avoid unnecessary restrictions and de facto bans. It is crucial to consider realistic exposure scenarios to ensure that regulations are based on accurate and relevant data. Finally, A.I.S.E. calls on the European Commission to fully assess the consequences of reclassifying ethanol on public health, healthcare costs and economic stability. A thorough impact assessment will provide a clear understanding of the potential ramifications and help guide informed decisions. The European Commission can demonstrate its commitment to simplifying legislation and supporting EU competitiveness by avoiding an unjustified reclassification that does not positively impact EU citizens, while negatively impacting EU industry. Supporting European competitiveness is essential for fostering innovation and economic growth.
Product Type	1,2,4
Alternative Identity and Properties	- Looking at the PT2 applications - especially in places with frequently touched surfaces like hospitals (disinfection of furniture, walls, and floors), industrial environments, education and childcare facilities - none of the other PT2 active substances are suitable alternatives to ethanol when considering its combined benefits, in terms of efficacy spectrum, fast antimicrobial action, surfaces compatibility and safety profile. - Other alcohols such as propanols demonstrate a limited virucidal activity compared to ethanol (especially against non-enveloped viruses). Oxidizing agent like peracetic acid, which presents a broader efficacy spectrum, is corrosive, which implies use of PPE and restricts its use on surfaces due to some materials incompatibility. The latest is particularly critical in healthcare settings, where compatibility with sensitive

	materials, such as medical equipment surfaces, is required to ensure safe use without causing corrosion or degradation. • Ethanol provides broad-spectrum disinfection that is essential for health and safety. • Ethanol is known for its ability to kill a wide range of microorganisms, including bacteria, viruses, and fungi. Keeping ethanol in multi-purpose cleaners ensures that they provide both cleaning and disinfecting action, offering comprehensive hygiene benefits in a single product. • Many public health agencies and environmental standards recognise ethanol as an effective and safe ingredient in cleaning products. Keeping ethanol in multi-purpose cleaners ensures compliance with these guidelines and maintains the product's acceptance in various markets. • European Centre for Disease Prevention and Control emphasises the importance of using ethanol-based cleaning products against Coronavirus. • Ethanol has important solvent properties needed in cleaning products: it is a highly effective solvent that helps dissolve dirt, grease, and organic matter on various surfaces. This makes it an essential ingredient in multi-purpose cleaners designed to handle tough cleaning jobs in kitchens, bathrooms, and other areas. • Ethanol has a high safety profile and leaves minimal residue: it is considered safe for use on surfaces that come into contact with food, as it breaks down into non-toxic byproducts (water and carbon dioxide). This is especially important in kitchens and dining areas, where cleaners must not leave harmful residues and should be non-tainting. • Compared to other chemical disinfectants, ethanol has a lower risk of causing skin irritation or allergic reactions when used as directed, making it suitable for household use by a wide range of consumers, including those with sensitive skin. • There is a lack of alternatives that can be used on as wide a range of surfaces: Ethanol at 70% concentration effectively disinfects a wide range of surfaces without causing damage, making it suitable for various materials, including those sensitive to harsh chemicals. In contrast, sodium hypochlorite, while also effective, may corrode or discolour certain surfaces, limiting its use to specific, more durable materials.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	

Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	The conclusion is provided in the boxes above and in the attachment.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	2025-04-28 A.I.S.E. Comments to Public Consultation ethanol - attachment.pdf
Attachments (confidential information)	

Justification for confidential attachment	

Comment 221	2025/04/28 17:34
Country	Belgium
Name of organization/institution	A.I.S.E.
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	A.I.S.E. is the European association representing detergents, disinfectants and maintenance products. Ethanol is an indispensable ingredient in a broad range of household, professional and industrial products, namely in biocidal products (use as active substance in disinfectants and use as co-formulant in insecticides and repellents) and in cleaning products such as hand dish washing liquids, laundry detergents and surface cleaners, where it is used for its solvent properties. Ethanol shows a unique combination of rapid, broad-spectrum antimicrobial activity and a favorable exposure profile in PT1 (Human hygiene biocidal products Hygienic and surgical hand disinfection by hand rubbing without rinsing), PT2 (Private area and public health area disinfectant) and PT4 (Food and feed area disinfectant) formulations that are unmatched by available alternatives. It has a broad-spectrum efficacy against bacteria, fungi, and both enveloped and non-enveloped viruses, and this within very short contact times. Its use in biocidal applications, whether as a hand disinfectant or a surface disinfectant—is essential for maintaining public health, particularly in high-risk environments. Reclassification that compromises these applications would jeopardize effective infection control and could lead to significant safety and supply challenges. In fact, ethanol is critical for human health and safety. More than 3.5 million cases of Health Acquired Infections (HAI) are estimated to occur in the EU/EEA each year, leading to more than 90 thousand deaths. Ethanol is endorsed by the WHO. It is known to be the most effective substance in the fight against HAIs and the only substance effective against viruses like polio. Ethanol is a vital ingredient in various cleaning and household products, such as surface disinfectants and skin repellents. Restaurants use ethanol-

	based products to prevent the spread of salmonella, ensuring food safety and public health. It is also a skin repellent essential since vector borne diseases are rising due to climate change in Europe. In many use cases, substitutes are either non-existent or less effective: - o In terms of HAIs, there is no alternative for fighting polio and other non-enveloped viruses. - o No other substance matches ethanol's efficacy, skin tolerability and safety profile for point-of-care hand hygiene. Other substances are known to dry and irritate the skin. The absence of an effective substitute could lead to increased infection rates and higher healthcare costs (Hand sanitizers in hospitals are used by nurses between 60 to 100 times per day, and insect repellents are applied to the skin). - o The absence of an effective substitute could lead to increased infection rates and higher healthcare costs. A recent study found that ethanol at a 70% concentration had a stronger effect on coronaviruses, with a contact time of just one minute, compared to 0.06% sodium hypochlorite. Ethanol was critical in combating COVID-19: it was widely available and cost-effective, unlike propanol and other alternatives. Industry was able to ramp up production and meet government requirements. In a world of geopolitical uncertainty and climate related disasters, ethanol-based hand disinfectants are a key tool in preventing the spread of disease in war torn and disaster areas, refugee camps and during rural outbreaks of deadly viruses such as Ebola when water and proper handwashing is inaccessible. Ethanol is safe for the environment: it mainly comes from renewable sources, it is fully biodegradable compared to its alternatives, it leaves no residue on surfaces, it evaporates quickly, and it is generally more sustainable than other options. When used as a co-formulant in insecticides and repellents, ethanol presents unique solvency properties, helps control viscosity and is highly compatible with the other formulation's ingredients. Conclusion Ethanol's reclassification means a de facto ban and would have massive consequences not only on European industry, but also on society as a whole, while not bringing any benefit to human health or the environment. Even with derogations, the availability of ethanol will be severely restricted due to local regulations. Authorities will have to face a host of (unintended) consequences including a change in infection patterns as well as higher costs. A.I.S.E believes that the proposed reclassification of ethanol is based on very flawed assumptions: it considers the effects of the substance after oral intake of high doses, in other words utilising data on the adverse effects of (excessive) drinking of alcoholic beverages. This is not based on the typical uses of ethanol

	in biocidal products. It also does not take into account mitigation strategies used in industry to provide safe products, such as denaturation of ethanol to prevent drinking of ethanol-containing products. The uptake of ethanol after skin contact or inhalation is negligible and better comparable to the intake of ethanol in non-alcoholic products such as apple juice, where ethanol occurs naturally. A.I.S.E. calls on the European authorities to recognise the essential role of ethanol. Ethanol should remain classified based on its real-world, biocidal use, rather than being inaccurately compared to alcohol consumption. Recognising ethanol's essential role in infection control and public health is vital for maintaining effective and safe disinfecting practices. Specifically, A.I.S.E. calls on ECHA to take realistic exposure routes into consideration. Risk assessments should distinguish between ingestion and dermal/inhalation exposures to avoid unnecessary restrictions and de facto bans. It is crucial to consider realistic exposure scenarios to ensure that regulations are based on accurate and relevant data. Finally, A.I.S.E. calls on the European Commission to fully assess the consequences of reclassifying ethanol on public health, healthcare costs and economic stability. A thorough impact assessment will provide a clear understanding of the potential ramifications and help guide informed decisions. The European Commission can demonstrate its commitment to simplifying legislation and supporting EU competitiveness by avoiding an unjustified reclassification that does not positively impact EU citizens, while negatively impacting EU industry. Supporting European competitiveness is essential for fostering innovation and economic growth.
Product Type	1,2,4
Alternative Identity and Properties	• Use of PT4 disinfectants is indispensable to ensure highest hygiene standards in the food and feed sectors. None of the other PT4 active substances are suitable alternatives to ethanol when considering its combined benefits, in terms of efficacy spectrum, fast antimicrobial action, safety profile and rapid evaporation profile. • Potential alternatives demonstrate a limited virucidal activity compared to ethanol (especially against non-enveloped viruses). • In addition, there is no alternative that matches ethanol's evaporation profile: potential alternatives such as propanols evaporate less quickly than ethanol, thus prolonging contact with surfaces, which is not desired for use in premises such as the food and feed sectors, where repeated disinfection of equipment, or storage areas is required. • Limiting the use of ethanol-based hand

	sanitisers would risk food safety. • At the farm - ethanol based disinfectants are key hand hygiene interventions in harvest areas where water and hand washing is inaccessible to prevent the transfer of human-borne viral and bacterial pathogens such as Hepatitis A or Norovirus and Salmonella to ready to eat foods (salads, berries etc) • The supply chain - as food is transferred from farm to table through various distribution canners, processing, retail, etc ethanol based disinfectants again prevent cross contamination of the food that ends on our plates. • Food processing - ethanol's based hand-disinfectants are used throughout the food processing industry to prevent cross contamination of food. In the area of low moisture food ethanol plays an even bigger role in being the 'go to' surface disinfectant to disinfect factories producing highly sensitive foods such as infant formula, dried dairy products, nuts and cereals. The advantage provided by ethanol in keeping water out of the cleaning cycle ensures the safety of these foods from pathogens such as Cronobacter sakazakii, E.coli and Salmonella. • In supermarkets and restaurants of all sizes ethanol provides a quick and easy disinfection of food contact surfaces in kitchens delis, meat counters and the surfaces of public areas like trolley handles, cash register conveyers and bathrooms.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	

Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	The conclusion is provided in the boxes above and in the attachment.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	2025-04-28 A.I.S.E. Comments to Public Consultation ethanol - attachment.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 222	2025/04/28 17:36
Country	Austria
Name of organization/institution	Österreichische Gesellschaft für Krankenhaushygiene / Austrian Society for Hospital Hygiene (ÖGKH)
I do not wish the name of my organisation/institution to be published on the ECHA website.	

General information	The Austrian Society for Hospital Hygiene (ÖGKH) is a scientific professional society whose goal is to strengthen hygiene teams and further develop existing hygiene standards in the Austrian healthcare system in dialogue with the stakeholders involved.
Product Type	1,2,4
Alternative Identity and Properties	No alternatives with comparable activity against hydrophilic non-enveloped viruses which can be used in handrubs. Ethanol exhibits unique activity in 80 % concentration against hydrophilic non-enveloped viruses. There are no alternative substances which are effective against enteroviruses and which can be used as an active substance in handrubs, including isopropanol. Ethanol was chosen as reference alcohol for EN 17430, the test standard for virucidal disinfection activity (Phase 2/Step 2). The decision was based on its efficacy and the fact that the majority of virucidal handrubs (activity against non-enveloped viruses) are based on ethanol.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	No products approved by ECHA as PT1 with virucidal activity
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	The substitution of ethanol with other virucidal active substances for routine hand antisepsis is likely to make handrub production more expensive for manufacturers and consumers and governments in Europe and worldwide.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Alternative PT1 substances such as quarternary compounds – which are, however, not virucidal - bear a risk of developing clinically relevant resistance or tolerance towards certain target organisms. No resistance development has been described for ethanol.
Information above is confidential	

Justification for confidentiality	
Availability	Ethanol is produced at a much larger scale in Europe than propanols or other alternative substances
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Hand hygiene has long been recognized as the building block for infection prevention and control by international experts. Alcohol-based handrubs are the gold standard and only ethanol-based handrubs exhibit a virucidal effect.
Information above is confidential	
Justification for confidentiality	
Other comments	No advantage can be seen for the protection of human and animal health and environment if ethanol is banned from routine use in biocides and other industrial applications which are not related to oral consumption of ethanol-based beverages or foodstuffs. A ban of ethanol for biocidal production and/or a restriction of use in Europe due to CMR classification would have a (negative) impact on the availability of effective ABHR handrubs in global crisis situations in Europe and other parts of the world.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 223	2025/04/28 17:50
Country	Germany

Name of organization/institution	Free and Hanseatic City of Hamburg & State of Schleswig-Holstein & Life Science Nord
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	
Product Type	1,2,4
Alternative Identity and Properties	see attachment
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	see attachment
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	see attachment
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	see attachment
Information above is confidential	
Justification for confidentiality	
Availability	see attachment
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	see attachment

Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	Statement of Hamburg, Schleswig-Holstein and LSN on the proposed CMR Classification of Ethanol .pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 224	2025/04/28 18:21
Country	France
Name of organization/institution	BRUNEL SAS
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	

Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol is a key substance in many areas of disinfection and detergents. It has properties that bring a real plus in terms of performance to the products that contain it and that are difficult to obtain with substances with a better profile.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	

Justification for confidential attachment	

Comment 225	2025/04/28 18:21
Country	Germany
Name of organization/institution	ICADA e.V.
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	

Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	The use of ethanol as a disinfectant in the cosmetic industry is a well-founded and responsible decision. Ethanol perfectly meets the requirements of ISO 22716:2007 regarding cleaning and disinfection, supports compliance with Regulation (EC) No 1223/2009, and also contributes significantly to ecological sustainability and the production of safe, high-quality cosmetic products.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	Ethanol ICADA_20280428.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 226	2025/04/28 18:29
Country	Germany
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	

Product Type	1,2,4
Alternative Identity and Properties	None.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	The attached statement demonstrates that ethanol is indispensable for pharmaceutical and homeopathic production and that no suitable or equivalent alternatives are currently available. Restrictions on ethanol use would have severe consequences for patient safety, product availability, and public health.
Information above is confidential	
Justification for confidentiality	
Other comments	Please refer to the attached statement.

Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 227	2025/04/28 18:58
Country	Switzerland
Name of organization/institution	Dottikon Exclusive Synthesis AG
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	We are writing on behalf of Dottikon Exclusive Synthesis AG with reference to the planned CMR classification of ethanol to express our opinion on the planned substitution.
Product Type	1,2,4
Alternative Identity and Properties	1-propanol, 2-propanol or quaternary ammonium compounds.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	As demonstrated by Kramer et al. (2022), the use of ethanol as a virucidal active substance is crucial for hand antiseptics which need to meet the criteria to be effective against non- enveloped viruses (2). Other alternatives such as 1-propanol or 2-propanol are known to perform worse in the same considered time period (2).

Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	According to GHS 1.1.2.6.2.1, the toxicological risk of a substance is defined as the product of hazard and exposure. Hazard classification should therefore not take exposure into consideration, but should be regarded as an intrinsic property of a substance. In order to identify a hazard, there need to be well-defined criteria for classification. To the best of our knowledge, the classification proposal is based on a large exposure to ethanol through massive oral consumption. This procedure seems to disregard the dose-response curves which are usually considered in hazard classification. Even though GHS 1.3.2.4.7 mentions the possible use of experiential evidence from humans for classification purposes, we wonder whether there is enough weight of evidence to support this classification toxic to reproduction according to category 2. Furthermore, the routes of exposure need to be addressed. Thus, for example, the exposure to ethanol in hand disinfectants is considered to be low, being due to potential dermal uptake (excessive exposure leads to a max. absorption of 2.3% (1) of ethanol), which appears to lead to systemically available ethanol concentrations in the range of those of beverages with equal or lower than 0.5%v/v (2) ethanol. Another study showed a low absorption through dermal exposure: Han et al. 2022 (3) measured blood ethanol concentrations (BEC) of breastfeeding women after the intense and frequent use of ethanol-based hand sanitizers. The study found that these BECs were 2.2 to 1'000 times smaller than BECs which are known to be associated with neurotoxicity adverse effect levels. Due to this difference in magnitude, the use of ethanol-based sanitizers is unlikely to lead to neurodevelopmental effects in infants.
Information above is confidential	
Justification for confidentiality	
Availability	

Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	We are concerned about the development to consider ethanol as a candidate for substitution for several reasons (see above). A substitution with other substances such as 1-propanol, 2-propanol or quaternary ammonium compounds could lead to an unknown toxicological risk profile for these substances as there is no data available for excessive oral consumption of these compounds by humans.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	(1): Kramer, A., Below, H., Bieber, N., Kampf, G., Toma, C. D., Huebner, N. O., & Assadian, O. (2007). Quantity of ethanol absorption after excessive hand disinfection using three commercially available hand rubs is minimal and below toxic levels for humans. BMC infectious diseases, 7, 117. https://doi.org/10.1186/1471-2334-7-117 (2): Kramer, A., Arvand, M., Christiansen, B., Dancer, S., Eggers, M., Exner, M., Müller, D., Mutters, N. T., Schwebke, I., & Pittet, D. (2022). Ethanol is indispensable for virucidal hand antisepsis: memorandum from the alcohol-based hand rub (ABHR) Task Force, WHO Collaborating Centre on Patient Safety, and the Commission for Hospital Hygiene and Infection Prevention (KRINKO), Robert Koch Institute, Berlin, Germany. Antimicrobial resistance and Infection control, 11, 93. https://doi.org/10.1186/s13756-022-01134-7 (3): Elan, A. A., Buerger, A. N., Allen, H., Vincent, M., Thornton, S. A., Unice, K. M., Maier, A., & Quifiones-Rivera, A. (2022). Assessment of ethanol exposure from hand sanitizer use and potential for developmental toxicity in nursing infants. Journal of Applied Toxicology, 42(9), 1424- 1442. https://doi.org/10.1002/jat.4284
Attachments (non-confidential information)	Letter Consultation Ethanol BPR_DOTTIKON ES_2025-04-28.pdf

Attachments (confidential information)	
Justification for confidential attachment	

Comment 228	2025/04/28 19:03
Country	Italy
Name of organization/institution	AssoDistil
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	AssoDistil brings together more than 60 industrial distilleries (about 95% of the national production of spirits and ethyl alcohol produced from agricultural raw materials); promotes the distillery sector in Italy and abroad; intervenes in regulatory processes at national and international institutions; is involved in the legal protection of Italian products; finances and disseminates economic-statistical files; actively follows regulatory developments in environmental matters and circular economy. The EU ethanol market can be divided into three segments: fuel, food and industrial. i) Fuel: Ethanol is used in mixture with petrol or as an alternative fuel. E10, for example, is a type of petrol containing up to 10% ethanol and can be used in most of today's internal combustion engines and hybrid vehicles, significantly reducing greenhouse gas emissions from transport. ii) Food: Ethanol can be used to make spirit drinks, as a food additive, for the extraction of flavourings, for the preservation of foods and for the production of white vinegar. iii) Industrial: ethanol is an essential renewable chemical component in various products (e.g. hygiene products, cosmetics, pharmaceuticals, solvents, paints and antifreeze fluids) to ensure hygiene and safety as well as a renewable raw material for the production of renewable chemicals (e.g. bioethylene). Bioethanol is produced in European biorefineries by fermenting sugars into alcohol. In the EU, these sugars typically come from a variety of agricultural sources such as wheat, corn, barley, rye, triticale and sugar beet. In Italy bioethanol is mainly obtained from residues of wine production (e.g. grape marc and wine lees) thus obtaining

	an advanced biofuel that contributes significantly to the reduction of gas-effect emissionsgreenhouse gas and thus to the achievement of EU transport decarbonisation targets. In 2023, European producers of renewable ethanol produced 6.44 billion liters of ethanol, operating at 80% of their 8.05 billion liters of installed capacity. Use as biofuel accounted for 85.9% of the use; other markets, such as industrial applications and beverages, accounted for 7.6% and 6.5%, respectively. AssoDistil would like to provide its comments to ECHA by underlining the irreplaceable use of ethanol and pointing out that a classification of ethanol as carcinogenic or toxic for reproduction would be detrimental to many biocidal products, would create a lack of alternatives and have critical consequences for public health.
Product Type	1,2,4
Alternative Identity and Properties	Human hygiene can be taken into account given the widespread use of hand sanitising gels in company premises or offices
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	

Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	The use of ethanol is essential to allow the health of environments. Specifically, its health and easy accessibility make alcohol-based products more efficient. Considering also that many of the operations carried out by the operators in order to sanitize the surfaces are carried out with the aid of gloves and/or other tools which prevent direct contact with the product
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 229	2025/04/28 19:38
Country	Turkey
Name of organization/institution	the Food and Sugar Industry Workers' Trade Union of Türkiye (Şeker-İş),
I do not wish the name of my organisation/institution to be published on the ECHA website.	

General information	On behalf of the Food and Sugar Industry Workers' Trade Union of Türkiye (Şeker-İş), representing all the beet sugar sector workers in Türkiye, I would like to submit the following opinion statement. This submission concerns Product Type 1 which involves (Human Hygiene Biocidal Products) used for hygienic and surgical hand disinfection without rinsing.
Product Type	1,2,4
Alternative Identity and Properties	It is well established fact that International Agency for Research on Cancer (IARC) has not classified the use of hygienic and surgical hand disinfection as a Group 1 carcinogen, except its consumption as an alcoholic beverage. Ethanol, produced from sugar beet, sugar cane, corn, potato and similar agricultural crops is highly effective in ensuring the protection for human hygiene at a very sensitive area of surgical operation and hospital environments owing to its instant and deep impact at broader spectrum of antibacterial activities. These qualities make ethanol one of the most important items for hand sanitization.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Technically, ethanol-based disinfectants are very easy to use and efficient. They can be used by simply rubbing into hands without rinsing through water. In addition to its simplicity of use, it is highly antiseptic material. In fact, WHO (2019) classifies ethanol "on the core list of basic care substances which, as a minimum, should be available" under categories antiseptics (15.1) and alcohol-based hand disinfectants (15.2). Moreover, the German Association for Applied Hygiene (VAH) coordinated study (2020) has the title of "As a biocidal active substance, ethanol is indispensable for hygienic hand disinfection". Even this title confirms very clearly the vital importance of ethanol in hygiene. To sum up, the generally accepted essential qualities of ethanol's practicality and its antibacterial effectiveness make ethanol-based disinfectants indispensable for all the institutions operating under delicate hygienic conditions which require utmost attention to ensuring bacteria free sanitation.
Information above is confidential	

Justification for confidentiality	
Economic Feasibility	Ethanol production has wider positive effects on; ☐ Employment, ☐ Agriculture, ☐ Rural development, and ☐ Green energy goals. Ethanol producing sugar and starch sectors directly and indirectly provide hundreds of thousands of people gainfully employment in Türkiye and Europe. More importantly, it is an agro-industry operating at the heart of rural communities and thus support rural communities. It is particularly important for countries like Türkiye and even for rural regions of Europe, since these sectors safeguard the migration of rural population towards urban areas. In this respect they act as important agents for rural development. Additionally, the data shows very clearly that renewable ethanol produced by ePURE members and other EU producers achieved an average 79.1% reduction in greenhouse gas emissions compared to fossil fuels in 2023. It is expected to improve further with the introduction of new technologies. Simply, it is an environmentally friendly solution. Last but not the least, the present production of sugar and starch-based ethanol is highly cost-effective. It makes ethanol a tempting alternative in the field of human disinfectants. As a result, re-classification of ethanol involves a great potential of wider and far-reaching negative effects on agriculture, industrial production, logistics, rural communities, and employment.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Many studies have examined elaborately the safety of ethanol in the use of ethanol as hygienic and surgical hand disinfection without rinsing and yet found no significant evidence of toxicity or carcinogenicity. In other words, it has proven safe as regards its use as disinfectant. Research on ethanol and its effects dates to 1888 and yet no study has reported a significant negative consequence. Recently, U.S. National Toxicology Program (NTP) and the European Food Safety Authority (EFSA) have not identified risks due to exposure through the skin or air. The above-mentioned German Association for Applied Hygiene (VAH) coordinated study (2020) emphasizes that “earlier studies have already demonstrated that ethanol is rarely able to enter the body through the skin and that finding is corroborated by more recent studies” Finally, Şeker-İş has also undertook research with the staff of the Social Security

	Institution of Türkiye concerning toxicity or carcinogenicity of ethanol covering the last 30 years found no reported cases of death or workforce loss among healthcare workers using ethanol-based hand sanitizer most intensively. There is no guarantee that the potential alternatives would be cost-effective and socially and economically acceptable and ensure safety and practicality.
Information above is confidential	
Justification for confidentiality	
Availability	Ethanol is produced at large scale across Europe and therefore the availability is not a problem. Moreover, the production and distribution are efficiently supported by well-established supply chains and logistics firms. The Covid-19 period has proven that huge scale of availability exists even the during the times of crisis.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Its efficacy, instant availability, practical use with no residue, cost-effectiveness and close support to rural communities while proving gainful employment for hundreds of thousands of individuals and strong support for a greener economy grants enormous advantages to ethanol. Therefore, as Şeker-İş, we strongly support maintaining present EU classification of ethanol for Product Type 1 and, by extension, the similar classification in the relevant Turkish legislation based on the EU Acquis.
Information above is confidential	
Justification for confidentiality	
Other comments	As elaborated under item 3, it is vital to consider the far-reaching repercussions of potential alternatives on economy, employment, agriculture, rural development and their contribution to the success of EU green deal objectives. In our view, the issue goes simply the chemical sector alone.
Information above is confidential	

Justification for confidentiality	
References	□ German Association for Applied Hygiene: https://vah-online.de/files/download/vah- Mitteilungen/VAH_Ethanol_biocide_29Oct2020_2.pdf □ European Centre for Disease Prevention and Control (ECDC) Guidelines on Hand Hygiene □ WHO: Guidelines on Hand Hygiene in Health Care (2009) □ WHO: Model List of Essential Medicines (2019) □ EU Biocidal Products Regulation (EU) No. 528/2012 □ Social Security Institution (of Türkiye) Statistical Yearbooks, □ IARC Monographs Vol. 100E – Personal Habits and Indoor Combustions: Ethanol in alcoholic beverages, 2012 □ EFSA Journal 2015: 13(6):4145-Scientific Opinion on Ethanol as a Food Additive □ National Toxicology Program (NTP), 14th Report on Carcinogens, 2016
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 230	2025/04/28 19:44
Country	Austria
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	Ethanol-based hand rubs are a cornerstone of infection prevention worldwide in both, healthcare and everyday settings. Their unique efficacy against a broad spectrum of pathogens, particularly non-enveloped viruses such as norovirus, adenovirus, or enterovirus, makes them indispensable in controlling outbreaks, especially in the absence of vaccines. In addition to their virucidal activity, ethanol is also effective against multidrug-resistant bacteria and other pathogens. During pandemics or outbreaks, ethanol based hand rubs often represent the most

	important non-pharmaceutical tool available to healthcare workers and the public for breaking the chain of transmission. Even outside crisis situations, they are essential for protecting against infection in daily life, such as in hospitals, care homes, schools, food production, and home care of vulnerable individuals. In the Austrian public health system, access to effective, fast-acting, and easy-to-use disinfectants is indispensable, not only in hospitals and clinics, but also in outpatient care and home nursing, such as mobile care units. Nursing homes for the elderly likewise depend on reliable disinfection to protect residents from frequent norovirus outbreaks. In educational settings, children are regularly exposed to enteroviruses and other easily transmitted infections, making hand hygiene a key preventive measure. The same applies to food safety, where proper hand disinfection before handling meals is essential to prevent contamination. Throughout Europe, including countries like Austria, ethanol-based hand rubs are firmly embedded in hygiene standards and recommended by both national expert committees and international authorities such as the World Health Organization (WHO). The Austrian Society for Hygiene, Microbiology and Preventive Medicine (ÖGHMP) maintains an official expert list of tested and approved disinfectants, including PT1 and PT2, where ethanol-based products feature prominently due to their reliable efficacy, safety and ease of use. This list is a trusted reference in hospitals, medical practices, long-term care facilities, and many other institutions across the country. No Adequate Alternative to Ethanol Despite ongoing efforts to find substitutes, there is currently no suitable alternative to ethanol. Other substances, such as propan-1-ol, propan-2-ol, chlorhexidine, quaternary ammonium compounds, peracetic acid, or chlorine-based agents present various limitations: they are often not sufficiently effective against certain pathogens, particularly non-enveloped viruses, can cause irritation or harm to the skin and respiratory tract, pose environmental concerns, or carry a higher risk of selecting antibiotic resistant pathogens. Ethanol, by contrast, uniquely combines high efficacy, excellent skin tolerability and rapid antimicrobial action, all while maintaining a strong safety profile. In the food industry, for instance, ethanol is the only active substance that allows for effective virucidal hand disinfection without introducing toxicological risks. Safe Use and Minimal Exposure The safety of dermal as well as of inhalational exposure to ethanol-based hand rubs is well documented. Ethanol absorption through skin or inhalation is negligible. Even with frequent use, systemic ethanol concentrations remain within the range of natural endogenous levels or below those

caused by consuming non-alcoholic beverages, such as apple juice or alcohol-free beer. There is no evidence of systemic toxicity from short-term or repeated topical use. This is supported by physiologically based pharmacokinetic models, experimental studies, and urinary biomarkers such as ethyl glucuronide. The WHO, along with various national health authorities and scientific societies (including the ÖGHMP), confirms that ethanol-based hand rubs are safe for routine use in both healthcare and community environments.

Misguided CMR Classification Debate

The current discussion within the European Chemicals Agency and the Biocidal Products Committee about classifying ethanol as carcinogenic, mutagenic or reprotoxic (CMR) is based on data from oral consumption, particularly alcohol abuse during pregnancy. These data are not applicable to the intended topical use of ethanol in biocidal products, where exposure occurs dermally or via inhalation. This misinterpretation in risk assessment presents serious practical implications: it could undermine the confidence in well-established hygiene practices of healthcare professionals and the public, thereby jeopardizing established and functioning infection prevention. Notably, ethanol is not classified as CMR for biocidal use under any other international regulatory framework. Ethanol is indispensable for Austria's Infection Prevention and Health Safety. Ethanol-based hand rubs are an irreplaceable pillar of modern infection control worldwide and also an essential component of infection prevention in the Austrian healthcare system, public infrastructure, the food industry and beyond. They offer unmatched benefits: broad-spectrum efficacy (including highly transmissible non-enveloped viruses as well as multiresistant bacterial and fungal pathogens), combined with safety and ease of use. No other disinfectant surpasses this profile. Given the lack of suitable alternatives and the critical role ethanol-based hand rubs play in public health, ethanol must continue to be approved as a biocide without CMR classification. The scientific evidence is clear, and a proper evaluation must reflect the actual route of exposure and use, not assumptions based on unrelated contexts. Ethanol is irreplaceable, safe when topically used, and indispensable for public health.

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Product Type	1,2,4
Alternative Identity and Properties	Ethanol has uniquely effective virucidal activity, making it the only alcohol-based hand rub substance that has been proven to reliably inactivate hydrophilic, non-enveloped viruses such as enteroviruses. This distinguishes ethanol from other alcohols, including propan-1-ol and propan-2-ol, which lack comparable efficacy against these highly transmissible pathogens. In line with the European Standard EN 1500, which has served for decades as the benchmark method for evaluating the in-vivo bactericidal efficacy of hand disinfectants in Europe and which remains a key reference in biocidal product authorization procedures, a corresponding reference method has been developed for assessing the virucidal efficacy of hand rubs. This is now described in the new European standard EN 17430, which defines an in vivo test procedure to evaluate the efficacy of hand disinfectants against both enveloped and non-enveloped viruses under practical conditions. Ethanol has been established as the reference alcohol of this European Norm, as it demonstrates reliable virucidal activity, especially against hydrophilic, non-enveloped viruses such as noroviruses (model: murine norovirus). The selection of ethanol as the reference substance is based on robust scientific evidence supporting its high efficacy, good skin tolerability, and safety in practical use and also on the fact that the vast majority of hand rubs with demonstrated activity against non-enveloped viruses are ethanol-based. The lack of effective alternatives further highlights the indispensable nature of ethanol in this context. No other

	biocidal active substance combines virucidal performance with the necessary skin compatibility and safety profile for repeated, everyday use in hand hygiene. While other agents such as propan-1-ol, propan-2-ol, peracetic acid, chlorine-based compounds, or oxidants may show in-vitro activity against non-enveloped viruses, their toxicological profiles render them unsuitable for inclusion in hand rub formulations as used in healthcare and public settings. Chlorine-based disinfectants and peracetic acid, for instance, are associated with significant adverse effects when used on the skin. Reports describe cases of allergic contact dermatitis linked to high-concentration chlorine solutions used for hand antisepsis. Peracetic acid is corrosive and irritating to the eyes, respiratory tract and skin, even at low concentrations. Inhalation can cause tearing, upper respiratory irritation and extreme discomfort. Moreover, chronic or repeated dermal exposure in animal models has led to concerning systemic effects such as organ damage, enzyme alterations and chromosomal aberrations. Such toxicological risks fundamentally preclude these substances from being used in hand hygiene. In contrast, ethanol demonstrates a favorable safety and tolerability profile under conditions of intended use. Its widespread acceptance is supported not only by empirical safety data and decades of routine application but also by international health authorities, including the WHO. Taken together, these facts make it clear that ethanol is not only uniquely effective but also the only viable option for safe, high-level hand disinfection against non-enveloped viruses. A move away from ethanol would not only compromise infection prevention strategies in healthcare, food hygiene, and public health, it would do so without a scientifically validated alternative. Therefore, continued approval of ethanol as a biocide without CMR classification is essential for safeguarding hygiene standards and public health across Europe. References: - European Norm (EN) 1500:2013. Chemical disinfectants and antiseptics - Hygienic hand disinfection - Test method and requirement (phase 2/ step 2). Brussels: Comité Européen de Normalisation; 2013. - Rotter, M.L.; Koller, W.; Wewalka, G.; Werner, H.P.; Ayliffe, G.A.; Babb, J.R. Evaluation of procedures for hygienic hand-disinfection: controlled parallel experiments on the Vienna test model. J Hyg (Lond) 1986, 96, 27-37. - Rotter, M.; Mittermayer, H.; Kundi, M. Investigations on the model of the artificially contaminated hand; proposal of a test method. Zentralbl Bakteriол Orig B 1974, 159, 560-581. German. PMID: 4618020. - Rotter, M.; Koller, W.; Kundi, M. Weitere Untersuchungen zur Wertbestimmung von Verfahren zur

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Technical Feasibility	Absence of Approved Virucidal Products under PT1 According to the most recent data available from the European Chemicals Agency (ECHA) database (accessed on April 17, 2025), there are currently no biocidal products classified and approved by ECHA as Product Type 1 (PT1) that demonstrate virucidal activity. This gap emphasizes the challenges which would arise if we would need effective and safe alternatives to ethanol for viral disinfection in everyday use, particularly in settings requiring rapid and reliable virus inactivation. References: - https://echa.europa.eu/documents/10162/0/art_95_list_en+%285%29.pdf/f8416518-b4ec-faba-c6fe-93d26c4165df?t=1741273132526
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Economic Feasibility	Replacing ethanol with alternative virucidal active substances - none of which are currently available and established for routine hand antisepsis - is out of sight and likely to increase production costs for manufacturers. This would also result in higher expenses for healthcare systems, governments, and end users, both in Europe and globally. References - https://echa.europa.eu/documents/10162/b3ce804b-1d11-f40c-931a-3d8f5605b74a - Kampf G, Scheithauer S, Lemmen S, Saliou P, Suchomel M. COVID-19-associated shortage of alcohol-based hand rubs, face masks, medical gloves, and gowns: proposal for a risk-adapted approach to ensure patient and healthcare worker safety. J Hosp Infect. 2020 Jul;105(3):424-427.

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Hazards and Risks of the Alternative	Infection Risk Ethanol-based hand rubs are indispensable in infection prevention and control. Their significance was especially evident during the COVID-19 pandemic, when hand hygiene was considered one of the most effective measures to combat the spread of the virus. Without ethanol in clinical practice, the risk of infection transmission would increase significantly, particularly when it comes to infection with non-enveloped viruses such as norovirus and enterovirus. The absence of ethanol as a virucidal disinfectant might not only jeopardize patient safety but also lead to higher treatment costs and longer hospital stays. Skin Irritation & Microbiome Hazards In clinical settings, healthcare workers perform hand disinfection over 100 times per day, particularly in high-intensity environments such as intensive care units. The WHO's "5 Moments for Hand Hygiene" framework encourages frequent hand antisepsis to prevent healthcare-associated infections, which leads to extremely high cumulative exposure to hand disinfectants across entire shifts. When considering alternative disinfectants, skin tolerability becomes a critical issue. Alternatives such as chlorine-based compounds, peracetic acid, or hydrogen peroxide may have theoretical virucidal efficacy, but they are not suitable for routine hand antisepsis due to their irritating, corrosive, or allergenic properties. These alternatives favour dryness, dermatitis or skin barrier damage, particularly when used repeatedly throughout the day. Moreover, disruption of the skin microbiome may have longer-term health implications. In contrast, ethanol is well tolerated, even with frequent use, and has been shown not to alter the natural hand microbiome, making it the preferred and safest option for repeated application in clinical environments. Compliance Risks Factors like skin tolerability, odor and general acceptance heavily influence user compliance. Substances like peracetic acid or sodium hypochlorite have pungent or unpleasant odors and higher irritation potential, which likely reduces compliance - thereby increasing health risks for users and patients alike. Antimicrobial Resistance and Health Hazards The COVID-19 pandemic led to a significant increase in the use of quaternary ammonium compounds (QACs) in both healthcare and community settings. However, this increased exposure has raised concerns about the potential development of microbial resistance or tolerance to QACs. Several studies have indicated that

	prolonged or sub-lethal exposure to QACs may select for adaptive responses in bacteria, which could contribute to cross-resistance to antibiotics and compromise long-term infection control strategies. Resistance to chlorhexidine has resulted in numerous outbreaks and healthcare-associated infections. To date, no microbial resistance to ethanol has been observed, even with frequent and prolonged use. This is likely due to its rapid and nonspecific mechanism of action, which does not allow for targeted microbial adaptation. Stability Hazards Alternative agents, like chlorine-based products or peracetic acid, are chemically unstable and highly sensitive to temperature. Lack of clear labeling on shelf-life after opening may result in the unknowing use of ineffective products. Ethanol-based hand rubs, when stored correctly, are chemically stable, and some manufacturers provide clear information on post-opening stability. Environmental Hazards Comparative life cycle assessment data for ethanol, bioethanol and other active substances should be taken into consideration. References: - Kampf G, Kramer A. Epidemiologic background of hand hygiene and evaluation of the most important agents for scrubs and rubs. Clin Microbiol Rev. 2004 Oct;17(4):863-93, table of contents. - Kramer A, Arvand M, Christiansen B, Dancer S, Eggers M, Exner M, Müller D, Mutters NT, Schwebke I, Pittet D. Ethanol is indispensable for virucidal hand antisepsis: memorandum from the alcohol-based hand rub (ABHR) Task Force, WHO Collaborating Centre on Patient Safety, and the Commission for Hospital Hygiene and Infection Prevention (KRINKO), Robert Koch Institute, Berlin, Germany. Antimicrob Resist Infect Control. 2022 Jul;11(1):93. - Kramer A, Borg Dahl M, Bengtsson MM, Boyce JM, Heckmann M, Meister M, Papke R, Pittet D, Reinhard A, Slevogt H, Wang H, Zwicker P, Urich T, Seifert U. No detrimental effect on the hand microbiome of health care staff by frequent alcohol-based antisepsis. Am J Infect Control. 2024 Nov 15:S0196-6553(24)00846-0. - Kampf G, Wigger-Alberti W, Wilhelm KP. Do atopsics tolerate alcohol-based hand rubs? A prospective, controlled, randomized double-blind clinical trial. Acta Derm Venereol. 2006;86(2):140-3. - Lotfinejad N, Peters A, Tartari E, Fankhauser-Rodriguez C, Pires D, Pittet D. Hand hygiene in health care: 20 years of ongoing advances and perspectives. Lancet Infect Dis. 2021 Aug;21(8):e209-e221. Erratum in: Lancet Infect Dis. 2021 Oct;21(10):e302. - Mouajou V, Adams K, DeLisle G, Quach C. Hand hygiene compliance in the prevention of hospital-acquired infections: a systematic review. J Hosp Infect. 2022 Jan;119:33-48. - Boyce JM. Quaternary ammonium disinfectants and antiseptics: tolerance,

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Availability	Alternatives to ethanol are typically less accessible and more expensive or have other major drawbacks such as chemical instability and potential for skin irritation. In contrast to other active substances, production infrastructure for ethanol is well established, ensuring supply security and price stability. Ethanol is widely available both globally and within Europe in sufficient quantities and can be produced on a large scale both from fossil sources and renewable raw materials (e.g. through fermentation of sugar or starch). Ethanol is produced at a significantly larger scale in Europe compared to propanols or other alternative active substances. It is used in a wide range of industrial applications beyond biocidal use, which ensures its broad availability across sectors. For local production in developing countries, WHO recommends an ethanol- or an isopropanol-based hand rub formulation for both, hygienic and surgical hand disinfection. Efficacy even against non-enveloped viruses could be demonstrated only with the formulation based on ethanol. In situations where commercial ethanol-based hand rubs are unavailable, they can be easily produced locally using the WHO standard formulation. Ensuring pandemic preparedness in Austria and Europe means maintaining rapid and affordable access to essential non-pharmaceutical measures such as hand

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Conclusion on suitability and availability of the alternative	Importantly, there is currently no adequate substitute for ethanol. Other substances such as propan-1-ol, propan-2-ol, chlorhexidine, quaternary ammonium compounds, chlorine-based agents, or peracetic acid either lack sufficient virucidal activity, pose safety concerns, or are not suitable for regular hand use due to skin irritation or corrosive effects. For example, chlorine and peracetic acid may have strong biocidal properties but are too aggressive for skin application and carry ecological and occupational safety risks. In contrast to ethanol, some of these substances are also associated with a higher potential for inducing microbial resistance, particularly with repeated or inappropriate use, which further limits their long-term

	applicability in hand hygiene. The safety of ethanol in hand hygiene applications is well established. Dermal or inhalative exposure under typical usage conditions does not pose a health risk, systemic ethanol levels remain within the range of endogenous background values, even with frequent use in confined spaces. Ethanol-based hand rubs remain indispensable for effective hand hygiene in healthcare and community settings. As topical appliances they offer a broad antimicrobial efficacy - including a unique efficacy against non-enveloped viruses - and a favorable safety profile under typical use conditions. Given the lack of viable alternatives and the potential public health impact of restricted access, ethanol must continue to be approved as a biocidal active substance devoid of a CMR classification.
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Other comments	Ethanol-based hand rubs have played an essential role in infection prevention across routine healthcare, outbreak response, and global pandemics - protecting patients, healthcare personnel, and the general public. Their proven efficacy, particularly against a broad spectrum of pathogens including non-enveloped viruses, underscores their indispensable role in maintaining hygiene standards and reducing the spread of infections. Restricting or banning the use of ethanol in biocidal products due to a CMR classification, despite its well-established safety profile under topical use, would not offer any clear benefit to human or animal health, nor to environmental protection. Ethanol use in hand rubs and industrial applications is fundamentally distinct from its use in alcoholic beverages or food products and must be evaluated accordingly. Such a regulatory restriction in Europe would have serious implications for global health security, particularly during health crises. Ethanol is widely available, cost-effective, and easy to produce locally in times of shortage. Limiting access would endanger preparedness and response capacity not only in Europe but also in regions that rely on European supply chains. Risk assessments for biocidal substances must be based on their actual use conditions and routes of exposure. According to the World Health Organization, the primary hazard associated with alcohol-based hand rubs, regardless of the alcohol type, is flammability, which can be effectively managed through standard precautions. If misuse via ingestion is a concern in specific settings, preventive strategies such as secured dispensers can

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	undermine compliance with hand hygiene protocols. Such outcomes would weaken infection control measures and pose a tangible risk to public health. Notably, no other international regulatory framework classifies ethanol for biocidal use as CMR.
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References	
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Comment 231	2025/04/28 19:54
Country	Turkey
Name of organization/institution	the Food and Sugar Industry Workers' Trade Union of Türkiye (Şeker-İş),
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	On behalf of the Food and Sugar Industry Workers' Trade Union of Türkiye (Şeker-İş), representing all workers in the beet sugar sector in Türkiye, we respectfully submit the following opinion statement concerning Product Type 2. The submission concerns the use of ethanol-based disinfectants for small surface disinfection by short-distance spraying, pouring, and wiping in healthcare institutions, laboratories, veterinary practices, and private area
Product Type	1,2,4
Alternative Identity and Properties	Technically, ethanol-based disinfectants are very easy to use and efficient. They can be used as small surface disinfection through short-distance spraying, pouring, and wiping in healthcare institutions, laboratories, veterinary

	practices, and private areas. In addition to its simplicity of use, it is highly antiseptic material. In fact, WHO (2019) classifies ethanol “on the core list of basic care substances which, as a minimum, should be available” under categories antiseptics (15.1) and alcohol-based hand disinfectants (15.2). Moreover, the German Association for Applied Hygiene (VAH) coordinated study (2020) has the title of “As a biocidal active substance, ethanol is indispensable for hygienic hand disinfection”. Even this title confirms very clearly the vital importance of ethanol in hygiene.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Ethanol-based disinfectants for small surface disinfection can be easily used and requires no prior preparation. These qualities make them ideal disinfectants to keep surfaces hygienic particularly where surface sanitisation has utmost importance as such hospitals, other health care facilities, medical laboratories and veterinary facilities. Ethanol has also some other practical advantages like quick evaporation and leaving no residue. In fact, as we remember well, during the COVID-19 pandemic, ethanol played a critical role in public health due to its high effectiveness as the main active ingredient in hand sanitizers. For this reason, the U.S. Centers for Disease Control and Prevention (CDC) states that hand sanitizers must contain at least 60% ethanol, and as expressed below. “Ethyl alcohol at concentrations of 60–80% is a potent virucidal agent and can inactivate all lipophilic viruses (e.g., herpes, vaccinia, and influenza viruses) and many hydrophilic viruses (e.g., adenoviruses, enteroviruses, rhinoviruses, and rotaviruses—excluding hepatitis A virus (HAV) and poliovirus). Isopropyl alcohol is ineffective against non-lipid enteroviruses but fully effective against lipid-containing viruses. Studies have also shown that both ethyl and isopropyl alcohol can inactivate hepatitis B virus (HBV) and herpes virus, while ethyl alcohol can also inactivate HIV, rotavirus, echovirus, and astrovirus.” Likewise, the World Health Organization (WHO) and the European Centre for Disease Prevention and Control (ECDC) continue to recommend ethanol as a primary disinfectant component. In short, it is an indispensable component for hygiene and public health.
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Economic Feasibility	Ethanol production has wider positive effects on; ☐ Employment, ☐ Agriculture, ☐ Rural development, and ☐ Green energy goals. Ethanol producing sugar and starch sectors directly and indirectly provide hundreds of thousands of people gainfully employment in Türkiye and Europe. More importantly, it is an agro-industry operating at the heart of rural communities and thus support rural communities. It is particularly important for countries like Türkiye and even for rural regions of Europe, since these sectors safeguard the migration of rural population towards urban areas. In this respect they act as important agents for rural development. Additionally, the data shows very clearly that renewable ethanol produced by ePURE members and other EU producers achieved an average 79.1% reduction in greenhouse gas emissions compared to fossil fuels in 2023. It is expected to improve further with the introduction of new technologies. Simply, it is an environmentally friendly solution. Last but not the least, the present production of sugar and starch-based ethanol is highly cost-effective. It makes ethanol a tempting alternative in the field of human disinfectants. As a result, re-classification of ethanol involves a great potential of wider and far-reaching negative effects on agriculture, industrial production, logistics, rural communities, and employment.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	The safety of ethanol-based disinfectants has been extensively studied. No significant risks related to the toxicity or carcinogenicity of ethanol in its application as a surface disinfectant have been identified. Studies from reputable organizations, such as the U.S. National Toxicology Program (NTP) and the European Food Safety Authority (EFSA), confirm that ethanol poses minimal health risks when used as intended. While alternatives to ethanol may exist, their safety, efficacy, and cost-effectiveness do not necessarily match the properties of ethanol. Moreover, new alternatives may not guarantee the same degree of effectiveness or economic viability. The German Association for Applied Hygiene (VAH, 2020) also stresses that ethanol remains indispensable for surface disinfection, especially in sensitive environments like hospitals and laboratories. An analysis of 74 studies on the issue by Andreas Sauerbrei also confirms them.

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Availability	Ethanol is produced at large scale across Europe and therefore the availability is not a problem. Moreover, the production and distribution are efficiently supported by well-established supply chains and logistics firms. The Covid-19 period has proven that huge scale of availability exists even the during the times of crisis.
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Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Its efficacy, instant availability, practical use with no residue, cost-effectiveness and close support to rural communities while proving gainful employment for hundreds of thousands of individuals and strong support for a greener economy grants enormous advantages to ethanol. Therefore, as Şeker-İş, we strongly support maintaining present EU classification of ethanol for Product Type 2 and, by extension, the similar classification in the relevant Turkish legislation based on the EU Acquis.
Information above is confidential	
Justification for confidentiality	
Other comments	As elaborated under item 3, it is vital to consider the far-reaching repercussions of potential alternatives on economy, employment, agriculture, rural development and their contribution to the success of EU green deal objectives. In our view, the issue goes simply the chemical sector alone.
Information above is confidential	
Justification for confidentiality	
References	• German Association for Applied Hygiene (VAH): VAH Report, 2020 • WHO: Guidelines on Hand Hygiene in Health Care (2009) • EU Biocidal Products Regulation (EU) No. 528/2012 • ePURE: Sustainability report, 2023 - Sauerbrei, A. (September 2020): https://doi.org/10.1002/mbo3.1097 • Social Security

	Institution (Turkey): Statistical Yearbooks • European Centre for Disease Prevention and Control (ECDC), COVID-19 Guidance 2020 • CDC of USA https://www.drugs.com/compare/ethanol-topical • IARC Monographs, Vol. 100E — Personal Habits and Indoor Combustions (2012) • EFSA Journal (2015): 13(6):4145 – Scientific Opinion on Ethanol as a Food Additive • ,Kampf, G. (2018). Efficacy of ethanol against viruses in hand disinfection. Journal of Hospital Infection, 98(4), 331–338
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Justification for confidential attachment	

Comment 232	2025/04/28 21:06
Country	Belgium
Name of organization/institution	BioMed Alliance
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	This reply is jointly prepared by BioMed Alliance (representing 35 European Medical Societies) and its member EFLM (representing 40 national scientific societies for Laboratory Medicine). It was prepared by Prof. Michael Neumaier, chair of the BioMed Alliance IVD Task Force. Healthcare, including medical laboratories, is impacted by all issues that are related to biomedical safety and hygiene. They deal 24/7 with potentially biohazardous, infected biospecimens in very large numbers and on a daily basis. Ethanol (EtOH) is a critical component in PT1 (EtOH-based hand rubs; EBHR) and PT2 (surface disinfection) applications within the laboratory and broader healthcare setting to assure high hygienic standards for staff safety. EBHR are easy and safe to use, are non-irritant and an effective biocidal measure for microbiological and virus pathogens. Alternatives to alcohol based disinfectants have

	shown repeatedly to be inferior, particularly in their efficiencies to inactivate non-enveloped viruses like Norovirus, the Coxsackie viruses and others estimated to be responsible for approx. 400 million clinical infection cases annually in wider Europe. Norovirus alone is estimated to be responsible for 58% of all food illnesses with 125 million cases worldwide. The COVID19 pandemic has very clearly emphasized the importance of EBHR for virus containment and interruption of the chains of infection. Specifically, it cannot be overemphasized that such hygienic measures are important in early stages of epidemics or pandemics when targeted countermeasure like vaccination are not yet available. As EBHR for the containment of infectious agents can be easily realized in all areas of societal contacts (i.e. not only hospitals and nursing homes, but in schools and kindergartens, in public transportation areas or in confined areas like correction facilities), the elimination of efficient disinfectants and easily established disinfection strategies will have catastrophic results in handling infections in the public arena. The burden of healthcare-associated infections in the European Economic area impacts on 4 million patients leading to prolonged hospital stays, higher medical costs, long-term complications and an addition 90,000 deaths annually. Given the wide-spread use, the extensive experience and scientific evidence on the external application of EtOH in the PT1 and PT2 (as well as the PT4) context, the justification of classifying EtOH as a category 1 CMR compound appears questionable. Several systematic studies have established that other alcohols like Propan-1-ol and Propan-2-ol possess lower potency as disinfectants particular with non-enveloped viruses. EtOH is only poorly resorbed through skin, less irritant and causes no long-term skin damage. There is no convincing evidence that EtOH is carcinogenic upon external exposure of the skin. Carcinogenicity data for EtOH stem from clinical studies and biological experiments based on repeated and prolonged oral ingestion of large quantities. EtOH is rapidly resorbed through internal body surfaces with up to 90% and 60% efficacy through oral absorption in the gut and lungs, respectively. In contrast, resorption through the skin is low (0.4-2%). There is no evidence that EBHR will have mutagenic effects or will convey a reprotoxicity in a fetus in pregnant women. With proper risk management (RMM) in place including denaturation and formulation, EtOH-based hand rubs remain a safe and effective solution for infection control and ingestion of EtOH is only a minor complication in workers using EBHRs.
Product Type	1,2,4

Alternative Identity and Properties	EtOH possesses high efficiency as a 80% v/v watery solution and works efficiently against hydrophilic non-enveloped viruses. Accordingly, EtOH is the reference standard in the EN17430 international norm, especially when compared to other alcohols in inactivation studies on said viruses. Specifically, Propanols have been investigated extensively and, while being marginally different amongst themselves, are inferior to EtOH. Used in EBHR, Propanols show higher long-term skin damage in part due to slower evaporation. Efficiency of Propanols is generally lower particularly for the inactivation of non-enveloped viruses with high public health relevance (e.g. Norovirus or Coxsackie viruses). It is anticipated that in a COVID19-like pandemic caused by a non-enveloped virus, Propanols would not provide protection as does EtOH (75). There is a good/sufficient margin of safety linked to the use of EtOH with no risk reduction to substitute EtOH with either of the Propanols. All studies e.g. from the German Association for Applied Hygiene (VAT) state that EtOH is indispensable for hygienic hand disinfection.
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Technical Feasibility	EBHR are easily applied and implemented in hygiene strategies in the medical laboratory and the wider healthcare setting. The awareness of correct exposure time to EtOH has been boosted during the COVID-19 pandemic and accessibility to EBHR dispensers has also been improved in the public space. 30 seconds of EBHR are considered sufficient and are being recommended. Shorter exposure times to EtOH are under consideration and are being investigated.
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Justification for confidentiality	
Economic Feasibility	Timelines for the development of alternatives to EBHR are not clear, owed to unclear transition times to alternative solutions. Also, research and development costs, regulatory costs and authorization expenditures cannot be reliably anticipated. In contrast, EtOH-based hand rubs solutions are standard safe products being produced at low costs within the EEA. They are widely recognized as the most economic option and a high reliance on renewable agricultural resources. Their production infrastructure is

	well-established within the EU and globally, utilizing biomass and agricultural residues. Replacement of production facilities with little evidence of necessity would cause economic burden on the healthcare system.
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Justification for confidentiality	
Hazards and Risks of the Alternative	Alternative candidate substances based on alcohols have proven to be more irritant (Propan-1-ol; Propan-2-ol). There are non-alcoholic potential alternatives of different molecular classes like chlorine compounds, Glycol Ethers, Acids and Carboxylates Non-alcoholic substances generally show low to intermediate virucidal activities and are therefore of limited utility for the tasks in healthcare easily covered by EtOH. Substances like active chlorines, lactic acid and others may also be corrosive and toxic in higher concentrations, which are required for their expected biological activities. Furthermore, the body of literature to characterize these compounds comprehensively, is not sufficient at present times.
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Availability	Ethanol is produced at a much larger scale in Europe than and of the other alternative substances. Also, production costs are limited due to available infrastructures. The margin of safety linked to the use of EtOH is not balanced by the risk reduction to substitute EtOH with either of the Propanols. Production of ethanol is available in Europe in sufficient quantities rendering its use in EBHR easily warranted. Should a global shortage of commercially available EBHR, local production is feasible. This needs to be taken into account considering preparedness for future pandemics, which require rapid and cost-effective access to vital non-pharmaceutical supplies such as handrubs for ALL people. Artificially decreasing the demand for EtOH in EBHR would potentially limit the availability critically when needed.
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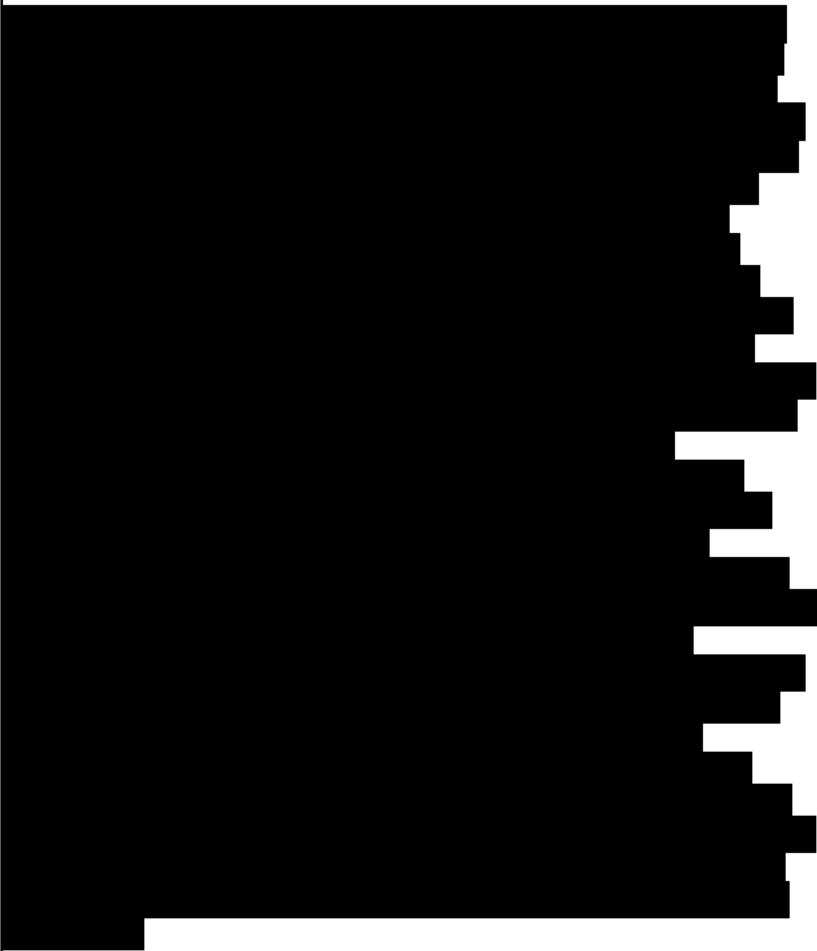
Conclusion on suitability and availability of the alternative	Hygiene in the medical arena is one of the biggest achievements and a cornerstone for modern medicine. EtOH-based PT1, PT2 and PT4 disinfectant strategies are indispensable particularly due to high efficiency for virus inactivation, low to no toxicity of the EtOH during EBHR, ease of production and safe application in the wider public with no medical supervision necessary. Favourable biodegradability of EtOH i.e. microbial degradation, evaporation and the lack of accumulation in natural ecosystems appears to make EtOH a safe compound for the use in outer disinfection. None of the alternate substances investigated (Propan-1-ol, Propan-2-ol, non-alcoholic compounds) is suitable to replace EtOH for hand rubs in health care and other settings for safety and performance reasons. None of the non-chemical methods (UV-sterilization, steam sterilization) is suitable for human skin. No candidate substance (alcoholic or non-alcoholic) is comparable regarding efficacy and safety. Also, alternative substances are not available in quantities required for broad use. Hazards through the use of EtOH appear to stem almost entirely from its misuse by oral ingestion, which is preventable with denatured EtOH and particular formulations. A fear of carcinogenicity, mutagenicity and reprotoxicity is not justified on the basis of scientific evidence. The role EtOH plays in public and medical hygiene aligns well with EU public health priorities under the OneHealth and “The absence of ethanol as a biocidal active substance would severely hinder the ability to maintain hygienic environments in healthcare settings. and is indispensable in hospitals ... and is compatible with diverse materials” (see p. 70/92). WHO concludes from the COVID19 experience that biocidal disinfection with EtOH is a critical components in pandemic preparedness (94). With proper risk management (RMM) in place including denaturation and formulation, EtOH remains a safe and effective solution for infection control.
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Other comments	
Information above is confidential	
Justification for confidentiality	

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Comment 233	2025/04/28 23:12

Country	Spain
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	Ethanol primarily acts by denaturing proteins in cell membranes and virus particles, solubilizing lipids, and causing dehydration. Due to its nonspecific mode of action, there is no risk of resistance. Its inherent properties include a fast and efficient killing effect, rapid evaporation without residues, long shelf life of formulated products, low degradation in open packages, and no formation of disinfection by-products or other toxicologically relevant chemical species for human health and the environment. Ethanol is naturally produced by intestinal bacteria. Fruit juices can contain up to 3 g of ethanol per liter, and apple juice contains 1 g per 500 mL. When using ethanol-based hand disinfectants, absorption through the skin and respiratory tract is low, with only a slight increase in blood alcohol concentration. Internal ethanol levels from disinfectant use are comparable to those from food and non-alcoholic beverages. In contrast, blood levels from alcoholic beverage consumption are significantly higher. Exposure from disinfectant use and ethanol as a chemical is not comparable to alcoholic beverage consumption, and lifetime occupational exposure is within the standard deviation of endogenous exposure. Ethanol-based hand and surface disinfection products have been used for decades. Comprehensive safety assessments have been conducted for medicinal, biocidal, or medical device approval. To date, there is no evidence of carcinogenic, mutagenic, or reprotoxic effects from the intended use of these products.
Product Type	1,2,4
Alternative Identity and Properties	The most effective protective measures against bacterial and viral infections have been proven to include hand disinfection and surface disinfection with ethanol. Propan-1-ol (EC: 200-746-9) and propan-2-ol (EC: 200-661-7) are also effective antimicrobial agents with significant market relevance and are already approved under BPR until 30/04/2029 and until 30/06/2026, respectively. Several BPR authorizations based on propanols are available in the ECHA database for biocidal products. However, these

	products do not achieve a full virucidal activity in relevant time.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Ethanol in disinfectants is an effective and safe substance for preventing healthcare-associated infections and antimicrobial resistance. It is valued for its broad-spectrum efficacy against bacteria (including mycobacteria), fungi, and both enveloped and non-enveloped viruses. Non-enveloped viruses are significantly more stable against chemical agents than enveloped viruses. Among the three alcohols used in hand rub formulations (ethanol, propan-1-ol, and propan-2-ol), only ethanol-based formulations proved effective within 30–60 seconds against non-enveloped viruses such as adeno-, polio-, human entero-, echo-, and coxsackie viruses in quantitative suspension assays. Formulations with propan-1-ol and propan-2-ol are not sufficiently active against non-enveloped viruses. Propan-1-ol was ineffective against coxsackie, poliovirus, and human enterovirus at 90% concentration within 5 minutes. Within 2 minutes, 80%, 90%, and 97% propan-1-ol and propan-2-ol, and within 3 minutes, 70% and 90% propan-1-ol and propan-2-ol, were ineffective against poliovirus. In contrast, ethanol was effective at concentrations of $\geq 70\%$ in suspension tests and in vivo on hands. Sodium hypochlorite, active chlorine, QACs, acids like acetic or lactic acid, biguanide, phenols, or phenoxyethanol do not meet application criteria as alternatives, as they are primarily suitable for hand washing formulations or used in combination with alcohol. Ethanol is crucial for infection control, especially in alcohol-based hand rubs (ABHRs) and surface disinfectants, due to its superior efficacy against both non-enveloped and enveloped viruses. Propan-1-ol and propan-2-ol are effective against enveloped viruses but insufficient against key non-enveloped viruses. There are no viable alternatives due to efficacy issues, material incompatibility, or unfavorable hazard profiles. The WHO lists ethanol formulations as essential medicines, highlighting their indispensability for infection prevention. Supported by VAH and DGKH, the scientific community and healthcare sector, along with 35 organizations worldwide, have published a scientific article urging ECHA to approve ethanol as a virucidal active substance for hand antiseptics without a CMR classification.

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Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Ethanol is classified as a flammable liquid (Category 2, H225) and an eye irritant (Category 2, H319) under CLP Regulation. It is currently under assessment as a biocidal active substance. The BPR Working Group concluded that ethanol meets exclusion criteria for carcinogenicity and reproductive toxicity, based mainly on oral consumption data. However, oral intake is prevented by denaturants in biocidal products, making such data irrelevant for hazard

	assessment. Human data on adverse effects should relate to chemical substances, not oral consumption. The International Agency for Research on Cancer (IARC) classifies alcoholic beverages, not ethanol itself, as carcinogenic. OECD and ECHA assessments support that ethanol's hazards manifest only at doses associated with alcohol consumption, not industrial use. Animal studies show adverse effects only at high oral doses. Ethanol's classification should consider actual risk from inhalation and dermal exposure, which are low. Occupational exposure does not significantly increase blood ethanol levels, and lifetime exposure remains within acceptable risk limits. Propan-1-ol and propan-2-ol are approved alternatives under BPR but pose higher risks, including flammability, eye damage, and potential dizziness. Propan-2-ol does not meet efficacy requirements as ethanol as a virucidal disinfectant.
Information above is confidential	
Justification for confidentiality	
Availability	Ethanol is widely available due to a diverse range of suppliers, fostering competition and reducing costs. This ensures that ethanol-based disinfectants are accessible in public health sectors, meeting hygiene standards without significant financial burden. Ethanol production can quickly scale to meet demand surges, as demonstrated during the COVID-19 pandemic, making it a reliable option for healthcare. In contrast, propan-1-ol and propan-2-ol have fewer suppliers, raising concerns about their ability to meet EU-wide demand, especially during high-demand situations. Ethanol's robust supply chain within the EU ensures stable access and mitigates risks of shortages, enabling rapid scaling to meet healthcare needs.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol rational use according CLP regulation does not include oral intake. Ethanol is the most cost-effective and widespread available substance for hand disinfection with efficacy against non-enveloped key virus in contrast to other options, according to current evidence on that substance and its use it should be available for elderly care and healthcare workers without CMR restrictions.

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Other comments	Ethanol, derived from renewable resources like biomass and agricultural residues, supports the EU's goals of reducing fossil fuel dependency and promoting circular economy principles. Its high biodegradability ensures a low environmental footprint, aligning with the EU's sustainability vision. In contrast, propan-1-ol and propan-2-ol are petrochemical derivatives from non-renewable resources. Ethanol's minimal environmental impact and high infection control standards support the EU's sustainability goals, including the European Green Deal and the Circular Economy Action Plan.
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References	
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Comment 234	2025/04/28 23:24
Country	Germany
Name of organization/institution	Conradylgruppe Verwaltungs GmbH
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Die Wirksamkeit von Ethanol gegen Bakterien, Hefen und behüllten Viren ist vergleichbar mit der von 1-Propanol und 2-Propanol. Eine umfassende Literaturlauswertung zur Wirksamkeit gegen unbehüllter Viren ergab jedoch, dass

	Ethanol gegen verschiedene Adenoviren, Polioviren, humane Enteroviren, Echoviren und verschiedene Coxsackieviren wirksamer ist als die alternativen. Ethanol ist dazu fähig Proteine effektiver zu denaturieren und damit Kapsidproteine unbehüllter Viren zu zerstören, denen die Lipidhülle fehlt. Auf Zerstörung dieser Lipidhülle basiert die antivirale Wirkung von den Propanol-Alkoholen. Für diese Anwendungsbereiche von Ethanol sind die Alternativen Stoffe ungeeignet.
Product Type	1,2,4
Alternative Identity and Properties	Für die Gewährleistung der menschlichen Hygiene ist Ethanol als Wirkstoff unverzichtbar. Die Wirksamkeit von Ethanol gegen Bakterien, Hefen und behüllten Viren ist vergleichbar mit der von 1-Propanol und 2-Propanol. Eine umfassende Literaturlauswertung zur Wirksamkeit gegen unbehüllter Viren ergab jedoch, dass Ethanol gegen verschiedene Adenoviren, Polioviren, humane Enteroviren, Echoviren und verschiedene Coxsackieviren wirksamer ist als die alternativen. Ethanol ist dazu fähig Proteine effektiver zu denaturieren und damit Kapsidproteine unbehüllter Viren zu zerstören, denen die Lipidhülle fehlt. Auf Zerstörung dieser Lipidhülle basiert die antivirale Wirkung von den Propanol-Alkoholen. Für diese Anwendungsbereiche von Ethanol sind die Alternativen Stoffe, wie Isopropanol ungeeignet.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Bei Verwendung von Alkoholen als z.B. Handdesinfektionsmittel in der Krankenhausreinigung, verdampft und trocknet Ethanol schneller, als die alternative Propanol, da Ethanol einen kleineren Siedepunkt und Dampfdruck hat. Zudem können Desinfektionsmittel auf Ethanolbasis in flüssiger Form verwendet werden, wodurch die Anwendung bei Tragen von Handschuhen, leichter und effizienter ist. Zudem ist die transdermale Aufnahme von Ethanol bei der Händedesinfektion bis zu zehnmal geringer als die orale Aufnahme von Getränken mit verstecktem Ethanolgehalt wie Apfelsaft, Kefir oder alkoholfreiem Bier. Um die Sicherheit und Hygiene von Patienten und vom Personal aufrechtzuerhalten, ist man auf die weitere Verfügbarkeit von Ethanol als Desinfektionsmittel angewiesen.

Information above is confidential	
Justification for confidentiality	
Economic Feasibility	In den letzten Jahren ist die Herstellung von Ethanol gestiegen, mit einer weiter steigenden Tendenz. Dies hängt mit dem Potential von Bioethanol als Kraftstoff zusammen. Als Bioethanol bezeichnet man Ethanol, das ausschließlich aus Biomasse oder den biologisch abbaubaren Anteilen von Abfällen hergestellt wurde und hauptsächlich als Treibstoff verwendet wird. Aufgrund der steigenden Produktion und des steigenden Verbrauchs von Ethanol im Land sowie der gestiegenen Nachfrage nach Biokraftstoffen für Kraftfahrzeuge wird erwartet, dass Deutschland den Ethanolmarkt dominieren wird. In Vergleich wird Biopropanol erst in Forschung und Entwicklung aber auch aus Glycerin einem Nebenprodukt der Herstellung von Biodiesel, gewonnen. In Europa gibt es deshalb mehr Ethanolhersteller als Propanolhersteller. Eine Umstellung auf Propanol wurde eine Steigerung der Kosten für die betroffenen einkaufenden Unternehmen mit sich ziehen. Die Auswirkung auf die Umwelt erscheint ebenfalls negativ auf Grund des Fehlens an Biopropanol.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Als Alternativen zu Ethanol werden zwei andere Alkohole in Betrachtung geozogen: 1-Propanol und 2-Propanol, auch als Isopropanol bekannt. 1-Propanol-Dämpfe reizen Augen, Haut und Schleimhäute. Direkter Kontakt der Flüssigkeit mit den Augen kann zu schweren Augenschäden führen. Bei der Aufnahme wirkt die Flüssigkeit ähnlich betäubend wie Ethanol und führt in höheren Konzentrationen zu Schwindel, Benommenheit und bei hohen Konzentrationen zu Rauschzuständen oder gar Bewusstlosigkeit. Aufgrund der Möglichkeit von schweren Augenschäden sollte für die manuelle Verwendung, wie zum Beispiel beim Einsatz als Reinigungsmittel, auf 1-Propanol verzichtet und das ungefährlichere 2-Propanol (Isopropanol) verwendet werden. Ist dies nicht möglich, sollte bei Arbeiten mit 1-Propanol eine Schutzbrille getragen werden. Die Dämpfe von 2-Propanol wirken jedoch auch betäubend. Der Kontakt verursacht Reizungen der Augen und der Schleimhäute. Beim Umgang sollte für ausreichende Lüftung gesorgt werden. 2-Propanol kann aber auch, wie andere sekundäre Alkohole, mit Luftsauerstoff explosionsfähige Peroxide

	bilden. Hier steigt somit die Gefährdung der Personen bei der Anwendung als Reinigungsmittel in Vergleich zur Anwendung von Ethanol.
Information above is confidential	
Justification for confidentiality	
Availability	Die geeigneten Alternativen sind in der benötigten Menge nicht verfügbar. In Europa gibt es mehr Ethanolhersteller als Propanolhersteller, da Ethanol auch aus Landwirtschaftlichenabfällen hergestellt werden kann. Eine Umstellung auf Propanol würde eine Schwachstelle in der Lieferkette hervorbringen, da alternative Substanzen deutlich teurer und weniger verfügbar sind. Hinzu muss man in Betracht ziehen, dass eine Ausweitung der Produktion von Ersatzstoffen massive Investitionen in neue Anlagen, Technologien und behördliche Genehmigungen erfordern würde und auf Widerstand von Behörden und NGOs stoßen wird.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Die Alternativen zu Ethanol sind nicht geeignet um Oberflächen wie auch die menschliche Haut vor unbehüllten Viren zu schützen. Hinzukommt die beschränkte Verfügbarkeit von Desinfektionsmitteln auf Propanol, durch den großen Ethanolmarkt in Europa.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	AttachementsECHA.zip

Attachments (confidential information)	
Justification for confidential attachment	

Comment 235	2025/04/28 23:28
Country	Germany
Name of organization/institution	Conradysgruppe Verwaltungs GmbH
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Die Wirksamkeit von Ethanol gegen Bakterien, Hefen und behüllten Viren ist vergleichbar mit der von 1-Propanol und 2-Propanol. Eine umfassende Literatursauswertung zur Wirksamkeit gegen unbehüllter Viren ergab jedoch, dass Ethanol gegen verschiedene Adenoviren, Polioviren, humane Enteroviren, Echoviren und verschiedene Coxsackieviren wirksamer ist als die alternativen. Ethanol ist dazu fähig Proteine effektiver zu denaturieren und damit Kapsidproteine unbehüllter Viren zu zerstören, denen die Lipidhülle fehlt. Auf Zerstörung dieser Lipidhülle basiert die antivirale Wirkung von den Propanol-Alkoholen. Für diese Anwendungsbereiche von Ethanol sind die Alternativen Stoffe ungeeignet.
Product Type	1,2,4
Alternative Identity and Properties	Für die Gewährleistung des Infektionsschutzes ist Ethanol als Wirkstoff unverzichtbar. Die Wirksamkeit von Ethanol gegen Bakterien, Hefen und behüllten Viren ist vergleichbar mit der von 1-Propanol und 2-Propanol. Eine umfassende Literatursauswertung zur Wirksamkeit gegen unbehüllter Viren ergab jedoch, dass Ethanol gegen verschiedene Noroviren, Adenoviren, Polioviren, humane Enteroviren, Echoviren und verschiedene Coxsackieviren viel wirksamer ist als die alternativen. Ethanol ist dazu fähig Proteine effektiver zu denaturieren und damit Kapsidproteine unbehüllter Viren zu zerstören, denen die Lipidhülle fehlt. Auf Zerstörung dieser Lipidhülle basiert die antivirale Wirkung von den Propanol-Alkoholen. Für diese Anwendungsbereiche von Ethanol sind die Alternativen

	Stoffe ungeeignet. Vor allem in Hinsicht auf die Tenazität von unbehüllten Viren, welche bis zu sieben Tage auf diversen Oberflächen aktiv verbleiben können.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Für die Desinfektion von Flächen und Gegenständen ist Ethanol seit Zeiten von Corona nicht mehr wegzudenken, da es schneller Verdampft und trocknet als die Alternativen mit Propanol-Alkoholen. Dadurch kann man einen positiven Effekt bei der Desinfektion von Böden und anderen Flächen die mit den Menschen in Kontakt kommen wie z.B. Türklinken beobachten, da eine Sturz- oder Rutschgefahr stark reduziert wird.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	In den letzten Jahren ist die Herstellung von Ethanol gestiegen, mit einer weiter steigenden Tendenz. Dies hängt mit der Potential von Bioethanol als Kraftstoff zusammen. Als Bioethanol bezeichnet man Ethanol, das ausschließlich aus Biomasse oder den biologisch abbaubaren Anteilen von Abfällen hergestellt wurde und hauptsächlich als Treibstoff verwendet wird. Aufgrund der steigenden Produktion und des steigenden Verbrauchs von Ethanol im Land sowie der gestiegenen Nachfrage nach Biokraftstoffen für Kraftfahrzeuge wird erwartet, dass Deutschland den Ethanolmarkt dominieren wird. In Vergleich wird Biopropanol erst in Forschung und Entwicklung aber auch aus Glycerin einem Nebenprodukt der Herstellung von Biodiesel, gewonnen. In Europa gibt es deshalb mehr Ethanolhersteller als Propanolhersteller. Eine Umstellung auf Propanol wurde eine Steigerung der Kosten für die betroffenen einkaufenden Unternehmen mit sich ziehen.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Als Alternativen zu Ethanol werden zwei andere Alkohole in Betrachtung geozogen: 1-Propanol und 2-Propanol, auch als Isopropanol bekannt. 1-Propanol-Dämpfe reizen Augen, Haut und Schleimhäute. Direkter Kontakt der Flüssigkeit mit

	den Augen kann zu schweren Augenschäden führen. Bei der Aufnahme wirkt die Flüssigkeit ähnlich betäubend wie Ethanol und führt in höheren Konzentrationen zu Schwindel, Benommenheit und bei hohen Konzentrationen zu Rauschzuständen oder gar Bewusstlosigkeit. Aufgrund der Möglichkeit von schweren Augenschäden sollte für die manuelle Verwendung, wie zum Beispiel beim Einsatz als Reinigungsmittel, auf 1-Propanol verzichtet und das ungefährlichere 2-Propanol (Isopropanol) verwendet werden. Ist dies nicht möglich, sollte bei Arbeiten mit 1-Propanol eine Schutzbrille getragen werden. Die Dämpfe von 2-Propanol wirken jedoch auch betäubend. Der Kontakt verursacht Reizungen der Augen und der Schleimhäute. Beim Umgang sollte für ausreichende Lüftung gesorgt werden. 2-Propanol kann aber auch, wie andere sekundäre Alkohole, mit Luftsauerstoff explosionsfähige Peroxide bilden. Hier steigt somit die Gefährdung der Personen bei der Anwendung als Reinigungsmittel in Vergleich zur Anwendung von Ethanol.
Information above is confidential	
Justification for confidentiality	
Availability	Bei geeigneten Alternativen sind in der benötigten Menge nicht verfügbar. In Europa gibt es mehr Ethanolhersteller als Propanolhersteller, da Ethanol auch aus Landwirtschaftlichenabfällen hergestellt werden kann. Eine Umstellung auf Propanol wurde eine Schwachstelle in der Lieferkette hervorbringen, da alternative Substanzen deutlich teurer und weniger verfügbar sind. Hinzu muss man in Betracht ziehen, dass eine Ausweitung der Produktion von Ersatzstoffen massive Investitionen in neue Anlagen, Technologien und behördliche Genehmigungen erfordern würde und auf Widerstand von Behörden und NGOs stoßen wird.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Die Alternativen zu Ethanol sind nicht geeignet um Oberflächen wie auch die menschliche Haut vor unbehüllten Viren zu schützen. Hinzukommt die beschränkte Verfügbarkeit von Desinfektionsmitteln auf Propanol, durch den großen Ethanolmarkt in Europa.

Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	siehe Attachements
Attachments (non-confidential information)	AttachementsECHA.zip
Attachments (confidential information)	
Justification for confidential attachment	

Comment 236	2025/04/28 23:35
Country	Germany
Name of organization/institution	Conradysgruppe Verwaltungs GmbH
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Die Wirksamkeit von Ethanol gegen Bakterien, Hefen und behüllten Viren ist vergleichbar mit der von 1-Propanol und 2-Propanol. Eine umfassende Literaturlauswertung zur Wirksamkeit gegen unbehüllter Viren ergab jedoch, dass Ethanol gegen verschiedene Adenoviren, Polioviren, humane Enteroviren, Echoviren und verschiedene Cocksackieviren wirksamer ist als die alternativen. Ethanol ist dazu fähig Proteine effektiver zu denaturieren und damit Kapsidproteine unbehüllter Viren zu zerstören, denen die Lipidhülle fehlt. Auf Zerstörung dieser Lipidhülle basiert die antivirale Wirkung von den Propanol-Alkoholen. Für diese Anwendungsbereiche von Ethanol sind die Alternativen Stoffe ungeeignet.

Product Type	1,2,4
Alternative Identity and Properties	Für die Gewährleistung der Lebensmittelsicherheit ist Ethanol als Wirkstoff unverzichtbar. Die Wirksamkeit von Ethanol gegen Bakterien, Hefen und behüllten Viren ist vergleichbar mit der von 1-Propanol und 2-Propanol. Eine umfassende Literaturlauswertung zur Wirksamkeit gegen unbehüllter Viren ergab jedoch, dass Ethanol gegen verschiedene Noroviren, Adenoviren, Polioviren, humane Enteroviren, Echoviren und verschiedene Cocksackieviren viel wirksamer ist als die Alternativen. Ethanol ist dazu fähig Proteine effektiver zu denaturieren und damit Kapsidproteine unbehüllter Viren zu zerstören, denen die Lipidhülle fehlt. Auf Zerstörung dieser Lipidhülle basiert die antivirale Wirkung von den Propanol-Alkoholen. Für diese Anwendungsbereiche von Ethanol sind die Alternativen Stoffe ungeeignet. Vor allem in Hinsicht auf die Tenazität von unbehüllten Viren, welche bis zu sieben Tage auf diversen Oberflächen aktiv verbleiben können. Hinzu kommt, die Lebensmittelrechtliche unbedenklichkeit beim Einsatz von Ethanol auf Grund der Rückstandslosigkeit gegenüber dem bedenklichen Einsatz von Alternativen im Umgang mit Lebensmitteln.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Ethanol eignet gut als Desinfektionsmittel für die Lebensmittelsicherheit, da es schneller trocknet als die alternativen, biologisch abbaubar ist und nicht als Kontamination nachweisbar ist. Ethanol kommt natürlich in vielen nicht alkoholischen Lebensmittel vor, dabei wird über oft einen versteckten Ethanolgehalt wie Apfelsaft, Kefir oder alkoholfreiem Bier gesprochen. Ethanol ist auf der einen Seite Rückstandsfrei abtrocknend und für den Fall dass ein Rest verbleiben würde auch lebensmittelrechtlich zugelassen.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	In den letzten Jahren ist die Herstellung von Ethanol gestiegen, mit einer weiter steigenden Tendenz. Dies hängt mit der Potential von Bioethanol als Kraftstoff zusammen. Als Bioethanol bezeichnet man Ethanol, das ausschließlich aus Biomasse oder den biologisch abbaubaren Anteilen von

	Abfällen hergestellt wurde und hauptsächlich als Treibstoff verwendet wird. Aufgrund der steigenden Produktion und des steigenden Verbrauchs von Ethanol im Land sowie der gestiegenen Nachfrage nach Biokraftstoffen für Kraftfahrzeuge wird erwartet, dass Deutschland den Ethanolmarkt dominieren wird. In Vergleich wird Biopropanol erst in Forschung und Entwicklung aber auch aus Glycerin einem Nebenprodukt der Herstellung von Biodiesel, gewonnen. In Europa gibt es deshalb mehr Ethanolhersteller als Propanolhersteller. Eine Umstellung auf Propanol wurde eine Steigerung der Kosten für die betroffenen einkaufenden Unternehmen mit sich ziehen.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Als Alternativen zu Ethanol werden zwei andere Alkohole in Betrachtung geozogen: 1-Propanol und 2-Propanol, auch als Isopropanol bekannt. 1-Propanol-Dämpfe reizen Augen, Haut und Schleimhäute. Direkter Kontakt der Flüssigkeit mit den Augen kann zu schweren Augenschäden führen. Bei der Aufnahme wirkt die Flüssigkeit ähnlich betäubend wie Ethanol und führt in höheren Konzentrationen zu Schwindel, Benommenheit und bei hohen Konzentrationen zu Rauschzuständen oder gar Bewusstlosigkeit. Aufgrund der Möglichkeit von schweren Augenschäden sollte für die manuelle Verwendung, wie zum Beispiel beim Einsatz als Reinigungsmittel, auf 1-Propanol verzichtet und das ungefährlichere 2-Propanol (Isopropanol) verwendet werden. Ist dies nicht möglich, sollte bei Arbeiten mit 1-Propanol eine Schutzbrille getragen werden. Die Dämpfe von 2-Propanol wirken jedoch auch betäubend. Der Kontakt verursacht Reizungen der Augen und der Schleimhäute. Beim Umgang sollte für ausreichende Lüftung gesorgt werden. 2-Propanol kann aber auch, wie andere sekundäre Alkohole, mit Luftsauerstoff explosionsfähige Peroxide bilden. Hier steigt somit die Gefährdung der Personen bei der Anwendung als Reinigungsmittel in Vergleich zur Anwendung von Ethanol
Information above is confidential	
Justification for confidentiality	
Availability	Bei geeigneten Alternativen sind in der benötigten Menge nicht verfügbar. In Europa gibt es mehr Ethanolhersteller als Propanolhersteller, da Ethanol auch aus

	Landwirtschaftlichenabfällen hergestellt werden kann. Eine Umstellung auf Propanol wurde eine Schwachstelle in der Lieferkette hervorbringen, da alternative Substanzen deutlich teurer und weniger verfügbar sind. Hinzu muss man in Betracht ziehen, dass eine Ausweitung der Produktion von Ersatzstoffen massive Investitionen in neue Anlagen, Technologien und behördliche Genehmigungen erfordern würde und auf Widerstand von Behörden und NGOs stoßen wird.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Die Alternativen zu Ethanol sind nicht geeignet um Oberflächen wie auch die menschliche Haut vor unbehüllten Viren zu schützen. Hinzukommt die beschränkte Verfügbarkeit von Desinfektionsmitteln auf Propanol, durch den großen Ethanolmarkt in Europa.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	siehe Attachments
Attachments (non-confidential information)	AttachementsECHA.zip
Attachments (confidential information)	
Justification for confidential attachment	

Comment 237	2025/04/29 00:37
Country	Austria

Name of organization/institution	Austrian Chamber of Pharmacists
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	In both pharmacies and hospital pharmacies, ethanol-based disinfectants are an essential tool used by pharmacists and healthcare staff for hygienic hand disinfection, as well as for the cleaning of surfaces and equipment.
Product Type	1,2,4
Alternative Identity and Properties	The only commonly known potentially alternative substances are 1-propanol (also referred to as n-propanol) and 2-propanol (isopropanol). When applied for 30 to 60 seconds – a typical exposure time in healthcare environments – ethanol demonstrates greater efficacy against non-enveloped viruses (such as adenoviruses, human enteroviruses, polioviruses, and human papillomaviruses) compared to 1- or 2-propanol. For bacteria and enveloped viruses, the three alcohols show similar levels of effectiveness. Non-enveloped viruses, which are easily transmitted through skin contact, account for an estimated 400 million infections annually across Europe, primarily involving rhinoviruses, rotaviruses, and papillomaviruses.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	From a purely technical perspective, it may be feasible to transition from ethanol-based to non-ethanol-based disinfectants in healthcare and pharmacy settings.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Specific cost comparisons for a switch to 1- or 2-propanol-based disinfectants are not available. However, it is expected that such a change would result in higher costs, as ethanol benefits from being a by-product of various industrial processes, whereas 1- and 2-propanol require dedicated production. Additionally, the number of suppliers

	for 1- and 2-propanol is considerably smaller than for ethanol.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Replacing ethanol with 1- or 2-propanol could increase infection risks among healthcare and pharmacy staff due to the lower efficacy of these alternatives against non-enveloped viruses (refer to Section 1). Such increased risks could lead to higher rates of staff absenteeism and reduced quality of care and pharmacy services. The healthcare system's ability to respond effectively to outbreaks would also be compromised: Ethanol's superior performance against certain pathogens would be lost, and even for pathogens where all three substances are equally effective, supply shortages could occur, particularly during sudden spikes in demand, such as during the early stages of the SARS-CoV-2 pandemic. Moreover, even in outbreaks where ethanol is less effective than 1- or 2-propanol, maintaining ethanol availability would provide critical flexibility, supporting general needs while allowing alternative substances to be prioritized for targeted interventions.
Information above is confidential	
Justification for confidentiality	
Availability	Current information indicates that 1-propanol is produced by three manufacturers, and 2-propanol by five, with several producers located outside of Europe. According to the ECHA Article 95 list (status as of March 6, 2025), there are 737 manufacturers or suppliers of ethanol within the European Union. Therefore, ethanol supply disruptions can be more easily mitigated compared to other substances. If demand were to surge unexpectedly, it is likely that ethanol production capacity could be expanded far more rapidly than that of 1- or 2-propanol.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	In conclusion, the negative impacts of discontinuing ethanol-based disinfectants would significantly outweigh any perceived advantages. This assessment remains valid even

	when considering only the safety of healthcare and pharmacy staff, without accounting for broader effects on patient health and public health. Under realistic usage conditions, ethanol does not pose a health risk through skin contact or inhalation, even with frequent use. Any regulatory decisions affecting pharmacy-based compounding and the availability of ethanol-based disinfectants should therefore be based on actual usage realities, not solely on theoretical considerations of the substance's intrinsic properties.
Information above is confidential	
Justification for confidentiality	
Other comments	Absorption of ethanol through the skin or by inhaling vapors during hand disinfection is minimal. Studies have demonstrated that even after repeated hygienic or surgical hand disinfection within short timeframes, ethanol levels in the blood remain well below toxic thresholds. Since such frequent use is rare in everyday practice, actual exposure levels are expected to be even lower. In realistic scenarios, the amount of ethanol absorbed is considerably less than the quantity typically ingested through alcoholic beverages – and even less than that consumed via beverages classified as alcohol-free, such as fruit juices, kefir, or non-alcoholic beer. Thus, ethanol exposure from disinfectants is negligible in comparison. Furthermore, studies show that blood alcohol concentrations increase 65 times more when using 1- or 2-propanol-based disinfectants than when using ethanol-based formulations. Apart from that, ethanol is an indispensable raw material in the daily operations of both community and hospital pharmacies. It is widely used as a pharmaceutical excipient in the preparation of compounded medicines, allowing pharmacists to produce standardized as well as patient-specific formulations based on individual prescriptions. Considering that a reclassification of ethanol in biocides could trigger a reassessment of its use in workplace environments as in compounding activities in pharmacies, we strongly advise against pursuing such a reclassification.
Information above is confidential	
Justification for confidentiality	
References	

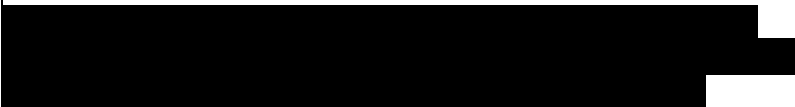
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 238	2025/04/29 00:58
Country	Sweden
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	

Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	There are alternatives but they have disadvantages in performance compared to ethanol. We will take a position on conclusions at the BPC.
Information above is confidential	
Justification for confidentiality	
Other comments	Även med den bredd av kompletterande produkter som finns att tillgå är det ingen produktgrupp som är sammantaget så pass effektiv men ändå skonsam, välanvänd och etablerad för desinfektion som de etanolbaserade produkterna. Det saknas lämpliga alternativ som kan användas ensamt på samma sätt i samma utsträckning med likvärdigt resultat. Ofta används etanol även i andra kritiska produkter för desinfektion exempelvis klorhexidinsprit.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	Swedish authority views on the fulfillment of Article 5(2) criteria by ethanol.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 239	2025/04/29 08:58

Country	Germany
Name of organization/institution	SONAX GmbH
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	SONAX GmbH is a German company based in Neuburg an der Donau, which manufactures and sells chemical products and services related to car care under this brand. SONAX GmbH is the market leader for car care products in Germany and one of the leading international companies in this field. The brand is represented in 110 countries worldwide. With over 400 employees, all located in Bavaria Germany, SONAX is strongly committed to further develop and support the regional social community. SONAX generated sales of around 160 million euros in 2024. The product range includes paint care products, products for manual interior and exterior cleaning of vehicles as well as car care products for the winter season. Special products for commercial vehicle cleaning, for industry and workshops, machine car care in car washes as well as cleaning and care products for use in professional vehicle valeting complete the range.
Product Type	1,2,4
Alternative Identity and Properties	Ethanol is one of the most important raw materials in SONAX winter products (e.g. Windscreen Washer fluids, De-icers), which make a significant contribution to the safety of vehicles (e.g. trucks, cars) during the winter months. Especially in harsh winter conditions with rain, snow, as well as roads with dirty slush, good visibility through a clean and ice-free windshield is crucial for accident-free travel. Ethanol containing cleaners show the strong ability to quickly dissolve hydrophobic substances such as leaking motor oil and unburnt fuel residues of cars. Furthermore, its low freezing point prevents the cleaner from freezing on the windshield and within the cleaning fluid tank. Additionally, it has further advantages over other substances (e.g., 2-propanol or glycols) at this application field: Ethanol has been in use safely and effectively for many years with no evidence of risk to humans or the environment. Specifically compared to methanol, which is banned under REACH for this use (lower 0.6% by weight, Annex XVII, Entry 69), but is still frequently used in such products, for example, in the USA or Asia, ethanol

	represents a safe alternative with a very low risk to human health. Other alternatives would increase the health risks of these products due to their risks associated with acute (single) inhalation exposure, e.g. 2-propanol (STOT SE3). The dermal or inhalation exposure to ethanol in this type of application is far below concentrations relevant for health risks associated with the substance. Furthermore, Ethanol has a lower inherent odor compared to its substitutes, e.g. glycols and 2-propanol. Since the application occurs while driving on open roads and areas, high biodegradability of the products used is of great importance for environmentally friendly use. Ethanol is highly biodegradable and therefore does not accumulate in the environment over long periods. Ethanol is available from a wide variety of renewable sources.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Ethanol has a low freezing point (-114 °C), combined with excellent cleaning performance at low temperatures, as well as low viscosity which makes it ideal for use in windshield cleaners during winter. Ethanol evaporates quickly and without remaining residues, which is particularly important for cleaning windshields at high speeds, ensuring safe usage. In contrast, cleaners based on glycol often tend to leave non-transparent residues that can negatively impact the visibility and show inferior material compatibility, which could result in damage to safety-critical components, such as headlights made of polycarbonate. 2-Propanol has similar properties but is less effective in cleaning performance. Additionally, the strong inherent odor would adversely affect the product quality. Ethanol is highly suitable for combination with other necessary substances, such as surfactants for enhanced cleaning performance or glycerin for maintaining and preserving the functionality of windshield wipers. Products based on ethanol are well miscible with water and can therefore be offered as concentrates, which reduces transportation volume.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	

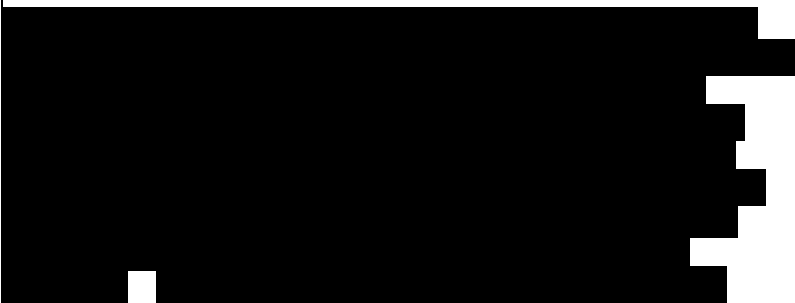
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	We are aware of the harmful effects of Ethanol abuse through regular oral intake and do not wish to dispute this. However, a CMR classification under the CLP Regulation would be made independently of the actual possible exposure during the use of washing and cleaning agents, which is dermal and inhalative, without taking the actual risk into account. Additionally, the abuse of technical Ethanol, as used in our products, for oral consumption is effectively prevented using denaturants. Furthermore, we add an additional bittering agent to our products to prevent accidental oral ingestion in small amounts. When comparing the DNEL for long-term inhalation exposure for

	the general population in the safety data sheets available to us, it is evident that ethanol (114 mg/m³) offers the safest use at the same application concentrations compared to possible alternatives, such as Propan-2-ol (89 mg/m³) or Ethylene Glycol (7 mg/m³). Furthermore, Ethanol is not classified as a skin-resorptive substance according to German TRGS 900, as reviewed by the German Committee on Hazardous Substances. Such a classification would indicate that the substance, due to its physicochemical properties, could be absorbed through intact skin and cause health damage. Substances in this category are marked with an "H" in TRGS 900. The alternative ethylene glycol would fall into this category. Based on these facts, we demand that any potential evaluation and classification consider the actual risk associated with the use of technical ethanol.
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	If Ethanol was classified as a candidate for substitution under the Biocidal Products Regulation, thus paving the way for CMR classification under the CLP Regulation, it would have massive effects not only in the hygiene sector, which manufacturers and industry representatives will surely address, but also on manufacturers of washing and cleaning agents, particularly concerning our products for winter windshield cleaning. There are no alternatives that offer comparable quality in terms of safety, cleaning performance, and availability. Furthermore, years of experience demonstrate the safe use of washing and cleaning agents based on ethanol.

Information above is confidential	
Justification for confidentiality	
Other comments	SONAX is aware that SONAX products are not directly affected by the BPR assessment. Nevertheless, we have decided to submit a comment due to the influence of this evaluation on the ongoing process for the harmonized classification under the CLP Regulation. Due to the importance and benefits of ethanol in the described use and other washing and cleaning agents, it is essential to approach the assessment of ethanol as a biocidal active substance with foresight and pragmatism. The classification of Ethanol based on data resulting from alcohol abuse, i.e., exclusively oral intake, does not, in our view, reflect the actual risk. Furthermore, such a reclassification would force us to substitute Ethanol in our products and instead rely on alternatives with worse environmental, health, and socioeconomic properties. This would contradict the intended goals of the European regulations aimed at protecting human health and the environment.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 240	2025/04/29 09:42
Country	Germany
Name of organization/institution	SONAX GmbH
I do not wish the name of my organisation/institution to be	

published on the ECHA website.	
General information	SONAX GmbH is a German company based in Neuburg an der Donau, which manufactures and sells chemical products and services related to car care under this brand. SONAX GmbH is the market leader for car care products in Germany and one of the leading international companies in this field. The brand is represented in 110 countries worldwide. With over 400 employees, all located in Bavaria Germany, SONAX is strongly committed to further develop and support the regional social community. SONAX generated sales of around 160 million euros in 2024. The product range includes paint care products, products for manual interior and exterior cleaning of vehicles as well as car care products for the winter season. Special products for commercial vehicle cleaning, for industry and workshops, machine car care in car washes as well as cleaning and care products for use in professional vehicle valeting complete the range.
Product Type	1,2,4
Alternative Identity and Properties	Ethanol is one of the most important raw materials in SONAX winter products (e.g. Windscreen Washer fluids, De-icers), which make a significant contribution to the safety of vehicles (e.g. trucks, cars) during the winter months. Especially in harsh winter conditions with rain, snow, as well as roads with dirty slush, good visibility through a clean and ice-free windshield is crucial for accident-free travel. Ethanol containing cleaners show the strong ability to quickly dissolve hydrophobic substances such as leaking motor oil and unburnt fuel residues of cars. Furthermore, its low freezing point prevents the cleaner from freezing on the windshield and within the cleaning fluid tank. Additionally, it has further advantages over other substances (e.g., 2-propanol or glycols) at this application field: Ethanol has been in use safely and effectively for many years with no evidence of risk to humans or the environment. Specifically compared to methanol, which is banned under REACH for this use (greater 0.6% by weight, Annex XVII, Entry 69), but is still frequently used in such products, for example, in the USA or Asia, ethanol represents a safe alternative with a very low risk to human health. Other alternatives would increase the health risks of these products due to their risks associated with acute (single) inhalation exposure, e.g. 2-propanol (STOT SE3). The dermal or inhalation exposure to ethanol in this type of application is far below concentrations relevant for health

	risks associated with the substance. Furthermore, Ethanol has a lower inherent odor compared to its substitutes, e.g. glycols and 2-propanol. Since the application occurs while driving on open roads and areas, high biodegradability of the products used is of great importance for environmentally friendly use. Ethanol is highly biodegradable and therefore does not accumulate in the environment over long periods. Ethanol is available from a wide variety of renewable sources.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Ethanol has a low freezing point (-114 °C), combined with excellent cleaning performance at low temperatures, as well as low viscosity which makes it ideal for use in windshield cleaners during winter. Ethanol evaporates quickly and without remaining residues, which is particularly important for cleaning windshields at high speeds, ensuring safe usage. In contrast, cleaners based on glycol often tend to leave non-transparent residues that can negatively impact the visibility and show inferior material compatibility, which could result in damage to safety-critical components, such as headlights made of polycarbonate. 2-Propanol has similar properties but is less effective in cleaning performance. Additionally, the strong inherent odor would adversely affect the product quality. Ethanol is highly suitable for combination with other necessary substances, such as surfactants for enhanced cleaning performance or glycerin for maintaining and preserving the functionality of windshield wipers. Products based on ethanol are well miscible with water and can therefore be offered as concentrates, which reduces transportation volume.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	

Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	We are aware of the harmful effects of Ethanol abuse through regular oral intake and do not wish to dispute this. However, a CMR classification under the CLP Regulation would be made independently of the actual possible exposure during the use of washing and cleaning agents, which is dermal and inhalative, without taking the actual risk into account. Additionally, the abuse of technical Ethanol, as used in our products, for oral consumption is effectively prevented using denaturants. Furthermore, we add an additional bittering agent to our products to prevent accidental oral ingestion in small amounts. When comparing the DNEL for long-term inhalation exposure for the general population in the safety data sheets available to us, it is evident that ethanol (114 mg/m³) offers the safest use at the same application concentrations compared to possible alternatives, such as Propan-2-ol (89 mg/m³) or Ethylene Glycol (7 mg/m³). Furthermore, Ethanol is not classified as a skin-resorptive substance according to

	German TRGS 900, as reviewed by the German Committee on Hazardous Substances. Such a classification would indicate that the substance, due to its physicochemical properties, could be absorbed through intact skin and cause health damage. Substances in this category are marked with an "H" in TRGS 900. The alternative ethylene glycol would fall into this category. Based on these facts, we demand that any potential evaluation and classification consider the actual risk associated with the use of technical ethanol.
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	If Ethanol was classified as a candidate for substitution under the Biocidal Products Regulation, thus paving the way for CMR classification under the CLP Regulation, it would have massive effects not only in the hygiene sector, which manufacturers and industry representatives will surely address, but also on manufacturers of washing and cleaning agents, particularly concerning our products for winter windshield cleaning. There are no alternatives that offer comparable quality in terms of safety, cleaning performance, and availability. Furthermore, years of experience demonstrate the safe use of washing and cleaning agents based on ethanol.
Information above is confidential	
Justification for confidentiality	

Other comments	SONAX is aware that SONAX products are not directly affected by the BPR assessment. Nevertheless, we have decided to submit a comment due to the influence of this evaluation on the ongoing process for the harmonized classification under the CLP Regulation. Due to the importance and benefits of ethanol in the described use and other washing and cleaning agents, it is essential to approach the assessment of ethanol as a biocidal active substance with foresight and pragmatism. The classification of Ethanol based on data resulting from alcohol abuse, i.e., exclusively oral intake, does not, in our view, reflect the actual risk. Furthermore, such a reclassification would force us to substitute Ethanol in our products and instead rely on alternatives with worse environmental, health, and socioeconomic properties. This would contradict the intended goals of the European regulations aimed at protecting human health and the environment.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 241	2025/04/29 09:49
Country	Germany
Name of organization/institution	SONAX GmbH
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	SONAX GmbH is a German company based in Neuburg an der Donau, which manufactures and sells chemical products and services related to car care under this brand. SONAX

	GmbH is the market leader for car care products in Germany and one of the leading international companies in this field. The brand is represented in 110 countries worldwide. With over 400 employees, all located in Bavaria Germany, SONAX is strongly committed to further develop and support the regional social community. SONAX generated sales of around 160 million euros in 2024. The product range includes paint care products, products for manual interior and exterior cleaning of vehicles as well as car care products for the winter season. Special products for commercial vehicle cleaning, for industry and workshops, machine car care in car washes as well as cleaning and care products for use in professional vehicle valeting complete the range.
Product Type	1,2,4
Alternative Identity and Properties	Ethanol is one of the most important raw materials in SONAX winter products (e.g. Windscreen Washer fluids, De-icers), which make a significant contribution to the safety of vehicles (e.g. trucks, cars) during the winter months. Especially in harsh winter conditions with rain, snow, as well as roads with dirty slush, good visibility through a clean and ice-free windshield is crucial for accident-free travel. Ethanol containing cleaners show the strong ability to quickly dissolve hydrophobic substances such as leaking motor oil and unburnt fuel residues of cars. Furthermore, its low freezing point prevents the cleaner from freezing on the windshield and within the cleaning fluid tank. Additionally, it has further advantages over other substances (e.g., 2-propanol or glycols) at this application field: Ethanol has been in use safely and effectively for many years with no evidence of risk to humans or the environment. Specifically compared to methanol, which is banned under REACH for this use (greater 0.6% by weight, Annex XVII, Entry 69), but is still frequently used in such products, for example, in the USA or Asia, ethanol represents a safe alternative with a very low risk to human health. Other alternatives would increase the health risks of these products due to their risks associated with acute (single) inhalation exposure, e.g. 2-propanol (STOT SE3). The dermal or inhalation exposure to ethanol in this type of application is far below concentrations relevant for health risks associated with the substance. Furthermore, Ethanol has a lower inherent odor compared to its substitutes, e.g. glycols and 2-propanol. Since the application occurs while driving on open roads and areas, high biodegradability of the products used is of great importance for environmentally friendly use. Ethanol is highly

	biodegradable and therefore does not accumulate in the environment over long periods. Ethanol is available from a wide variety of renewable sources.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Ethanol has a low freezing point (-114 °C), combined with excellent cleaning performance at low temperatures, as well as low viscosity which makes it ideal for use in windshield cleaners during winter. Ethanol evaporates quickly and without remaining residues, which is particularly important for cleaning windshields at high speeds, ensuring safe usage. In contrast, cleaners based on glycol often tend to leave non-transparent residues that can negatively impact the visibility and show inferior material compatibility, which could result in damage to safety-critical components, such as headlights made of polycarbonate. 2-Propanol has similar properties but is less effective in cleaning performance. Additionally, the strong inherent odor would adversely affect the product quality. Ethanol is highly suitable for combination with other necessary substances, such as surfactants for enhanced cleaning performance or glycerin for maintaining and preserving the functionality of windshield wipers. Products based on ethanol are well miscible with water and can therefore be offered as concentrates, which reduces transportation volume.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	 A large rectangular area of the table is completely redacted with a solid black fill. A small white square is visible near the bottom left corner of the redacted area.

Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	We are aware of the harmful effects of Ethanol abuse through regular oral intake and do not wish to dispute this. However, a CMR classification under the CLP Regulation would be made independently of the actual possible exposure during the use of washing and cleaning agents, which is dermal and inhalative, without taking the actual risk into account. Additionally, the abuse of technical Ethanol, as used in our products, for oral consumption is effectively prevented using denaturants. Furthermore, we add an additional bittering agent to our products to prevent accidental oral ingestion in small amounts. When comparing the DNEL for long-term inhalation exposure for the general population in the safety data sheets available to us, it is evident that ethanol (114 mg/m³) offers the safest use at the same application concentrations compared to possible alternatives, such as Propan-2-ol (89 mg/m³) or Ethylene Glycol (7 mg/m³). Furthermore, Ethanol is not classified as a skin-resorptive substance according to German TRGS 900, as reviewed by the German Committee on Hazardous Substances. Such a classification would indicate that the substance, due to its physicochemical properties, could be absorbed through intact skin and cause health damage. Substances in this category are marked with an "H" in TRGS 900. The alternative ethylene glycol

	would fall into this category. Based on these facts, we demand that any potential evaluation and classification consider the actual risk associated with the use of technical ethanol.
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	If Ethanol was classified as a candidate for substitution under the Biocidal Products Regulation, thus paving the way for CMR classification under the CLP Regulation, it would have massive effects not only in the hygiene sector, which manufacturers and industry representatives will surely address, but also on manufacturers of washing and cleaning agents, particularly concerning our products for winter windshield cleaning. There are no alternatives that offer comparable quality in terms of safety, cleaning performance, and availability. Furthermore, years of experience demonstrate the safe use of washing and cleaning agents based on ethanol.
Information above is confidential	
Justification for confidentiality	
Other comments	SONAX is aware that SONAX products are not directly affected by the BPR assessment. Nevertheless, we have decided to submit a comment due to the influence of this evaluation on the ongoing process for the harmonized classification under the CLP Regulation. Due to the importance and benefits of ethanol in the described use and other washing and cleaning agents, it is essential to

	approach the assessment of ethanol as a biocidal active substance with foresight and pragmatism. The classification of Ethanol based on data resulting from alcohol abuse, i.e., exclusively oral intake, does not, in our view, reflect the actual risk. Furthermore, such a reclassification would force us to substitute Ethanol in our products and instead rely on alternatives with worse environmental, health, and socioeconomic properties. This would contradict the intended goals of the European regulations aimed at protecting human health and the environment.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 242	2025/04/29 09:56
Country	Sweden
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	

Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	The idea of restricting ethanol is mad. Where has the aspect och "common sense" gone?
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	The story about a miracle molecule.pdf

Attachments (confidential information)	
Justification for confidential attachment	

Comment 243	2025/04/29 10:22
Country	Germany
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	The detailed comment of the DE CA is given in the attachment.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	

Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	For the German market, the potential alternatives to ethanol as a hand disinfectant for the non-professional user were assessed (see attachment). In summary, none of the available alternative active substances are suitable substitutes for ethanol: either they are not suitable for use in leave-on hand disinfectants, or they do not offer the same efficacy as ethanol. No biocidal products with comparable properties are available in Germany.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	Ethanol_Public_Consultation_Comment_DE_CA.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 244	2025/04/29 10:48
Country	Spain

Name of organization/institution	anefp
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Summary The proposed classification of ethanol as a CMR substance (carcinogenic, mutagenic, toxic for reproduction) by the European Chemicals Agency (ECHA) would have serious consequences for the healthcare system, infection control, and patient safety. For this reason, numerous medical associations are urgently calling for this classification to be withdrawn. The approval of ethanol as an active biocidal substance for hand and surface disinfectants is currently being evaluated under Regulation (EU) No. 528/2012 on biocidal products . Biocidal Products Committee (BPC), has concluded that ethanol should be classified as a CMR substance 1A or 1B. Such substances are excluded from approval, meaning ethanol would no longer be available for use in disinfectants. The assessment considered data on oral consumption and misuse, which do not reflect the use of hand and surface disinfectants and do not allow for a proper conclusion regarding dermal or inhalation exposure. The proposed CMR classification carries significant legal implications that would result in severe restrictions and could be considered a de facto ban. This would also have fatal consequences for infection prevention. Ethanol is expected to be indispensable to society and industry due to its excellent virucidal effect (especially against non-enveloped viruses such as poliovirus or human coxsackievirus) and sustainability. Medical associations, hygiene expert committees, interest groups, and industry agree that ethanol is essential for infection prevention in the population and have been appealing to policymakers to ensure ethanol remains unrestricted since the inappropriate classification became known. Approximately 600,000 nosocomial infections (hospital-acquired infections) occur annually in Germany. In addition to causing human suffering, with between 15,000 and 18,000 deaths each year, these infections also represent an avoidable cost of €2 billion for the German healthcare system. In Spain, 8.18% of patients admitted to healthcare facilities acquire nosocomial infections according to EPINE 2023. Ethanol has been an essential component of medical hygiene for decades, especially in alcohol-based hand disinfectants. Studies show that the use of ethanol-based disinfectants can demonstrably reduce nosocomial infections

	and improve infection protection for patients and healthcare personnel. During the COVID-19 pandemic, ethanol was crucial in breaking infection chains and maintaining medical care.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Technical Feasibility / Efficacy Ethanol used in disinfectants is an effective and safe agent for preventing healthcare-associated infections and the spread of antimicrobial resistance. Non-enveloped viruses are significantly more stable against chemical agents than enveloped viruses. Of the three alcohols used in hand disinfectant formulations (ethanol, 1-propanol, and 2-propanol), only ethanol-based formulations proved effective within 30 to 60 seconds against non-enveloped viruses such as adenovirus, poliovirus, human enterovirus, human papillomavirus, polyomavirus, echovirus, and coxsackievirus in quantitative suspension tests. Formulations containing 1-propanol and 2-propanol are not sufficiently active. 1-propanol was ineffective against coxsackievirus, poliovirus, and human enterovirus at 90% concentration in 5 minutes. At 2 minutes, 80%, 90%, and 97% concentrations of 1-propanol and 2-propanol were ineffective against poliovirus, as were 70% and 90% at 3 minutes. In contrast, ethanol was effective at concentrations $\geq 70\%$ in suspension and in vivo on hands. The WHO lists ethanol-based formulations as essential medicines. According to WHO, ethanol is indispensable and essential for infection prevention.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Ethanol is a highly cost-effective active substance for disinfection due to its lower production costs and broad availability. In contrast, 1-propanol and 2-propanol are petrochemical derivatives. Their production processes are energy-intensive, resulting in higher costs and significant environmental drawbacks.

Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Hazards and Risks Classification is a “hazard-based approach” and does not consider actual user risk. Exposure to disinfectants is not comparable to alcoholic beverage consumption, and oral consumption data are therefore not useful for adequately assessing workplace or consumer product hazards and risks. Ethanol evaporates quickly from the skin, and dermal absorption is low. In addition, occupational inhalation does not lead to significant increases in blood ethanol levels. Ethanol concentrations in workplace air are generally well below national occupational exposure limits. Therefore, exposure to ethanol via dermal application or inhalation from biocidal product use does not result in blood alcohol levels in the human body that have been shown to cause cancer and/or have adverse reproductive effects. WHO/IARC has not classified ethanol as a carcinogenic chemical for humans.
Information above is confidential	
Justification for confidentiality	
Availability	Ethanol is readily available on the market due to a wide range of formulators and active substance manufacturers. This abundance of suppliers fosters competition, further reducing costs and ensuring that a variety of ethanol-based disinfectants are accessible to users in public health sectors, enabling compliance with hygiene standards without significant financial burden. Moreover, ethanol production is more adaptable to sudden surges in demand, allowing faster scale-up compared to 1-propanol or 2-propanol production, as clearly demonstrated during the COVID-19 pandemic. This makes ethanol not only more available but also a more reliable and practical option to meet high demand in critical sectors like healthcare. 1-propanol and 2-propanol are available as alternatives, but their supply situation raises potential concerns. According to the BPR Regulation, only 9 active substance/product suppliers are listed for 1-propanol and 69 for 2-propanol in PT1 for human hygiene, compared to 247 for ethanol, reflecting ethanol’s significantly broader availability and production base.
Information above is confidential	

Justification for confidentiality	
Conclusion on suitability and availability of the alternative	/ Sustainability Ethanol is primarily derived from renewable resources such as biomass and agricultural waste, thus supporting the EU's commitment to reducing fossil fuel dependence while promoting circular economic principles. Its renewable sources and high biodegradability result in a low environmental footprint, minimizing environmental persistence and ensuring alignment with the EU's vision for reducing ecological harm through sustainable resource use. In contrast, 1-propanol and 2-propanol are petrochemical derivatives dependent on non-renewable resources.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 245	2025/04/29 10:53
Country	France
Name of organization/institution	Groupe Paredes Orapi
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	

Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	No study done.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	

Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 246	2025/04/29 10:52
Country	Switzerland
Name of organization/institution	scienceindustries Switzerland
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Under the umbrella of the European Chemicals Agency (ECHA), various substances are continuously assessed to determine whether they pose a risk to human health and the environment. Such an evaluation of the substance ethanol is currently underway. This risk assessment has entered a decisive phase. Observers of the process see a concrete danger that ethanol will be classified by the ECHA next year in accordance with the requirements of Regulation (EC) No. 1272/2008 (EU CLP Regulation) as toxic to reproduction according to category 2 or even as a so-called CMR substance of the highest hazard category 1, i.e. as carcinogenic (C), mutagenic (M) and toxic to reproduction (R). scienceindustries Switzerland is the trade association Chemie Pharma Biotech. Its approximately 250 member companies are mainly active in the research, development, manufacture or sale of pharmaceutical specialities, vitamins, plant protection products, flavours and fragrances as well as industrial speciality chemicals. They employ around 70,000 people in Switzerland. scienceindustries is committed to innovation-friendly framework conditions, the global elimination of trade barriers and improving the acceptance of research and technologies. Fundamental considerations In Germany, the German Medical Association, the National

	Association of Statutory Health Insurance Physicians, the National Association of Dentists, the National Association of Statutory Health Insurance Dentists, the National Association of German Pharmacists and the German Hospital Federation are very concerned about this development. Due to its superior effectiveness, ethanol is essential as a disinfectant in medical and dental practices as well as in hospitals for effective protection against infection. Ethanol is essential for the protection of both patients and healthcare staff. In this context, we refer to the scientific publication referenced with this letter: „Medical associations and expert committees urge that ethanol be approved as a virucidal active substance for use in hand antiseptics under the European Biocidal Products Regulation, without a CMR classification“ (Kramer et al. 2024). Ethanol has been recognised by the WHO as an ‘essential medicine’ for almost 50 years (WHO, Modern List of Essential Medicines, 2023). Ethanol has a proven carcinogenic effect only when ingested orally! We consider it crucial that the area of application is also considered when assessing the risk and categorising ethanol. For a harmonised classification, the risk posed by oral intake must not be decisive. This applies in particular to the use in disinfectants. An intended oral intake constitutes a misuse and is in practice already excluded by denaturation. Experience shows that the quantities of ethanol absorbed through hand disinfection are below toxicologically relevant concentrations. Last but not least, the repeated daily use of hand and surface disinfectants in medicine over many decades proves that this type of application is safe. Above all, however, it should be noted that ethanol has superior efficacy against certain clinically relevant viruses compared to other alcohols. In the ongoing decision-making process, the overriding interest of patients and healthcare staff in effective protection against infection must not be disregarded. The unrestricted use of ethanol as a disinfectant is essential to prevent infection. We are writing in reference to a letter dated 10th June 2024 by several European associations such as but not limited to AISE, Cosmetics Europe, FoodDrink Europe, IFRA and others to the European Commission, to express their and our serious concerns about the ongoing evaluation of Ethanol under the Biocidal Products Regulation (Regulation (EU) 528/2012, “BPR”), which includes a proposal for a CMR classification based on human consumption data (and not as such related to specific biocidal uses) and threatens to generate a disproportionate impact across multiple sectors and industries in Europe. The Greek competent authorities, who are acting as evaluating authority for Ethanol under the BPR, finalised their initial assessment dossier (“CAR”) on 8th

	March 2024 and sent it to the European Chemicals Agency (ECHA) to continue its evaluation process at EU level. Among other elements, the Greek Biocidal authorities propose a classification of Ethanol as reproductive toxicant Category 2. It is our understanding that studies used to support this proposed classification are based on human consumption data of Ethanol, while the effects that need to be considered in a biocidal assessment are skin contact and respiratory exposure. Human consumption data should not be relevant for this assessment, as dermal as well as inhalation exposure poses neither specific risks nor a hazard and are safe for biocidal applications of Ethanol.
Product Type	1,2,4
Alternative Identity and Properties	See Attachment
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	See Attachment
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	See Attachment
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	See Attachment
Information above is confidential	
Justification for confidentiality	
Availability	See Attachment
Information above is confidential	
Justification for confidentiality	

Conclusion on suitability and availability of the alternative	The classification of Ethanol is anticipated to have significant and disproportionate impacts on a wide range of sectors including the ones represented by the signing associations to this letter, whilst the primary reason for concern - human consumption of Ethanol in an excessive way and its resulting consequences - will remain unimpacted. We therefore call upon your support to procedurally detach the hazard classification of Ethanol from the ongoing risk assessment evaluation process considering the extraordinary nature of the biocidal Ethanol dossier. While we understand that the Commission does not usually intervene during the risk assessment phase of Biocidal active substances, there is an issue of principle that justifies such involvement on this case: given its exceptional nature, discussions on the hazard properties of Ethanol should not be managed under the Biocidal framework, which should focus on the risk assessment of its use as a Biocide. Ethanol being a “backlog dossier” (falling under previous BPD rules), there is no obligation to include a Hazard classification to proceed with the risk assessment.
Information above is confidential	
Justification for confidentiality	
Other comments	See Attachment
Information above is confidential	
Justification for confidentiality	
References	In addition, we refer to the three attached documents, prepared by eppa: • ANALYSIS OF ALTERNATIVES for the use of Ethanol in Human hygiene products for the primary purpose of disinfecting the skin or scalp (Product Type 1) under the Biocidal Products Regulation • ANALYSIS OF ALTERNATIVES for the use of Ethanol For the use of Ethanol in disinfectants and algaecides not intended for direct application to humans or animals (Product Type 2) • ANALYSIS OF ALTERNATIVES for the use of Ethanol For the use of Ethanol as disinfectant in the Food and feed area (Product Type 4)
Attachments (non-confidential information)	250429_SCIN-ECHA-EtOH-cons-Pt124_aoa_en.zip
Attachments (confidential information)	

Justification for confidential attachment	

Comment 247	2025/04/29 10:54
Country	Germany
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	In food and beverage industry, Ethanol is mainly used for rapid disinfection (max. 1 min.) of small parts. For this application, it is crucial that the active substance has the following properties: - fast mode of action - no rinsing required - not corrosive to materials - not corrosive to the skin (no PPE required) - easy handling - suitable for ecological production (suitable for FiBL, Demeter, Bioland,...) - broad efficacy spectrum
Product Type	1,2,4
Alternative Identity and Properties	1. Organic acids (e.g. lactic acid, glycolic acid) 2. Peracetic acid 3. Active chlorine 4. QAC 5. N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine (Diamine) 6. Chlorine dioxide 7. Hydrogen peroxide 8. nPA 9. IPA
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	1. Organic acids are not suitable for rapid disinfection as they would have to be applied in very high concentrations. In these concentrations the acids would be corrosive to the materials used. Furthermore, even if DRA would not be a problem, they leave a sticky film on the surfaces and can effect the food, thus they have to be rinsed. 2. Peracetic acid is not suitable for rapid disinfection as it would have to be applied in very high concentrations. Generally, peracetic acid is very corrosive to the materials used, especially in the concentrations needed. 3. Active chlorine is not suitable for rapid disinfection as it would have to be applied in very high concentrations. In these concentrations, it is very corrosive

	to the materials used. Another disadvantage is the short shelf-life of products with active chlorine. 4. QACs are not suitable for rapid disinfection as they would have to be applied in very high concentrations. In these concentrations QACs would be corrosive to the materials used. Furthermore, they have to be rinsed. 5. Diamine is not suitable for rapid disinfection as it would have to be applied in very high concentrations. Due to the very low AEL of the substance, these high concentrations would not be a safe use in regards to HHRA and ENVRA (see PT8 decision on the active substance). 6. Chlorine dioxide (in-situ generated) would be suitable for rapid disinfection. However, after application the surfaces would have to be rinsed. Furthermore, the active substance must be generated in an additional step. 7. Hydrogen peroxide would not be suitable for rapid disinfection. Generally, hydrogen peroxide is used over longer time periods (longer than 30 min.). At short contact times the substance does not have sufficient efficacy (EN13697 would not pass). 8. nPA would be a suitable alternative for rapid disinfection. The application is the same as for ethanol, the substance does not have to be rinsed. 9. IPA would be a suitable alternative for rapid disinfection. The application is the same as for ethanol, the substance does not have to be rinsed.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Generally, the costs of the other active substances listed are in the final application much cheaper compared to ethanol (excl. IPA/nPA, which are more expensive than ethanol). Furthermore, for chlorine dioxide additionally an equipment is required which results in higher costs.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Generally, for the alternatives (except other alcohols) PPE would be required during mixing and loading, unless RTU products would be used. The concentrated products usually on the market are at least classified as corrosive to the skin. The classification of the application solution would normally be pH driven, for application solutions without an extreme pH, the hazard would probably be similar to the one of ethanol.

Information above is confidential	
Justification for confidentiality	
Availability	In case of a pandemic outbreak there will be an increased demand for the alternatives, thus it is essential to maintain a high range of suitable substances to prevent any shortages in the availability. Like for example for the foot and mouth disease full virucidal products are required and here ethanol would be the only active substance for hand disinfection.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Based on the information above, only other alcohols (IPA and nPA) can be regarded as suitable alternatives for ethanol. For the other active substances listed, rinsing would be required, leading to higher water consumption as well as more work steps. However, the main advantage of ethanol is its full virucidal efficacy. Especially during an outbreak it is crucial to have a fast working, easy to handle disinfectant with virucidal activity available. This can be observed at the moment concerning the outbreak of the foot-and-mouth-disease (FMD) in Hungary and Czech Republic. Although this effects mainly PT3 areas, food chain demands full virucidal disinfectants for the disinfection of slaughter houses to prevent infections. Additionally, ethanol is produced from renewable resources which is an important aspect for the European Green Deal. Therefore, ethanol is indispensable in the food industry.
Information above is confidential	
Justification for confidentiality	
Other comments	Suitable for ecological production (e.g. FiBL, Demeter, Bioland) are only organic acids, peracetic acid, hydrogen peroxide, nPA, and IPA. Furthermore, QACs are politically banned in many production companies, especially in the dairy food chain in Germany.
Information above is confidential	
Justification for confidentiality	

References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 248	2025/04/29 11:34
Country	Germany
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	
Product Type	1,2,4
Alternative Identity and Properties	Ethanol is a raw material for many applications, e.g. for the extraction of many chemicals; as a solvent for oils, fats, resins and many dyes, among other things; for the production, preservation and stabilization of pharmaceutical preparations and medicines, as a cleaning agent or additive. It has important properties that are as follows: ☐ Fast, residue-free volatility: Due to its low molecular weight, ethanol evaporates very quickly and dries residue-free - an advantage, for example, in the rapid disinfection of surfaces. ☐ Odorlessness and colorlessness: Other substances besides ethanol often have a more unpleasant smell and can potentially cause dizziness or other neurological effects (e.g., propan-2-ol); chlorinated compounds may smell harsh or pungent depending on the concentration, as with acetic acid; this is particularly relevant in hospital settings. ☐ Unique viral efficacy among alcohols: Ethanol-based disinfectants lead to a faster and wider efficacy against a broad range of micro-organisms. A unique feature of ethanol is its effectiveness against non-enveloped viruses, e.g. Polioviruses, coxsackieviruses, echoviruses and the enterovirus A71. Of

the three alcohols used in hand rub formulations (ethanol, propan-1-ol and propan-2-ol), only eth-anol-based formulations proved to be effective within 30–60 s against non-enveloped viruses such as adeno-, polio-, human entero-, echo- and coxsackie viruses in quantitative suspension assays (Kramer et al., 2022). With propanol-only based formulations, a prolonged exposure time is necessary; this will reduce the compliance for hand disinfection and thus, put patients to risk of healthcare-associated infections. □ Flexibility in the application: Ethanol is very well suited for combination with other active ingredients such as acids and with excipients such as glycerine. This means that appropriate formulations can increase the effectiveness and skin compatibility of hand disinfectants, for example. □ High safety and compatibility: Exposure to ethanol via application to the skin (dermal exposure) or by breathing in ethanol in the air (inhalation), being the two potential routes of exposure from the production or use of biocidal products, does not result in levels of ethanol in the human body that have been shown to cause cancer and/or have adverse reproductive effects. The dermal or inhalative uptake, e.g. during hand disinfection, is far below toxicologically relevant concentrations. Ethanol evaporates rapidly from the skin. Dermal absorption is low. Ethanol may pose a health hazard to humans, but only at exposure levels comparable to those from alcoholic beverage consumption. Such risks are unlikely to occur in industrial applications (OECD, 2004) . The concentration of Ethanol in the ambient air in workplaces is generally well below (6 to 20 times) national occupational exposure limits (OEL) over an eight-hour period (e.g. OEL for Ethanol in Germany is 380 mg/m³; compliance with this limit value ensures that a blood concentration relevant to health is not reached through inhalation (AGS, 2006). □ International relevance: Ethanol is used worldwide as an active ingredient in hand disinfectants. The WHO lists ethanol as an indispensable active ingredient for antiseptic applications (Kramer et al., 2022). □ Save for the environment: Ethanol as a raw material is produced from agricultural products (renewable sources). It is biodegradable. Ethanol does not accumulate in the environment in the long term. In addition, it is also important for the food industry as an ingredient and functional substance. Ethanol is used as a solvent or extraction agent, e.g. for plant extracts or as a carrier for food flavorings. As an ingredient, ethanol cannot be replaced by other substances. Especially in the area of baby food and organic food production, as well as for disinfection of machines and systems, ethanol-based disinfectants are

	one of the few remaining disinfectants after the elimination of other biocidal active ingredients such as quaternary ammonium compounds, e.g. BAC and DDAC, and chlorine-based substances. With its special antimicrobial properties and the fact that it is anhydrous and evaporates quickly and without residue, ethanol is irreplaceable in dairies. The contained alcohols of the submitting companies' products react mainly by denaturing cell membranes and proteins and other cellular components. Due to the unspecific mode of action of the alcohols, there is ☐ no risk of resistance phenomena, ☐ fast and efficient killing effect, Due to the favourable physiochemical characteristics, there is ☐ fast evaporation from surfaces during action, ☐ no residues on surfaces, ☐ longevity of formulated products, ☐ low degree of deterioration for open packages, ☐ no formation of disinfection by products or other toxicologically relevant chemical species for human health and environment. Generally, other chemicals used in disinfectants are propanol, iodine, peracetic acid, sodium hypochlorite, chlorhexidine gluconate and quaternary ammonium compounds (CHDG & QAC), monochloramine, chlorocresol, hydrogen peroxide, lactic acid and phenoxyethanol. Nevertheless, they cannot be considered as candidates for substitution. The substances are not suitable to replace ethanol. Reasons are as follows ☐ Propanol: They are lacking full virucidal activity. ☐ Iodine: It is not fast enough for efficacy. It has a higher risk of accidental poisoning and is inactivated by large amounts of protein contaminations (so-called protein error). It is coloured (red brown) and exhibits a typical smell. It is not volatile and thus, remains on the skin after disinfection; as replacement for ethanol in hand disinfections, regular hand washing would be necessary to remove excess layers of iodine accumulating on the skin. ☐ Peracetic Acid: It is corrosive and shows reactivity with other chemicals in product formulations. Peracetic acid has a higher risk of accidental poisoning. ☐ Sodium hypochlorite: It shows no evaporation, is corrosive and shows reactivity with other chemicals in product formulations. It has a higher risk of accidental poisoning. Reactive chlorine compounds like sodium hypochlorite are considered to form carcinogenic AOX (Adsorbable organic halides) in the environment. Hypochlorite's typical smell might reduce compliance in hygienic hand disinfection. ☐ CHDG & QAC: They do not have full virucidal activity. Instead, they leave residues and are not fast acting. ☐ Monochloramine: It causes harmful byproducts (DBP formation) and can only be in situ generated. It is not storable. ☐ Chlorocresol: It has Phenol as degradation

	product and a higher risk of accidental poisoning. □ Hydrogen Peroxide: It causes micro lesions on the skin, it is not fast acting and does not evapo-rate. It is corrosive and not effective at low concentrations and ambient temperatures. It has a higher risk of accidental poisoning. It is unstable and requires controversially discussed stabilisers as additives. □ Lactic Acid: It is not fully virucidal and has odor. □ Phenoxyethanol: It is not fully virucidal. It has a higher risk of accidental poisoning. To conclude, of all alcohols used, only products containing ethanol are effective against hydrophilic non-enveloped viruses within 30-60 s. While noroviruses can still be inactivated by formulations containing 2-propanol and 1-propanol, these alcohols are not effective enough against adenoviruses, human enteroviruses such as echoviruses and Coxsackie viruses and polioviruses. Virucidal formulations can even be used against human papillomaviruses. Also, regarding practical application times there is no alternative to ethanol. Ethanol is therefore essential for combating infections caused by the mentioned viruses. There is no substitute biocidal active substance with equal efficacy particularly against non-enveloped viruses.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Currently, there are only few companies in Europe that produce alternatives to ethanol. The increase of production capacities of alternatives is associated with tremendous technical effort. New facilities must be built, new technologies to be installed, new production permits requested, and hurdles from authorities and NGOs are expected. Generally, there are not sufficient production sites available in the EU for any other alcohol. In contrary, production must be changed or adopted to enable the production of other alcohols. Also, safety management needs to be implemented or massively increased to fulfil the regulatory requirements. □ Iodine: As iodine has residue formation and harmful byproducts (DBP), the production chain must be changed and adopted technically. □ Peracetic Acid: Peracetic acid is corrosive. It shows reactivity with other chemicals in product formulations, which requires an adopted production process. In comparison to ethanol, it has even higher safety standards for workers and higher storage standards. Peracetic acid has a higher risk of accidental poisoning. □ Sodium hypochlorite: It produces harmful byproducts (DBP-

	formation). It is corrosive and shows reactivity with other chemicals in product formulations. It has a higher risk of accidental poisoning, which requires higher safety standards for workers. The production chain must be changed in order to deal with byproducts and the reactivity with other chemicals. □ CHDG & QAC: It has residues, which require a changed production process. □ Monochloramine: It produces harmful byproducts (DBP formation), is linked to in situ generation only. Both require a change in production and thus massive investment. □ Chlorocresol: Phenol as degradation product. It has a higher risk of accidental poisoning which increases the safety standards for workers. □ Hydrogen Peroxide: It is linked to higher safety standards for workers and higher storage standards; and it has higher risk of accidental poisoning. □ Lactic Acid: It is odor-forming, which requires an adopted production. □ Phenoxyethanol: It has a higher risk of accidental poisoning which requires higher safety standards for workers. In summary, for a sufficient production of alternative alcohols, considerable investment would be required. Production facilities need to be converted, e.g. companies must install large ventilation and closed systems.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Ethanol is widely recognized as the most economically feasible option due to its cost-effective production methods and reliance on renewable agricultural resources. Its production infrastructure is well-established within the EU and globally, utilizing biomass and agricultural residues. This ensures not only affordability but also alignment with the EU's sustainability goals under the European Green Deal and Circular Economy Action Plan. The abundance of suppliers fosters competition, further driving down costs and ensuring that a variety of ethanol-based disinfectant products are accessible to users in the human health industry. Ethanol, due to its basic compounds, is generally available, easy and fast, green and sustainable to produce ensuring a constant supply. The increase of production capacities of alternatives is associated with tremendous costs. New facilities have to be built, new technologies to be installed, new production permits requested, and hurdles from authorities and NGOs are expected. Production processes in the pharmaceutical and food industry are subject to the highest hygiene requirements. A change of production in sense of substitution of ethanol would be

	linked to even higher standards and thus higher costs. Other alcohols require specific and higher safety standards, in situ production capacities, special residue treatment among others. All together a massive additional investment would be required. □ Propanol: Propanols are petrochemical derivatives, relying on non-renewable resources. Their production processes are energy-intensive, resulting in higher costs and significant environmental drawbacks. These substances are not produced sustainably and lack the renewable sourcing advantages of ethanol. Furthermore, their reliance on imported raw materials adds to their economic and environmental challenges, increasing the EU's dependency on external supply chains. □ Iodine: not authorized for PT2, is coloured and does not evaporate without residue, it cannot be used in PT4 applications, also problematic due to potential DBPs. □ Peracetic Acid: High production and storage standards are linked to an intensive increase of costs. □ Sodium hypochlorite: Unstable and corrosive, not odor-free, formation of DBPs possible, requires rinsing □ CHDG & QAC: Due to its residues it is linked to high production costs. Not allowed in certain food production areas, Maximum Residue Levels (MRLs) in food and feed have to be observed. □ Monochloramine: Since only in situ generation is possible the production is linked to higher costs. □ Chlorocresol: Due to its residues it is linked to high production costs. Chlorocresol is unsuitable for use in food hygiene. Its application under PT4 is effectively excluded, as it does not act residue-free, is toxicologically concerning, and poses sensory as well as regulatory issues. □ Hydrogen Peroxide: High production, safety and storage standards are linked to an intensive increase of costs. □ Lactic acid: Lactic acid is permitted for use in PT4 but is limited in practice due to its lack of full virucidal activity, odor formation, and potential material compatibility issues. It is not a suitable substitute for ethanol in critical hygiene applications involving food. □ Phenoxyethanol: Phenoxyethanol is unsuitable for use in food hygiene. It lacks full virucidal efficacy, raises toxicological concerns, and is not authorized for use on food-contact surfaces. It is rather used as a second active in blends or in PT6 applications. In addition, accept from ethanol alcohol raw materials must be imported from non-EU-countries especially petrol-producing countries. Thus, the production chain massively depends on volatile and autocratic system. The production chain needs to be increased due to the treatment of residues.

Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	The hazard-oriented approach to classification for ethanol is based exclusively on data on food and beverages and their oral intake or misuse without further risk assessment. It is not suitable for the evaluation of technical application or the ingredient ethanol itself. Instead, it should be examined whether a harmonized classification of ethanol is necessary at all, especially as this would counteract the increase in consumer health protection. Looking at ethanol as a disinfectant it is as safe as following arguments indicate. □ The OECD reviewed ethanol 2004 (OECD, 2004) and concluded that "Ethanol possesses properties that may indicate a risk to human health, but only at doses associated with the consumption of alcoholic beverages. In the context of an industrial chemical, these risks do not justify further investigation, as they are not likely to arise from the manufacture and use of ethanol and ethanol-containing products." Since ethanol is denaturized, an improper oral intake can be excluded. In addition, the applicable occupational health and safety regulations prevent from oral intake. □ The toxicological risk assessments indicates that dermal and inhalation exposure to ethanol-containing chemicals in industrial, professional, and consumer sectors are safe. Ethanol has a binding occupational exposure limit value (OEL) of 380 mg/m³, which must be used to assess inhalation exposure at workplaces as part of the risk assessment and to check the effectiveness of protective measures. Ethanol is listed in TRGS 900 "Occupational exposure limit values" with the note "Y" as a substance for which there is no risk to the unborn child if the occupational exposure limit value is observed. Compliance with the OEL for ethanol ensures both the protection of employees and - if the activity is carried out by a pregnant woman - the protection of the unborn child. □ Ethanol is well tolerated and dries quickly on the skin. It is therefore not considered a skin-resorptive substance in Germany. If substances have skin-resorptive properties, they can also be absorbed through intact skin due to their physio-chemical properties and cause damage to health. Skin-resorptive substances are marked with "H" in TRGS 900. This is not the case with ethanol. □ The alcohol concentration in the blood does not reach the same level through dermal or inhalation exposure as it does from consumption via beverages, and remains within the standard deviation of the endogenous body

	burden. The BG BAU (statutory accident insurance institutions in Germany) has carried out numerous workplace measurements for activities involving cleaning agents containing ethanol, such as glass cleaners, in some cases under worst-case conditions. The occupational exposure limit (OEL) for ethanol was met in all measurements. Considering only the actual risks, other active substances in disinfectants than ethanol may have an even higher hazard and risk. □ Propanol: CNS-depressant effects at elevated concentrations; lacks full virucidal activity, especially against non-enveloped viruses; irritating (propan-2-ol) or corrosive (propan-1-ol) to eyes. □ Iodine: Recognized as an endocrine disruptor affecting thyroid hormones in humans and wildlife; forms disinfection by-products (DBPs) such as iodamines; contact allergen – may trigger eczema and allergic reactions; oxidative and irritant, affecting skin, eyes, and respiratory tract; cytotoxic in cell culture studies; risk of iodism upon repeated exposure □ Peracetic Acid (PAA): Highly reactive, strong oxidizer; corrosive to skin, eyes, and mucous membranes; inhalation can cause respiratory irritation and injury; □ Sodium hypochlorite: Can form carcinogenic by-products like trihalomethanes (THMs); mutagenic and genotoxic potential through reaction products; irritant to mucous membranes, poses inhalation hazard; chemically incompatible with many other substances – risk of exothermic reactions and chlorine gas release □ CHDG & QAC: Potential to promote antimicrobial resistance; cytotoxic in human cell culture models; residues remain on treated surfaces; this has a negative impact on the environment and may require rinsing in critical areas as an additional step; corrosive (e.g. skin or eye damage Category 1 (H314/318)) □ Monochloramine: Can lead to formation of nitrosamines, known carcinogens; reacts with organic matter to form toxic by-products; chemically unstable, requires in situ generation; risk of long-term inhalation effects □ Chlorocresol: Phenolic compound with potential hepatotoxicity; contact allergen, associated with eczema and allergic skin reactions; irritating to skin, eyes, and respiratory tract; low biodegradability, posing environmental risk □ Hydrogen Peroxide: Causes oxidative stress, potentially leading to cell damage; shown to be carcinogenic in animal studies at high concentrations; can cause skin irritation and microlesions; severely irritating to eyes and hazardous when aerosolized; chemically unstable in mixtures, may cause exothermic reactions □ Lactic Acid: Lacks full virucidal activity, limited efficacy against non-enveloped viruses; can cause odor formation upon contact with organic materials □ Phenoxyethanol:

	Corrosive to eyes, may cause respiratory irritation; may cause kidney toxicity up-on repeated exposure; absorbable through the skin, particularly with damaged skin barriers In summary, the remaining substitutes of ethanol bear an even higher risk for humans and the environment.
Information above is confidential	
Justification for confidentiality	
Availability	Currently, there are only few companies in Europe that produce alternatives to ethanol. The increase of production capacities of alternatives is associated with tremendous technical effort. New facilities must be built, new technologies to be installed, new production permits requested, and hurdles from authorities and NGOs are expected. Ethanol is widely recognized as the most economically feasible option due to its cost-effective production methods and reliance on renewable agricultural resources. Its production infrastructure is well-established within the EU and globally, utilizing biomass and agricultural residues. Ethanol is readily available in the market due to a diverse range of formulators and active substance manufacturers. By contrast, it benefits from a well-established supply chain with a robust network of suppliers across the EU. On the EU Article 95 list, 247 suppliers of ethanol are registered. Additionally, ethanol production is more adaptable to demand surges, allowing for quicker upscaling compared to the production of propan-1-ol or propan-2-ol, which was convincingly demonstrated during the COVID-19 pandemic. This makes ethanol not only more available but also a more reliable, thus, displays the only practical option for meeting the high demand in critical sectors like healthcare. Ethanol benefits from a robust and diversified supply chain within the EU, ensuring stable and reliable access even during periods of increased demand, such as the COVID-19 pandemic. The European standards for infection prevention and disinfection are not only of great importance in Europe, but are also recognized in the USA, Canada and the Asia-Pacific region. This availability mitigates risks of supply shortages and enables rapid scaling to meet healthcare demands. The abundance of suppliers of ethanol fosters competition, further driving down costs and ensuring that a variety of ethanol-based disinfectant products are accessible to users in the human health industry. □ Propanol: In contrast, propanol is a petrochemical derivative, relying on non-renewable resources from non-EU-countries. The Article 95 list

	identifies 9 suppliers for propan-1-ol and 69 suppliers for propan-2-ol under PT1, compared to the 247 suppliers for ethanol, reflecting the significantly broader availability and production base for ethanol. The limited number of suppliers is particularly concerning, as it may not be sufficient to meet EU-wide demand for disinfectants. Also, a required rapid upscaling, e.g. during a pandemic or other high-demand situations, would not be possible. □ Iodine: Iodine is mainly extracted from brine, which is a byproduct of natural gas extraction. There are several plants in the USA and Japan that extract iodine from brine; Japan produces around 30% of the iodine extracted from natural gas brine worldwide, i.e. production takes place outside the EU. □ Peracetic Acid: Peracetic acid is produced through the reaction of acetic acid and hydrogen peroxide. Its availability is moderate, with production facilities in several EU countries. □ Sodium hypochlorite: Sodium hypochlorite is widely available due to its relatively simple production process. It can be produced on-site in many facilities, enhancing its availability. However, its instability during storage can pose challenges for long-term stockpiling. □ CHDG & QAC: Chlorhexidine digluconate (CHDG) and Quaternary Ammonium Compounds (QAC) have moderate availability. QACs are produced by several manufacturers, but their use is subject to regulatory scrutiny due to potential resistance development in microorganisms. □ Monochloramine: Monochloramine has limited availability compared to more common disinfectants. It is typically generated on-site from hypochlorous acid and an ammonium salt. □ Chlorocresol: Chlorocresol has limited availability, with fewer suppliers compared to more common disinfectants. Its production and use are subject to strict regulations due to potential environmental concerns. □ Hydrogen Peroxide: Hydrogen peroxide is widely available and produced by numerous manufacturers globally. Its production process is well-established, and it benefits from a diverse supply chain. However, concentrations suitable for disinfection (typically $\geq 3\%$) may be subject to regulatory restrictions on transport and storage due to its classification as an oxidizing agent. Additionally, its stability and shelf life can be affected by storage conditions, which may impact availability in certain supply chains. □ Lactic Acid: Lactic acid is readily available due to its production from renewable resources through fermentation processes. However, its availability is not as extensive as ethanol. □ Phenoxyethanol: Phenoxyethanol has moderate availability. It is used in various industries, including cosmetics and pharmaceuticals, which contributes to its stable supply

	chain. However, its availability is not as extensive as ethanol. To conclude: Experts warn that new pandemics with a virus as the causative agent are highly likely. The possibility that only a virucidal disinfectant can interrupt the transmission path is therefore realistic. But it's not just about effectiveness: Without ethanol, Europe is at risk of not being able to react in a fast manner to protect the population in case of a new pandemic. Ethanol is readily available and there are far fewer propanol producers than ethanol producers. Europe needs well-formulated, tested products to protect the skin health of our healthcare staff.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	see attachment
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	AGS – Ausschuss für Gefahrstoffe (2006, updated 2025) Technische Regeln für Gefahrstoffe: Arbeitsplatzgrenzwerte (TRGS 900). BArBl, Heft 1/2006, pp. 41–55. Last amended in: GMBI 2025, p. 155 [No. 8], 20 March 2025. Issued by the Bundesministerium für Arbeit und Soziales (BMAS). ECHA Article 95 list https://echa.europa.eu/fr/information-on-chemicals/active-substance-suppliers Kramer, A., Arvand, M., Christiansen, B., Dancer, S., Eggers, M., Exner, M., Müller, D., Mutters, N.T., Schwebke, I. and Pittet, D., 2022. Ethanol is indispensable for virucidal hand antisepsis: memorandum from the alcohol-based hand rub (ABHR) Task Force, WHO Collaborating Centre on Patient Safety, and the Commission for Hospital Hygiene and Infection Prevention (KRINKO), Robert Koch Institute, Berlin, Germany. Antimicrobial Resistance & Infection Control, 11(1), p.93. doi:10.1186/s13756-022-01134-7. Lachenmeier, D. W., Przybylski, M. C., & Rehm, J. (2012).

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Attachments (non-confidential information)	250429_Ethanol consultation_7 Conclusion.pdf
Attachments (confidential information)	
Justification for confidential attachment	

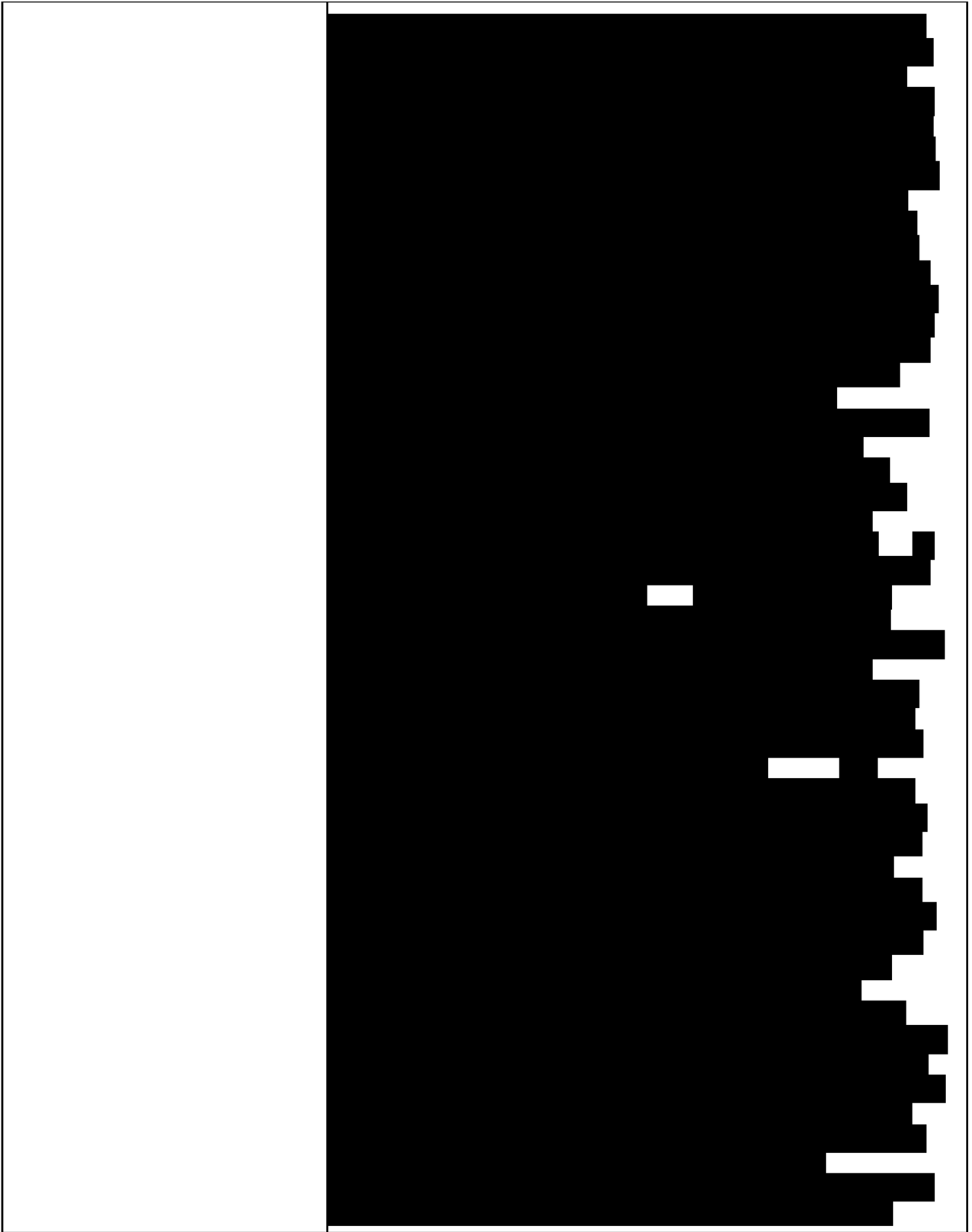
Comment 249	2025/04/29 11:38
Country	Finland
Name of organization/institution	██████████
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	██████████ is a Finnish renewable ethanol producer from Finnish grain. Our main market for ethanol is Finland and the different industries operating in Finland.
Product Type	1,2,4
Alternative Identity and Properties	There is no equally effective and broad-spectrum substitute for ethanol that would have the same effect.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	

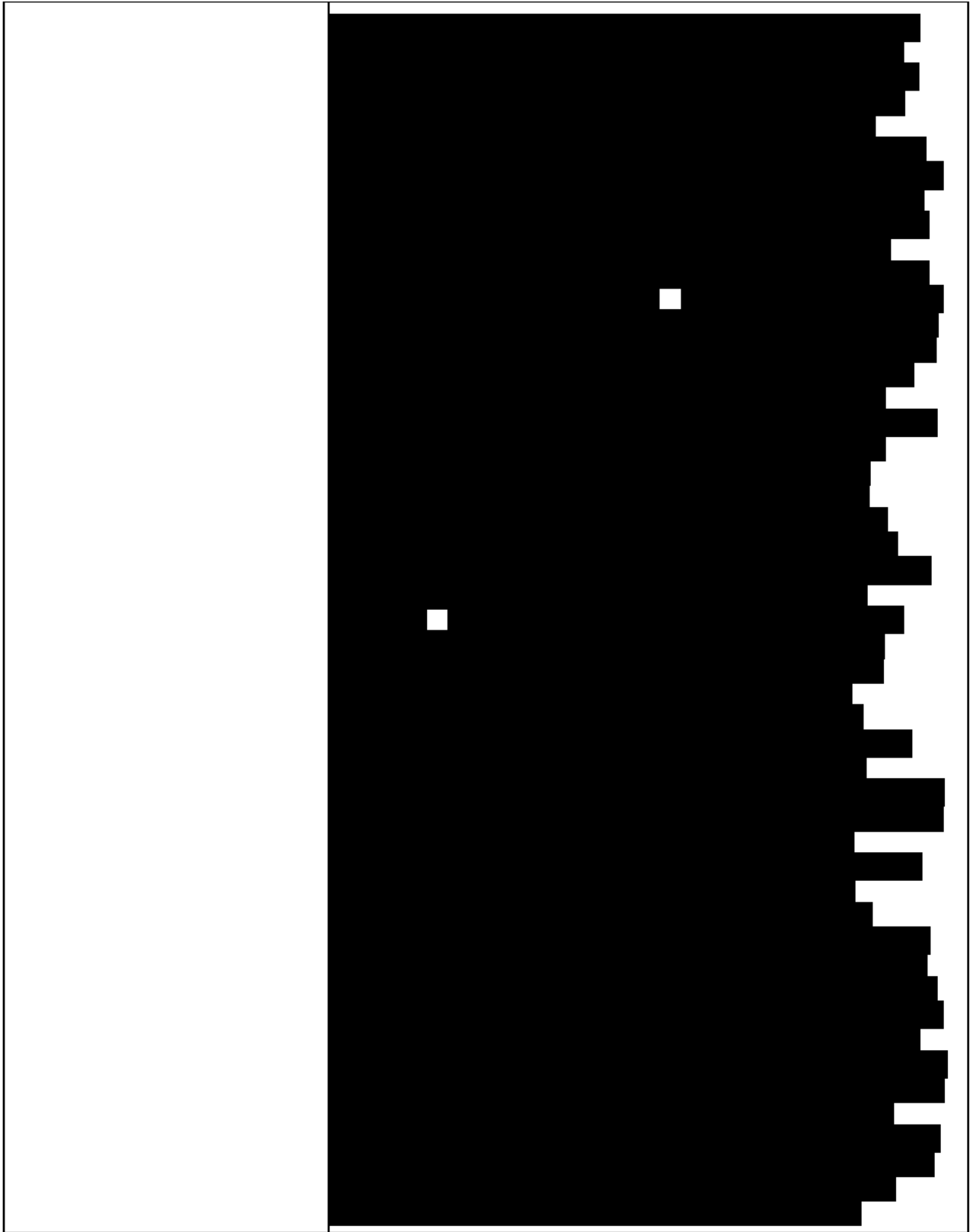
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	There is no equally effective and broad-spectrum substitute for ethanol that would have the same effect. No alternative with equal skin friendliness.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	

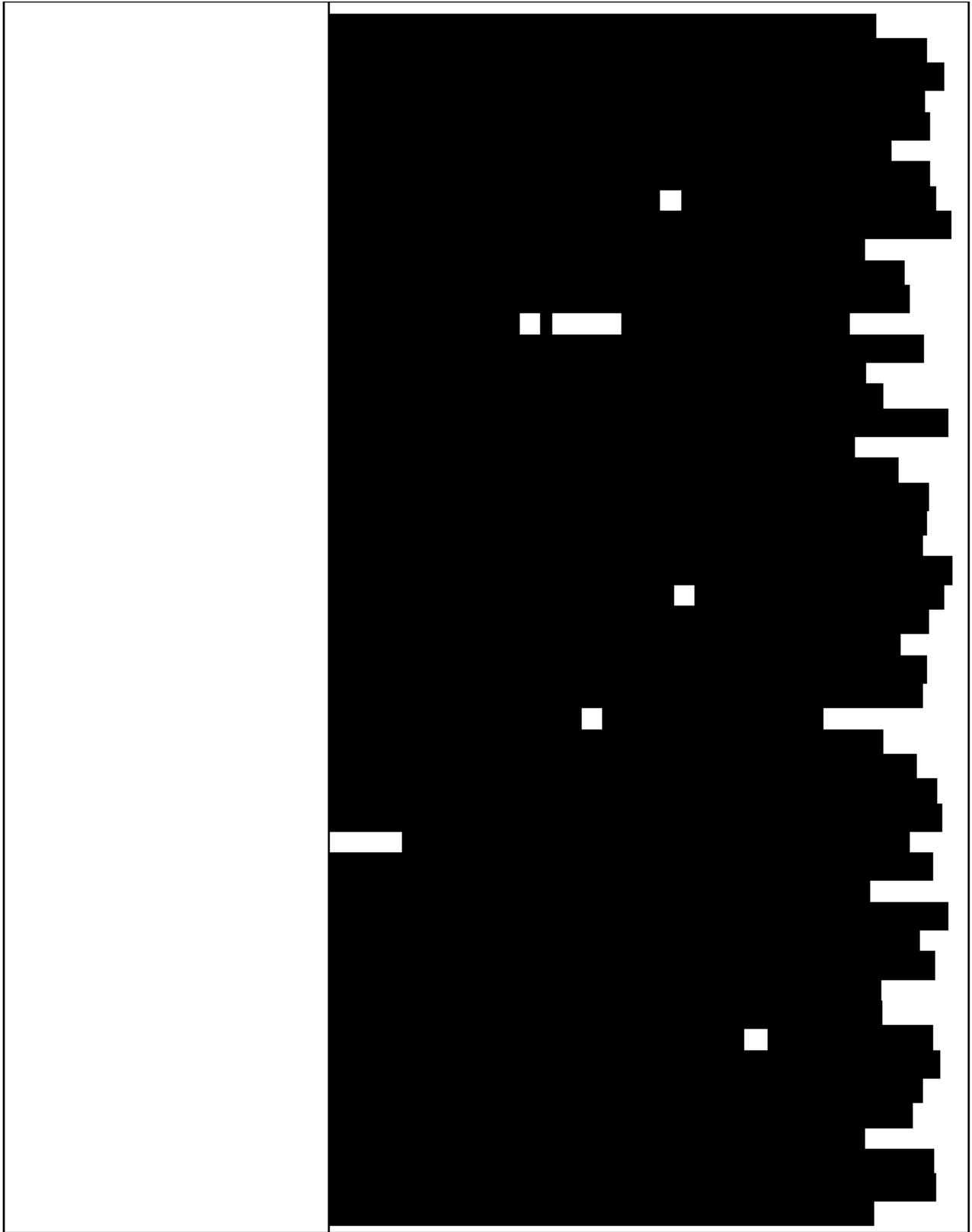
Justification for confidential attachment	

Comment 250	2025/04/29 12:28
Country	Spain
Name of organization/institution	██████████
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	

Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	PT1 – Human hygiene biocidal products Hygienic and surgical hand disinfection by hand rubbing without rinsing • There is no substitute biocidal active substance with similar time-effective profile against non-enveloped viruses such as norovirus, enteroviruses, and adenoviruses, but also enveloped viruses such as SARS-COV-2: ethanol effectively inactivates a wide range of pathogens within seconds, reducing contact times and product usage, which streamlines workflow in critical settings like hospitals. • In addition, there is no alternative that matches ethanol's skin tolerability - potential alternatives such as propanols evaporate less quickly than ethanol, thus prolonging dermal exposure, which makes them unsuitable for use in premises such as healthcare where hand disinfection is required at a very high frequency. • Ethanol-based hand sanitisers are indispensable in infection prevention and control both in hospitals and citizens' daily lives. • The WHO has recognised the importance of these products through their inclusion in the Essential Medicines List. • Limiting the use of ethanol-based hand sanitisers would put public health at risk. • No substitute matches ethanol's efficacy against non-enveloped viruses like Adenovirus, Enterovirus, and Norovirus, which are not vaccine preventable. With the rise of viruses such as Norovirus, which causes millions of cases of gastroenteritis, and the return of Poliovirus, it is crucial for Europe to keep strong preventive measures in place to limit the spread of these viruses. Ethanol-based hand rubs have no equal in their ability to fight these viruses effectively and remain essential for preventing infections.
Information above is confidential	
Justification for confidentiality	
Other comments	







Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 251	2025/04/29 12:57
Country	Greece
Name of organization/institution	Mega disposables SA
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Mega Disposables SA is a Greek company, founded 45 years ago that has grown organically to become Greece's market leader in the personal hygiene sector (biocide PT1 products, sanitary napkins, baby diapers, adult incontinence pads, wet wipes). With more than 40% of its turnover coming from its exports, it has become one of the largest manufacturers of personal hygiene products in Europe. With a portfolio of well-known brands, that have gained consumers' trust, Mega offers an innovative product line for personal hygiene that is entrusted also by big players in the field. With 40 years of experience producing and selling biocide PT1 products (9 products under Mega's brand name and 3 private label products) and being a market leader in this sector in Greece, Mega would like to provide detailed feedback on the importance of ethanol as a biocidal active substance for human hygiene in PT1 products in sprayable and wet wipes form, as it is an active substance widely approved and trusted by the consumers for its efficacy and safety. Ethanol, particularly in the form of hand sanitizers is the dominant active ingredient in roughly 97% of consumers hand sanitizers [1]. It has proven to be an essential tool in preventing the spread of infectious diseases [2]. This submission outlines the technical, economic, and risk-related aspects of ethanol's use as a biocidal product, emphasizing its essentiality and the limited alternatives available. Mega is in the process of conducting a clinical study dedicated to the investigation into whether ethanol can be "transmitted" systemically through transdermal exposure (use) and in what quantities.
Product Type	1,2,4
Alternative Identity and Properties	It is extremely difficult to use an alternative instead of ethanol for the below reasons: • Effectiveness against target organisms: Ethanol is highly effective against a broad spectrum of pathogens, including bacteria, viruses, and fungi. Its mechanism of action—denaturing proteins and disrupting cell membranes—ensures rapid inactivation of

	microorganisms. Key points include: -Broad-Spectrum Efficacy: Ethanol is particularly effective against enveloped viruses (e.g., influenza, coronaviruses) and many bacteria (e.g., *E. coli*, *S. aureus*). - Rapid Action: Ethanol acts within seconds, which is critical for preventing the transmission of infectious agents in healthcare settings, public spaces, and households. Alternatives such as isopropanol, benzalkonium chloride, and hydrogen peroxide either have narrower spectra of activity, require longer contact times, or are less effective against certain pathogens [10]. For example, benzalkonium chloride is less effective against non-enveloped viruses [11], and hydrogen peroxide requires longer exposure times to achieve similar efficacy [12].
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Justification for confidentiality	
Technical Feasibility	1.Efficacy Against Pathogens: Ethanol is highly effective against a broad spectrum of pathogens, including bacteria, viruses, and fungi [3]. Its mechanism of action involves denaturing proteins and disrupting cell membranes, leading to the rapid inactivation of microorganisms [4]. Studies have demonstrated that ethanol is particularly effective against enveloped viruses, such as influenza and coronaviruses, making it a critical component of hand sanitizers and disinfectants [5]. Also, long self life of formulated products ensure stability and usability over time. Mega has undergone efficacy tests for the below EN tests: - Bacteria (EN1276, EN1500) - Yeast (EN1650) - Viruses H1N1, H2N2 (EN14476) Mega's wipes under the brand WET HANKIES EXTRA SAFE were the first biocide wet wipes in Greece with confirmed action against the coronavirus SARS-CoV-2 strain (EN 14476), even at 50% of ethanol (lower than what WHO had announced), acting as a powerful protective weapon during the pandemic period. 2. Rapid Action and Residual Effects: Ethanol acts quickly, often within seconds, which is crucial for preventing the transmission of infectious agents in healthcare settings, public spaces, and households[6]. Unlike some other biocidal agents, ethanol evaporates quickly, leaving no residue, which is advantageous for use on skin and sensitive surfaces, having a minimal risk of generating resistance, due to its swift, broad mechanism of action [7]. Topical application leads to rapid evaporation yielding minimal skin absorption and hence no significant systemic exposure. 3. Compatibility with Formulations: Ethanol is compatible with

	other ingredients commonly used in biocidal products, such as emollients, thickeners, and fragrances [8]. This compatibility allows for the formulation of products that are both effective and user-friendly, encouraging compliance with hygiene practices [9].
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Economic Feasibility	Economic Benefits of Ethanol in Biocidal Products: - Cost-Effectiveness: Ethanol is relatively inexpensive compared to some alternative biocidal agents. Its widespread availability and established production infrastructure contribute to its cost-effectiveness, making it accessible for use in both high-income and low-income settings [13]. - Reduced Healthcare Costs: By effectively reducing the transmission of infectious diseases, ethanol-based biocidal products contribute to lower healthcare costs. Preventing infections reduces the burden on healthcare systems and enhances productivity in workplaces and schools. A prohibition on ethanol would instantly render most existing formulations defunct – effectively upending ~97% of the current hand sanitizer market . Manufacturers of these products, from large corporations to small businesses, would face enormous losses in product inventory and sunk R&D costs. Many companies have production lines, machinery, and supply contracts dedicated to ethanol-based formulations; they would either have to invest heavily in reformulation (identifying, testing, and approving new active ingredients) or cease production. This kind of overhaul is costly and time-consuming, requiring new efficacy and safety evaluations that could cost millions of dollars and take years. The likely result is factory shutdowns, job losses, and business closures, especially among smaller producers who cannot easily pivot. Manufacturers would need to pay for new raw materials, retool production lines, and possibly licensing fees for patented alternatives – expenses likely passed on to consumers. The end result could be more expensive personal disinfectants that might deter regular use or access. During the COVID-19 pandemic, we saw how critical abundant, affordable hand sanitizer was; an alcohol ban could reverse those gains, making disinfectants scarcer or cost-prohibitive for some communities.
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Hazards and Risks of the Alternative	Exposure: Ethanol is well-suited for human exposure due to its favorable safety profile when used as directed: - Skin Tolerance: Ethanol is generally well-tolerated on the skin, especially when formulated with emollients and moisturizers to prevent dryness and irritation. - Rapid Evaporation: Ethanol evaporates quickly, leaving no residue, which minimizes prolonged exposure and reduces the risk of irritation or toxicity. In contrast, alternatives like hydrogen peroxide can cause skin irritation and damage, while benzalkonium chloride may leave residues that could lead to prolonged exposure and potential sensitization. The hazards associated with alternative biocidal substances make them less suitable for widespread use: - Isopropanol was proposed as an alternative to ethanol. However, it is more irritating to the skin and has a stronger chemical-like odor, reducing user acceptability [14]. Mega has undertaken trials with Isopropanol wipes and the results were disappointing. Mega conducted a panel test at 2022 with 51 volunteers to examine the acceptance of isopropanol wipes. 100% of the comments from the users were negative rejecting the wipes after evaluating the smell, the skin sensation and the general view. The same panel test showed 100% preference for ethanol wipes (see the attached file_isopropyl alcohol wipes panel test 6.22_signed). After the rejection of isopropanol wipes due to the bad smell, Mega tried to cover the smell with fragrances requesting from the fragrance producers perfumes specially designed to cover this specific smell. The results were disappointing. After testing more than 30 perfumes from 8 different suppliers, none of them could cover the bad smell of isopropanol to give an acceptable product. Also, Mega made stability test for isopropanol wipes vs ethanol wipes at 2022. The results showed much more evaporation of isopropanol. In addition, isopropanol was very aggressive to the packaging making the packages delaminate and as a result lead to lotion weight loss (see the attached file_stability test_ISOPROPYL-ETHYL ALCOHOL 6.22 signed_). - Benzalkonium Chloride: This compound can cause skin sensitization and is less effective against certain viruses. It also poses environmental risks due to its persistence in water systems [15]. - Hydrogen Peroxide: Highly corrosive and irritating to the skin and mucous membranes, hydrogen peroxide requires careful handling and poses risks of chemical burns [16]. Ethanol, by comparison, has a well-understood safety profile and poses fewer risks when used as directed. It remains the most balanced option, offering high efficacy, rapid action, and

	user acceptability. Ethanol's use as a biocidal substance requires fewer protective measures compared to alternatives: - Human Health: Ethanol is safe for topical use when formulated correctly. Risks associated with ingestion or misuse can be mitigated through proper labeling, child-resistant packaging, and public education. - Animals: Ethanol poses minimal risk to animals when used as intended, as it evaporates quickly and does not leave harmful residues. - Environment: Ethanol is biodegradable and does not persist in the environment, reducing its ecological impact. Alternatives like benzalkonium chloride and hydrogen peroxide require stricter handling and disposal protocols to mitigate their environmental and health risks. For example, benzalkonium chloride can be toxic to aquatic life, and hydrogen peroxide requires neutralization before disposal to prevent environmental harm. Ethanol is present everywhere: Ethanol is found in many natural food stuffs like fruit juices or bread and is present at low levels in all people (fermentation in the human digestive system). Whilst there are known hazard issues associated with excessive drinking of alcoholic beverages, consequences of use of alcohol as a beverage must not be used as a proxy for exposure through non beverage uses. In addition, science shows that inhalation of alcohol never leads to increase in alcohol level in the blood any near to those observed after ingestion. Furthermore, it evaporates quickly, and in real life, uptake of ethanol through the skin or inhalation is negligible. Classifying ethanol undermines the credibility of the CLP Regulation: Classifying ethanol as a category 1 CMR under biocides would characterise it as a dangerous chemical and would send confusing messages to those who handle chemicals, both workers and consumers. It would undermine the important safety messages that need to be communicated to those handling far more dangerous chemicals - when a substance that the public is very familiar with and is permitted for sale for drinking is regarded as dangerous for use as a chemical.
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	

Conclusion on suitability and availability of the alternative	Essentiality of Ethanol as a Biocidal active substance: Ethanol is essential for maintaining public health, particularly in the context of emerging infectious diseases and antimicrobial resistance. Its broad-spectrum efficacy, rapid action, and cost-effectiveness make it indispensable for hygiene practices in healthcare, food preparation, and everyday life. The limited availability of equally effective and practical alternatives underscores the need for continued support for ethanol as a biocidal active substance. Ethanol is under assessment for potential classification as carcinogenic and/or toxic to reproduction. However: - o There is no conclusive evidence of carcinogenicity from real-world exposure levels. - o Toxicological evaluations should differentiate ingestion vs. topical and inhalation exposure. - o Any classification must consider risk-based assessment rather than hazard-only classification. Ethanol is a vital biocidal product for human hygiene, offering unparalleled efficacy, cost-effectiveness, and user acceptability. Its essentiality is further highlighted by the limited alternatives available [21]. Mega urges to continue supporting the use of ethanol in biocidal products through robust regulatory frameworks, research investments, and public education initiatives. Mega is in the process of conducting a clinical study dedicated to the investigation into whether ethanol can be "transmitted" systemically through transdermal exposure (use) and in what quantities. Thank you for considering this feedback.
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Justification for confidentiality	
Other comments	Risks of banning ethanol If ethanol is substituted or restricted, the following risks must be considered: 1.Lack of equally effective alternatives: • No substitute biocidal active substance offers equal virucidal efficacy against non-enveloped viruses. •Other active substances have higher toxicity profiles or leave residues. 2.Supply chain vulnerabilities: • Alternative substances are significantly more expensive and less available. • Scaling up production for substitutes would require massive investments in new facilities, technologies, and regulatory approvals, facing resistance from authorities and NGOs. 3.Potential public health risks: • Reduced availability of effective disinfectants could increase infection rates in healthcare, food processing, and public hygiene [17]. • Increased use of weaker disinfectants may lead to higher microbial resistance [18]. • There's also a risk that a

	black market or DIY production of alcohol sanitizers would emerge (as seen early in the pandemic when supply was tight), raising concerns about quality control – indeed, contaminated or improperly formulated homemade sanitizers (e.g. methanol-tainted products) caused poisonings during 2020. Keeping regulated ethanol-based products available ensures public access to a safe, effective means of disinfection, whereas a ban could drive the public toward unsafe practices • Loss of trust on safety procedures and product labeling from the public. Ethanol-based disinfectants have become a cornerstone of public hygiene practices worldwide, especially during infectious disease outbreaks, like during the COVID-19 pandemic. In hospitals and clinics, ethanol-based hand rubs are considered the gold standard for hand hygiene. Both WHO and CDC recommend ethanol hand rubs as the preferred method for routine antisepsis [19]. So a potential ban of ethanol will lead to a complete lack of consumer trust in the words of responsible health authorities [20]. Ethanol is a unique case, being one of the most widely used basic chemicals in numerous applications worldwide. A BPC recommendation for a CMR classification leading to exclusion or substitution criteria will: -Prevent the usage of Ethanol by the general public (hand gels) and professional users (hospitals) where no suitable alternatives exist that are effective against non-enveloped viruses representing 60-70% of human infecting viruses. -Impact various industries beyond biocidal applications linked to cosmetic products, chemical agents at work, food contact materials, EU Ecolabel, waste, medical devices, and general food law. Extrapolating epidemiological drink data to worker/consumer exposure is invalid. The scientific basis to classify a substance under biocidal legislation as a Cat. 1 Carcinogenic and Toxic for Reproduction substance using results from intake data of foodstuffs is unsound and inappropriate.
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Justification for confidentiality	
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Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 252	2025/04/29 13:09
Country	Estonia
Name of organization/institution	Estonian Chemical Industry Association
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Estonian Chemical Industry Association (Eesti Keemiatööstuse Liit) is an organization representing Estonian chemical companies in the entire value chain – substance manufactures, mixture formulators and distributors in the fields of detergents, disinfectants, biocides, household products, paints, solvents, cosmetics etc. Ethanol is an essential ingredient used by our member companies in a broad range of household, professional and industrial products. In addition to its indispensable use as an active substance in disinfectants and as a co-formulant in insecticides and repellents, it is also important in cleaning products such as hand dish washing liquids, laundry detergents, surface cleaners, windshield washer fluid and also in fragrance products such as perfumes, reed diffusers and other cosmetics. Ethanol is crucial to our sector and viable alternatives do not exist Ethanol shows a unique combination of rapid, broad-spectrum antimicrobial activity and a favorable exposure profile in PT1, PT2 and PT4 formulations that is unmatched by available alternatives. It has a broad-spectrum efficacy against bacteria, fungi, and both enveloped and non-enveloped viruses, and this within very short contact times. Its use in biocidal applications, whether as a hand disinfectant or a surface disinfectant—is

	essential for maintaining public health, particularly in high-risk environments. Reclassification that compromises these applications would jeopardize effective infection control and could lead to significant safety and supply challenges. In fact, Ethanol is critical for human health and safety. More than 3.5 million cases of HealthCare Associated Infections (HCAI) are estimated to occur in the EU/EEA each year, leading to more than 90 thousand deaths. Ethanol is endorsed by the WHO. It is known to be the most effective substance in the fight against HCAs and the only substance effective against viruses like polio. Ethanol is a vital ingredient in various cleaning and household products, such as surface disinfectants and skin repellents. Restaurants and food industry use ethanol-based products to prevent the spread of salmonella, ensuring food safety and public health. It is also a skin repellent essential since vector borne diseases are rising due to climate change in Europe. Ethanol is essential not only for its strong disinfectant action, but also for being the most used solvent in the formulation of all product categories. When used as a co-formulant in insecticides and repellents, ethanol presents un-matched solvency properties, helps control viscosity and is highly compatibility with the other formulation's ingredients. The solvency property of ethanol is in fact unique: non-soluble in water active ingredients dissolve easily and are extremely stable during the shelf life and as soon as the product is applied to a surface the solvent evaporates, and only the benefits of the active ingredient remain. This characteristic leads the substance to be used widely. Ethanol is commonly present in the formulation of all those products that require rapid evaporation of the solvent after application, such as skin repellents (PT19), ready-to-use insecticides (PT18) or perfumes (contained in most of consumer products). There are also no alternatives in the pharmaceutical and food industries, and in the production of flavours and fragrances, where ethanol is used to extract active ingredients of natural origin. Alternative considerations Across many critical use cases, viable substitutes for ethanol are either non-existent or significantly less effective, both in terms of efficacy and overall safety. With regards to healthcare-associated infections (HCAs), no alternative biocidal active substance provides comparable effectiveness against non-enveloped viruses such as poliovirus, adenoviruses, and noroviruses. These pathogens are particularly resilient and non-enveloped viruses remain among the most difficult to inactivate. Ethanol's proven rapid action against this group of viruses remains unmatched, making it indispensable for infection prevention strategies in healthcare environments.

	For point-of-care hand hygiene, no other substance matches ethanol's unique combination of broad-spectrum efficacy, rapid antimicrobial action, excellent skin tolerability, and minimal irritation profile. Other alcohols, such as propanols, while partially effective against certain pathogens, evaporate more slowly, increase skin exposure times, and are associated with greater dermal irritation and drying effects. Non-alcohol alternatives like chlorhexidine, hydrogen peroxide, or quaternary ammonium compounds (QACs) lack either the rapid virucidal activity or the broad pathogen spectrum required for effective hand hygiene — and many pose additional sensitisation or residue issues. Given that healthcare workers apply hand sanitisers between 60 to 100 times per day, ensuring skin compatibility is not merely a comfort factor, but a necessity for maintaining compliance with hygiene protocols and protecting skin health over time. The absence of an effective substitute for ethanol would likely lead to a sharp increase in infection rates, both in healthcare facilities and in public settings. Higher infection rates would, in turn, result in substantially increased healthcare costs due to longer hospital stays, additional treatments, workforce absenteeism, and broader public health impacts. Some alternative substances might warrant limited consideration under specific conditions for different PTs: propanols, oxidising agents like peracetic acid, chlorine compounds and hydrogen peroxide, lactic acid, Quaternary Ammonium Compounds. Ultimately, while a few alternative substances could theoretically serve in niche scenarios, none possesses the combination of immediate virucidal efficacy, operational practicality, skin safety, regulatory acceptance, and public trust that ethanol-based formulations uniquely provide. Ethanol remains irreplaceable as the cornerstone of effective human hygiene and infection prevention strategies across healthcare, food industry, and public environments. Economic feasibility Ethanol production is highly cost-competitive due to optimized production processes and economies of scale that significantly lower its manufacturing costs compared to alternative disinfectants. Propan-1-ol and propan-2-ol are significantly more expensive than ethanol. Their higher production costs, coupled with their narrower spectrum of action (ineffective against nonenveloped viruses), result in additional costs for supplementary disinfectants in healthcare settings. The longer contact times required for effective disinfection with these substances also contribute to their reduced cost-effectiveness, as larger quantities are needed for equivalent results. In addition to its technical superiority, ethanol also offers significant economic advantages over alternative

disinfectants. While some alternative substances, such as propanols or oxidising agents like peracetic acid and chlorine compounds, may initially appear competitive in unit cost, their overall application costs are considerably higher. These alternatives often require longer contact times, greater product volumes, specialised application protocols, additional personal protective equipment, or post-application rinsing, all of which increase operational expenses. Furthermore, the use of harsher disinfectants may lead to material degradation or corrosion of sensitive surfaces and equipment, resulting in additional maintenance and replacement costs. In contrast, ethanol's rapid evaporation, broad material compatibility, minimal residue, and well-established public and regulatory acceptance ensure not only effective disinfection but also lower total costs across healthcare, food production, and public hygiene environments. Therefore, beyond its unmatched efficacy and safety, ethanol remains the most economically viable choice for widespread disinfection applications.

Hazards and risks The assessment of the CMR toxicity of ethanol is based on experience from the misuse of alcoholic beverages, i.e. exclusively on oral intake. When used as a chemical, this is not relevant and does not play a role in occupational hazards, so these data are not suitable for classification as an industrial chemical or in consumer products. Typically, ethanol is used in the chemical industry in denatured form to prevent oral uptake. Making regulatory decisions based on extrapolations from studies — which are unlikely to be realistic considering the actual use of a substance — to real-world scenarios, does not seem reasonable. If the purpose of the hazard identification and risk problem formulation questions is to understand the human health effects associated with chronic high-dose ethanol consumption, then such toxicity testing would indeed be appropriate. Conversely, if the purpose of the hazard identification and risk problem formulation is to address much lower exposures to ethanol in occupational and other environmental scenarios, then chronic toxicity testing based on very high doses is clearly not appropriate (Principles of dose-setting in toxicology studies: the importance of kinetics for ensuring human safety). When considering alternatives to ethanol-based disinfectants, propanols (such as isopropanol and n-propanol) are often cited as the primary potential substitutes. However, a closer examination reveals that the scientific basis for comparing ethanol's carcinogenicity, mutagenicity, and reproductive toxicity (CMR) potential to that of propanols is neither proportional nor scientifically justified. The REACH registration dossiers available through ECHA's chemical

	database (ECHA CHEM) indicate that for propanols, only a limited number of studies exist addressing the carcinogenicity endpoint. Moreover, these studies are largely based on dermal and inhalation exposure routes at doses typical for classical chemical testing protocols. Importantly, no substantial human epidemiological data are available to support or contextualize the findings for propanols. In contrast, ethanol has been subjected to an exceptionally extensive and rigorous body of research. Its CMR classification debates are predominantly informed by high-dose oral exposure studies — reflecting alcohol consumption levels far exceeding any conceivable exposure from its use in disinfectants. Furthermore, there is a substantial body of human epidemiological data, largely derived from decades of public health research into alcohol consumption, that informs ethanol's toxicological profile. This human data includes known confounding factors such as lifestyle, co-exposures, and comorbidities, which are absent from standard chemical risk assessments for other substances. Thus, ethanol's hazard profile, particularly its CMR concerns, is based on high-dose systemic oral exposure and chronic abuse, not on dermal or inhalation exposure at the levels relevant to its use in biocidal products. This contrasts sharply with the typical datasets available for other chemical substances. A proportional, scientifically sound risk comparison must consider the nature, quality, and relevance of the available data — not merely the formal existence of studies. Given that biocidal use of ethanol predominantly involves dermal exposure and inhalation of low vapour concentrations during brief applications, the extrapolation of high-dose oral ingestion data to these exposure scenarios is scientifically inappropriate. Conversely, the lack of comprehensive human-relevant data for other substances might leave significant uncertainty about their true long-term safety profile when used intensively, especially under the high-frequency hand hygiene protocols demanded in healthcare and food environments. Accordingly, any regulatory treatment that penalizes ethanol based on high-dose oral ingestion risks, while not treating other substances comparatively, constitutes a disproportionate and inconsistent application of scientific principles. A fair and scientifically justified regulatory assessment must weigh both the quality and relevance of the underlying evidence, including the realistic routes and levels of exposure in intended uses. In light of these considerations, ethanol remains the better-characterised, better-understood, and thus more reliably manageable active substance for widespread human hygiene applications, including hand

disinfection. In addition, ethanol is safe for the environment: it mainly comes from renewable sources, it is fully biodegradable compared to its alternatives, it leaves no residue on surfaces, it evaporates quickly, and it is generally more sustainable than other options. Availability Ethanol benefits from a well-established supply chain with a robust network of suppliers across the EU. Additionally, ethanol production is more adaptable to demand surges, allowing for quicker scaling compared to the production of propan-1-ol or propan-2-ol, which was convincingly demonstrated during the COVID-19 pandemic. This makes ethanol not only more available but also a more reliable and practical option for meeting high-demand needs in critical sectors like healthcare. Ethanol was critical in combating COVID-19: it was widely available and cost-effective, unlike propanol and other alternatives. The industry was able to ramp up production and meet government requirements. In a world of geopolitical uncertainty and climate related disasters, ethanol-based hand disinfectants are a key tool in preventing the spread of disease in war torn and disaster areas, refugee camps and during rural outbreaks of deadly viruses such as Ebola when water and proper handwashing is inaccessible. Regulatory considerations The EU should move towards a more risk-based approach rather than a hazard-based approach in chemicals management. Europe places too much emphasis on hazards as the main driver for decision-making, to the point where it is questionable whether certain decisions are based on balanced and consistent scientific assessments. The competent body for the classification of substances is primarily the European Chemicals Agency's Committee for Risk Assessment (RAC), which is responsible for the harmonised classification and labelling process under the CLP Regulation. To avoid unnecessary confusion, ethanol should be allowed to complete its CLP process before its approval process under the BPR takes place. Therefore, we call for the current biocidal process to be concluded without reclassification or postponed until complete socio-economic assessment is conducted and the need for refined harmonized C&L for ethanol is properly assessed. Summary The use of ethanol as a disinfectant, as an industrial chemical and as part of consumer products is essential, safe and must be preserved! Annex I Additional information on the de facto ban Ethanol's reclassification means a de facto ban and would have massive consequences not only on European industry, but also on society as a whole, while not bringing any benefit to human health or the environment. The evaluation of the CMR endpoints and a subsequent decision on these endpoints by the BP Committee and European

	Commission would result in official statement on the CMR properties of Ethanol for Biocidal Uses. This available information would have to be taken into account by all users of Ethanol during their self-classification process. Thus, a classification within the Biocide sector would be transferred into all sectors. Additionally, this official position on the CMR properties could influence the opinion-forming process of other CLP committees and thus affect the currently ongoing harmonised classification process. For a substance meeting the criteria for carcinogenicity, regulatory obligations apply under the following regulations and directives (and there are more in the pipeline) - source: Fulfilling the criteria for CLP classification: the implications for substances under the EU chemicals legislation; Diana Kättström, Anna Beronius et al • Substances meeting the criteria for carcinogenicity may be added to Annex XIV of the REACH Regulation, which lists substances requiring authorisation (Article 57). Entries 28–30 of Annex XVII of the REACH Regulation impose a ban on the sale to the general public of substances classified as Category 1A or 1B carcinogenic, mutagenic, or toxic to reproduction, as well as mixtures containing such substances above a specified concentration limit (generally 0.1%). In addition, the placing on the market of tattoo inks containing Category 1A, 1B, or 2 carcinogens is restricted (Annex XVII entry 75). • Under the Biocidal Products Regulation and the Plant Protection Products Regulation, active substances classified as Category 1A or 1B carcinogens are generally not approved as active substances [Biocidal Products Regulation Article 5(1), Plant Protection Products Regulation Annex II point 3.6.3]. However, under certain circumstances and for a limited time, they may be approved as candidates for substitution [Biocidal Products Regulation Article 10(4), Plant Protection Products Regulation Article 24(1)]. For such substances, the Biocidal Products Regulation limits approval to a maximum of five years [Article 4(1)], and the Plant Protection Products Regulation to a maximum of seven years [Article 24(1)]. Biocidal products containing candidate substances must not be made available to the general public [Article 19(4)]. • According to the Prior Informed Consent (PIC) Regulation, the export of substances subject to the PIC procedure is prohibited if they are classified as Category 1A or 1B carcinogens [Article 14(7)]. • For industrial installations, the Industrial Emissions Directive requires the substitution of classified carcinogens with less hazardous substances as soon as possible (Article 58). • To protect workers, the Carcinogens and Mutagens Directive imposes obligations on employers to assess exposure to carcinogens, reduce the use of such substances, prevent exposure risks,

	and take necessary precautionary measures [Article 3(2), Article 4(1), Article 5]. Employers must also monitor workers' health, keep health records for at least 40 years, and notify the competent authority of any cancer cases arising from exposure to carcinogens [Articles 6, 10(1), 11, 14–16, 18]. • Similarly, the Chemical Agents Directive aims to protect workers' health by requiring employers to assess the presence of hazardous substances and the risks to health, and to implement preventive measures [Article 3(1), Article 4(1)]. Employers must make information available about hazardous substances, such as safety data sheets, and any necessary precautions or emergency procedures (Articles 7, 8, 10). • The Young Workers Directive prohibits employing workers under the age of 18 in jobs involving substances meeting any category of carcinogenicity criteria [Annex, entry 3(a)]. • The Pregnant and Breastfeeding Workers Directive requires employers to assess the exposure of pregnant women, women who have recently given birth, or breastfeeding workers to any category of carcinogens, and to take measures to mitigate risks [Annex I, entry 3(a)]. • Under the Regulation on Active and Intelligent Materials and Articles Intended to Come into Contact with Food, carcinogenic substances must not be used in material components designed to prolong shelf life or monitor food condition, even if not in direct contact with food [Article 5(c)]. • The Plastics and Materials Regulation restricts the use of carcinogens in multilayer plastic materials and articles made from different materials, even when there is no direct food contact (Articles 13, 14). • Substances classified as Category 1A or 1B carcinogens are prohibited in cosmetic products under the Cosmetics Regulation. Category 2 carcinogens are also prohibited unless an expert committee has assessed and deemed them safe (Article 15). • The In Vitro Diagnostic Medical Devices Regulation and the Medical Devices Regulation require that in vitro and medical devices be designed and manufactured so that levels of harmonised classified carcinogens are as low as possible (Annex I, entry 10). Additionally, the Medical Devices Regulation requires information about precautions related to the presence of carcinogens to be included in instructions provided to users/patients (Annex I, Chapters II and III). • The Toy Safety Directive prohibits the use of any substances classified as carcinogenic of any category in toys, toy parts, or components (Annex II, Chapter III, entry 3).
Product Type	1,2,4

Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	In conclusion, ethanol's unique combination of fast action, broad efficacy, excellent skin compatibility, user acceptability, environmental safety, and proven impact on public health outcomes establishes it as an irreplaceable active substance in hand disinfection. No current alternative matches the comprehensive benefits ethanol provides in safeguarding health in clinical, occupational, and everyday environments.
Information above is confidential	
Justification for confidentiality	

Other comments	PT1 – Human hygiene biocidal products: Hygienic and surgical hand disinfection by hand rubbing without rinsing There is currently no alternative biocidal active substance that can match ethanol's rapid and broad-spectrum effectiveness against non-enveloped viruses, such as norovirus, adenoviruses, enteroviruses (for which no vaccines are available) and poliovirus, as well as enveloped viruses like SARS-CoV-2. Given the rising prevalence of viruses like norovirus, responsible for millions of cases of gastroenteritis annually, and the re-emergence of poliovirus, it is imperative that Europe maintains robust preventive measures. Ethanol-based hand rubs remain unparalleled in their ability to combat these viruses effectively and are vital for protecting public health. Ethanol demonstrates the ability to inactivate a wide range of pathogens within seconds, significantly reducing contact times and product usage, thus enhancing workflow efficiency in critical environments such as healthcare facilities. Its rapid action is especially crucial in emergency and high-traffic settings, where swift hand disinfection is required to prevent cross-contamination and maintain patient safety. Furthermore, ethanol remains effective even in the presence of organic material, such as blood or other bodily fluids, unlike many other disinfectants whose efficacy is compromised under such conditions. This robustness makes ethanol highly reliable for both routine and emergency hygiene procedures. Moreover, no substitute offers ethanol's exceptional skin tolerability, which is vital for maintaining high compliance among healthcare workers and the general public. Alternatives such as propanols evaporate more slowly, thereby increasing dermal exposure and raising the risk of skin irritation or dermatitis, particularly with frequent use. In contrast, ethanol's rapid evaporation minimises contact time, significantly reducing the likelihood of skin reactions. Compared to other biocidal agents, ethanol also has a notably lower sensitisation potential, making it better suited for repeated daily application by individuals with sensitive skin. In addition to its excellent skin tolerability, ethanol-based hand sanitisers offer superior cosmetic acceptability, as they leave minimal residue and do not cause stickiness or unpleasant odours after application. This increases user satisfaction and promotes regular use, a key factor in maintaining effective hygiene standards. Ethanol-based hand sanitisers are indispensable tools for infection prevention and control, both in clinical environments and in everyday life. The World Health Organization (WHO) has recognised the critical importance of these products by including ethanol-based hand rubs in its Essential Medicines List. Restricting the

	availability or use of ethanol-based hand sanitisers would significantly endanger public health and weaken established infection control practices across Europe. Evidence from the WHO shows that campaigns promoting hand hygiene with ethanol-based sanitisers have led to a 50% reduction in healthcare-associated infections (HCAIs) across Europe over the past decade. Nevertheless, HCAs continue to cause over 4.3 million cases each year in the European Union and European Economic Area (EU/EEA), leading to approximately 37,000 directly attributable deaths, 16 million additional hospital days, and contributing to between 90,000 and 110,000 deaths annually. Should ethanol be classified as a carcinogenic, mutagenic, or toxic for reproduction (CMR) substance, its prohibition in hospitals could reverse this progress and potentially double the current rate of healthcare-associated infections. Beyond the healthcare setting, ethanol-based hand rubs play a crucial role in public health protection during outbreaks and pandemics, where fast, effective, and widely available disinfection options are essential. Ethanol's broad acceptability, biodegradability into non-toxic byproducts (water and carbon dioxide), and resilience during supply chain disruptions further strengthen its strategic importance as the cornerstone of human hygiene biocidal products.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	ECHA public consultation_ethanol_EKTL input.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 253	2025/04/29 13:23
Country	Estonia
Name of organization/institution	Estonian Chemical Industry Association

I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Estonian Chemical Industry Association (Eesti Keemiatööstuse Liit) is an organization representing Estonian chemical companies in the entire value chain – substance manufactures, mixture formulators and distributors in the fields of detergents, disinfectants, biocides, household products, paints, solvents, cosmetics etc. Ethanol is an essential ingredient used by our member companies in a broad range of household, professional and industrial products. In addition to its indispensable use as an active substance in disinfectants and as a co-formulant in insecticides and repellents, it is also important in cleaning products such as hand dish washing liquids, laundry detergents, surface cleaners, windshield washer fluid and also in fragrance products such as perfumes, reed diffusers and other cosmetics. Ethanol is crucial to our sector and viable alternatives do not exist Ethanol shows a unique combination of rapid, broad-spectrum antimicrobial activity and a favorable exposure profile in PT1, PT2 and PT4 formulations that is unmatched by available alternatives. It has a broad-spectrum efficacy against bacteria, fungi, and both enveloped and non-enveloped viruses, and this within very short contact times. Its use in biocidal applications, whether as a hand disinfectant or a surface disinfectant—is essential for maintaining public health, particularly in high-risk environments. Reclassification that compromises these applications would jeopardize effective infection control and could lead to significant safety and supply challenges. In fact, Ethanol is critical for human health and safety. More than 3.5 million cases of HealthCare Associated Infections (HCAI) are estimated to occur in the EU/EEA each year, leading to more than 90 thousand deaths. Ethanol is endorsed by the WHO. It is known to be the most effective substance in the fight against HCAs and the only substance effective against viruses like polio. Ethanol is a vital ingredient in various cleaning and household products, such as surface disinfectants and skin repellents. Restaurants and food industry use ethanol-based products to prevent the spread of salmonella, ensuring food safety and public health. It is also a skin repellent essential since vector borne diseases are rising due to climate change in Europe. Ethanol is essential not only for its strong disinfectant action, but also for being the most used solvent in the formulation of all product categories. When used as a co-formulant in insecticides and repellents, ethanol presents

	un-matched solvency properties, helps control viscosity and is highly compatibility with the other formulation's ingredients. The solvency property of ethanol is in fact unique: non-soluble in water active ingredients dissolve easily and are extremely stable during the shelf life and as soon as the product is applied to a surface the solvent evaporates, and only the benefits of the active ingredient remain. This characteristic leads the substance to be used widely. Ethanol is commonly present in the formulation of all those products that require rapid evaporation of the solvent after application, such as skin repellents (PT19), ready-to-use insecticides (PT18) or perfumes (contained in most of consumer products). There are also no alternatives in the pharmaceutical and food industries, and in the production of flavours and fragrances, where ethanol is used to extract active ingredients of natural origin. Alternative considerations Across many critical use cases, viable substitutes for ethanol are either non-existent or significantly less effective, both in terms of efficacy and overall safety. With regards to healthcare-associated infections (HCAIs), no alternative biocidal active substance provides comparable effectiveness against non-enveloped viruses such as poliovirus, adenoviruses, and noroviruses. These pathogens are particularly resilient and non-enveloped viruses remain among the most difficult to inactivate. Ethanol's proven rapid action against this group of viruses remains unmatched, making it indispensable for infection prevention strategies in healthcare environments. For point-of-care hand hygiene, no other substance matches ethanol's unique combination of broad-spectrum efficacy, rapid antimicrobial action, excellent skin tolerability, and minimal irritation profile. Other alcohols, such as propanols, while partially effective against certain pathogens, evaporate more slowly, increase skin exposure times, and are associated with greater dermal irritation and drying effects. Non-alcohol alternatives like chlorhexidine, hydrogen peroxide, or quaternary ammonium compounds (QACs) lack either the rapid virucidal activity or the broad pathogen spectrum required for effective hand hygiene — and many pose additional sensitisation or residue issues. Given that healthcare workers apply hand sanitisers between 60 to 100 times per day, ensuring skin compatibility is not merely a comfort factor, but a necessity for maintaining compliance with hygiene protocols and protecting skin health over time. The absence of an effective substitute for ethanol would likely lead to a sharp increase in infection rates, both in healthcare facilities and in public settings. Higher infection rates would, in turn, result in substantially increased healthcare costs due to

	longer hospital stays, additional treatments, workforce absenteeism, and broader public health impacts. Some alternative substances might warrant limited consideration under specific conditions for different PTs: propanols, oxidising agents like peracetic acid, chlorine compounds and hydrogen peroxide, lactic acid, Quaternary Ammonium Compounds. Ultimately, while a few alternative substances could theoretically serve in niche scenarios, none possesses the combination of immediate virucidal efficacy, operational practicality, skin safety, regulatory acceptance, and public trust that ethanol-based formulations uniquely provide. Ethanol remains irreplaceable as the cornerstone of effective human hygiene and infection prevention strategies across healthcare, food industry, and public environments. Economic feasibility Ethanol production is highly cost-competitive due to optimized production processes and economies of scale that significantly lower its manufacturing costs compared to alternative disinfectants. Propan-1-ol and propan-2-ol are significantly more expensive than ethanol. Their higher production costs, coupled with their narrower spectrum of action (ineffective against nonenveloped viruses), result in additional costs for supplementary disinfectants in healthcare settings. The longer contact times required for effective disinfection with these substances also contribute to their reduced cost-effectiveness, as larger quantities are needed for equivalent results. In addition to its technical superiority, ethanol also offers significant economic advantages over alternative disinfectants. While some alternative substances, such as propanols or oxidising agents like peracetic acid and chlorine compounds, may initially appear competitive in unit cost, their overall application costs are considerably higher. These alternatives often require longer contact times, greater product volumes, specialised application protocols, additional personal protective equipment, or post-application rinsing, all of which increase operational expenses. Furthermore, the use of harsher disinfectants may lead to material degradation or corrosion of sensitive surfaces and equipment, resulting in additional maintenance and replacement costs. In contrast, ethanol's rapid evaporation, broad material compatibility, minimal residue, and well-established public and regulatory acceptance ensure not only effective disinfection but also lower total costs across healthcare, food production, and public hygiene environments. Therefore, beyond its unmatched efficacy and safety, ethanol remains the most economically viable choice for widespread disinfection applications. Hazards and risks The assessment of the CMR toxicity of ethanol is based on experience from the misuse of alcoholic

	beverages, i.e. exclusively on oral intake. When used as a chemical, this is not relevant and does not play a role in occupational hazards, so these data are not suitable for classification as an industrial chemical or in consumer products. Typically, ethanol is used in the chemical industry in denatured form to prevent oral uptake. Making regulatory decisions based on extrapolations from studies — which are unlikely to be realistic considering the actual use of a substance — to real-world scenarios, does not seem reasonable. If the purpose of the hazard identification and risk problem formulation questions is to understand the human health effects associated with chronic high-dose ethanol consumption, then such toxicity testing would indeed be appropriate. Conversely, if the purpose of the hazard identification and risk problem formulation is to address much lower exposures to ethanol in occupational and other environmental scenarios, then chronic toxicity testing based on very high doses is clearly not appropriate (Principles of dose-setting in toxicology studies: the importance of kinetics for ensuring human safety). When considering alternatives to ethanol-based disinfectants, propanols (such as isopropanol and n-propanol) are often cited as the primary potential substitutes. However, a closer examination reveals that the scientific basis for comparing ethanol's carcinogenicity, mutagenicity, and reproductive toxicity (CMR) potential to that of propanols is neither proportional nor scientifically justified. The REACH registration dossiers available through ECHA's chemical database (ECHA CHEM) indicate that for propanols, only a limited number of studies exist addressing the carcinogenicity endpoint. Moreover, these studies are largely based on dermal and inhalation exposure routes at doses typical for classical chemical testing protocols. Importantly, no substantial human epidemiological data are available to support or contextualize the findings for propanols. In contrast, ethanol has been subjected to an exceptionally extensive and rigorous body of research. Its CMR classification debates are predominantly informed by high-dose oral exposure studies — reflecting alcohol consumption levels far exceeding any conceivable exposure from its use in disinfectants. Furthermore, there is a substantial body of human epidemiological data, largely derived from decades of public health research into alcohol consumption, that informs ethanol's toxicological profile. This human data includes known confounding factors such as lifestyle, co-exposures, and comorbidities, which are absent from standard chemical risk assessments for other substances. Thus, ethanol's hazard profile, particularly its CMR concerns, is based on high-dose systemic oral

	exposure and chronic abuse, not on dermal or inhalation exposure at the levels relevant to its use in biocidal products. This contrasts sharply with the typical datasets available for other chemical substances. A proportional, scientifically sound risk comparison must consider the nature, quality, and relevance of the available data — not merely the formal existence of studies. Given that biocidal use of ethanol predominantly involves dermal exposure and inhalation of low vapour concentrations during brief applications, the extrapolation of high-dose oral ingestion data to these exposure scenarios is scientifically inappropriate. Conversely, the lack of comprehensive human-relevant data for other substances might leave significant uncertainty about their true long-term safety profile when used intensively, especially under the high-frequency hand hygiene protocols demanded in healthcare and food environments. Accordingly, any regulatory treatment that penalizes ethanol based on high-dose oral ingestion risks, while not treating other substances comparatively, constitutes a disproportionate and inconsistent application of scientific principles. A fair and scientifically justified regulatory assessment must weigh both the quality and relevance of the underlying evidence, including the realistic routes and levels of exposure in intended uses. In light of these considerations, ethanol remains the better-characterised, better-understood, and thus more reliably manageable active substance for widespread human hygiene applications, including hand disinfection. In addition, ethanol is safe for the environment: it mainly comes from renewable sources, it is fully biodegradable compared to its alternatives, it leaves no residue on surfaces, it evaporates quickly, and it is generally more sustainable than other options. Availability Ethanol benefits from a well-established supply chain with a robust network of suppliers across the EU. Additionally, ethanol production is more adaptable to demand surges, allowing for quicker scaling compared to the production of propan-1-ol or propan-2-ol, which was convincingly demonstrated during the COVID-19 pandemic. This makes ethanol not only more available but also a more reliable and practical option for meeting high-demand needs in critical sectors like healthcare. Ethanol was critical in combating COVID-19: it was widely available and cost-effective, unlike propanol and other alternatives. The industry was able to ramp up production and meet government requirements. In a world of geopolitical uncertainty and climate related disasters, ethanol-based hand disinfectants are a key tool in preventing the spread of disease in war torn and disaster areas, refugee camps and during rural outbreaks of deadly

	viruses such as Ebola when water and proper handwashing is inaccessible. Regulatory considerations The EU should move towards a more risk-based approach rather than a hazard-based approach in chemicals management. Europe places too much emphasis on hazards as the main driver for decision-making, to the point where it is questionable whether certain decisions are based on balanced and consistent scientific assessments. The competent body for the classification of substances is primarily the European Chemicals Agency's Committee for Risk Assessment (RAC), which is responsible for the harmonised classification and labelling process under the CLP Regulation. To avoid unnecessary confusion, ethanol should be allowed to complete its CLP process before its approval process under the BPR takes place. Therefore, we call for the current biocidal process to be concluded without reclassification or postponed until complete socio-economic assessment is conducted and the need for refined harmonized C&L for ethanol is properly assessed. Summary The use of ethanol as a disinfectant, as an industrial chemical and as part of consumer products is essential, safe and must be preserved! Annex I Additional information on the de facto ban Ethanol's reclassification means a de facto ban and would have massive consequences not only on European industry, but also on society as a whole, while not bringing any benefit to human health or the environment. The evaluation of the CMR endpoints and a subsequent decision on these endpoints by the BP Committee and European Commission would result in official statement on the CMR properties of Ethanol for Biocidal Uses. This available information would have to be taken into account by all users of Ethanol during their self-classification process. Thus, a classification within the Biocide sector would be transferred into all sectors. Additionally, this official position on the CMR properties could influence the opinion-forming process of other CLP committees and thus affect the currently ongoing harmonised classification process. For a substance meeting the criteria for carcinogenicity, regulatory obligations apply under the following regulations and directives (and there are more in the pipeline) - source: Fulfilling the criteria for CLP classification: the implications for substances under the EU chemicals legislation; Diana Kättström, Anna Beronius et al • Substances meeting the criteria for carcinogenicity may be added to Annex XIV of the REACH Regulation, which lists substances requiring authorisation (Article 57). Entries 28–30 of Annex XVII of the REACH Regulation impose a ban on the sale to the general public of substances classified as Category 1A or 1B carcinogenic, mutagenic, or toxic to reproduction, as well as mixtures containing such

	substances above a specified concentration limit (generally 0.1%). In addition, the placing on the market of tattoo inks containing Category 1A, 1B, or 2 carcinogens is restricted (Annex XVII entry 75). • Under the Biocidal Products Regulation and the Plant Protection Products Regulation, active substances classified as Category 1A or 1B carcinogens are generally not approved as active substances [Biocidal Products Regulation Article 5(1), Plant Protection Products Regulation Annex II point 3.6.3]. However, under certain circumstances and for a limited time, they may be approved as candidates for substitution [Biocidal Products Regulation Article 10(4), Plant Protection Products Regulation Article 24(1)]. For such substances, the Biocidal Products Regulation limits approval to a maximum of five years [Article 4(1)], and the Plant Protection Products Regulation to a maximum of seven years [Article 24(1)]. Biocidal products containing candidate substances must not be made available to the general public [Article 19(4)]. • According to the Prior Informed Consent (PIC) Regulation, the export of substances subject to the PIC procedure is prohibited if they are classified as Category 1A or 1B carcinogens [Article 14(7)]. • For industrial installations, the Industrial Emissions Directive requires the substitution of classified carcinogens with less hazardous substances as soon as possible (Article 58). • To protect workers, the Carcinogens and Mutagens Directive imposes obligations on employers to assess exposure to carcinogens, reduce the use of such substances, prevent exposure risks, and take necessary precautionary measures [Article 3(2), Article 4(1), Article 5]. Employers must also monitor workers' health, keep health records for at least 40 years, and notify the competent authority of any cancer cases arising from exposure to carcinogens [Articles 6, 10(1), 11, 14–16, 18]. • Similarly, the Chemical Agents Directive aims to protect workers' health by requiring employers to assess the presence of hazardous substances and the risks to health, and to implement preventive measures [Article 3(1), Article 4(1)]. Employers must make information available about hazardous substances, such as safety data sheets, and any necessary precautions or emergency procedures (Articles 7, 8, 10). • The Young Workers Directive prohibits employing workers under the age of 18 in jobs involving substances meeting any category of carcinogenicity criteria [Annex, entry 3(a)]. • The Pregnant and Breastfeeding Workers Directive requires employers to assess the exposure of pregnant women, women who have recently given birth, or breastfeeding workers to any category of carcinogens, and to take measures to mitigate risks [Annex I, entry 3(a)]. • Under the Regulation on Active and

	Intelligent Materials and Articles Intended to Come into Contact with Food, carcinogenic substances must not be used in material components designed to prolong shelf life or monitor food condition, even if not in direct contact with food [Article 5(c)]. • The Plastics and Materials Regulation restricts the use of carcinogens in multilayer plastic materials and articles made from different materials, even when there is no direct food contact (Articles 13, 14). • Substances classified as Category 1A or 1B carcinogens are prohibited in cosmetic products under the Cosmetics Regulation. Category 2 carcinogens are also prohibited unless an expert committee has assessed and deemed them safe (Article 15). • The In Vitro Diagnostic Medical Devices Regulation and the Medical Devices Regulation require that in vitro and medical devices be designed and manufactured so that levels of harmonised classified carcinogens are as low as possible (Annex I, entry 10). Additionally, the Medical Devices Regulation requires information about precautions related to the presence of carcinogens to be included in instructions provided to users/patients (Annex I, Chapters II and III). • The Toy Safety Directive prohibits the use of any substances classified as carcinogenic of any category in toys, toy parts, or components (Annex II, Chapter III, entry 3).
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	

Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Summary: Ethanol is the most effective and practical disinfectant for PT2 applications in both private and public health areas, including hospitals, schools, and childcare facilities. It offers rapid, broad-spectrum antimicrobial action, surface compatibility, safety for frequent human contact, and environmental sustainability. Unlike other disinfectants such as propanols, peracetic acid, or sodium hypochlorite, ethanol is non-corrosive, non-irritant, and suitable for sensitive equipment and surfaces. Its solvent properties and minimal residue make it ideal for multi-purpose cleaners, and it is widely trusted by both regulatory bodies and consumers.
Information above is confidential	
Justification for confidentiality	
Other comments	PT2 - Private area and public health area disinfectant When considering PT2 applications, particularly in environments with frequently touched surfaces such as hospitals (including the disinfection of furniture, walls, and floors), industrial settings, educational institutions, and childcare facilities, it becomes evident that no other PT2 active substance offers a viable alternative to ethanol when evaluated against its combined advantages. Ethanol uniquely provides a comprehensive efficacy spectrum, rapid antimicrobial action, compatibility with various surfaces, and an excellent safety profile, setting it apart from other available substances. Other alcohols, such as propanols, exhibit limited virucidal activity compared to ethanol, particularly against non-enveloped viruses. Oxidising agents like peracetic acid, while offering a broader efficacy spectrum, present significant drawbacks: peracetic acid is corrosive, necessitating the use of personal protective

	equipment (PPE) and restricting its use due to material incompatibility. This limitation is particularly critical in healthcare settings, where the disinfection of sensitive materials, such as medical equipment surfaces, must not compromise material integrity through corrosion or degradation. In addition to its broad-spectrum antimicrobial action, ethanol offers several practical advantages that are critical for effective hygiene management. Its rapid evaporation rate eliminates the need for wiping down surfaces post-application, ensuring quick turnaround times in busy environments and reducing the risk of cross-contamination. Unlike many oxidising disinfectants, ethanol does not corrode metals or damage sensitive electronic equipment, making it ideal for use in settings that rely heavily on medical devices, laboratory instruments, and digital technology. Ethanol's effectiveness is also maintained across a broad range of temperatures, whereas some disinfectants lose efficacy under varying environmental conditions. Furthermore, its relatively low toxicity and high compatibility with human skin compared to other chemical agents ensure better alignment with personal safety standards, particularly in environments where frequent human contact is unavoidable. Ethanol delivers broad-spectrum disinfection that is essential for maintaining health and safety standards. It is well-recognised for its ability to eliminate a wide array of microorganisms, including bacteria, viruses, and fungi. The inclusion of ethanol in multi-purpose cleaning products ensures both effective cleaning and disinfection, providing comprehensive hygiene benefits within a single formulation. Many public health agencies and environmental authorities acknowledge ethanol as a safe and effective ingredient in cleaning products. Maintaining ethanol's role in multi-purpose cleaners ensures compliance with recognised standards and sustains market acceptance across various regions. Notably, the European Centre for Disease Prevention and Control has emphasised the importance of using ethanol-based cleaning products in the fight against coronaviruses. Ethanol also possesses critical solvent properties essential for cleaning products. It effectively dissolves dirt, grease, and organic matter on a variety of surfaces, making it indispensable in multi-purpose cleaners designed for demanding environments such as kitchens, bathrooms, and heavily trafficked areas. Importantly, ethanol breaks down into non-toxic by-products, namely water and carbon dioxide, leaving minimal residue, and making it safe for use on surfaces that come into contact with food. Compared to many other chemical disinfectants, ethanol presents a lower risk of causing skin irritation or

	allergic reactions when used as directed. This characteristic makes ethanol-based products particularly suitable for household use by a wide range of consumers, including those with sensitive skin. In addition, ethanol enjoys strong public trust, with consumers recognising its safety and effectiveness, which fosters higher compliance with hygiene recommendations. There is also a distinct lack of alternative substances capable of being safely and effectively used on such a wide range of surfaces. Ethanol, at a 70% concentration, achieves effective disinfection without causing surface damage, making it suitable even for sensitive materials. In contrast, substances like sodium hypochlorite, although effective as disinfectants, tend to corrode or discolour various materials, significantly limiting their applicability. Finally, ethanol presents fewer environmental concerns compared to many chemical alternatives. Thanks to its rapid biodegradation into harmless components, ethanol offers a lower ecological footprint, reinforcing its role as an environmentally responsible choice for sustainable hygiene practices.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	ECHA public consultation_ethanol_EKTL input.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 254	2025/04/29 13:30
Country	Estonia
Name of organization/institution	Estonian Chemical Industry Association
I do not wish the name of my organisation/institution to be published on the ECHA website.	

General information	Estonian Chemical Industry Association (Eesti Keemiatööstuse Liit) is an organization representing Estonian chemical companies in the entire value chain – substance manufactures, mixture formulators and distributors in the fields of detergents, disinfectants, biocides, household products, paints, solvents, cosmetics etc. Ethanol is an essential ingredient used by our member companies in a broad range of household, professional and industrial products. In addition to its indispensable use as an active substance in disinfectants and as a co-formulant in insecticides and repellents, it is also important in cleaning products such as hand dish washing liquids, laundry detergents, surface cleaners, windshield washer fluid and also in fragrance products such as perfumes, reed diffusers and other cosmetics. Ethanol is crucial to our sector and viable alternatives do not exist Ethanol shows a unique combination of rapid, broad-spectrum antimicrobial activity and a favorable exposure profile in PT1, PT2 and PT4 formulations that is unmatched by available alternatives. It has a broad-spectrum efficacy against bacteria, fungi, and both enveloped and non-enveloped viruses, and this within very short contact times. Its use in biocidal applications, whether as a hand disinfectant or a surface disinfectant—is essential for maintaining public health, particularly in high-risk environments. Reclassification that compromises these applications would jeopardize effective infection control and could lead to significant safety and supply challenges. In fact, Ethanol is critical for human health and safety. More than 3.5 million cases of HealthCare Associated Infections (HCAI) are estimated to occur in the EU/EEA each year, leading to more than 90 thousand deaths. Ethanol is endorsed by the WHO. It is known to be the most effective substance in the fight against HCAs and the only substance effective against viruses like polio. Ethanol is a vital ingredient in various cleaning and household products, such as surface disinfectants and skin repellents. Restaurants and food industry use ethanol-based products to prevent the spread of salmonella, ensuring food safety and public health. It is also a skin repellent essential since vector borne diseases are rising due to climate change in Europe. Ethanol is essential not only for its strong disinfectant action, but also for being the most used solvent in the formulation of all product categories. When used as a co-formulant in insecticides and repellents, ethanol presents un-matched solvency properties, helps control viscosity and is highly compatibility with the other formulation's ingredients. The solvency property of ethanol is in fact unique: non-soluble in water active ingredients dissolve easily and are extremely stable during the shelf life and as

	soon as the product is applied to a surface the solvent evaporates, and only the benefits of the active ingredient remain. This characteristic leads the substance to be used widely. Ethanol is commonly present in the formulation of all those products that require rapid evaporation of the solvent after application, such as skin repellents (PT19), ready-to-use insecticides (PT18) or perfumes (contained in most of consumer products). There are also no alternatives in the pharmaceutical and food industries, and in the production of flavours and fragrances, where ethanol is used to extract active ingredients of natural origin. Alternative considerations Across many critical use cases, viable substitutes for ethanol are either non-existent or significantly less effective, both in terms of efficacy and overall safety. With regards to healthcare-associated infections (HCAs), no alternative biocidal active substance provides comparable effectiveness against non-enveloped viruses such as poliovirus, adenoviruses, and noroviruses. These pathogens are particularly resilient and non-enveloped viruses remain among the most difficult to inactivate. Ethanol's proven rapid action against this group of viruses remains unmatched, making it indispensable for infection prevention strategies in healthcare environments. For point-of-care hand hygiene, no other substance matches ethanol's unique combination of broad-spectrum efficacy, rapid antimicrobial action, excellent skin tolerability, and minimal irritation profile. Other alcohols, such as propanols, while partially effective against certain pathogens, evaporate more slowly, increase skin exposure times, and are associated with greater dermal irritation and drying effects. Non-alcohol alternatives like chlorhexidine, hydrogen peroxide, or quaternary ammonium compounds (QACs) lack either the rapid virucidal activity or the broad pathogen spectrum required for effective hand hygiene — and many pose additional sensitisation or residue issues. Given that healthcare workers apply hand sanitisers between 60 to 100 times per day, ensuring skin compatibility is not merely a comfort factor, but a necessity for maintaining compliance with hygiene protocols and protecting skin health over time. The absence of an effective substitute for ethanol would likely lead to a sharp increase in infection rates, both in healthcare facilities and in public settings. Higher infection rates would, in turn, result in substantially increased healthcare costs due to longer hospital stays, additional treatments, workforce absenteeism, and broader public health impacts. Some alternative substances might warrant limited consideration under specific conditions for different PTs: propanols, oxidising agents like peracetic acid, chlorine compounds and

	hydrogen peroxide, lactic acid, Quaternary Ammonium Compounds. Ultimately, while a few alternative substances could theoretically serve in niche scenarios, none possesses the combination of immediate virucidal efficacy, operational practicality, skin safety, regulatory acceptance, and public trust that ethanol-based formulations uniquely provide. Ethanol remains irreplaceable as the cornerstone of effective human hygiene and infection prevention strategies across healthcare, food industry, and public environments. Economic feasibility Ethanol production is highly cost-competitive due to optimized production processes and economies of scale that significantly lower its manufacturing costs compared to alternative disinfectants. Propan-1-ol and propan-2-ol are significantly more expensive than ethanol. Their higher production costs, coupled with their narrower spectrum of action (ineffective against nonenveloped viruses), result in additional costs for supplementary disinfectants in healthcare settings. The longer contact times required for effective disinfection with these substances also contribute to their reduced cost-effectiveness, as larger quantities are needed for equivalent results. In addition to its technical superiority, ethanol also offers significant economic advantages over alternative disinfectants. While some alternative substances, such as propanols or oxidising agents like peracetic acid and chlorine compounds, may initially appear competitive in unit cost, their overall application costs are considerably higher. These alternatives often require longer contact times, greater product volumes, specialised application protocols, additional personal protective equipment, or post-application rinsing, all of which increase operational expenses. Furthermore, the use of harsher disinfectants may lead to material degradation or corrosion of sensitive surfaces and equipment, resulting in additional maintenance and replacement costs. In contrast, ethanol's rapid evaporation, broad material compatibility, minimal residue, and well-established public and regulatory acceptance ensure not only effective disinfection but also lower total costs across healthcare, food production, and public hygiene environments. Therefore, beyond its unmatched efficacy and safety, ethanol remains the most economically viable choice for widespread disinfection applications. Hazards and risks The assessment of the CMR toxicity of ethanol is based on experience from the misuse of alcoholic beverages, i.e. exclusively on oral intake. When used as a chemical, this is not relevant and does not play a role in occupational hazards, so these data are not suitable for classification as an industrial chemical or in consumer products. Typically, ethanol is used in the chemical industry

in denatured form to prevent oral uptake. Making regulatory decisions based on extrapolations from studies — which are unlikely to be realistic considering the actual use of a substance — to real-world scenarios, does not seem reasonable. If the purpose of the hazard identification and risk problem formulation questions is to understand the human health effects associated with chronic high-dose ethanol consumption, then such toxicity testing would indeed be appropriate. Conversely, if the purpose of the hazard identification and risk problem formulation is to address much lower exposures to ethanol in occupational and other environmental scenarios, then chronic toxicity testing based on very high doses is clearly not appropriate (Principles of dose-setting in toxicology studies: the importance of kinetics for ensuring human safety). When considering alternatives to ethanol-based disinfectants, propanols (such as isopropanol and n-propanol) are often cited as the primary potential substitutes. However, a closer examination reveals that the scientific basis for comparing ethanol's carcinogenicity, mutagenicity, and reproductive toxicity (CMR) potential to that of propanols is neither proportional nor scientifically justified. The REACH registration dossiers available through ECHA's chemical database (ECHA CHEM) indicate that for propanols, only a limited number of studies exist addressing the carcinogenicity endpoint. Moreover, these studies are largely based on dermal and inhalation exposure routes at doses typical for classical chemical testing protocols. Importantly, no substantial human epidemiological data are available to support or contextualize the findings for propanols. In contrast, ethanol has been subjected to an exceptionally extensive and rigorous body of research. Its CMR classification debates are predominantly informed by high-dose oral exposure studies — reflecting alcohol consumption levels far exceeding any conceivable exposure from its use in disinfectants. Furthermore, there is a substantial body of human epidemiological data, largely derived from decades of public health research into alcohol consumption, that informs ethanol's toxicological profile. This human data includes known confounding factors such as lifestyle, co-exposures, and comorbidities, which are absent from standard chemical risk assessments for other substances. Thus, ethanol's hazard profile, particularly its CMR concerns, is based on high-dose systemic oral exposure and chronic abuse, not on dermal or inhalation exposure at the levels relevant to its use in biocidal products. This contrasts sharply with the typical datasets available for other chemical substances. A proportional, scientifically sound risk comparison must consider the

	nature, quality, and relevance of the available data — not merely the formal existence of studies. Given that biocidal use of ethanol predominantly involves dermal exposure and inhalation of low vapour concentrations during brief applications, the extrapolation of high-dose oral ingestion data to these exposure scenarios is scientifically inappropriate. Conversely, the lack of comprehensive human-relevant data for other substances might leave significant uncertainty about their true long-term safety profile when used intensively, especially under the high-frequency hand hygiene protocols demanded in healthcare and food environments. Accordingly, any regulatory treatment that penalizes ethanol based on high-dose oral ingestion risks, while not treating other substances comparatively, constitutes a disproportionate and inconsistent application of scientific principles. A fair and scientifically justified regulatory assessment must weigh both the quality and relevance of the underlying evidence, including the realistic routes and levels of exposure in intended uses. In light of these considerations, ethanol remains the better-characterised, better-understood, and thus more reliably manageable active substance for widespread human hygiene applications, including hand disinfection. In addition, ethanol is safe for the environment: it mainly comes from renewable sources, it is fully biodegradable compared to its alternatives, it leaves no residue on surfaces, it evaporates quickly, and it is generally more sustainable than other options. Availability Ethanol benefits from a well-established supply chain with a robust network of suppliers across the EU. Additionally, ethanol production is more adaptable to demand surges, allowing for quicker scaling compared to the production of propan-1-ol or propan-2-ol, which was convincingly demonstrated during the COVID-19 pandemic. This makes ethanol not only more available but also a more reliable and practical option for meeting high-demand needs in critical sectors like healthcare. Ethanol was critical in combating COVID-19: it was widely available and cost-effective, unlike propanol and other alternatives. The industry was able to ramp up production and meet government requirements. In a world of geopolitical uncertainty and climate related disasters, ethanol-based hand disinfectants are a key tool in preventing the spread of disease in war torn and disaster areas, refugee camps and during rural outbreaks of deadly viruses such as Ebola when water and proper handwashing is inaccessible. Regulatory considerations The EU should move towards a more risk-based approach rather than a hazard-based approach in chemicals management. Europe places too much emphasis on hazards as the main driver for

	decision-making, to the point where it is questionable whether certain decisions are based on balanced and consistent scientific assessments. The competent body for the classification of substances is primarily the European Chemicals Agency's Committee for Risk Assessment (RAC), which is responsible for the harmonised classification and labelling process under the CLP Regulation. To avoid unnecessary confusion, ethanol should be allowed to complete its CLP process before its approval process under the BPR takes place. Therefore, we call for the current biocidal process to be concluded without reclassification or postponed until complete socio-economic assessment is conducted and the need for refined harmonized C&L for ethanol is properly assessed. Summary The use of ethanol as a disinfectant, as an industrial chemical and as part of consumer products is essential, safe and must be preserved! Annex I Additional information on the de facto ban Ethanol's reclassification means a de facto ban and would have massive consequences not only on European industry, but also on society as a whole, while not bringing any benefit to human health or the environment. The evaluation of the CMR endpoints and a subsequent decision on these endpoints by the BP Committee and European Commission would result in official statement on the CMR properties of Ethanol for Biocidal Uses. This available information would have to be taken into account by all users of Ethanol during their self-classification process. Thus, a classification within the Biocide sector would be transferred into all sectors. Additionally, this official position on the CMR properties could influence the opinion-forming process of other CLP committees and thus affect the currently ongoing harmonised classification process. For a substance meeting the criteria for carcinogenicity, regulatory obligations apply under the following regulations and directives (and there are more in the pipeline) - source: Fulfilling the criteria for CLP classification: the implications for substances under the EU chemicals legislation; Diana Kättström, Anna Beronius et al • Substances meeting the criteria for carcinogenicity may be added to Annex XIV of the REACH Regulation, which lists substances requiring authorisation (Article 57). Entries 28–30 of Annex XVII of the REACH Regulation impose a ban on the sale to the general public of substances classified as Category 1A or 1B carcinogenic, mutagenic, or toxic to reproduction, as well as mixtures containing such substances above a specified concentration limit (generally 0.1%). In addition, the placing on the market of tattoo inks containing Category 1A, 1B, or 2 carcinogens is restricted (Annex XVII entry 75). • Under the Biocidal Products Regulation and the Plant Protection Products Regulation,

	active substances classified as Category 1A or 1B carcinogens are generally not approved as active substances [Biocidal Products Regulation Article 5(1), Plant Protection Products Regulation Annex II point 3.6.3]. However, under certain circumstances and for a limited time, they may be approved as candidates for substitution [Biocidal Products Regulation Article 10(4), Plant Protection Products Regulation Article 24(1)]. For such substances, the Biocidal Products Regulation limits approval to a maximum of five years [Article 4(1)], and the Plant Protection Products Regulation to a maximum of seven years [Article 24(1)]. Biocidal products containing candidate substances must not be made available to the general public [Article 19(4)]. • According to the Prior Informed Consent (PIC) Regulation, the export of substances subject to the PIC procedure is prohibited if they are classified as Category 1A or 1B carcinogens [Article 14(7)]. • For industrial installations, the Industrial Emissions Directive requires the substitution of classified carcinogens with less hazardous substances as soon as possible (Article 58). • To protect workers, the Carcinogens and Mutagens Directive imposes obligations on employers to assess exposure to carcinogens, reduce the use of such substances, prevent exposure risks, and take necessary precautionary measures [Article 3(2), Article 4(1), Article 5]. Employers must also monitor workers' health, keep health records for at least 40 years, and notify the competent authority of any cancer cases arising from exposure to carcinogens [Articles 6, 10(1), 11, 14–16, 18]. • Similarly, the Chemical Agents Directive aims to protect workers' health by requiring employers to assess the presence of hazardous substances and the risks to health, and to implement preventive measures [Article 3(1), Article 4(1)]. Employers must make information available about hazardous substances, such as safety data sheets, and any necessary precautions or emergency procedures (Articles 7, 8, 10). • The Young Workers Directive prohibits employing workers under the age of 18 in jobs involving substances meeting any category of carcinogenicity criteria [Annex, entry 3(a)]. • The Pregnant and Breastfeeding Workers Directive requires employers to assess the exposure of pregnant women, women who have recently given birth, or breastfeeding workers to any category of carcinogens, and to take measures to mitigate risks [Annex I, entry 3(a)]. • Under the Regulation on Active and Intelligent Materials and Articles Intended to Come into Contact with Food, carcinogenic substances must not be used in material components designed to prolong shelf life or monitor food condition, even if not in direct contact with food [Article 5(c)]. • The Plastics and Materials Regulation

	restricts the use of carcinogens in multilayer plastic materials and articles made from different materials, even when there is no direct food contact (Articles 13, 14). • Substances classified as Category 1A or 1B carcinogens are prohibited in cosmetic products under the Cosmetics Regulation. Category 2 carcinogens are also prohibited unless an expert committee has assessed and deemed them safe (Article 15). • The In Vitro Diagnostic Medical Devices Regulation and the Medical Devices Regulation require that in vitro and medical devices be designed and manufactured so that levels of harmonised classified carcinogens are as low as possible (Annex I, entry 10). Additionally, the Medical Devices Regulation requires information about precautions related to the presence of carcinogens to be included in instructions provided to users/patients (Annex I, Chapters II and III). • The Toy Safety Directive prohibits the use of any substances classified as carcinogenic of any category in toys, toy parts, or components (Annex II, Chapter III, entry 3).
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	

Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Summary: Ethanol is the leading disinfectant for PT4 (food and feed area) applications due to its unmatched combination of rapid antimicrobial action, broad-spectrum efficacy, quick evaporation, surface compatibility, and safety for food contact. It prevents cross-contamination throughout the food chain—from farms to consumers—without leaving residues or requiring rinsing. Ethanol's effectiveness in dry environments, regulatory approval, and environmental sustainability make it indispensable for maintaining food safety, operational efficiency, and public trust, with no viable alternatives currently available.
Information above is confidential	
Justification for confidentiality	
Other comments	PT4 - Food and feed area disinfectant The use of PT4 disinfectants is indispensable for maintaining the highest hygiene standards within the food and feed sectors. Among the available active substances, none offer a suitable alternative to ethanol when considering the combination of its broad efficacy spectrum, rapid antimicrobial action, excellent safety profile, rapid evaporation, and regulatory acceptance for use on food contact surfaces. Ethanol's unique properties distinguish it clearly from all other available substances. Alternative disinfectants demonstrate notably limited virucidal activity compared to ethanol, particularly against non-enveloped viruses, which represent a significant challenge in food hygiene. Moreover, no available substitute matches ethanol's rapid evaporation profile. Substances such as propanols evaporate significantly more slowly, resulting in prolonged surface contact times—an undesirable feature in food and feed environments where surfaces must be rapidly disinfected and quickly returned to use to maintain uninterrupted operations. Restricting the use of ethanol-based disinfectants would pose a serious risk to food safety. Ethanol-based hand hygiene interventions are essential at the farm level, particularly in harvest areas where access to water and traditional handwashing facilities is limited. In such settings, ethanol-based products are critical to preventing the transfer of human-borne viral and bacterial

	pathogens, including Hepatitis A, Norovirus, and Salmonella, to ready-to-eat foods such as salads and berries. Throughout the food supply chain—from farms to distribution centres, processing facilities, retail outlets, and ultimately to consumers' tables—ethanol-based disinfectants play a crucial role in preventing cross-contamination. Their application at critical control points ensures that the integrity and safety of food products are preserved during every stage of handling, processing, and distribution. Within the food processing industry, ethanol is widely relied upon to minimise the risk of foodborne contamination. Its role is particularly vital in low-moisture food production, where it serves as the preferred surface disinfectant for facilities manufacturing highly sensitive products such as infant formula, dried dairy products, nuts, and cereals. Ethanol's advantage lies in its ability to maintain a dry cleaning cycle, which is essential to prevent the growth of pathogens such as <i>Cronobacter sakazakii</i>, <i>E. coli</i>, and <i>Salmonella</i>, while eliminating the risk of introducing moisture into sensitive production environments. In supermarkets, restaurants, and foodservice establishments of all sizes, ethanol-based disinfectants offer a fast and effective method for ensuring the hygiene of food contact surfaces in kitchens, deli counters, and meat preparation areas. Furthermore, their use extends to public areas, enabling the efficient disinfection of shopping trolley handles, cash register conveyors, and restroom facilities, thereby safeguarding both food handling environments and public health. Ethanol's unparalleled suitability for food and feed settings is further evidenced by its regulatory acceptance for use on food contact surfaces without requiring post-application rinsing. In contrast, many alternative disinfectants necessitate rinsing, adding operational complexity and increasing water consumption. Additionally, ethanol evaporates cleanly without leaving residues that could affect the taste, smell, or appearance of food, preserving the sensory qualities essential to consumer trust and satisfaction. Its rapid drying time is critical for maintaining operational efficiency, allowing food production and retail facilities to resume normal activities almost immediately after disinfection. Ethanol also poses minimal risk of harmful chemical residues, decomposing into harmless by-products such as water and carbon dioxide, in stark contrast to alternative disinfectants that may leave persistent and potentially harmful residues. Ethanol maintains its efficacy even in the presence of organic matter—such as blood, fats, or food debris—conditions where many oxidising agents lose their effectiveness. Its compatibility with a wide range of surfaces, including

	stainless steel, plastics, and delicate materials, without causing corrosion or degradation, reduces the need for multiple types of disinfectants across different settings, thereby simplifying hygiene management. Moreover, ethanol enjoys high levels of public trust and acceptance due to its widespread familiarity in products such as alcoholic beverages and sanitisers. This consumer confidence supports compliance with hygiene practices across the food and feed sectors. Its widespread local production from renewable sources further enhances supply chain resilience and contributes to environmental sustainability, aligning with the goals of the EU Green Deal and the broader transition to greener, circular economies. In light of these numerous advantages, ethanol remains a cornerstone of safe, effective, and sustainable hygiene practices throughout the food and feed production and distribution chain. No other substance matches its unique combination of efficacy, safety, operational practicality, environmental responsibility, and regulatory acceptance.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	ECHA public consultation_ethanol_EKTL input.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 255	2025/04/29 13:51
Country	Germany
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1

General information	Ethanol is being used as a comparably non-toxic solvent used for printing ink to print food-contact-materials (or other types of packaging material).
Product Type	1,2,4
Alternative Identity and Properties	Alternative solvents for solvent based printing are toluol, benzol, mineral oils, etc. which can be considered more toxic. Alternative printing ink systems with no need of solvents are not safer (photoinitiators etc.).
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Exchanging solvent based printing ink systems to other systems is very expensive (multiple double-digit-millions per machine).
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	See number 1.
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	We want to highlight the position of the German VCI (https://www.vci.de/themen/chemikaliensicherheit/einstufung-kennzeichnung/ethanol-einstufung-vci-position.jsp) which sums up our position very well. Due to the hazard-

	based (instead of risk-based) evaluation, as a society, we would lose an easy and sustainably produceable solvent which is comparably safe. Ethanol has undoubtedly toxic properties, but those arise first and foremost by significant oral abuse. Due to the principle of cross-referencing in EU regulation, a CMR classification (and the ensuing consequences) will lead to further problems which will ultimately result in the disappearance of ethanol as a practically usable chemical agent. An example for cross-referencing e.g. are design-for-recyclability requirements (which are an important part of the EU Green Deal) that would require to not use any hazardous chemicals, or that CMR substances are not permitted to be in food contact materials. So by the cross-referencing, even if this is not intended, an absolute prohibition of ethanol is reached within certain contexts.
Information above is confidential	
Justification for confidentiality	
Other comments	EU principle of cross-referencing creates more problems because of a CMR classification that might not have been foreseen (effect on sustainability/circularity and food-contact-material, etc.). Hazard based instead of risk based classification means that (comparably safe, considering their use-case) chemicals with well-rounded properties are pushed from the market to be replaced with unforeseeable replacements.
Information above is confidential	
Justification for confidentiality	
References	https://www.vci.de/themen/chemikaliensicherheit/einstufung-kennzeichnung/ethanol-einstufung-vci-position.jsp
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 256	2025/04/29 13:55
Country	Belgium
Name of organization/institution	EFPIA (European Federation of Pharmaceutical Industries and Associations)
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	
Product Type	1,2,4
Alternative Identity and Properties	PT2: Isopropyl alcohol (CAS no 67-63-0) (various conc mix with water) Mixture E (aminoethanol (CAS 141-43-5)/didecyldimethylammonium chloride (CAS 7173-51-5)/potassium carbonate CAS 584-08-7/fatty alcohol polyglycoether CAS 68439-49-6/isopropyl alcohol CAS 67-63-0) Mixture V : (pentapotassium bis(peroxymonosulphate) bis(sulphate) (CAS 70693-62-8)/ Benzenesulfonic acid, C10-13-alkyl derivs., sodium salts CAS 68411-30-3)/malic acid (CAS 6915-15-7)/ sulphamidic acid (CAS 5329-14-6)/ potassium hydrogensulphate (CAS 7646-93-7)/ dipotassium disulphate (CAS 7790-62-7)/sodium toluenesulphonate (CAS 12068-03-0)/ dipotassium peroxodisulphate (CAS 7727-21-1)/dipentene (CAS 138-86-3) To note that, as stated in the attachments in the public consultation, (analysis of alternatives): the use of isopropanol (IPA), Propan-2-ol), even if it might be able to provide similar technical properties, suffers from higher costs, limited supply chains, and limited efficacy against non-enveloped viruses, making them less practical for frequent surface disinfection.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	For PT1 human hygiene: GMP manufacturing of medicinal products: No alternatives for cleaning and disinfection when entering GMP zones. If alternative found, re-validation can take many years. For PT2: Disinfection of cell labs: So far, no alternative found that does not kill the cell lines. GMP manufacturing of medicinal products: Validated disinfecting/cleaning processes involve ethanol. If alternative found, re-validation can take many years.

	Currently ethanol cleaning and disinfection is part of licence to operate. Ethanol is part of the validated disinfection and cleaning methods for analytical instruments. Cannot be replaced for existing equipment. Ethanol is used as a disinfectant when working with genetically modified microorganisms. Currently no alternative identified. The validation standards are based on the context of use of ethanol. The feasibility of substitution depends on conducting new validation testing to ensure that the alternative preserves ethanol's essential chemical properties and functionality, maintaining its effectiveness in the specific applications and uses without introducing unintended consequences. General combined cleaning and disinfection of labs and offices: Products containing isopropanol are available on the market, but reluctant to use as more acute toxic than ethanol. Mixture E and mixture V have been tried but leave residues and can corrode steel surfaces.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	We endorse the PT economic impact analysis regarding the use of ethanol over other substitution: Ethanol emerges as the most economically viable option for PT2 applications due to: - Lower production costs and alignment with sustainability objectives. - Widespread availability and robust supply chain networks within the EU. - High cost-effectiveness, driven by its broad-spectrum efficacy, rapid action and adaptability, position it as the leading choice for surface disinfection across diverse settings. The alternatives (propan-1-ol, propan-2-ol, citric acid, and copper sulfate pentahydrate) are economically less favorable: Propan-1-ol and propan-2-ol suffer from higher costs, limited supply chains, and limited efficacy against non-enveloped viruses, making them less practical for frequent surface disinfection. L(+)lactic acid is not broadly effective against the full range of pathogens required for PT2 applications, limiting its suitability for these diverse environments. Given these factors, ethanol remains the most practical and cost-effective choice for PT2 surface disinfection, ensuring effective infection control. The research, qualification, supply and implementation factors of substituting ethanol would bring economic burden to pharmaceutical resources and bring resource constraints into investing in more critical alternatives R&D. Not only will there be no added benefit to workers, but it would be

	counterproductive to foster innovation in Europe. In terms of hazards and risks, ethanol and isopropanol have similar properties. However, ethanol evaporates faster, and as the main route of occupational exposure when used in PT2 is inhalation, workers will be exposed for a shorter time. By contrast, the mixtures tested as per above, are corrosive and toxic to aquatic life with long lasting effects. Ethanol has lower volatile organic compound (VOC) emissions compared to isopropanol, reducing air pollution and smog formation. Ethanol is often classified as "Generally Recognized as Safe" (GRAS) by the FDA, while isopropanol has more restrictions in food and pharmaceutical applications. "Isopropanol and n-propanol caused significant stratum corneum and keratinocyte perturbation in vitro together with damage to skin condition and function in vivo whereas ethanol did not. [...] Ethanol-based sanitizers are better tolerated by skin, particularly in high-use settings, than other alcohols and should be the active ingredient of choice." Ref: (Cartner T, Brand N, Tian K, Saud A, Carr T, Stapleton P, Lane ME, Rawlings AV. Effect of different alcohols on stratum corneum kallikrein 5 and phospholipase A2 together with epidermal keratinocytes and skin irritation. Int J Cosmet Sci. 2017 Apr;39(2):188-196. doi: 10.1111/ics.12364. Epub 2016 Sep 22. PMID: 27578266.) Both ethyl alcohol and isopropyl alcohol are flammable liquids which share similarities in their physicochemical properties (flash point, water solubility, boiling point) nonetheless one could find differences in evaporation rate, potency, auto-ignition temperature and material compatibility, limiting a 1:1 substitution. Although isopropanol has a narrower concentration range with regard to the formation of explosive alcohol-air mixtures, isopropanol has a decisive safety-related disadvantage. Like other secondary alcohols, 2-propanol can form explosive peroxides with atmospheric oxygen. In ten-year-old original containers of isopropanol, for example, a peroxide content of 1% was found. Peroxide concentrations of up to 4.2% have been reported. This has led to some serious accidents when distilling IPA to dryness. (BGChemie.de „Accidents due to peroxide-forming substances“).
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	

Information above is confidential	
Justification for confidentiality	
Availability	Ethanol can be produced from renewable sources (e.g., corn, sugarcane, or cellulosic biomass), making it more environmentally sustainable. Isopropanol, on the other hand, is derived from petrochemicals, which rely on fossil fuel extraction and hence not aligned with Europe sustainable development. We endorse the Analysis of Alternatives for use of ethanol for PT2 Section 6.1.6: Ethanol benefits from a robust and diversified supply chain with over 240 suppliers in the EU, ensuring reliability even during high demand. Alternative substances like isopropanol have significantly fewer suppliers, raising concerns about their ability to meet EU-wide demand, especially during crises. Ethanol's established supply chain and adaptability to demand surges make it a more reliable option for critical sectors like healthcare.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol is essential in pharmaceutical manufacturing, serving as not only an irreplaceable disinfectant but also at the pharmaceutical product level. It ensures product stability, shelf life, and manufacturability, with no viable alternative. A potential ban on ethanol due to its classification as a CMR substance under BPR would impact the medicinal products and medical devices', R&D and manufacturing, as well as manufacturing processes, by cascading consequences into overlapping frameworks (i.e. REACH). Currently, the classification proposal is only based on the hazard of ethanol ingestion. When the route of administration needs to be taken into account for hazard characterisation, Ethanol is used as safe and effective application on skin and surfaces. Restricting ethanol use would compromise hygiene, healthcare, and the protection of vulnerable populations, particularly in hospitals and during pandemics. Furthermore, exemptions would likely be ineffective due to regulatory burdens. To ensure a secure supply of disinfectants, cleaners, pharmaceuticals, medical devices, and IVDs to the population, as well as the production and delivery capacity of corresponding end products, we do not recommend substituting ethanol by any regrettable alternatives such as isopropanol. Classifying ethanol as a CMR substance for the inhalation and dermal

	route would far miss the purpose of the Biocidal Products and CLP Regulations, which is to improve human health. Instead, it would result in a significant deterioration in hygiene and healthcare.
Information above is confidential	
Justification for confidentiality	
Other comments	Acute Toxicity Isopropyl is not intended for human consumption and is toxic to ingest. Drinking even a small amount of rubbing alcohol can lead to severe health issues, including alcohol poisoning and organ damage. Ethanol in alcoholic beverages is intended for adult consumption in moderation. When consumed responsibly, it may provide some social and recreational benefits. However, excessive and irresponsible drinking can lead to health problems, addiction, and other negative consequences. Ingesting Isopropanol affects the central nervous system and can lead to coma, painful throat and airway burns, swelling, seizures, dangerously low blood pressure, and heart attack. Ethanol is a central nervous system depressant and can cause intoxication with symptoms such as slurred speech, sedation, and unsteadiness. Excessive alcohol consumption can lead to impaired judgment, motor skills, and coordination. When isopropyl alcohol is ingested, it is rapidly absorbed by the body, leading to a peak in blood levels between 30 minutes and 3 hours after ingestion. The body metabolizes isopropyl alcohol differently from ethanol, converting it into acetone. Acetone is a gastrointestinal irritant that can cause abdominal pain, nausea, vomiting, bleeding in the stomach and intestines, and even bladder rupture. Additionally, it triggers severe depression of the central nervous system, leading to dizziness, headaches, inebriation, and potentially coma. Rubbing alcohol is much more potent than ethanol found in alcoholic beverages. It is more intoxicating at comparable concentrations and more likely to produce impaired consciousness, dangerously low blood pressure, and even cardiopulmonary collapse if you drink rubbing alcohol. Drinking rubbing alcohol can lead to a range of life-threatening conditions, including internal bleeding, depressed cardiovascular function, shock, organ damage, and death.
Information above is confidential	
Justification for confidentiality	

References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 257	2025/04/29 13:58
Country	Poland
Name of organization/institution	BGW Sp. z o.o.
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Since 1990, BGW Sp. z o.o. has been developing its services by improving production processes. Initially, the company focused on the trade of liquid fuels and engine oils. Over the years, through continuous development and investments, the company expanded its offerings to include services such as eco-fuels, animal feed production, and excise duty consulting. However, the primary focus of our company became ethanol production.
Product Type	1,2,4
Alternative Identity and Properties	Ethanol is effective against viruses and can be combined with other alcohols to achieve a powerful synergistic effect against various microorganisms. Ethanol is a highly effective microbicide that can prevent infections in humans and animals when used as disinfectant on skin and contact surfaces, including those caused by nosocomial multi-resistant microorganisms. It is well tolerated by humans and most animals. It is produced from cereals with a low carbon footprint and is available worldwide. Ethanol is the only skin-compatible substance for humans and most animals that inactivates non-enveloped viruses. The only alternatives with similar antimicrobial efficacy and possibly similar tolerability are n-propanol and isopropanol. However, they do not have the ability to inactivate non-

	enveloped viruses. Therefore, general use of these two alternatives is in combination with ethanol to ensure the required antimicrobial efficacy in disinfectants for human hygiene. According to the Robert Koch Institute, no carcinogenicity, teratogenicity, or mutagenicity has been described for this combination, considering the type of exposure declared.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	n-Propanol and isopropanol are effective antimicrobial biocides. However, the Assessment of Alternatives by the Alcohol Task Force for all three product types in question (P1, PT2 and PT4) showed that there is, by far, no better alternative to ethanol for disinfection against non-enveloped viruses such as polio-, entero-, and noroviruses. Unlike ethanol, n-Propanol and isopropanol are not produced from renewable raw materials. They are a by-product of petroleum refining, where crude oil or natural gas is processed. Therefore, the carbon footprint of these products is very high compared to ethanol.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	During the COVID-19 pandemic, ethanol was the only product available in sufficient quantities, supplied by various sources, and the only sanitizer able to combat the Coronavirus and other non-enveloped viruses and hence ensure safety of patients, vulnerable populations, hospital staff, and the public. n-propanol and isopropanol are significantly more expensive (currently 50% above ethanol) and highly price volatile due to their limited availability (see below) and costly production process. During the Covid pandemic prices increased by 300-400% while ethanol price elevation of 50-80% had been experienced. The main reason for the price characteristics of n-propanol and isopropanol is the limited availability of fewer than 10 sources worldwide. As experienced during COVID- 19 pandemic, limited availability of n-propanol and isopropanol led to dramatic price increases. Therefore, restricting to these two alternatives would put governments worldwide under dramatic economic pressure in future endemic and pandemic situations, especially in developing countries

Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	The intention to classify ethanol as CMR is based solely on the description of dangerous misuse through ingestion via food and drink, while local topical application is considered safe. Ethanol is also a less toxic solvent compared to n-propanol and isopropanol. According to the safety data sheets, the oral LD50 in rats for the alternatives (n-propanol 1,870 mg/kg; isopropanol 4,570 mg/kg) is much lower than for ethanol (7,060 mg/kg). Hence, accidental oral intake of n-propanol and isopropanol disinfectants would be much more dangerous than that of ethanol.
Information above is confidential	
Justification for confidentiality	
Availability	n-Propanol and isopropanol are produced by fewer than 10 companies worldwide (including Shell, Ineos, Exxon). These are mainly petroleum giants that produce npropanol and isopropanol from by-products of petroleum refining, where crude oil or natural gas is processed. Thus, future overall availability and today's local procurement options are limited. The estimated annual production volumes of n-propanol and isopropanol in Europe are 100,000 tons and 700,000 tons, respectively. In comparison, 5 million tons of ethanol are produced in Europe per year. Ethanol can be sourced from over 100 producers in Europe alone. Since ethanol is plant-based, it is available worldwide in all regions. Furthermore, future availability is secured through renewable raw materials. As seen during the COVID-19 pandemic, only ethanol producers were able to flexibly and locally provide the additional quantities at short notice. Experts estimate the next pandemic to occur before 2030. It is unclear how the European population will manage disease prevention without ethanol as disinfectant, and hence how the European population would accept the decision of the EU Commission to ban ethanol as a CMR.
Information above is confidential	
Justification for confidentiality	

Conclusion on suitability and availability of the alternative	A CMR classification would have far-reaching negative consequences for hygiene, the economy and the environment. It would lead to substitution by petrochemically produced alcohols such as isopropanol or n-propanol, substances that are often more questionable from a toxicological point of view and whose ecological balance is significantly worse. As described, the possible alternative products are therefore not suitable to replace ethanol in terms of efficiency, availability, economic feasibility, sustainability, and safety. Furthermore, it cannot be ruled out that classification of the alternatives nPropanol and isopropanol as CMR could be justified. These factors apply beyond the human hygiene and health sector, particularly to the cosmetic industry. We strongly recommend refraining from classifying ethanol as CMR for the following reasons: 1. Ethanol must continue to be available for use in human hygiene as well as a standard ingredient in the cosmetic and chemical industry, as it has been established for millennia due to its advantageous properties mentioned above. 2. The classification is based on studies that have analyzed risks not associated with its use in human hygiene or cosmetic products. 3. The classification is, in our view, as described in point 2, illogical and could therefore reduce the acceptance of EU institutions and European goals in terms of sustainability, independence, competitiveness, and reduction of bureaucracy. 4. It would lead to higher costs and threaten the industry, while no positive effect for human hygiene or health in general would be achieved.
Information above is confidential	
Justification for confidentiality	
Other comments	The intended classification of ethanol as CMR is based on data not suitable for assessing the risk of its use in human hygiene. Carcinogenicity, reproductive toxicity, and possibly mutagenicity have only been demonstrated when ethanol was abusively and extensively ingested, while topical local application has been proven to be safe. Studies show that even under extreme conditions of dermal or inhalation exposure, only minimal amounts of ethanol were absorbed, which are considered harmless from a toxicological point of view. Ethanol has a comparatively low toxicity and is indispensable in numerous applications due to its unique properties. On the other hand by the current standards of evaluation CMR would probably also be demonstrated for n-propanol and isopropanol if the effects of ingestion by humans could be evaluated to the same extent. However,

	ethanol is likely the only microbicide that also exists as an ingredient in food and beverages in higher concentrations. It is also important to stress that for technical or most other uses, except for drinking alcohol, denatured ethanol is supplied and used, which is not suitable for drinking and therefore not comparable to drinking alcohol. The CMR classification of ethanol threatens the existence of hundreds of products and companies along the value chain of ethanol-containing products in the European Union, since CLH-obligation will not only apply on biocides. It would increase bureaucratic efforts, costs, and dependence on producers from third countries. For ethanol as an odorless and skin-friendly solvent and preservative, there is no sustainable, cost-effective, and easily manageable replacement in terms of occupational safety.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

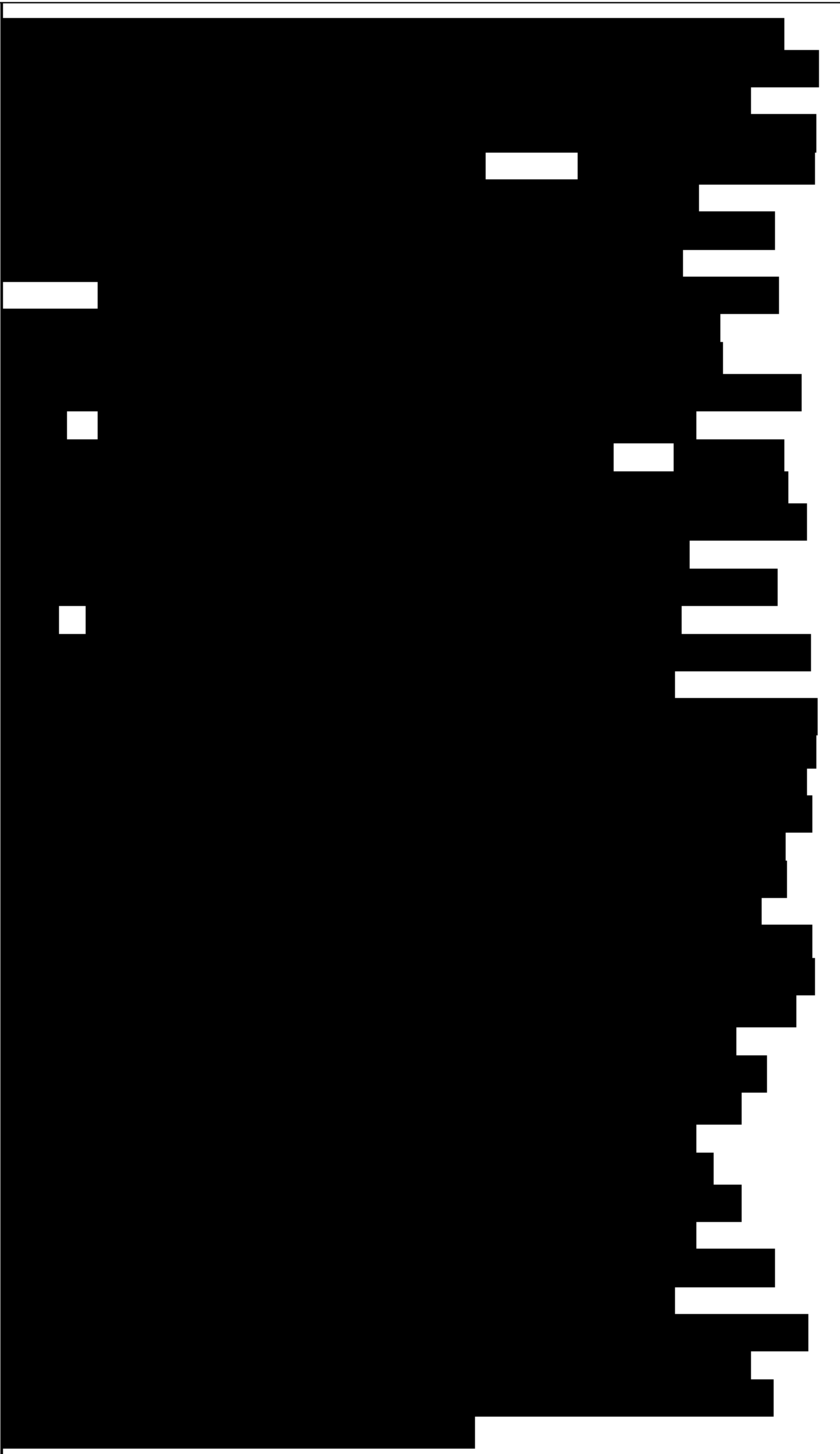
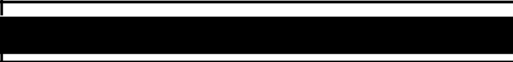
Comment 258	2025/04/29 13:58
Country	Slovenia
Name of organization/institution	Association of Chemical Industries of Slovenia
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	
Product Type	1,2,4

Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Please see attachment.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	

References	
Attachments (non-confidential information)	KPČ input ETANOL _april2025.docx
Attachments (confidential information)	
Justification for confidential attachment	

Comment 259	2025/04/29 14:06
Country	Germany
Name of organization/institution	Dyckerhoff Pharma GmbH & Co. KG
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Dyckerhoff Pharma GmbH & Co KG is a family-owned pharmaceutical company (SME) with manufacturing of starting materials for multipurpose use, e.g., active pharmaceutical ingredients, medicinal products and cosmetics. Dyckerhoff Pharma manufactures these products for own purposes and based on contract manufacturing. Dyckerhoff Pharma is member of the association of pharmaceutical companies "Pharma Deutschland" and we refer to the statement of Pharma Deutschland. We provide company specific information in chapter 6. Other Comments and 7. Conclusion on suitability and availability of the alternative and summary. During pandemic Dyckerhoff Pharma was able to manufacture ethanol disinfectant for use in production and for infection protection of employees since it was not available on the market. Due to the access to own ethanol production the manufacturing was maintained during pandemic. Since Dyckerhoff Pharma also manufactures medicinal products which are listed under drug shortages in Germany a CMR classification/ CLH evaluation would have negative impact on the availability of these products.
Product Type	1,2,4

Alternative Identity and Properties	See statement "Pharma Deutschland"
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	See statement "Pharma Deutschland"
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	See statement "Pharma Deutschland"
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	There is no alternative substance available for the above-mentioned needs that meets the requirements for manufacturing of starting material, pharmaceutical substances, medicinal products and cosmetics. Additionally, there is no alternative that provides the same efficacy against microbiological contamination. Ethanol is environmentally sustainable.
Information above is confidential	
Justification for confidentiality	

Other comments	
Information above is confidential	
Justification for confidentiality	

References	See statement "Pharma Deutschland"
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 260	2025/04/29 14:37
Country	Netherlands
Name of organization/institution	Centraal Bureau Drogisterijbedrijven
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	CBD is concerned about the impact of the possible classification of ethanol as carcinogenic and/or reprotoxic (CMR) category 1 under the Biocidal Products Regulation (BPR) on the availability to consumers of necessary products (biocides) for hygiene and pest control/insecticides. Ethanol is used either as active substance or a co-formulant in these biocidal products. In this context, CBD requests the EC to identify the direct and indirect consequences of these classifications before the EC decides on the approval of ethanol under the BPR. A CMR classification of ethanol without considering the potential exposures has far-reaching consequences that may compromise public health because of the important role ethanol plays in biocidal products for consumers. Alternatives to ethanol are not readily available because ethanol generally cannot be substituted 1-to-1 because of its diverse functionality. If there are no substitutes, CBD fears the accessibility of necessary biocides to consumers.
Product Type	1,2,4
Alternative Identity and Properties	N/A

Information above is confidential	
Justification for confidentiality	
Technical Feasibility	N/A
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	N/A
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	N/A
Information above is confidential	
Justification for confidentiality	
Availability	N/A
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	N/A
Information above is confidential	
Justification for confidentiality	
Other comments	N/A
Information above is confidential	
Justification for confidentiality	
References	

Attachments (non-confidential information)	ECHA consultation.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 261	2025/04/29 14:46
Country	Germany
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	We welcome the opportunity to comment to ECHA's consultation on potential candidates for substitution for ethanol. We are a company producing flavours to be used in food, cosmetics and tobacco applications. We are using ethanol in the manufacture of extracts and as solvent in flavour applications. The hand disinfectant products for our workers contain 50 % ethanol.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	

Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Declaring ethanol a potential candidate for substitution will have a high impact on workers safety with regards to hand sanitizers. A harmonised classification within CMR hazard class(es) as follow-up would have serious consequences for other industries with significant impact on consumer products.
Information above is confidential	
Justification for confidentiality	
Other comments	Use of ethanol in biocides Biocides - The use of ethanol in hand disinfectant products is beneficial for the workers as it is one of the few substances that are fully virucidal and efficient against non-enveloped viruses such as noroviruses and polioviruses. It has a well-documented safety profile. Its rapid evaporation, leaving no residue, contributes to ease of use and thus to workers' safety. Use of ethanol in the manufacture of flavouring substances Manufacture and purification of extracts – ethanol is used as a solvent in manufacture of extracts. It can solubilize a unique combination of constituents or impurities that is difficult to extract or to remove with other solvents, e.g. hexane, 2-propanol, acetone or water. Examples for such specific extracts with a wide range of use are absolues (manufacturing process) and washed oils (removal of waxes being an impurity). It is relatively easy to remove compared to solvents such as water or propylene glycol. Remaining solvent residue is acceptable as ethanol is an approved

	extraction solvent for all uses under Directive 2009/32/EC (Annex I), an authorised flavouring substance (FI No. 02.078) within the Union List of Flavouring substances, under Commission Implementing Regulation (EU) No 872/2012. It is authorised for use in all categories of flavoured food. Additionally, it is not listed in Annex II of the cosmetics regulation (Regulation (EC) No 1223/2009). Use of ethanol in flavours Flavour use - The use of ethanol as solvent in flavour applications is known and applied for centuries. It is one of the solvents enabling hydrophobic flavours to be mixed in a hydrophilic matrix. Compared to other possible solvents, it has a relatively weak taste and smell that – if used in respective concentrations in the final mixture – is perceived as acceptable by consumers. Contrary to other flavour approved solvents like propylene glycol, it doesn't have restrictions on the maximum concentration level per application. Other solvents or additives might not have the same versatility in applications, industrial use experience or sensory profile, or they might not be approved in all required applications. REACH registrations of ethanol containing extracts Many of the extracts used in applications relevant to Title II of the REACH regulation (e.g. cosmetics) are REACH registered as UVCB substance. The extraction solvent is part of the substance identity profile of the UVCB. If an extract still containing ethanol as one of its constituents above the limit for mixture classification does not fall under the exception of CLP Article 5(6), it will be classified as CMR due to the ethanol residue. Such a classification would render an extract unusable in tobacco and cosmetics applications, and, with regards to REACH restrictions 28, 29 and 30 in Annex XVII of the REACH regulation in most consumer products as well. Additionally, an ethanol-containing extract not being classified as CMR due to CLP Article 5(6) cannot be used in flavour mixtures as freely after classification of ethanol as CMR substance, as the ethanol content would nonetheless contribute to classification of these mixtures. To circumvent these problems of ethanol-containing extracts, alternative extracts with a different solvent could be manufactured. They would have a different substance identity. The registration dossier of the ethanol-containing extract would have to be reworked to re-register these new non-ethanol-based extracts, putting an additional strain on industry. Impact of the classification of ethanol Recognizing ethanol as a potential candidate for substitution is usually followed by a harmonised classification in the appropriate hazard classes and categories. There is an ongoing CLH intention by Greece. Declaring ethanol as a potential candidate for substitution in Biocides might influence this or another

	process to classify in a CMR subcategory 1B or 1A. A CMR classification of ethanol in one of the subcategories 1A or 1B would have serious consequences in multiple legislations: Food flavours – ethanol classified as CMR substance would lead to pressure from customers to remove the ethanol content as much as possible, leading to reformulation of thousands of flavour formulations within the industry. As said above, specific extracts such as absolues and washed oils (removal of waxes as impurity) would be impossible to use due to such customer demand. That would reduce the range of available flavours in foodstuffs considerably. Cosmetics – ethanol as solvent would be impossible to use, and extracts such as absolues are not usable in cosmetic products if the ethanol content is above the minimum achievable limit – as clarified by the substance definition in Article 1(b) of Regulation (EC) No. 1223/2009 in combination with Article 17 of the same regulation. Other consumer applications – presence of ethanol in e.g. fragranced household products above the limit for classification of the mixture as CMR 1A or 1B would invoke REACH restrictions 28, 29 or 30 (Annex XVII of Regulation (EC) 1907/2006) and prevent these mixtures to be sold to end-users. This will extremely diminish the range of e.g. scents available to consumers as well as the number of ethanol-containing products on the market. Tobacco – ethanol as solvent would be forbidden by Article 7(6)(e) of Directive 2014/40/EU. The number of allowed solvents for tobacco flavours with an acceptable sensory profile for users of tobacco and alternative products would be diminished. Biocide – ethanol would not be available as active substance in hand disinfectants, reducing the already low number of substances effective against non-enveloped viruses that have a similar ease of use by fast evaporation and leaving no residues. Industry having REACH registered UVCB substances containing ethanol – although extracts containing ethanol above the mixture classification limit could be exempt from classification as CMR by CLP article 5(6), their use in consumer products, regulated under diverse legislations as outlined above, will be significantly diminished if ethanol was classified as CMR. Consequently, alternative UVCB substances for these uses, manufactured without ethanol, have to be found. Creating and submitting REACH registrations for all these alternative substances will put a significant strain on industry.
Information above is confidential	
Justification for confidentiality	

References	
Attachments (non-confidential information)	Ethanol_comment_2025-04-29.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 262	2025/04/29 15:02
Country	Sweden
Name of organization/institution	Bröderna Berner AB
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Ethanol is the cornerstone of infection prevention control. During COVID-19 pandemic ethanol was required all over the world to save lives and enable normal life as we know it. Currently AMR (Antimicrobial resistance) is one of the biggest challenge for humans according to WHO. Hygiene measures including ethanol disinfectants in healthcare settings are cost-effective and practical and WHO recommended procedures to prevent AMR and deaths that it causes. In addition, in a world of geopolitical uncertainty, the healthcare sector has to be well equipped with effective hygiene products. Ethanol CMR properties exist via oral route, it has been known for ages. Disinfectants are not for drinking, the ethanol containing chemicals are additionally denaturized to prevent misuse.
Product Type	1,2,4
Alternative Identity and Properties	The only potential alternatives are 1-propanol and 2-propanol. Like ethanol, they are H225 flammable liquids. Like ethanol, 2-propanol is H319 eye irritant, but 1-propanol is worse, H318 eye damaging. Propanols are also H336 drowsiness or dizziness causing substances. Propanols are not effective against non-enveloped viruses like noro, adeno and polio, while ethanol is effective. Propanols evaporate slower than ethanol, so they stay longer on skin leading to

	longer dermal exposure. It is also a harm for a healthcare worker to wait for a hand rub to dry longer. And the most important thing: there is not enough data on propanol hazards via oral route, since it has not been drunk loads as ethanol has been drunk during ages. It is known that propanols are acutely more dangerous to human health via oral route than ethanol. Assessing the chemistry of alcohols, propanols should also be classified as CMR substances via oral route.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Propanols are H336 drowsiness or dizziness causing substances, this has to be considered during manufacturing the products.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Propanols are more expensive than ethanol and propanols are not widely available like ethanol is. The effect on raw material cost would be millions euros for a mid-size company. The increasing cost would be finally allocated for the healthcare sector and consumers.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Propanols as alcohols would have at least the same CMR effects via oral route (once it would have been investigated in detail) as ethanol. Propanols are not effective against non-enveloped viruses. Propanols would increase the cost of disinfection. This would obviously lead to reduced hygiene measures. At the end we would have less effective products with propanols, they wouldn't be better for human health, and they would cost more and be less sustainable. Hygiene would decrease, AMR would increase, and we would get more diseases and deaths.
Information above is confidential	
Justification for confidentiality	

Availability	Propanols are manufactured from non-renewable fossil resources, while ethanol is mostly manufactured from renewable, sustainable sources. Propanols are not widely available, and it is expensive compared to ethanol.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	The only potential alternatives are 1-propanol and 2-propanol. Propanols are not effective against non-enveloped viruses like noro, adeno and polio. Propanols as alcohols would have at least the same CMR effects via oral route (once it would have been investigated in detail) as ethanol. At the end we would have less effective products with propanols, they wouldn't be better for human health, and they would cost more and be less sustainable. Hygiene would decrease, AMR would increase, and we would get more diseases and deaths.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 263	2025/04/29 15:06
Country	Germany

Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	Due to the matter of act that Ethanol is a widely spread solvent with numerous applications the amount of Ethanol being produced is about several factors higher than Propanol or Iso-Propanol (2-Propanol). Due to this fact the availability as a raw material for disinfection was given all over Europe. Propanol or Iso-Propanol (2-Propanol) would not have been available in a sufficient amount.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	

Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	A classification as CMR cat 1 or 2 would have serious implications in worker's safety requirement in terms equipment and personal. This can motivate to move industrial production of e.g. pharmaceuticals to outer Europe on the one hand, on the other hand this will not motivate to set up pharmaceutical production in Europe. This will not support the efforts for "crisis preparedness" in Europe.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 264	2025/04/29 15:18
Country	Germany
Name of organization/institution	
I do not wish the name of my organisation/institution to be	1

published on the ECHA website.	
General information	In food and beverage industry and in agriculture, Ethanol is mainly used for hand disinfection (max. 1 min.). For this application, it is crucial that the active substance has the following properties: - fast mode of action - not irritant to the skin - easy handling - suitable for ecological production (suitable for FiBL, Demeter, Bioland,...) - broad efficacy spectrum - no candidate of substitution (e.g. DCP, iodine/PVP-iodine) - no CMR (CAT 1 + 2) (e.g. OPP, hydrogen peroxide) - no residues on the skin after disinfection (e.g. lactic acid, QAC, active chlorine generated from sodium hypochlorite) - no allergie (e.g. chlorocresol)
Product Type	1,2,4
Alternative Identity and Properties	1. peracetic acid 2. CHDG 3. 2-Phenoxyethanol 4. nPA 5. IPA
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	1. Generally peracetic acid is an alternative for ethanol. It is effective against bacteria, fungi and viruses. But in the concentration range the pungent odour of peracetic acid is perceptible. For many users this is not acceptable. 2. CHDG is much less effective against bacteria, fungi and viruses compared to ethanol. Also CHDG is difficult to formulate in products. 3. Generally 2-Phenoxyethanol is an alternative for ethanol. Compared to ethanol it is not active against any viruses. 4.+5. Generally nPA and IPA is an alternative for ethanol, but nPA and IPA are not effective against non-enveloped viruses.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Generally, the costs of the other active substances listed are in the final application much cheaper compared to ethanol (excl. IPA/nPA, which are more expensive than ethanol).
Information above is confidential	
Justification for confidentiality	

Hazards and Risks of the Alternative	Generally, the hazards and risks of the marketed products should be the same compared to ethanol based products.
Information above is confidential	
Justification for confidentiality	
Availability	1. At the moment no products with peracetic acid are approved under BPR for PT 1 2. CHDG is not approved yet. Therefore the future is not clear. 3. 2-phenoxyethanol is not approved yet. Therefore the future is not clear. 4. nPA / IPA are available. In case of a pandemic outbreak there will be an increased demand for the alternatives, thus it is essential to maintain a high range of suitable substances to prevent any shortages in the availability. Like for example for the foot and mouth disease full virucidal products are required and here ethanol would be the only active substance for hand disinfection.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Based on the information above, only other alcohols (IPA and nPA) can be regarded as suitable alternatives for ethanol. However, the main advantage of ethanol is its full virucidal efficacy. Especially during an outbreak it is crucial to have a fast working, easy to handle disinfectant with virucidal activity available. This can be observed at the moment concerning the outbreak of the foot-and-mouth-disease (FMD) in Hungary and Czech Republic. Therefore personal hygiene (hand disinfection) with full virucidal efficacy (ethanol) is essential in all areas in the food and beverage industry and in agriculture to protect human and animals from infections. Additionally, ethanol is produced from renewable resources which is an important aspect for the European Green Deal. Therefore, ethanol is indispensable in the food and beverage industry and agriculture.
Information above is confidential	
Justification for confidentiality	
Other comments	The five mentioned alternatives are suitable for ecological production (e.g. FiBL, Demeter, Bioland). Furthermore,

	QACs are politically banned in many production companies, especially in the dairy food chain in Germany.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 265	2025/04/29 15:25
Country	Netherlands
Name of organization/institution	Kimberly - Clark B.V.
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Ethanol (CAS No 64-17-5) is widely used as a biocidal active substance in various disinfectant products, including those for human hygiene. Maintaining ethanol's approval under the Biocidal Products Regulation is crucial for ensuring hygiene standards, making it vital for public health in the EU.
Product Type	1,2,4
Alternative Identity and Properties	Ethanol remains the preferred substance for our product due to its superior efficacy, broad availability, and favorable formulation properties. While propan-2-ol has been identified as a potential alternative, it does not fully match the efficacy of ethanol, particularly against a broad-spectrum activity that includes bacteria, fungi, and viruses (enveloped and non-enveloped) under short contact time like 30 sec. Therefore this analysis will focus on propan-2-ol as an ethanol alternative. 2-phenoxyethanol and Propan-

	1-ol are perceived negatively by the consumers for skin care products therefore those substances are not alternative for us. Other already approved PT-1 substances are lacking efficacy for viruses that is crucial for our products.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Switching from ethanol to propan-2-ol would necessitate significant reformulation efforts. Ethanol currently supports multiple formulation type including liquid, foam, wet wipes, gel. This change would impact other raw materials in the formulation, requiring adjustments to ensure correct pH and viscosity. Comprehensive laboratory tests would be needed to assess efficacy, physical properties, stability, and technological requirements. Additionally, manufacturing processes would need to be adapted, and personnel trained to handle the new substance and any new raw materials. The estimated cost for reformulation is a hundreds of thousands of euros per formula. Ethanol is essential to prevent or control a danger to human health, animal health, or the environment, especially due to its broad efficacy against viruses.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Propan-2-ol, while already approved, does not serve as a true alternative to ethanol. The regulatory approval process involves substantial costs, including authority fees, letters of access, and new data requirements, hundreds of thousands of euros. Furthermore, propan-2-ol is less widely available than ethanol, potentially increasing formulation costs. Not approving ethanol would have a disproportionate negative impact on society compared to the risk arising from its use. It is expected that due to rising costs of energy, fees, and reformulations, propan-2-ol products will end up more expensive than ethanol. Based on pandemic experience, every household in the EU should be able to buy disinfectants if needed.
Information above is confidential	
Justification for confidentiality	

Hazards and Risks of the Alternative	Propan-2-ol is not classified as a Carcinogenic, Mutagenic, or Reproductive toxicant (CMR), which is a positive aspect of this substance. However, hazard properties is not the most effective parameters for comparing alternatives. Since the authorization of a biocidal active substance is based on its specific uses and risk- based approach, not hazard itself.
Information above is confidential	
Justification for confidentiality	
Availability	The availability of propan-2-ol is limited compared to ethanol, showed by comparison of Article 95 sources, which may result in higher costs for formulations containing propan-2-ol. If ethanol is not approved, it is estimated the active substance will be significantly reduced due to lower production for non-biocidal uses. If a pandemic like COVID-19 occurs again, the EU will be unprepared and will have to rely on chemicals sourced from outside the region. Based on pandemic experience, every household in the EU should be able to buy disinfectants if needed, most common today is ethanol-based or make their own according to the WHO formula, if needed. This won't be possible if ethanol is not approved.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Given the technical, economic, and availability challenges associated with available alternatives, ethanol remains the most viable substance for our product. The extensive reformulation costs, regulatory hurdles, and limited availability of alternative substances, further support the continued use of ethanol. According to the Article 5 of CLP The identified information must be examined to ensure it is adequate, reliable, and scientifically valid for the purpose of hazard evaluation. Using data from drinking to support CMR classification shouldn't be allowed as it is not related to substance reasonable use for hand disinfection and dermal absorption. Therefore, not approving ethanol would have disproportionate negative impact on its essential role in health and safety, compared to low risk associated with ethanol use for hand disinfection.
Information above is confidential	

Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 266	2025/04/29 15:27
Country	Germany
Name of organization/institution	CG Chemikaliengesellschaft mbH & Co. KG
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	We sell Ethanol as a disinfection product. High demand during pandemic situations.
Product Type	1,2,4
Alternative Identity and Properties	Denatured Ethanol is also used for technical applications e.g. windshield washer fluid in Automotive industry worldwide.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	No alternative with comparative efficacy.

Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Disinfection with high performance.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Misuse is avoided by denaturation. For specific species other alcoholic disinfections are not as effective as ethanol.
Information above is confidential	
Justification for confidentiality	
Availability	In case of high demand (pandemic) all sources must be available.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	No substitute for disinfection against the relevant species is available for PT1. Use of Ethanol (cleaning/solvent) in industrial area is crucial
Information above is confidential	
Justification for confidentiality	
Other comments	Additionally, Ethanol is available from renewable sources.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	Public Consultation ECHA EtOH_CG Automotive.pdf
Attachments (confidential information)	

Justification for confidential attachment	

Comment 267	2025/04/29 15:29
Country	Sweden
Name of organization/institution	Kemisk Tekniska Företagen, KTF
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Kemisk Tekniska Företagen, KTF, är en branschförening för företag som bland annat sätter desinfektionsmedel, rengöringsmedel och kosmetiska produkter på den svenska marknaden, både för professionellt och privat bruk. Etanol berör alla våra branscher eftersom det är en oundgänglig ingrediens i en rad olika konsument-, yrkes- och industriprodukter, särskilt i desinfektionsmedel och rengöringsmedel. ETANOLENS EGENSKAPER OCH BETYDELSE Etanol har en snabb, antimikrobiell funktion med bred effekt och en gynnsam exponeringsprofil i alla desinficerande formuleringar, vilket alternativa ämnen saknar. Det är effektivt mot bakterier, svampar och virus, och detta på mycket kort kontaktid. Dess användning i biocidapplikationer – både som handdesinfektionsmedel och som ytdesinfektionsmedel – är avgörande för att upprätthålla folkhälsan, särskilt inom vård och omsorg. En omklassificering skulle begränsa dessa användningar och skulle medföra betydande påverkan på människors hälsa och säkerhet. Över 3,5 miljoner fall av vårdrelaterade infektioner (HAI) uppskattas inträffa varje år inom EU/EES, vilket leder till över 90 000 dödsfall. Etanol är rekommenderat av WHO och är känt som det mest effektiva ämnet i kampen mot vårdrelaterade infektioner, samt det enda verksamma ämnet mot virus som t.ex. polio. Etanol är huvudsakligen baserat på förnybara resurser och är fullständigt biologiskt nedbrytbart. Det lämnar inga skadliga rester på ytor och avdunstar snabbt och är generellt mer hållbart än andra alternativ, vilket sammantaget gör det till ett förstahandsval inom desinfektionsmedel. Etanol är även en säker och viktig ingrediens i olika rengörings- och hushållsprodukter. Ämnet har viktiga lösningsegenskaper som behövs i rengöringsprodukter: det är ett mycket effektivt lösningsmedel som hjälper till att lösa upp smuts,

	fett och organiskt material på olika ytor. Detta gör etanol till en oumbärlig ingrediens i rengöringsmedel som är avsedda för krävande rengöringsuppgifter i kök, badrum och andra områden. I många användningsområden saknas ersättningar, eller så är de mindre effektiva: • När det gäller vårdrelaterade infektioner finns inget alternativ till etanol för bekämpning av polio och andra icke-höljeförsedda virus. • Inget annat ämne matchar etanols effektivitet, hudtolerans och säkerhetsprofil för handhygien vid patientnära vård. Andra ämnen är kända för att torka ut och irritera huden. Avsaknaden av ett effektivt alternativ kan leda till ökade infektionsfrekvenser och högre vårdkostnader. • Etanol var avgörande i bekämpningen av COVID-19; det var allmänt tillgängligt och kostnadseffektivt, till skillnad från andra alternativ. Industrin kunde snabbt öka produktionen och möta myndigheternas krav. I en värld präglad av geopolitiska osäkerheter och klimatrelaterade katastrofer är etanolbaserade handdesinfektionsmedel ett viktigt verktyg för att förebygga spridning av sjukdomar i krigsdrabbade och katastrofområden, flyktingläger och vid utbrott av dödliga virus. RISKER MED OMKLASSIFICERING En ändring i klassificeringen skulle påverka folkhälsan negativt, leda till ökade sjukvårdskostnader och försvåra tillgång till viktiga desinfektionsmedel. En omklassificering av etanol innebär i praktiken ett förbud och skulle få enorma konsekvenser inte bara för den europeiska industrin, utan även för samhället i stort, utan att medföra några fördelar för människors hälsa eller miljön. Även med ett eventuellt undantag för vissa applikationer kommer tillgången på etanol att begränsas kraftigt. Samhället kommer att behöva hantera en rad oavsiktliga konsekvenser eftersom en klassificering får följdverkningar i många andra regelverk inom EU och i nationella lagstiftningar. SAMMANFATTNING OCH UPPMANING KTF menar att den föreslagna omklassificeringen av etanol bygger på felaktiga antaganden; den utgår från effekterna efter oralt intag av höga doser, det vill säga baseras på data om negativa effekter av överdriven alkoholkonsumtion. Detta speglar inte den typiska användningen av etanol i biocidprodukter och kemiska produkter. Det tar heller inte hänsyn till riskhanteringsstrategier som industrin använder för att säkerställa säkra produkter, såsom denaturering av etanol för att förhindra förtäring av produkter som innehåller etanol. Upptaget av etanol genom hudkontakt eller inandning är försumbar och kan snarare jämföras med intaget av etanol i icke-alkoholhaltiga livsmedel, såsom apelsinjuice där etanol förekommer naturligt. KTF uppmanar de europeiska myndigheterna att ta hänsyn till

	etanolens avgörande roll för folkhälsan, vårdkostnader och den ekonomiska stabiliteten. En klassificering bör baseras på verkliga exponeringsscenarier vid normal användning av kemiska produkter och desinfektionsmedel. Vid en felaktig klassificering riskerar vi försämrade folkhälsa, försämrade konkurrenskraft och betydande negativa konsekvenser för samhället. Vi uppmanar till att pausa processen för att noga utreda konsekvenserna av en omklassificering innan beslut fattas.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	

Conclusion on suitability and availability of the alternative	PT1 – Desinfektionsmedel för mänsklig hygien Etanolbaserade handdesinfektionsmedel är oundgängliga för infektionsförebyggande åtgärder, både på sjukhus och i människors dagliga liv. Det finns inget alternativ som kan ersätta etanol och som har ett lika effektivt skydd mot icke-höljeförsedda virus såsom norovirus, enterovirus och adenovirus, men även mot höljeförsedda virus såsom SARS-COV-2. Etanol inaktiverar effektivt ett brett spektrum av patogener inom sekunder, vilket minskar kontakttider och produktanvändning och därmed effektiviserar arbetsflödet i kritiska miljöer som t.ex. inom sjukvård. PT2 – Desinfektionsmedel och algicider som inte är avsedda att användas direkt på människor eller djur För användning av PT2-produkter – särskilt i miljöer med ofta berörda ytor som sjukhus (desinfektion av möbler, väggar och golv) och industriella miljöer samt – finns inga andra PT2-aktiva substanser som är lämpliga alternativ till etanol. Andra alkoholer såsom propanoler uppvisar begränsad effekt på virus jämfört med etanol (särskilt mot icke-höljeförsedda virus). Oxiderande medel som perättiksyra, som visserligen har ett bredare effektivitetspektrum, är korrosiva och kräver därför användning av personlig skyddsutrustning (PPE) och begränsar dess användning på grund av risken att skada ytan på materialet. PT4 – Desinfektionsmedel för ytor som kommer i kontakt med livsmedel och djurfoder Användning av PT4-desinfektionsmedel är oundgänglig för att säkerställa en hög hygienstandard inom livsmedels- och foderbranschen. Att begränsa användningen av etanolbaserade desinfektionsmedel skulle innebära en risk för livsmedelssäkerheten. Inga andra PT4-aktiva substanser är lämpliga alternativ till etanol när man beaktar dess kombinerade fördelar vad gäller effektivitetspektrum, snabb antimikrobiell verkan, säkerhetsprofil och snabb avdunstningsförmåga. Potentiella alternativ uppvisar en begränsad effektivitet mot virus jämfört med etanol.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	

Attachments (non-confidential information)	Etanol synpunkter från KTF 2025-04-29.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 268	2025/04/29 16:06
Country	Germany
Name of organization/institution	IKW - Industrieverband Körperpflege- und Waschmittel e.V.
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Der Kompetenzpartner Schönheitspflege des Industrieverbands Körperpflege- und Waschmittel e. V. (IKW) unterstützt, berät und vertritt die über 350 Mitgliedsunternehmen in Deutschland, welche teilweise oder ausschließlich kosmetische Mittel herstellen und/oder vertreiben, wobei ein Großteil dieser Unternehmen aus KMUs besteht. Insgesamt ergibt sich so ein Marktvolumen im Bereich der Schönheitspflege innerhalb Deutschlands von über 16,9 Milliarden Euro mit einem zusätzlichen Exportvolumen von 9 Milliarden Euro. Alkoholhaltige Desinfektionsmittel sind immer wichtig, wenn bei der Herstellung von Produkten, wie auch bei kosmetischen Mitteln, ein hoher hygienischer Anspruch im Mittelpunkt steht. Ethanol (Alkohol) ist ein sicherer und wichtiger Inhaltsstoff in der Kosmetik. In kosmetischen Mitteln wird er beispielsweise als Lösungsmittel und aufgrund seiner antibakteriellen Eigenschaften in unterschiedlichsten Konzentrationen verwendet. So unterstützt Ethanol als rasch verdunstendes Lösungsmittel zum Beispiel in Deos das Gefühl von Frische und sorgt bei Haarsprays für eine besonders feine Verteilung der Wirkstoffe auf dem Haar. In vielen Mundwässern ist Ethanol zwecks einer antibakteriellen Wirkung oder als Lösungsvermittler enthalten. In Abschminkprodukten hilft der Stoff bei der Entfernung von Make-up oder sonstigen fetthaltigen Rückständen. Ohne die spezifischen lösenden Eigenschaften von Ethanol könnten viele ätherische Öle und Duftstoffe in

	kosmetischen Mitteln und Parfums nicht genutzt werden. Eine mögliche Einstufung von Ethanol als CMR-Stoff (CMR: krebserregend (C), mutagen (M), reproduktionstoxisch (R)) hätte für die Verwendung dieses Stoffes auch in kosmetischen Mitteln weitere gravierende Folgen: Eine CMR-Einstufung im Biozidrecht beeinflusst die Einstufung im Chemikalienrecht. Aufgrund der direkten Verknüpfung des Kosmetikrechts mit dem Chemikalienrecht wäre der Einsatz von Ethanol in kosmetischen Mitteln nach der erfolgten Einstufung verboten. In Folge dürfte dieser wichtige Stoff kurzfristig nicht mehr in kosmetischen Mitteln verwendet werden. Der neue Einstufungsvorschlag als CMR-Stoff bezieht sich auf die grundlegenden Stoffeigenschaften von Ethanol und beruht auf den beobachteten Effekten bei einer übermäßigen oralen Aufnahme. Das in kosmetischen Mitteln eingesetzte Ethanol ist vergällt, d.h. für den menschlichen Verzehr unbrauchbar. Somit ist das Risiko eines übermäßigen oralen Verzehrs unwahrscheinlich. Im Rahmen einer für jedes kosmetische Mittel erforderlichen Sicherheitsbewertung wird die Sicherheit des individuellen Produktes auch unter Betrachtung u. a. der Exposition von einem eigens dafür verantwortlichen Sicherheitsbewerter bewertet. Auch bei vergleichsweise hohen Einsatzkonzentrationen von Ethanol in einigen kosmetischen Mitteln, wie zum Beispiel in Parfums, ist die Exposition des Verbrauchers in aller Regel sehr gering, selbst bei einer oralen Anwendung kosmetischer Mittel wie beispielsweise über Mundwässer. Nach Ansicht des IKW ist es deshalb essenziell, die Gefahreneinstufung von Ethanol nach der CLP-Verordnung von seiner laufenden Bewertung als biozider Wirkstoff zu trennen, da die CMR-Einstufung aufgrund der rein chemischen Stoffeigenschaften von Ethanol bei oraler Aufnahme erfolgt, die für die kosmetische Verwendung nicht relevant ist.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	

Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Mangel an geeigneten Alternativen Ethanol erfüllt mehrere Funktionen, ein Einsatz alternativer Produkte ist dadurch nur teilweise durch die Verwendung komplexer Lösungen möglich. - Lösungsmittel: Ethanol löst verschiedene kosmetische Inhaltsstoffe und verbessert die Produktleistung - Flüchtigkeit: Ethanol trägt zum Verbrauchererlebnis bei, indem es für ein Frischegefühl sowie für eine feine Verteilung der Wirkstoffe sorgt - Antimikrobielle Eigenschaften: Ethanol besitzt inhärente antimikrobielle Eigenschaften und trägt somit zu einem geringeren Einsatz von Konservierungsmitteln und zur mikrobiellen Stabilisierung von Produkten bei. Eine CMR-Einstufung von Ethanol würde zum Verlust eines wichtigen, gut verträglichen und biologisch abbaubaren Inhaltsstoffs von kosmetischen Mitteln führen. Dem Konsultationsbeitrag unseres Europäischen Dachverbandes Cosmetics Europe stimmen wir vollumfänglich zu.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	

Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 269	2025/04/29 16:14
Country	Belgium
Name of organization/institution	Copa-Cogeca
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Consultation Response on Ethanol – Biocidal Use (ECHA Public Consultation) _____ 1. General Remarks We appreciate the opportunity to provide feedback on the ongoing public consultation launched by the European Chemicals Agency (ECHA) concerning the classification of ethanol as a candidate for substitution under the Biocidal Products Regulation (Regulation (EU) No 528/2012 – BPR). While we acknowledge the importance of protecting public health, animal welfare, and the environment, we would like to warn about the consequences of a non-approval of ethanol as a biocide, as it could lead to severe and disproportionate consequences across multiple sectors of society. _____ 2. Disproportionate Societal Impact Ethanol plays a critical role in a broad range of sectors, including: • Healthcare: medical disinfectants, surgical sterilization, hand sanitizers • Food and Hospitality: surface cleaning, hygiene in kitchens, catering, and food manufacturing • Cosmetics and Personal Care: perfumes, deodorants, oral hygiene • Agriculture and Animal Care: hygiene and disinfection in livestock and veterinary contexts • Public

	Services: schools, elderly care, emergency response A non-approval would likely restrict or prohibit the use of ethanol in many biocidal applications. This would pose serious challenges to hygiene, public health, and food safety, while also significantly increasing costs and regulatory burdens for businesses and public institutions. 3. Relevance of Article 5(2) of the Biocidal Products Regulation According to Article 5(2) of the BPR, active substances that would normally not be approved due to their hazardous properties may still be approved if non-approval would lead to disproportionate negative impacts on society compared to the risk posed by the use of the substance. Furthermore, the same article highlights the need to consider the actual availability of effective and technically and economically feasible alternatives. In the case of ethanol, it is currently irreplaceable in many disinfection applications due to its proven efficacy, availability, cost-effectiveness, and low environmental persistence. We therefore urge ECHA and the competent authorities to carefully evaluate: • the essential nature of ethanol for public health and food safety; • the absence of viable alternatives in many applications; • the broader societal costs of restricting ethanol use. 4. Conclusion and Recommendation We respectfully call on ECHA and the evaluating Member States to: • ensure a balanced, science-based, and use-specific risk assessment; • apply the derogation mechanisms under Article 5(2) where applicable; • and avoid regulatory decisions that may jeopardize hygiene, health, and safety across sectors without offering realistic alternatives.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	

Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol plays a critical role in a broad range of sectors, including: • Healthcare: medical disinfectants, surgical sterilization, hand sanitizers • Food and Hospitality: surface cleaning, hygiene in kitchens, catering, and food manufacturing • Cosmetics and Personal Care: perfumes, deodorants, oral hygiene • Agriculture and Animal Care: hygiene and disinfection in livestock and veterinary contexts • Public Services: schools, elderly care, emergency response A non-approval would likely restrict or prohibit the use of ethanol in many biocidal applications. This would pose serious challenges to hygiene, public health, and food safety, while also significantly increasing costs and regulatory burdens for businesses and public institutions. Conclusion and Recommendation We respectfully call on ECHA and the evaluating Member States to: • ensure a balanced, science-based, and use-specific risk assessment; • apply the derogation mechanisms under Article 5(2) where applicable; • and avoid regulatory decisions that may jeopardize hygiene, health, and safety across sectors without offering realistic alternatives.
Information above is confidential	
Justification for confidentiality	

Other comments	Consultation Response on Ethanol – Biocidal Use (ECHA Public Consultation) _____ 1. General Remarks We appreciate the opportunity to provide feedback on the ongoing public consultation launched by the European Chemicals Agency (ECHA) concerning the classification of ethanol as a candidate for substitution under the Biocidal Products Regulation (Regulation (EU) No 528/2012 – BPR). While we acknowledge the importance of protecting public health, animal welfare, and the environment, we would like to warn about the consequences of a non-approval of ethanol as a biocide, as it could lead to severe and disproportionate consequences across multiple sectors of society. _____ 2. Disproportionate Societal Impact Ethanol plays a critical role in a broad range of sectors, including: • Healthcare: medical disinfectants, surgical sterilization, hand sanitizers • Food and Hospitality: surface cleaning, hygiene in kitchens, catering, and food manufacturing • Cosmetics and Personal Care: perfumes, deodorants, oral hygiene • Agriculture and Animal Care: hygiene and disinfection in livestock and veterinary contexts • Public Services: schools, elderly care, emergency response A non-approval would likely restrict or prohibit the use of ethanol in many biocidal applications. This would pose serious challenges to hygiene, public health, and food safety, while also significantly increasing costs and regulatory burdens for businesses and public institutions. _____ 3. Relevance of Article 5(2) of the Biocidal Products Regulation According to Article 5(2) of the BPR, active substances that would normally not be approved due to their hazardous properties may still be approved if non-approval would lead to disproportionate negative impacts on society compared to the risk posed by the use of the substance. Furthermore, the same article highlights the need to consider the actual availability of effective and technically and economically feasible alternatives. In the case of ethanol, it is currently irreplaceable in many disinfection applications due to its proven efficacy, availability, cost-effectiveness, and low environmental persistence. We therefore urge ECHA and the competent authorities to carefully evaluate: • the essential nature of ethanol for public health and food safety; • the absence of viable alternatives in many applications; • the broader societal costs of restricting ethanol use. _____ 4. Conclusion and Recommendation We respectfully call on

	ECHA and the evaluating Member States to: • ensure a balanced, science-based, and use-specific risk assessment; • apply the derogation mechanisms under Article 5(2) where applicable; • and avoid regulatory decisions that may jeopardize hygiene, health, and safety across sectors without offering realistic alternatives.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 270	2025/04/29 16:20
Country	Germany
Name of organization/institution	mre-netz regio rhein-ahr
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Über mre-netz regio rhein-ahr Das mre-netz regio rhein-ahr wurde 2010 gegründet und ist ein überregionaler Zusammenschluss von 10 Gesundheitsämtern in den Bundesländern Nordrhein-Westfalen und Rheinland-Pfalz. Es ist ein Infektionsschutznetzwerk, das das Management von multiresistenten Erregern und anderen Infektionserkrankungen koordiniert. Ziel ist eine Harmonisierung im Umgang mit Präventionsmaßnahmen bezüglich Infektionserkrankungen. Dabei arbeitet es mit allen Akteuren von medizinischen Gesundheitseinrichtungen zusammen, sehr eng auch mit allen regionalen Krankenhäusern und Pflegeeinrichtungen. Einsatz von ethanolhaltigen Händedesinfektionsmitteln Hände sind das Übertragungsvehikel Nr. 1 von Erregern. Die

	Händedesinfektion stellt die wichtigste Maßnahme der Infektionsprävention dar, die mit der höchsten Evidenz belegt ist. Dabei ist der Hauptwirkstoff von Händedesinfektionsmitteln Alkohol und hierbei zu einem erheblichen Teil Ethanol. Ethanol hat nachweisbar eine viruzide, bakterizide, fungizide und tuberkulozide Wirksamkeit. Vor allem für unbehüllte Viren stellt Ethanol eine unverzichtbare Substanz dar. Ethanol als Händedesinfektionsmittel stellt kein relevantes Gesundheitsrisiko bei sachgerechter Anwendung dar. Ebenso erfolgt keine nennenswerte Resorption von Ethanol über die Haut. Ethanolbasierte Händedesinfektionsmittel sind zudem ein wichtiger Faktor bezüglich der Krisenresilienz. Eine Bewertung von Ethanol in Händedesinfektionsmitteln auf Basis seiner Wirkung bei oraler Ingestion ist nicht nachvollziehbar, da die Auswirkungen bei oraler Aufnahme sehr verschieden im Vergleich zur Nutzung als Händedesinfektionsmittel sind.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	

Justification for confidentiality	[REDACTED]
Technical Feasibility	[REDACTED]
Information above is confidential	[REDACTED]
Justification for confidentiality	[REDACTED]
Economic Feasibility	[REDACTED]
Information above is confidential	[REDACTED]
Justification for confidentiality	[REDACTED]
Hazards and Risks of the Alternative	[REDACTED]

Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Alkoholische Händedesinfektionsmittel sind in der Infektionsprävention unerlässlich und nehmen den höchsten Stellwert ein. Es gibt aktuell keine geeigneten Alternativen für Ethanol als Wirkstoff für Händedesinfektionsmittel, v.a. für unbehüllte Viren. Ein Verbot von Ethanol und die Substitution durch weniger geeignete Substanzen hätte daher für die Infektionsprävention außerordentlich schwerwiegende Folgen. Es ist davon auszugehen, dass europaweit die Zahl an Infektionserkrankungen, inklusive Ausbrüchen, ansteigen würde. Dies könnte verlängerte Hospitalisierungsraten sowie gesteigerte Mortalitätsraten zur Folge haben. All das würde zudem zu höheren Kosten für betroffene Einrichtungen und die Gesellschaft führen. Zudem ist nicht nachvollziehbar, warum die Bewertung von Ethanol als Biozid unabhängig vom Weg der Aufnahme erfolgt. Ethanol als Wirkstoff in Händedesinfektionsmitteln wird nur in nicht relevanter Menge über die Haut aufgenommen und ist somit in keiner Weise vergleichbar mit der oralen Aufnahme von Ethanol in Getränken.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	

Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 271	2025/04/29 16:26
Country	Italy
Name of organization/institution	Caviro Extra SpA
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Caviro Extra has produced Agricultural derived Ethanol for more than 40 years. Different feedstocks are used, each separately, in the fermentation process: wine by-products (grape marc and wine lees), cereals, sugar beet, sugar cane are the main common. Each one has agricultural origin, although the first one is also a “2nd Generation” Ethanol, as it comes from a byproduct/waste. Depending on the different specs, origin, process of production, Ethanol can have different destinations: • Industrial: it’s the widest spectrum of final destinations, as it can varies from cosmetic, to solvent (for ink, but also for active principles in pharma industry), sanitizing or cleaning agent, etc. • Food: all the most common spirits have food grade ethanol as their base. But also industrial bakery fopr conservation and special preparations with fruits. • Fuel: ethanol can be used as it is, in direct blend with gasoline (up to 10% in the common EU enigines), but also can be processed to obtain ETBE. If the Ethanol comes from “food feedstock”, then it is considered “1st Generation”, while if it derives from a by-product (like the one coming from grape marc or wine lees) the nit is considered “2nd generation”. Both kinds can be sustainable according to the amount and type of energy used in the

	process of production. In Italy the main feedstock for ethanol production is wine-related by-products. Italy, with more than 40 million liters of wine produced every year, is one of the biggest producers in Europe, besides France and Spain. Distilleries such as Caviro Extra play a major role in the wine economy because the recovery of ethanol from the by-products let the circular economy model effectively take place, helping also the farmers with the final revenue of their efforts, sharing with them part of the added value. Caviro Extra spa is indeed 100% controlled by Caviro Group, one of the biggest reality, not only in Italy, of wine market. In addition to this, the most advanced sustainability models can be applied to ethanol production, using also the residue biomass for the production of the renewable energy involved in the process. With this configuration, ethanol with a GHG Saving of more than 90% can be obtained. For all the uses above, Ethanol is the only 100% natural alternative. With its variety of possible uses, Ethanol becomes the most versatile choice. As regarding possible alternatives to Ethanol, we have to distinguish the different sectors. For food (wine, beer, spirits in general) the only option is to eliminate entirely the alcohol content. This solves the issue for the food itself, but creates a new stream of alcohol which can be used, mostly, in the fuel sector. Speaking of which, there are different renewable fuels, such as biodiesel and HVO, but Ethanol (direct or as ETBE) is the only one compatible with gasoline fueled engines (Hybrid ones, too). In the end, regarding industrial use, Ethanol is the best alternative also as a biocide, both for human hygiene and for sanitizing surfaces. We have to think at the Covid-19 period, where huge amounts of biocide were essential to prevent and contain the contagion: ethanol has been a quick and appropriate answer to that need.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	

Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Propan-1-ol and propan-2-ol can be two alternatives as a biocide, but they are both deriving from a synthesis process with crude oil as a raw material. Only a few big oil companies in the world produce propanol and its price is widely affected by oil and energy worldwide market. Propanol doesn't have the immediate availability of ethanol, but, above all, it doesn't have the same effectiveness as a biocide. Propanol is in fact not active against particular encapsulated viruses, where instead ethanol proved its efficacy during the pandemic period. Propanol has mainly the same risk characteristics as ethanol, especially concerning flammability (Class 2 both). As a biocide, skin contact and possible inhalation have the same risks for both. Propanol is then more difficult to find, to purchase, the price is highly volatile and it's not sustainable (oil origin). Ethanol has a more stable price, but above all it can give a substantial help to all local wine industries. Propanol is a base chemical like thousands of other substances produced only by a few big oil companies. Our company is aware of the situation of propanol market, because we purchase it to mix it with ethanol in 1-5% proportion to denaturate the ethanol (with other different substances) to prevent this "biocide" ethanol to go on the food market. In conclusion, assessing the risk of cancerogenity with the use of ethanol, also for skin contact and inhalation, would provoke a big damage not only to the biocide sector, but to all other sectors mentioned above, because there will be no real substitute, but on the other hand the new assessed

	characteristics of ethanol will force producers and users to make big investments to handle it.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 272	2025/04/29 16:38
Country	France
Name of organization/institution	Fédération des entreprises de la beauté (FEBEA)
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	FEBEA is the French professional trade association of cosmetic product manufacturers (including perfumes, makeup, skincare, hygiene, toiletry, and haircare products). It promotes the initiatives and commitments of a high-performing, responsible, and contributing cosmetics industry. It advocates for the interests of the cosmetics sector with public authorities, the economic and scientific community, and civil society. FEBEA wishes to stress the significant implications of classifying ethanol as a Carcinogenic, Mutagenic, and/ or Reproductive toxicant (CMR) substance and urges a comprehensive review of the

	balance between negative and positive consequences of CMR classification of ethanol, particularly concerning its downstream uses in the cosmetics sector. This document outlines the potential disruptions, lack of consumer benefit, additional regulatory burdens, and strategic considerations for EU policymakers and the European Chemicals Agency (ECHA). Ethanol used in cosmetic products is denatured, i.e. unfit for consumption. By that alone, a consumer risk of (regular or excessive) oral consumption is negated and any CMR property assigned to ethanol as pure chemical substance, based on oral intake, would not be relevant to cosmetic use. FEBEA believes that it's crucial to detach the hazard classification of ethanol (harmonized classification under the CLP) from its ongoing evaluation as a biocidal active substance. FEBEA therefore represents interests of French companies with the national authorities as well as with the European authorities through Cosmetics Europe (European Federation of Cosmetic Industries) as member. As such, FEBEA fully shares the position expressed by Cosmetics Europe during the present consultation.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	

Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Lack of Suitable Alternatives Ethanol serves multiple functions in cosmetics that cannot be easily replaced by a single ingredient: • Solubilizing Properties: Ethanol dissolves various cosmetic ingredients and enhances product performance. • Volatile Properties: It contributes to consumer experience by providing freshness and reducing stickiness. • Antimicrobial Activity: Ethanol's inherent antimicrobial properties allow less use of preservatives and contribute to disinfecting functionality of products.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 273	2025/04/29 16:55
Country	Germany
Name of organization/institution	Ecolab Deutschland GmbH

I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	
Product Type	1,2,4
Alternative Identity and Properties	There are no viable alternatives to ethanol based biocidal products owing to various attributes of ethanol including but not limited to its wide spectrum efficacy, speed of action, availability, economic feasibility, compatibility, biodegradability, no residue and more. See our detailed comments in section 6 and 7.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	

Conclusion on suitability and availability of the alternative	Ecolab, a manufacturer of biocides, including ethanol-based hand and surface disinfectants for use across the healthcare, food and pharma sectors, strongly believes the classification proposal of European Biocidal Authorities goes against the fundamental BPR principles of protecting human health and making Europe a safer place. Society relies on ethanol-based hand sanitizer and disinfectants because they are effective, and they keep us safe. This was made painfully obvious during the COVID-19 pandemic, and it remains true to this day. See our comments in section 6 on safe use of ethanol and the reasons why no alternatives exist on the market today that could replace ethanol in the many ways that it is used to protect public health and food safety. It will also describe why the use of data on oral consumption of alcoholic beverages for classification purposes is a flawed approach to determining the fate of ethanol as a biocidal active substance. Proceeding with the classification of ethanol as a CMR substance will result in significant harm as well as erode the trust invested to date by EU citizens in European and national Authorities responsible for safeguarding human health and food safety.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	ETHANOL BASED BIOCIDAL PRODUCTS ARE SAFE ALL humans are exposed to low levels of ethanol in daily life. Ethanol is produced endogenously in the intestines of nearly all individuals, albeit at doses not comparable to consumption of alcoholic drinks. The microflora of the digestive tract converts carbohydrates into ethanol and carbon dioxide (gas) under anaerobic conditions. In addition, we take up ethanol at low levels via our normal diet. A high variety of food and beverages contain low doses of ethanol, resulting in a continuous alimentary low dose uptake of ethanol. According to a recent review of WHO collaboration centre on patient safety and the commission for hospital hygiene and infection prevention (KRINKO), Robert Koch Institute, Germany, the increase in blood alcohol levels after using ethanol-based hand disinfectants is comparable to an increase after consumption of beverages with hidden alcohol content (approx 0.5 % v/v) such as apple juice or non-alcoholic beer. Average values of

	1.41 g/l in vegetable juices, 3.03 g/kg or g/l in instant meals, soups or sauces, 8.61 g/kg in jam and 18.11 g/kg in sweets like marzipan and filled chocolate have been detected in non-alcoholic food and beverages (Reimann et al. 2023). A study with 1557 participants revealed physiological blood ethanol levels in the absence of alcohol consumption with a median value of 0.4 mg/L up to a maximum value of 35.2 mg/L (Al-Awadhi et al. 2004). PBPK (Physiologically Based Pharmacokinetic) modelling of a high frequency application rate of ethanol-based hand rubs 7 times per hour resulted in a blood alcohol concentration of 3.9 mg/L which is in the physiological range of blood ethanol levels (Maier et al. 2015). Ethanol is currently the predominant biocidal active when it comes to hand sanitizers sold to the general public in the European Union. With respect to potential acute effects upon accidental ingestion, 2-propanol is twice as potent when it comes to the function as CNS (central nervous system) depressant compared to ethanol. For 1-propanol, the ED50 value for narcosis in rabbits was approximately four times lower than for ethanol. The acute oral toxicity of ethanol is lower compared to that of 1-propanol and 2-propanol (~ 15.000 mg/kg bw compared to values between 4000 and 7000 mg/kg bw as described in the BPR active substance dossiers). Considering that hand sanitisers are not used at high frequency rates by the general public, it can be expected that the internal ethanol burden will remain unchanged when ethanol-based skin disinfectants are used. Considering in addition, the low acute toxicity potential of ethanol, it can be concluded that a classification of ethanol as CMR substance will result in the loss of a safe, accessible and affordable biocidal active for the general public. It can be concluded that during the common usage of ethanol based biocidal products the ethanol blood levels remain comparable to ethanol exposure from non-alcoholic food sources and therefore ethanol based biocidal products pose no risk to human health. PT1 - Loss or restriction of ethanol weakens the EU's response to future pandemics putting EU citizens at unnecessary risk This month, April 2025, saw an historic agreement between member countries of the World Health Organization to work together on future pandemics and other emerging threats (Press release: WHO Member States conclude negotiations and make significant progress on draft pandemic agreement) Infectious agents do not respect country boundaries, borders or regulatory rules and as seen by the devastating effects of COVID-19 all countries must work together to protect the health of our global population. The loss or severe restriction of ethanol prior to the next pandemic, health emergency or natural disaster

	creates a great deal of risk for the people affected. Ethanol is the WHO's gold standard of hand hygiene and plays a vital role in both emergency response and in clinical settings to break the chain of infection. Ethanol was used widely across the globe to prevent the spread of COVID-19 but was also used extensively during Ebola outbreaks, in refugee camps and following the growing number of severe weather events and natural disasters that have occurred this century. Restricting the access of ethanol in the EU may not only prolong or worsen these types of events but also sends a mixed message to the public who have a familiarity and trust in the substance as a tool for infection prevention. The message that other countries and regions will be protected but EU will not, will be a difficult one to convey to the public and may result in unsafe practices as citizens attempt to protect themselves. Infectious agents do not respect country boundaries, borders or regulatory rules and as seen by the devastating effects of COVID-19 all countries must work together to protect the health of our global population. The loss or severe restriction of ethanol prior to the next pandemic, health emergency or natural disaster creates a great deal of risk for the people affected. Ethanol is the WHO's gold standard of hand hygiene and plays a vital role in both emergency response and in clinical settings to break the chain of infection. Ethanol was used widely across the globe to prevent the spread of COVID-19 but was also used extensively during Ebola outbreaks, in refugee camps and following the growing number of severe weather events and natural disasters that have occurred this century. Restricting the access of ethanol in the EU may not only prolong or worse these types of events but also sends a mixed message to the public who have a familiarity and trust in the substance as a tool for infection prevention. The message that other countries and regions will be protected but EU will not, will be a difficult one to convey to the public and may result in unsafe practices as citizen attempt to protect themselves. Ethanol has been used for centuries as a substance known to kill germs. As far back as Egyptian times, palm wine was used to both clean and protect wounds from infection and as an embalming fluid. In the modern world ethanol-based products are used extensively in many sectors where fast acting, broad biocidal activity and low residues are needed. From hand sanitizers and surface disinfectants in fast food restaurants and supermarkets to disinfection of equipment to manufacture of lifesaving drugs ethanol has many lesser known but critical uses. In many of these cases ethanol is irreplaceable due to its unique combination of technical properties. PROPOSED CMR CLASSIFICATION IS A FLAWED APPROACH

	As part of the evaluation of ethanol as biocidal active substance, it has been concluded that ethanol meets conditions of BPR Article 10(1), exclusion criteria pursuant to Article 5(1): – 5(1) (a) criteria to be classified as carcinogen category 1A or 1B and 5(1)(c) criteria to be classified as toxic for reproduction category 1A or 1B. A classification of ethanol, driven by data on adverse effects from drinking alcoholic beverages contradicts the formal requirements for hazard classification as defined by Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation). According to Article 5 of the CLP Regulation, classification must be based on the forms and physical state in which a chemical can be reasonably expected to be used. Alcohol consumption is not a form in which ethanol can be expected to be reasonably used when formulated and sold as a biocide or as ingredient in other chemical mixtures. The intended classification does not reflect possible hazards associated with a biocidal use of ethanol for PT-1, PT-2 or PT-4. Epidemiological data on adverse effects from drinking alcohol and data from animal tests carried out at test doses well above the limit dose defined in OECD test guidelines and the CLP regulation to mimic ethanol exposure levels reached only by drinking alcohol are not considered relevant for classification purposes under CLP. The CLP guidance document (Guidance on the Application of the CLP Criteria Part 3: Health Hazards Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP of substances and mixtures Version 5.0 November 2024) states for single exposure target organ toxicity category 3 (narcosis effects) and repeated exposure target organ toxicity that data on "deliberate exposure (i.e., abuse) is unlikely to provide sufficient robust evidence to support classification without other evidence as they do not mirror realistic exposure conditions". This includes case reports from accidental over-exposure situations (page 231 and page 255). Data on alcohol consumption which leads to high peak blood alcohol concentrations which cannot be reached via the dermal and inhalation route of exposure during the use of ethanol containing biocides are not considered to provide robust evidence of possible hazards of ethanol when used as chemical substance. A single alcoholic drink (standard amount of 12 g ethanol) leads to a peak blood concentration of ~ 250 mg/L in a 70 kg adult. In contrast, maximum concentrations measured in blood after surgical and hygienic hand disinfection were between 20 to 30 mg/L under exaggerated, non-realistic use conditions (20 hygienic hand disinfections, application of 4 ml each time over a time period of 30 minutes and 10 surgical hand disinfections, 200

	ml (20 ml each time) hand rub applied over a period of 80 minutes) (Kramer, 2007). In summary, data on toxicological effects of chronic alcohol consumption are not considered relevant for the use of ethanol as biocidal active substance which results only in low internal exposure via the skin and inhalation. Exposure via the oral route in toxicologically relevant doses (drinking of ethanol-based biocides) can be ruled out, as ethanol is typically denatured to prevent this misuse scenario. CMR CLASSIFICATION WILL RESULT IN SIGNIFICANT HARM The main objective of the BPR (EU 528/2012) is to improve free movement of biocidal products while ensuring high level of protection of both human health and the environment. The proposed classification would fail the European Union in delivering either of these objectives. - o Protection of human health EU hospitals and other public institutions rely on Ethanol for hand disinfection and surface disinfection. Ethanol is the only active substance that is effective against enveloped, as well as non-enveloped viruses. The role that Ethanol played during COVID pandemic can't be overstated. The absence of effective hand rubs against non-enveloped viruses such as norovirus, adenoviruses, and enteroviruses D68 and 71 (which are not vaccine-preventable) poses significant public health risks (reference: GMS Hygiene and Infection Control 2024, Vol. 19, ISSN 2196-5226). Currently. There are no alternatives that are as effective as Ethanol against viruses. Outside of clinical settings, ethanol hand disinfectants are relied upon in the daily life by the general public. Ethanol hand disinfectants are affordable, accessible, easy to use and trusted as biocidal products by families across Europe. In particular, hand washing with soap and water can be inaccessible in many situations and therefore Ethanol based hand disinfectants provide the security of infection prevention when hand washing is not possible. These products protect the general public from viruses like Norovirus and Influenza and bacteria such as Salmonella and Staphylococcus aureus that are often in circulation in communities or through food. A classification as a CMR Cat 1 would mean that these products will be forced off the market and general public would lose access to an important chemistry that they rely on today. - o Impact on movement/supply/competitiveness of biocidal products containing Ethanol within and outside of Europe A decision to classify ethanol will eliminate the option for Union authorisation thus creating a patchwork of authorisations and restrictions across the EU. The biocidal industry of the European Union would become less competitive if proposed changes are implemented. While there is no universal tracking tool, it's estimated that the EU

	ethanol market is worth around EUR 9.54 billion, with a forecast of EUR 13.65 billion by 2030. Significant portion (up to 20%) of this is used in biocidal applications. A CMR classification would severely restrict the supply flexibility and availability of Ethanol in Europe as the suppliers would be reluctant to adopt such classification and thereby prioritise supply in other regions outside of the EU. This would also result in higher cost to source Ethanol for essential uses. NATIONAL LEGISLATION IMPACT – Worker safety In the European Union national worker safety legislations are in place to protect workers, including pregnant or breastfeeding woman from health hazards. The implied classification of ethanol as CMR Cat 1 can be considered to equal a ban of ethanol as biocidal active by the workforce, especially for its use as hand sanitizer in the healthcare sector as important tool in infection prevention. Employers would have to apply the so-called STOP principle (substitution, technical measures, organizational measures, personal protective equipment) in a tiered approach and substitute ethanol containing products with a less hazardous substance in a first step wherever possible. Work-place monitoring of ethanol exposure limits would be obligatory to control strict adherence to occupational exposure limits. Furthermore, extensive health surveillance activities, training and information, individual risk assessments, definition of emergency procedures and reporting and documentation obligations would be required. Risk tools typically used for the assessment of occupational risks (e.g. Workplace Control Scheme for Hazardous Substances (EMKG), Baua, Germany) do not allow workers to handle a substance classified in a CMR (carcinogenic, mutagenic, reproductive toxicity) category 2 without protective gloves and substances classified as CMR category 1 require handling in a closed system in case of a potential skin contact. Besides worker safety implications based on legal requirements, a classification of Ethanol in a CMR category will result in a dramatic loss of acceptance of ethanol-based hand sanitizers and disinfectant products in the work force. Hand disinfection is the number tool 1 tool to prevent and control infections from spreading in a hospital but also in preventing spread of diseases in the community. We encourage the authorities to carefully consider the unintended consequences and possible loss of life that could result from the decision made on such an important chemistry.
References	

Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 274	2025/04/29 17:21
Country	Spain
Name of organization/institution	STANPA - ASOCIACIÓN NACIONAL DE PERFUMERÍA Y COSMÉTICA (reg. no. 59762612330-05)
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Stanpa es la Asociación Nacional de Perfumería y Cosmética en España, en la que participan más de 300 empresas, tanto PYMES como multinacionales, que representan más del 90% del sector a nivel nacional. El sector de perfumería y cosmética es un motor clave para la economía española contribuyendo al 1.03% del PIB, con un valor de mercado interior de 11.200 millones de euros (+7.7% vs. 2023) y exportaciones por un valor de 9.589 millones (+23%, +43% perfumes vs. 2023) en 2024. España es el segundo exportador mundial de perfumes, tras Francia¹. Stanpa desea expresar su profunda preocupación ante la posible clasificación del etanol como sustancia carcinogénica, mutagénica o tóxica para la reproducción (CMR), actualmente en consideración en paralelo al proceso reevaluación como sustancia biocida. La asociación insta a las autoridades competentes a llevar a cabo una revisión exhaustiva que tenga en cuenta el impacto desproporcionado que esta clasificación podría tener sobre el uso de un ingrediente esencial como el etanol, en múltiples sectores —entre ellos, el de la perfumería y la cosmética— sin que dicha medida contribuya de forma efectiva al objetivo principal de proteger al consumidor frente a los riesgos asociados al consumo excesivo por vía oral. La propuesta de clasificación como sustancia CMR se basa exclusivamente en datos de exposición por ingestión oral, y no tiene en cuenta otras vías como la dérmica o la inhalatoria. Por ejemplo, si bien una mujer embarazada

	debe evitar el consumo de alcohol debido a su potencial efecto tóxico para el feto, puede utilizar de forma segura productos con etanol aplicados sobre la piel —como perfumes, desodorantes, lociones o geles hidroalcohólicos— sin que ello represente un riesgo ni para su salud ni para la del feto. Sin embargo, el enfoque actual del Reglamento CLP bajo el cual se hace la clasificación armonizada de sustancias, no contempla esta diferenciación en la vía de exposición. Además, el etanol utilizado en cosmética está desnaturalizado, es decir, ha sido tratado para hacerlo no apto para ser ingerido, por lo que una clasificación basada exclusivamente en datos de ingesta carece de relevancia para su uso en este contexto. El etanol es un ingrediente clave e insustituible, presente en prácticamente el 100% de los perfumes, y en entre el 30% y el 40% de los productos de cuidado e higiene personal ². En productos cosméticos, el etanol cumple funciones esenciales: actúa como solvente, conservante y agente antimicrobiano, aportando propiedades únicas en productos como perfumes, desodorantes, cremas, protectores solares, enjuagues bucales y productos capilares. Actualmente, no existen alternativas que igualen su rendimiento, perfil de seguridad y coste. En conclusión, desde Stanpa solicitamos que se separe el proceso de clasificación armonizada del etanol en el marco del Reglamento CLP de su reevaluación como sustancia biocida, debido al impacto desproporcionado que dicha clasificación tendría sobre el sector de la perfumería y la cosmética. Esta medida comprometería seriamente la competitividad del sector, frenaría la innovación, pondría en riesgo miles de empleos y restringiría el acceso del consumidor a productos esenciales, sin contribuir al verdadero objetivo de salud pública: reducir los efectos adversos asociados al consumo excesivo a través de bebidas alcohólicas. Resulta especialmente urgente en el actual escenario de guerra arancelaria impulsada por Estados Unidos, que ya tensiona gravemente la competitividad de sectores exportadores como el nuestro, no añadir elementos de complejidad como sería la clasificación del etanol. Añadir barreras regulatorias internas que afectan directamente a la viabilidad y operativa del sector no solo agrava la situación, sino que debilita la capacidad de nuestras empresas para responder con agilidad y eficacia en un entorno global cada vez más complejo y exigente. ¹Fuente: Stanpa. Radiografía del Sector 2024. ²Fuente: Cosmetics Europe & Stanpa survey (January 2025)
Product Type	1,2,4

Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	El etanol desempeña un papel fundamental en los productos de perfumería y cosmética, cumpliendo múltiples funciones para las cuales no existe, en la actualidad, un ingrediente alternativo que ofrezca una combinación equivalente de funcionalidades, seguridad demostrada y viabilidad técnica y económica: 1.Función disolvente: El etanol facilita la disolución de diversos ingredientes cosméticos, optimizando la eficacia y la estabilidad de las formulaciones, y permitiendo el desarrollo de productos de alta calidad y rendimiento. 2. Propiedades volátiles: Gracias a su rápida evaporación, el etanol proporciona una sensación inmediata de frescor durante la aplicación y contribuye a evitar la sensación pegajosa que podría derivarse del uso de ingredientes no adecuadamente solubilizados. 3. Acción

	antimicrobiana: Las propiedades antimicrobianas intrínsecas del etanol favorecen la preservación de los productos cosméticos, reduciendo la necesidad de otros conservantes, y aportan, además, beneficios añadidos en términos de higiene y seguridad del producto.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	Potential CMR Classification of Ethanol_Stanpa_Position_Paper_Abril 2025 final share.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 275	2025/04/29 17:54
Country	Spain
Name of organization/institution	ASOCIACION ESPAÑOLA DEL BIOETANOL
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	The Spanish Bioethanol Association (Bio-E) represents the interests of the bioethanol value chain in Spain. Bio-E advocates for the role of bioethanol as a renewable, sustainable fuel key to the decarbonization of transport and the circular economy. The Spanish Bioethanol Association (Bio-E) wishes to submit its comments to ECHA, highlighting that ethanol is a very specific substance due to the diversity of its uses, including food, industrial, and fuel applications.

	These uses involve extremely different pathways and levels of human exposure.
Product Type	1,2,4
Alternative Identity and Properties	Bioethanol is produced in European biorefineries by fermenting sugars derived from raw materials such as wheat, corn, barley, rye, triticale, sugar beet, as well as residues from cereal and beet processing. The EU ethanol market can be roughly divided into three segments: • Potable: Ethanol is used to produce spirits such as vodka or gin, food additives, aroma extraction, food preservation, and white vinegar production. • Industrial: Ethanol is essential in products such as disinfectants, cosmetics, pharmaceuticals, solvents, paints, and antifreeze liquids, and serves as a renewable feedstock for bio-based chemical production. • Fuel: Used as a gasoline additive (e.g., E10, containing up to 10% ethanol) or as an alternative fuel, significantly reducing greenhouse gas emissions
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	• Ethanol is unique as both a food product (beverages) and as a chemical for industrial and fuel applications. • Its use in hospitals and healthcare centers as a disinfectant is vital, as demonstrated during the COVID-19 pandemic. • There is currently no biocidal alternative with the same effectiveness against both enveloped and non-enveloped viruses. • Industrial use of ethanol as a solvent and raw material is essential and hard to replace.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Classifying ethanol as CMR would: • Undermine the credibility of the CLP Regulation and cause confusion among workers and consumers. Since alcohol is a familiar substance whose sale for consumption is permitted, why would its use as a chemical substance be considered dangerous? • Consequently, it would undermine critical safety messages meant for handling truly hazardous chemicals. • Cause enormous socioeconomic harm without health benefits, and indeed cause harm by removing

	effective disinfectants. • Negatively affect essential sectors without viable alternatives.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Scientific Data and Risk Assessments • Inhalation or skin contact with ethanol results in very low exposure levels, far below those of ingestion. • Studies indicate that its rapid evaporation and low skin absorption make exposure insignificant under real-world conditions.
Information above is confidential	
Justification for confidentiality	
Availability	Ethanol intended for human consumption is subject to excise taxes and strict regulations, whereas ethanol for industrial and biocidal uses is denatured to prevent consumption. This separation ensures that risk assessments for different uses should not be mixed or confused.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	• Data on human abusive consumption are not valid for assessing industrial or biocidal uses where dermal or inhalation exposure is minimal and insignificant. • No proven carcinogenic or reproductive risks exist for these uses. • Classification would create serious public health issues and economic harm due to the lack of alternatives. • The discussion should be addressed by the Risk Assessment Committee (RAC) under CLP, and not by the Biocidal Products Committee (BPC), given the complexity of the classification debate.
Information above is confidential	
Justification for confidentiality	
Other comments	Since potable alcohol is completely separated from other end uses by customs regulations, and blood alcohol levels from ingestion are much higher than those from inhalation or skin contact, data on alcohol abuse as a beverage should not be used to classify ethanol as CMR 1 for non-beverage

	uses, such as biocides. Furthermore, classifying ethanol as a carcinogen or reproductive toxin would be detrimental to many biocides, would create a lack of alternatives, and would have critical consequences for public health and other industrial uses
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	BioE_comentarios_ECHA_etanol_biocida ENGLISH.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 276	2025/04/29 18:05
Country	Netherlands
Name of organization/institution	Kimberly-Clark BV
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Despite several potential substitutes, none are suitable to replace ethanol-based products for PT2 applications. Ethanol's unmatched effectiveness, safety, and rapid disinfection are crucial for maintaining hygiene in healthcare, especially during crises like COVID-19. Ethanol's broad-spectrum efficacy against wide range of pathogens, including bacteria, fungi, and both enveloped and non-enveloped viruses makes it essential for environments requiring high hygiene standards, such as healthcare facilities, pharmaceutical sites, and public spaces.
Product Type	1,2,4
Alternative Identity and Properties	Potential alternatives include Propan-1-ol, Propan-2-ol, L(+)lactic acid, Peracetic acid, and Biphenyl-2-ol, and non-

	chemical methods like UV-C light and steam sterilization. Despite their consideration, none are suitable to replace ethanol-based products for PT2 applications, especially in healthcare settings where broad-spectrum efficacy and rapid disinfection are essential. More information is provided in the next sections.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	- The following alternatives: Propan-1-ol, Propan-2-ol, L(+)-lactic acid, Peracetic acid, and Biphenyl-2-ol, do not meet the technical criteria for PT2 surface disinfection in healthcare settings. They lack the broad spectrum of efficacy, rapid action, and safety needed for effective infection control. - Non-chemical methods can complement disinfection, especially for high-touch surfaces and airborne pathogens, adding protection and reducing HAIs. - Transitioning to alternatives may require significant investments in production facilities, potentially costing several million euros per company. Therefore, Ethanol remains the optimal choice for PT2 applications due to its unmatched efficacy, cost-effectiveness, and versatility, ensuring effective disinfection while prioritizing worker safety.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	The alternatives are economically less favorable due to higher costs, limited supply chains, and limited efficacy against non-enveloped viruses leading to limited suitability for these diverse environments. Ethanol is more cost-effective for PT2 applications, offering lower production costs, rapid disinfection, and broad-spectrum efficacy, and making it economically viable for widespread use in healthcare, schools, hotels, and public transport systems.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	From a human risk perspective, there is no reduction in risk when using Ethanol compared to Propan-1-ol, Propan-2-ol, and L(+)-lactic acid. Both Peracetic acid and Biphenyl-2-ol do

	not offer a better human risk profile than Ethanol, making them non-viable alternatives. Regarding environmental risk, using alternatives to Ethanol does not result in risk reduction, as the overall risk to environmental compartments remains unchanged.
Information above is confidential	
Justification for confidentiality	
Availability	Considering the availability of alternatives to ethanol, here are the key points: - Limited Suppliers: Alternatives like Propan-1-ol, Propan-2-ol, L(+)lactic acid, and Biphenyl-2-ol have a limited number of approved suppliers. This can be problematic in meeting EU-wide demand, especially during high-demand situations like pandemics. - Supply Chain Robustness: Ethanol benefits from a robust and diversified supply chain with over 240 suppliers across the EU. This ensures reliable availability even during health crises, such as the COVID-19 pandemic. - Market Presence: While the alternatives are present in the market, their limited supply chain may not be sufficient to ensure consistent availability and meet the high demand for disinfectants. In summary, ethanol's extensive and diversified supply chain makes it a more reliable choice for PT2 applications, particularly during periods of increased demand.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	No viable alternative to Ethanol for PT2 surface disinfection meets the comprehensive technical, operational, and economic requirements. Ethanol remains unmatched in its broad-spectrum efficacy, rapid action, and cost-effectiveness, making it indispensable for maintaining high hygiene standards, particularly in healthcare. Its role in maintaining infection control standards and protecting public health, especially during crises like COVID-19, underscores its indispensability in various settings. Key Points: - Effective against a wide range of pathogens, including bacteria, fungi, and both enveloped and non-enveloped viruses. Alternatives do not consistently meet these criteria. - Provides quick disinfection, crucial in high-turnover environments like hospitals and public transport systems. Many alternatives have slower action times, compromising infection control. - Ethanol-based disinfectants are straightforward to apply and have fast drying times.

	Alternatives may require more complex application methods or longer drying times, reducing operational efficiency. - Ethanol has a well-established safety profile for dermal and inhalation exposure, making it suitable for frequent use in healthcare settings. - Economically viable due to lower production costs and widespread availability. Alternatives often come with higher costs and limited supply chains, making them less feasible for large-scale use. - Ethanol benefits from a robust and diversified supply chain with over 240 suppliers across the EU, ensuring reliable availability even during health crises. Alternatives have fewer approved suppliers, leading to potential shortages during high-demand situations. - While alternatives like UV-C light and steam sterilization show promise as complementary measures, they cannot replace Ethanol as primary disinfectants due to higher costs and limited applicability.
Information above is confidential	
Justification for confidentiality	
Other comments	The proposed classification and human toxicity findings for Ethanol primarily rely on data from oral exposure. However, for biocidal uses, the exposure routes for ethanol-based disinfectants are exclusively dermal and inhalation. Due to the nature of PT2 biocidal use, the exposure levels are negligibly low.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 277	2025/04/29 18:08
Country	Germany

Name of organization/institution	Verband der chemischen Industrie e.V. (VCI)
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	VCI urges the European Commission, the ECHA and the relevant authorities to reconsider the proposed classification of ethanol as a CMR substance. The classification should

	consider the described socio-economic impacts and the absence of viable alternatives. Ethanol's essential role in various sectors, particularly in healthcare, underscores the need for a balanced and risk-based approach to its regulation.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	VCI submission Consultation on Potential Candidates for Substitution Ethanol_25.04.25.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 278	2025/04/29 18:22
Country	Germany
Name of organization/institution	Ecolab Deutschland GmbH
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	
Product Type	1,2,4
Alternative Identity and Properties	There are no viable alternatives to ethanol based biocidal products owing to various attributes of ethanol including but not limited to its wide spectrum efficacy, speed of action, availability, economic feasibility, compatibility,

	biodegradability, no residue and more. See our detailed comments in section 6 and 7.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ecolab, a manufacturer of biocides, including ethanol-based hand and surface disinfectants for use across the healthcare, food and pharma sectors, strongly believes the classification proposal of European Biocidal Authorities goes against the fundamental BPR principles of protecting human health and making Europe a safer place. Society relies on ethanol-based hand sanitizer and disinfectants because they are effective, and they keep us safe. This was made painfully obvious during the COVID-19 pandemic, and it remains true to this day. See our comments in section 6 on safe use of ethanol and the reasons why no alternatives exist on the market today that could replace ethanol in the many ways that it is used to protect public health and food safety. It will also describe why the use of data on oral

	consumption of alcoholic beverages for classification purposes is a flawed approach to determining the fate of ethanol as a biocidal active substance. Proceeding with the classification of ethanol as a CMR substance will result in significant harm as well as erode the trust invested to date by EU citizens in European and national Authorities responsible for safeguarding human health and food safety. The proposal to classify ethanol as a CMR Cat1 substance will limit the availability and will make end users believe ethanol based biocidal products are unsafe, when in fact the scientific evidence about ethanol safety and effectiveness shows this proposal will make Europeans less safe.
Information above is confidential	
Justification for confidentiality	
Other comments	ETHANOL BASED BIOCIDAL PRODUCTS ARE SAFE All humans are exposed to low levels of ethanol in daily life. Ethanol is produced endogenously in the intestines of nearly all individuals, albeit at doses not comparable to consumption of alcoholic drinks. The microflora of the digestive tract converts carbohydrates into ethanol and carbon dioxide (gas) under anaerobic conditions. In addition, we take up ethanol at low levels via our normal diet. A high variety of food and beverages contain low doses of ethanol, resulting in a continuous alimentary low dose uptake of ethanol. According to a recent review of WHO collaboration centre on patient safety and the commission for hospital hygiene and infection prevention (KRINKO), Robert Koch Institute, Germany, the increase in blood alcohol levels after using ethanol-based hand disinfectants is comparable to an increase after consumption of beverages with hidden alcohol content (approx. 0.5 % v/v) such as apple juice or non-alcoholic beer. Average values of 1.41 g/l in vegetable juices, 3.03 g/kg or g/l in instant meals, soups or sauces, 8.61 g/kg in jam and 18.11 g/kg in sweets like marzipan and filled chocolate have been detected in non-alcoholic food and beverages (Reimann et al. 2023). A study with 1557 participants revealed physiological blood ethanol levels in the absence of alcohol consumption with a median value of 0.4 mg/L up to a maximum value of 35.2 mg/L (Al-Awadhi et al. 2004). PBPK (Physiologically Based Pharmacokinetic) modelling of a high frequency application rate of ethanol-based hand rubs 7 times per hour resulted in a blood alcohol concentration of 3.9 mg/L which is in the physiological range of blood ethanol levels (Maier et al. 2015). Ethanol is currently the

	predominant biocidal active when it comes to hand sanitizers sold to the general public in the European Union. With respect to potential acute effects upon accidental ingestion, 2-propanol is twice as potent when it comes to the function as CNS (central nervous system) depressant compared to ethanol. For 1-propanol, the ED50 value for narcosis in rabbits was approximately four times lower than for ethanol. The acute oral toxicity of ethanol is lower compared to that of 1-propanol and 2-propanol (~ 15.000 mg/kg bw compared to values between 4000 and 7000 mg/kg bw as described in the BPR active substance dossiers). Considering that hand sanitisers are not used at high frequency rates by the general public, it can be expected that the internal ethanol burden will remain unchanged when ethanol-based skin disinfectants are used. Considering in addition, the low acute toxicity potential of ethanol, it can be concluded that a classification of ethanol as CMR substance will result in the loss of a safe, accessible and affordable biocidal active for the general public. It can be concluded that during the common usage of ethanol based biocidal products the ethanol blood levels remain comparable to ethanol exposure from non-alcoholic food sources and therefore ethanol based biocidal products pose no risk to human health. Ethanol has been used for centuries as a substance known to kill germs. As far back as Egyptian times palm wine was used to both clean and protect wounds from infection and as an embalming fluid. In the modern world ethanol-based products are used extensively in many sectors where fast acting, broad biocidal activity and low residues are needed. From hand sanitizers and surface disinfectants in hospitals, fast food restaurants and supermarkets, to disinfection of equipment to manufacture lifesaving drugs, ethanol has many lesser known but critical uses. In many of these cases ethanol is irreplaceable due to its unique combination of technical properties. PT2 - Ethanol is a critical disinfection tool used to protect the safety of life-saving drugs produced by the pharma industry Ethanol-based disinfectants play a crucial role in the pharmaceutical industry due to their effectiveness in eliminating a wide range of microorganisms, including bacteria, viruses, and fungi. In pharmaceutical manufacturing, these disinfectants are essential for maintaining sterile environments, ensuring that products are free from microbial contamination. Prior to entry into cleanroom areas ethanol-based hand disinfectants are used after handwashing to disinfect and reduce potential contaminants being introduced into the most sensitive areas of production. They are used to disinfect surfaces, equipment, and even the gloved hands of personnel to

	prevent the introduction of pathogens during production, both in the carefully controlled environments of clean rooms and in general production areas. The attributes of ethanol-based products that fit the needs of the pharmaceutical industry include rapid evaporation rates and broad-spectrum antimicrobial activity providing a reliable means of contamination control. Ethanol-based biocides are often selected for critical areas within pharmaceutical cleanrooms due to their low residue profile thus avoiding the risk of leaving harmful residues on equipment that could seriously affect the safety and effectiveness of the medicines being made. PROPOSED CMR CLASSIFICATION IS A FLAWED APPROACH As part of the evaluation of ethanol as biocidal active substance, it has been concluded that ethanol meets conditions of BPR Article 10(1), exclusion criteria pursuant to Article 5(1): – 5(1) (a) criteria to be classified as carcinogen category 1A or 1B and 5(1)(c) criteria to be classified as toxic for reproduction category 1A or 1B. A classification of ethanol, driven by data on adverse effects from drinking alcoholic beverages contradicts the formal requirements for hazard classification as defined by Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation). According to Article 5 of the CLP Regulation, classification must be based on the forms and physical state in which a chemical can be reasonably expected to be used. Alcohol consumption is not a form in which ethanol can be expected to be reasonably used when formulated and sold as a biocide or as ingredient in other chemical mixtures. The intended classification does not reflect possible hazards associated with a biocidal use of ethanol for PT-1, PT-2 or PT-4. Epidemiological data on adverse effects from drinking alcohol and data from animal tests carried out at test doses well above the limit dose defined in OECD test guidelines and the CLP regulation to mimic ethanol exposure levels reached only by drinking alcohol are not considered relevant for classification purposes under CLP. The CLP guidance document (Guidance on the Application of the CLP Criteria Part 3: Health Hazards Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP of substances and mixtures Version 5.0 November 2024) states for single exposure target organ toxicity category 3 (narcosis effects) and repeated exposure target organ toxicity that data on "deliberate exposure (i.e., abuse) is unlikely to provide sufficient robust evidence to support classification without other evidence as they do not mirror realistic exposure conditions". This includes case reports from accidental over-exposure situations (page 231 and page 255). Data on alcohol consumption which leads to high

	peak blood alcohol concentrations which cannot be reached via the dermal and inhalation route of exposure during the use of ethanol containing biocides are not considered to provide robust evidence of possible hazards of ethanol when used as chemical substance. A single alcoholic drink (standard amount of 12 g ethanol) leads to a peak blood concentration of ~ 250 mg/L in a 70 kg adult. In contrast, maximum concentrations measured in blood after surgical and hygienic hand disinfection were between 20 to 30 mg/L under exaggerated, non-realistic use conditions (20 hygienic hand disinfections, application of 4 ml each time over a time period of 30 minutes and 10 surgical hand disinfections, 200 ml (20 ml each time) hand rub applied over a period of 80 minutes) (Kramer, 2007). In summary, data on toxicological effects of chronic alcohol consumption are not considered relevant for the use of ethanol as biocidal active substance which results only in low internal exposure via the skin and inhalation. Exposure via the oral route in toxicologically relevant doses (drinking of ethanol-based biocides) can be ruled out, as ethanol is typically denatured to prevent this misuse scenario. CMR CLASSIFICATION WILL RESULT IN SIGNIFICANT HARM The main objective of the BPR (EU 528/2012) is to improve free movement of biocidal products while ensuring high level of protection of both human health and the environment. The proposed classification would fail the European Union in delivering either of these objectives. o Protection of human health EU hospitals and other public institutions rely on Ethanol for hand disinfection and surface disinfection. Ethanol is the only active substance that is effective against enveloped, as well as non-enveloped viruses. The role that Ethanol played during COVID pandemic can't be overstated. The absence of effective hand rubs against non-enveloped viruses such as norovirus, adenoviruses, and enteroviruses D68 and 71 (which are not vaccine-preventable) poses significant public health risks (reference: GMS Hygiene and Infection Control 2024, Vol. 19, ISSN 2196-5226). Currently. There are no alternatives that are as effective as Ethanol against viruses. Outside of clinical settings, ethanol hand disinfectants are relied upon in the daily life by the general public. Ethanol hand disinfectants are affordable, accessible, easy to use and trusted as biocidal products by families across Europe. In particular, hand washing with soap and water can be inaccessible in many situations and therefore Ethanol based hand disinfectants provide the security of infection prevention when hand washing is not possible. These products protect the general public from viruses like Norovirus and Influenza and bacteria such as Salmonella and Staphylococcus aureus that are often in

	circulation in communities or through food. A classification as a CMR Cat 1 would mean that these products will be forced off the market and general public would lose access to an important chemistry that they rely on today. o Impact on movement/supply/competitiveness of biocidal products containing Ethanol within and outside of Europe A decision to classify ethanol will eliminate the option for Union authorisation thus creating a patchwork of authorisations and restrictions across the EU. The biocidal industry of the European Union would become less competitive if proposed changes are implemented. While there is no universal tracking tool, it's estimated that the EU ethanol market is worth around EUR 9.54 billion, with a forecast of EUR 13.65 billion by 2030. Significant portion (up to 20%) of this is used in biocidal applications. A CMR classification would severely restrict the supply flexibility and availability of Ethanol in Europe as the suppliers would be reluctant to adopt such classification and thereby prioritise supply in other regions outside of the EU. This would also result in higher cost to source Ethanol for essential uses. NATIONAL LEGISLATION IMPACT – Worker safety In the European Union national worker safety legislations are in place to protect workers, including pregnant or breastfeeding woman from health hazards. The implied classification of ethanol as CMR Cat 1 can be considered to equal a ban of ethanol as biocidal active by the workforce, especially for its use as hand sanitizer in the healthcare sector as important tool in infection prevention. Employers would have to apply the so-called STOP principle (substitution, technical measures, organizational measures, personal protective equipment) in a tiered approach and substitute ethanol containing products with a less hazardous substance in a first step wherever possible. Work-place monitoring of ethanol exposure limits would be obligatory to control strict adherence to occupational exposure limits. Furthermore, extensive health surveillance activities, training and information, individual risk assessments, definition of emergency procedures and reporting and documentation obligations would be required. Risk tools typically used for the assessment of occupational risks (e.g. Workplace Control Scheme for Hazardous Substances (EMKG), Baua, Germany) do not allow workers to handle a substance classified in a CMR (carcinogenic, mutagenic, reproductive toxicity) category 2 without protective gloves and substances classified as CMR category 1 require handling in a closed system in case of a potential skin contact. Besides worker safety implications based on legal requirements, a classification of Ethanol in a CMR category will result in a dramatic loss of acceptance of ethanol-based

	hand sanitizers and disinfectant products in the work force. Hand disinfection is the number tool 1 tool to prevent and control infections from spreading in a hospital but also in preventing spread of diseases in the community. We encourage the authorities to carefully consider the unintended consequences and possible loss of life that could result from the decision made on such an important chemistry.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 279	2025/04/29 18:27
Country	Germany
Name of organization/institution	Ecolab Deutschland GmbH
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	
Product Type	1,2,4
Alternative Identity and Properties	There are no viable alternatives to ethanol based biocidal products owing to various attributes of ethanol including but not limited to its wide spectrum efficacy, speed of action, availability, economic feasibility, compatibility, biodegradability, no residue and more. See our detailed comments in section 6 and 7.

Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ecolab, a manufacturer of biocides, including ethanol-based hand and surface disinfectants for use across the healthcare, food and pharma sectors, strongly believes the classification proposal of European Biocidal Authorities goes against the fundamental BPR principles of protecting human health and making Europe a safer place. Society relies on ethanol-based hand sanitizer and disinfectants because they are effective, and they keep us safe. This was made painfully obvious during the COVID-19 pandemic, and it remains true to this day. See our comments in section 6 on safe use of ethanol and the reasons why no alternatives exist on the market today that could replace ethanol in the many ways that it is used to protect public health and food safety. It will also describe why the use of data on oral consumption of alcoholic beverages for classification purposes is a flawed approach to determining the fate of ethanol as a biocidal active substance. Proceeding with the

	classification of ethanol as a CMR substance will result in significant harm as well as erode the trust invested to date by EU citizens in European and national Authorities responsible for safeguarding human health and food safety. The proposal to classify ethanol as a CMR Cat1 substance will limit the availability and will make end users believe ethanol based biocidal products are unsafe, when in fact the scientific evidence about ethanol safety and effectiveness shows this proposal will make Europeans less safe.
Information above is confidential	
Justification for confidentiality	
Other comments	ETHANOL BASED BIOCIDAL PRODUCTS ARE SAFE All humans are exposed to low levels of ethanol in daily life. Ethanol is produced endogenously in the intestines of nearly all individuals, albeit at doses not comparable to consumption of alcoholic drinks. The microflora of the digestive tract converts carbohydrates into ethanol and carbon dioxide (gas) under anaerobic conditions. In addition, we take up ethanol at low levels via our normal diet. A high variety of food and beverages contain low doses of ethanol, resulting in a continuous alimentary low dose uptake of ethanol. According to a recent review of WHO collaboration centre on patient safety and the commission for hospital hygiene and infection prevention (KRINKO), Robert Koch Institute, Germany, the increase in blood alcohol levels after using ethanol-based hand disinfectants is comparable to an increase after consumption of beverages with hidden alcohol content (approx. 0.5 % v/v) such as apple juice or non-alcoholic beer. Average values of 1.41 g/l in vegetable juices, 3.03 g/kg or g/l in instant meals, soups or sauces, 8.61 g/kg in jam and 18.11 g/kg in sweets like marzipan and filled chocolate have been detected in non-alcoholic food and beverages (Reimann et al. 2023). A study with 1557 participants revealed physiological blood ethanol levels in the absence of alcohol consumption with a median value of 0.4 mg/L up to a maximum value of 35.2 mg/L (Al-Awadhi et al. 2004). PBPK (Physiologically Based Pharmacokinetic) modelling of a high frequency application rate of ethanol-based hand rubs 7 times per hour resulted in a blood alcohol concentration of 3.9 mg/L which is in the physiological range of blood ethanol levels (Maier et al. 2015). Ethanol is currently the predominant biocidal active when it comes to hand sanitizers sold to the general public in the European Union. With respect to potential acute effects upon accidental

ingestion, 2-propanol is twice as potent when it comes to the function as CNS (central nervous system) depressant compared to ethanol. For 1-propanol, the ED50 value for narcosis in rabbits was approximately four times lower than for ethanol. The acute oral toxicity of ethanol is lower compared to that of 1-propanol and 2-propanol (~ 15.000 mg/kg bw compared to values between 4000 and 7000 mg/kg bw as described in the BPR active substance dossiers). Considering that hand sanitisers are not used at high frequency rates by the general public, it can be expected that the internal ethanol burden will remain unchanged when ethanol-based skin disinfectants are used. Considering in addition, the low acute toxicity potential of ethanol, it can be concluded that a classification of ethanol as CMR substance will result in the loss of a safe, accessible and affordable biocidal active for the general public. It can be concluded that during the common usage of ethanol based biocidal products the ethanol blood levels remain comparable to ethanol exposure from non-alcoholic food sources and therefore ethanol based biocidal products pose no risk to human health. Ethanol has been used for centuries as a substance known to kill germs. As far back as Egyptian times, palm wine was used to both clean and protect wounds from infection and as an embalming fluid. In the modern world ethanol-based products are used extensively in many sectors where fast acting, broad biocidal activity and low residues are needed. From hand sanitizers and surface disinfectants in fast food restaurants and supermarkets to disinfection of equipment to manufacture of lifesaving drugs ethanol has many lesser known but critical uses. In many of these cases ethanol is irreplaceable due to its unique combination of technical properties. PT4 - Ethanol is a critical disinfection tool used to protect the food safety of low moisture foods (LMF) including infant formula Low moisture foods are an important part of our food system, characterized by their convenience and long shelf life. They include bakery goods, cereals, chocolate, dry dairy, nuts, spices and fried or baked chips, grains, protein powders and baby formula. LMF are known for their inherent safety because most microbes cannot survive or grow in or on them. This safety however must be created during harvest and manufacture and must ensure the exclusion of water from the environment and ultimately the food. Unfortunately, recent food recalls and outbreaks involving infant formula in the US (4 cases, 2 infant death and huge shortages in infant formula due to extensive recall) and chocolate in the EU (456 cases of Salmonella, 90% of the cases were children under 10 years old) have increased the need by food producers to be

	vigilant and adhere to the strictest sanitation and disinfection practices in their facilities. Low moisture or dry food production areas are usually cleaned without water for the purpose of minimizing growth of microbial pathogens. The Codex Alimentarius (a collection of internationally recognized standards, codes of practice, guidelines, and other recommendations published by the Food and Agriculture Organization (FAO) and World Health Organization (WHO) of the United Nations relating to food) recommends alcohol-based disinfectants for the LMF processing environment due to their antimicrobial efficacy and quick evaporation. Therefore, ethanol-based disinfectants are relied on heavily in the low moisture food industry due to their broad spectrum of kill, technical attributes, availability and cost. Salmonella is the main concern in these environments due to its persistence on dry foods and in food manufacturing facilities. E. coli O157:H7, Listeria and Cronobacter (mainly associated with infant formula) also remain of major concern in this sector of the food industry. All three are susceptible to ethanol. Ethanol-based disinfectants are used in the form of wipes, liquid or foam products for application to food processing equipment. The disinfection step is carried out as a last step following dry cleaning, vacuuming scraping etc and considered as a critical control point to prevent contamination or cross contamination to the food. The products are easily applied, act quickly and evaporate rapidly without leaving residues that could transfer to food. Common disinfectant products based on alternative active ingredients cannot be reliably substituted 1.1 for ethanol-based products for LMF production disinfection. Oxidative chemistries and Quats are generally diluted significantly in water leading to long dry times and an introduction of excessive moisture into an environment that needs to be kept dry. Some disinfectants have an unfavourable residue profile that could potentially result in chemical transfer to food. Significant changes to procedures and validations for food safety outcomes will need to be carried out before it can be established if certain LMF can be produced safely without ethanol. PROPOSED CMR CLASSIFICATION IS A FLAWED APPROACH As part of the evaluation of ethanol as biocidal active substance, it has been concluded that ethanol meets conditions of BPR Article 10(1), exclusion criteria pursuant to Article 5(1): – 5(1) (a) criteria to be classified as carcinogen category 1A or 1B and 5(1)(c) criteria to be classified as toxic for reproduction category 1A or 1B. A classification of ethanol, driven by data on adverse effects from drinking alcoholic beverages contradicts the formal requirements for hazard classification as defined by Regulation (EC) No 1272/2008 on the

	classification, labelling and packaging of substances and mixtures (CLP Regulation). According to Article 5 of the CLP Regulation, classification must be based on the forms and physical state in which a chemical can be reasonably expected to be used. Alcohol consumption is not a form in which ethanol can be expected to be reasonably used when formulated and sold as a biocide or as ingredient in other chemical mixtures. The intended classification does not reflect possible hazards associated with a biocidal use of ethanol for PT-1, PT-2 or PT-4. Epidemiological data on adverse effects from drinking alcohol and data from animal tests carried out at test doses well above the limit dose defined in OECD test guidelines and the CLP regulation to mimic ethanol exposure levels reached only by drinking alcohol are not considered relevant for classification purposes under CLP. The CLP guidance document (Guidance on the Application of the CLP Criteria Part 3: Health Hazards Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP of substances and mixtures Version 5.0 November 2024) states for single exposure target organ toxicity category 3 (narcosis effects) and repeated exposure target organ toxicity that data on "deliberate exposure (i.e., abuse) is unlikely to provide sufficient robust evidence to support classification without other evidence as they do not mirror realistic exposure conditions". This includes case reports from accidental over-exposure situations (page 231 and page 255). Data on alcohol consumption which leads to high peak blood alcohol concentrations which cannot be reached via the dermal and inhalation route of exposure during the use of ethanol containing biocides are not considered to provide robust evidence of possible hazards of ethanol when used as chemical substance. A single alcoholic drink (standard amount of 12 g ethanol) leads to a peak blood concentration of ~ 250 mg/L in a 70 kg adult. In contrast, maximum concentrations measured in blood after surgical and hygienic hand disinfection were between 20 to 30 mg/L under exaggerated, non-realistic use conditions (20 hygienic hand disinfections, application of 4 ml each time over a time period of 30 minutes and 10 surgical hand disinfections, 200 ml (20 ml each time) hand rub applied over a period of 80 minutes) (Kramer, 2007). In summary, data on toxicological effects of chronic alcohol consumption are not considered relevant for the use of ethanol as biocidal active substance which results only in low internal exposure via the skin and inhalation. Exposure via the oral route in toxicologically relevant doses (drinking of ethanol-based biocides) can be ruled out, as ethanol is typically denatured to prevent this misuse scenario. CMR CLASSIFICATION

	WILL RESULT IN SIGNIFICANT HARM The main objective of the BPR (EU 528/2012) is to improve free movement of biocidal products while ensuring high level of protection of both human health and the environment. The proposed classification would fail the European Union in delivering either of these objectives. - o Protection of human health EU hospitals and other public institutions rely on Ethanol for hand disinfection and surface disinfection. Ethanol is the only active substance that is effective against enveloped, as well as non-enveloped viruses. The role that Ethanol played during COVID pandemic can't be overstated. The absence of effective hand rubs against non-enveloped viruses such as norovirus, adenoviruses, and enteroviruses D68 and 71 (which are not vaccine-preventable) poses significant public health risks (reference: GMS Hygiene and Infection Control 2024, Vol. 19, ISSN 2196-5226). Currently. There are no alternatives that are as effective as Ethanol against viruses. Outside of clinical settings, ethanol hand disinfectants are relied upon in the daily life by the general public. Ethanol hand disinfectants are affordable, accessible, easy to use and trusted as biocidal products by families across Europe. In particular, hand washing with soap and water can be inaccessible in many situations and therefore Ethanol based hand disinfectants provide the security of infection prevention when hand washing is not possible. These products protect the general public from viruses like Norovirus and Influenza and bacteria such as Salmonella and Staphylococcus aureus that are often in circulation in communities or through food. A classification as a CMR Cat 1 would mean that these products will be forced off the market and general public would lose access to an important chemistry that they rely on today. - o Impact on movement/supply/competitiveness of biocidal products containing Ethanol within and outside of Europe A decision to classify ethanol will eliminate the option for Union authorisation thus creating a patchwork of authorisations and restrictions across the EU. The biocidal industry of the European Union would become less competitive if proposed changes are implemented. While there is no universal tracking tool, it's estimated that the EU ethanol market is worth around EUR 9.54 billion, with a forecast of EUR 13.65 billion by 2030. Significant portion (up to 20%) of this is used in biocidal applications. A CMR classification would severely restrict the supply flexibility and availability of Ethanol in Europe as the suppliers would be reluctant to adopt such classification and thereby prioritise supply in other regions outside of the EU. This would also result in higher cost to source Ethanol for essential uses. National legislation impact – Worker safety

	In the European Union national worker safety legislations are in place to protect workers, including pregnant or breastfeeding woman from health hazards. The implied classification of ethanol as CMR Cat 1 can be considered to equal a ban of ethanol as biocidal active by the workforce, especially for its use as hand sanitizer in the healthcare sector as important tool in infection prevention. Employers would have to apply the so-called STOP principle (substitution, technical measures, organizational measures, personal protective equipment) in a tiered approach and substitute ethanol containing products with a less hazardous substance in a first step wherever possible. Work-place monitoring of ethanol exposure limits would be obligatory to control strict adherence to occupational exposure limits. Furthermore, extensive health surveillance activities, training and information, individual risk assessments, definition of emergency procedures and reporting and documentation obligations would be required. Risk tools typically used for the assessment of occupational risks (e.g. Workplace Control Scheme for Hazardous Substances (EMKG), Baua, Germany) do not allow workers to handle a substance classified in a CMR (carcinogenic, mutagenic, reproductive toxicity) category 2 without protective gloves and substances classified as CMR category 1 require handling in a closed system in case of a potential skin contact. Besides worker safety implications based on legal requirements, a classification of Ethanol in a CMR category will result in a dramatic loss of acceptance of ethanol-based hand sanitizers and disinfectant products in the work force. Hand disinfection is the number tool 1 tool to prevent and control infections from spreading in a hospital but also in preventing spread of diseases in the community. We encourage the authorities to carefully consider the unintended consequences and possible loss of life that could result from the decision made on such an important chemistry.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	

Justification for confidential attachment	

Comment 280	2025/04/29 18:51
Country	Belgium
Name of organization/institution	EuroCommerce
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Ethanol plays a vital role throughout the food supply chain - from transportation and processing to final delivery - but is particularly important for the European retail and wholesale sector where it is widely used to support hygiene, food safety, and overall consumer protection. Ethanol is widely used by retailers as i. surface disinfectant, ii. hand sanitizer and iii. cleaning product to maintain high standards of cleanliness in stores, restaurants, and service areas. Ethanol is the most effective, simplest, safest, rapid, user-friendly, and environmentally safe disinfectant. All types of retailers, ranging from supermarkets and pet stores to crafts professionals, such as butchers and bakeries, make general use of ethanol-based disinfectants to clean the working spaces. Ethanol-based disinfectants and antiseptics are commonly applied through short-distance spraying, pouring, and wiping—methods that are both practical and efficient in fast-paced retail environments. These products are used by both staff and customers to disinfect hands and surfaces. Within stores, ethanol is routinely employed to disinfect areas such as delicatessen, meat counters, bakery counters, hot food counters, salad bars, ice cream counters, cheese counters, sandwich preparation zones, and to clean utensils, cutting boards, knives/cutting tools, appliances, slicing machines, shopping trolleys, checkout conveyors, and other frequently touched surfaces. To date, European retailers and wholesalers primarily rely on ethanol in all the above cases, as no alternative has proven equally cost-effective, practical, effective, safe, and readily available. By ensuring a hygienic environment, ethanol not only helps protect public health and prevent the spread of germs but also reinforces consumer trust and supports the smooth operation of retail businesses across Europe. In addition to contributing to the protection of public health, being the

	fastest, simplest and most effective disinfectant, ethanol naturally contributes to protecting companies and brands from reputational risks arising from any incidents related to food-borne illnesses.
Product Type	1,2,4
Alternative Identity and Properties	Our sector uses ethanol because it is effective, economically viable, safe and available. To date, European retailers and wholesalers primarily rely on ethanol in all the above cases, as no alternative has proven equally cost-effective, practical, effective, safe, and readily available.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Ethanol is the simplest, fastest and most effective disinfection method. The advantages of ethanol are its rapid effectiveness, availability, user-friendliness and safe environmental profile. It is easy to use, leaves no residues on surfaces, making it safe for food contact applications, it evaporates rapidly, ensuring convenient use in healthcare and public settings. This means that food contact surfaces can be disinfected efficiently in terms of time, labour and costs (reducing downtime in the food industry) without additional rinsing. Some members mentioned that isopropanol was replaced by ethanol many years ago because it was highly impractical to use. There was no ready-to-use product on the market back then, which meant that the isopropanol had to be transferred from canisters and mixed 1:1 with water before it could be used. This also required safety training for employees. Furthermore, quaternary ammonium was considered but rejected for use.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Although alternative disinfectants – such as hydrogen peroxide, isopropanol, lactic acid, quat-based products - have occasionally been tried out or considered by some members, their high costs and limited practicality result in European retailers and wholesalers using primarily ethanol. The advantages of ethanol are its rapid effectiveness, availability, user-friendliness and safe environmental profile. The alternatives that do exist are significantly more expensive, available only in very small quantities and not

	practical (as they require longer exposure time and they need rinsing). Ethanol production is well-established with stable supply chains. The few alternative biocides face higher production costs, lower availability, and logistical challenges. Regulatory decisions should account for economic feasibility and continuity of supply to prevent market disruptions. A ban on ethanol could cause a disruption in the supply of surface disinfectants intended for food and feed areas (PT 4 products), since there are not many alternatives, and they are not produced in the quantities needed to substitute ethanol.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Ethanol is safe and effective. It does not contaminate food and is odourless, making it suitable for food-related applications. Disinfection with ethanol-based products protects consumers from food-borne illnesses such as listeria, salmonella and E-coli, while when used in hand sanitizers (for example in the form of wipes for trolleys or checkout counters), it also protects consumers against viruses such as Covid, influenza and noroviruses. A potential public health risk if alternative substances get established is that reduced availability of effective disinfectants could increase infection rates in healthcare, food processing, and public hygiene. In addition to the already serious public health implications, there is a significant risk of reputational damage to the businesses concerned.
Information above is confidential	
Justification for confidentiality	
Availability	Alternative substances are significantly less available, and their widespread use could cause supply chain vulnerabilities: Scaling up production for substitutes would require massive investments in new facilities, technologies, and regulatory approvals.
Information above is confidential	
Justification for confidentiality	

Conclusion on suitability and availability of the alternative	Our sector uses ethanol because it is effective, economically viable, safe and available. To date, European retailers and wholesalers primarily rely on ethanol in all the above cases, as no alternative has proven equally cost-effective, practical, effective, safe, and readily available.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	20250429_EuroCommerce contribution to ECHA consultation on Ethanol_final.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 281	2025/04/29 19:58
Country	Denmark
Name of organization/institution	ECA Consortium A/S
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	This hearing has been convened to evaluate and consider potential alternatives of ethanol in Product Type 1 (PT 1) biocidal products intended for human hygiene use, within the framework of European chemical legislation, specifically Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products (Biocidal Products Regulation, BPR). Ethanol is widely used as a biocidal active substance in hand sanitizers and related

	hygiene products, typically applied in liquid or gel formulations without rinsing. Despite its proven efficacy, ethanol presents certain health and safety concerns, including its classification as flammable and its potential for adverse health effects depending on use and exposure. In alignment with the EU's commitment to the safe and sustainable use of chemicals, this hearing seeks to identify and assess viable alternatives that can meet hygiene requirements while reducing risk to human health and the environment. It should be noted that active chlorine released from hypochlorous acid (HOCl) is already available on the market as a biocidal active substance and has demonstrated high efficacy against bacteria, viruses, and fungi. HOCl is not classified as a carcinogen, mutagen, or reproductive toxin (CMR) and is widely used in medical, food, and public hygiene contexts. HOCl therefore represents a strong alternative to ethanol, given its existing authorization and established commercial use in various biocidal applications.
Product Type	1,2,4
Alternative Identity and Properties	Ethanol, while widely used as an active substance in biocidal products, presents notable safety concerns. It is classified as highly flammable, which poses significant hazards in environments such as military installations, industrial facilities, and healthcare settings, where strict safety protocols are essential. These flammability risks complicate the transport, storage, and on-site use of ethanol, especially in confined or high-risk areas. In addition, ethanol is subject to scrutiny under European chemical legislation due to its potential classification as a carcinogen, mutagen, or reproductive toxin (CMR) under certain conditions of use and concentration. This raises further concerns about its long-term safety, particularly with frequent or occupational exposure. By contrast, hypochlorous acid (HOCl) offers a significantly safer profile. It is non-flammable, making it more suitable for transport and use in sensitive or high-security environments. Moreover, HOCl is not classified as a CMR substance, and its use does not carry the same toxicological concerns associated with ethanol. With established biocidal efficacy and a favorable safety profile, HOCl represents a strong alternative in human hygiene applications.
Information above is confidential	
Justification for confidentiality	

Technical Feasibility	Hypochlorous acid (HOCl) offers significant potential as a biocidal alternative, with its stability and efficacy in use largely dependent on its degradation rate over time. Under current ECHA guidelines, biocidal products are required to maintain no more than a 10% degradation over their shelf life. While this standard presents an opportunity for further optimization, ensuring HOCl formulations remain within this limit can be a focus for ongoing development, aiming to enhance their stability and biocidal performance. However, recent industry discussions have proposed increasing the allowable degradation threshold to 30%, which could significantly enhance the regulatory viability of HOCl. If accepted, this adjustment would offer more flexibility in shelf life management, making HOCl a more competitive and feasible substitute for ethanol in Product Type 1 biocidal applications.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	The economic feasibility of hypochlorous acid (HOCl) as a substitute for ethanol in biocidal applications depends on ensuring consistent manufacturing standards to maintain its efficacy across various uses. Reliable and standardized production is essential to guarantee the quality and performance of HOCl-based products in both large-scale and consumer settings. A key consideration in the economic evaluation of HOCl is the choice between on-site generation and pre-packaged bottled products. While bottled HOCl products can offer convenience and portability, on-site generators may be more cost-effective in large-scale disinfection operations, such as in industrial or healthcare environments. ECHA may favor the use of on-site HOCl generators due to their ability to provide fresh, on-demand production, which can ensure efficacy and reduce concerns about degradation over time. This shift towards on-site generation could make HOCl a more economically viable option in settings where large volumes of biocidal products are required, further enhancing its market potential. Switching to HOCl reduces CO₂ emissions associated with long-distance ethanol transportation. Local production and simplified logistics lower environmental impacts while boosting local employment and technological capabilities. Economically, HOCl-based disinfection products are cost-competitive and often more affordable than alcohol-based alternatives, particularly over time.

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Hazards and Risks of the Alternative	While hypochlorous acid (HOCl) is a highly effective biocide, it poses certain hazards when handled improperly, particularly in its concentrated form. However, it is typically marketed in low concentrations in water or gel solutions maintaining its biocidal efficacy, which significantly reduces its risks in everyday use. In concentrated form, HOCl is corrosive and can cause severe irritation or burns to the skin, eyes, and mucous membranes. Inhalation of HOCl vapors or mist may irritate the respiratory system, leading to coughing and shortness of breath, especially in poorly ventilated environments. As a strong oxidizing agent, HOCl can react violently with incompatible substances, potentially releasing harmful gases or heat. Its use also carries potential environmental risks, particularly if improperly disposed of, as high concentrations can disrupt ecosystems. Additionally, when exposed to heat or light, HOCl may degrade into chlorine gas, which is toxic and can cause serious respiratory issues. Proper handling, storage, and disposal practices are essential to mitigate these risks, including using diluted solutions, ensuring adequate ventilation, and following safety protocols to prevent accidental exposure.
Information above is confidential	
Justification for confidentiality	
Availability	The production of hypochlorous acid (HOCl) is primarily based on salt and water, which undergo electrolysis to produce HOCl. This process, known as electrolytic generation, involves the use of simple, widely available materials. This makes HOCl an economically attractive option, as salt is a readily available, low-cost raw material sourced globally. Given the abundance of salt and its widespread availability, the production of HOCl can be achieved with minimal reliance on complex or scarce raw materials. This ensures supply chain stability and reduces exposure to significant price volatility or geopolitical constraints, as can sometimes affect more specialized chemicals. Additionally, this low-cost precursor contributes to the overall economic feasibility of HOCl-based products, especially when produced on-site for large-scale disinfection applications. The widespread availability of salt also supports decentralized production, making HOCl a highly

	flexible and scalable solution for both small-scale and large-scale operations. This flexibility is particularly valuable in settings where local generation of biocidal products is preferred, such as healthcare facilities or industrial plants. In contrast, ethanol production typically requires more complex raw materials, such as corn, sugarcane, or grain-based feedstocks, that must be fermented and distilled. These processes demand significant energy input and specialized equipment. Ethanol supply chains are also vulnerable to fluctuations in crop yields, climate variability, and geopolitical disruptions, leading to greater price volatility and potential supply chain instability. This is especially relevant in regions facing crop shortages or changing agricultural policies. The European Union's ethanol supply is particularly exposed to such vulnerabilities. It heavily depends on imports from third countries, including Pakistan, the United States, Brazil, and Peru. In 2023 alone, the EU imported over 2 billion litres of ethanol, placing critical public health infrastructure, such as hygiene and sanitation, at the mercy of global trade fluctuations and geopolitical risks. In contrast, HOCl can be produced locally across Europe, ensuring continuous availability and significantly reducing reliance on volatile global supply chains. Promoting local HOCl production enhances the EU's strategic autonomy, aligning with the objectives of the European Green Deal and the broader goal of open strategic autonomy. In terms of flexibility and scalability, HOCl production is particularly advantageous. The electrolytic generation process allows for decentralized, on-site production at the point of use. This enables scalable deployment in diverse environments, whether in healthcare facilities or industrial settings, and ensures fresh, on-demand production. It also reduces the logistics costs associated with transporting and storing bulk ethanol, which must be delivered in pre-packaged forms and requires more extensive infrastructure and distribution networks. Altogether, these features make HOCl a cost-effective, sustainable, and strategically resilient alternative to ethanol in biocidal applications.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Hypochlorous acid (HOCl) shows strong potential as an alternative to ethanol in Product Type 1 biocidal products for human hygiene. Its commercial availability and broad-spectrum efficacy against bacteria, viruses, and fungi, along

	with its non-flammable nature and favorable safety profile, make it particularly suitable for sensitive environments such as healthcare, industrial, and military settings. Unlike ethanol, HOCl is not classified as a CMR substance, enhancing its safety appeal. Although HOCl's stability remains a regulatory hurdle due to current ECHA guidelines limiting degradation to 10%, ongoing discussions to raise this limit to 30% could significantly improve its regulatory acceptance and market competitiveness. Economically, HOCl's viability depends on consistent manufacturing standards to ensure product stability. A key factor in its market success will be the choice between on-site generation and pre-packaged solutions. On-site generation offers advantages such as lower transport costs, reduced CO₂ emissions, and improved product freshness, particularly beneficial for large-scale disinfection operations. If ECHA favors this method, it may further enhance HOCl's economic attractiveness. In conclusion, HOCl stands out as a viable, safe, and effective alternative to ethanol in human hygiene biocidal products. With potential regulatory adjustments and advancements in production methods, it could become a highly competitive and sustainable option in the market.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 282	2025/04/29 20:07
Country	France

Name of organization/institution	██████████
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	
Product Type	1,2,4
Alternative Identity and Properties	PT1 products with lactic acid as active substance : Hygienic handwash product (Hand disinfectant soap) - Hygienic hand rub product (Hand disinfectant foam without rinse and hand/skin disinfectant wipes) All these products based on lactic acid show today efficacy against bacteria yeasts and enveloped viruses (Including Influenza virus, A/H1N1, Coronavirus, Vaccinia virus, ...) with contact time identical to alcoholic solution (30 seconds) and efficacies are validated by European authorities thanks to simplified marketing authorisations. Moreover, unlike alcohol based disinfectant, lactic acid based disinfectants are efficient in absence and also in presence of organic soiled on hands. Lactic acid products aren't efficient against the majority of non-enveloped viruses for a contact time compatible for PT1 products, however some products have already been proved to be efficient against Rotavirus (see confidential documents). Moreover, some studies showed that ethanol is not always efficient (Ji-Hyoung et al., efficacy of chemical disinfectant compounds against Human Norovirus, 2015). Moreover, most common nosocomial infections and last outbreaks in Europe are due to bacteria or enveloped viruses which is the activity spectrum for lactic acid based products. during the Covid-19 pandemia, alcolohic based hand rub solutions and lactic acid based hand rub were both largely contributing to hands hygiene and effective against coronavirus spreading.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Lactic acid is a biocidal active substance readily available on European territory with 2 major registered suppliers. Easily soluble in water, lactic acid makes it possible to obtain aqueous formulations applicable for PT1 human hygiene in various galenic forms and are compatible with frequent use of these disinfectant solutions for hands. The numerous

	products authorized throughout Europe in PT1 based on lactic acid include hand washing and disinfection solutions (with rinsing) suitable for the medical and industrial sectors, hand disinfection solutions by friction (without rinsing) suitable for the general public and the industrial and medical environment) and hand disinfectant wipes. Lactic acid-based products comply with the regulatory requirements required for PT1 applications by the BPR Regulation with a suitable contact time of between 30 and 60 seconds. The available products have bactericidal activity according to the application standards EN1499 and EN1500, yeasticidal activity according to the standards EN1650 and EN13624 and activity on all enveloped viruses (EN14476+A1), covering a broad spectrum of micro-organisms involved in hygiene or epidemic issues.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Lactic acid is a substance whose production and availability are guaranteed by a robust and established supply chain in Europe, ensuring sourcing independence for the European market. Two actors are currently listed on the Article 95 list of the BPR Regulation, and each has production units allowing for the placing on the market of several thousands tons of lactic acid per year. The main use of lactic acid in Europe is in the food industry (additive E270). Its use in the biocidal sector is relatively new and represents only a small share of actual production. Like ethanol, lactic acid is produced by the fermentation of sugar molasses residues, derived from corn, wheat, or beet from locally produced raw materials, close to the manufacturing sites. It perfectly aligns with the European Commission's desire for a circular economy. Its cost is estimated at around 1.4 – 2€/Kg, making it an affordable active substance. Furthermore, unlike ethanol, which requires a high concentration (more than 80% v/v) to demonstrate a biocidal effect on bacteria, yeasts, and viruses, lactic acid in the various dossiers under European authorizations is used at much lower concentrations (less than 6%) and more particularly between 1 and 2% for the majority of ready-to-use products for PT1. This use at low dosage makes it an economically advantageous solution as an alternative to various active substances, including alcohols
Information above is confidential	

Justification for confidentiality	
Hazards and Risks of the Alternative	Comparison of substance active hazards: Lactic acid: Physical hazards: none Health hazards: Causes severe skin burns and eye damage and causes serious eye damage Environmental hazards: none Ethanol: Physical hazards : Highly flammable liquid and vapour Health hazards: Cause serious eye irritation Environmental hazards: None Ethanol is considered as a VOC, whereas lactic acid is not. As a result, lactic acid-based products do not contain VOCs, with the exception of perfumes. Maximum hazards for concentrated products are only for corrosion and irritation. Lactic acid is H314 in its concentrated form but use at the correct dose, the products are CLP-free. CLP-free products available, eligible for simplified authorisations (more than 200 products approved) "All EtOH-based solutions contain more than 80% v/v, leading to a flammable classification of the products. In contrast, lactic acid and lactic acid-based products are not classified as flammable." No danger to the environment In view of the data available on the ECHA website on 23 April 2025, we have drawn up a comparison of the environmental profiles of these two substances. Lactic acid (CAS: 50-21-5, last modified : 04/01/2023) and ethanol (CAS : 64-17-5, last modified : 17/05/2023) both have similar ecotoxicological profiles. They both are highly mobile in aquatic environments, readily biodegradable and have a low bioaccumulation potential in addition to a low toxicity for aquatic environments. They are finally both not classified for environmental hazards. These two substances therefore both present an equivalent environmental risk. No toxic residues, substance used in the food industry (E270) Reduced risk mitigation measures for the storage and use of products vs ethanol-based products
Information above is confidential	
Justification for confidentiality	
Availability	Readily available on the market, derived from the upcycling of sugar beet waste and corn syrup. Lactic acid is an active substance registered in Annex I and in Article 95 of the Biocides Regulation (BPR). Several suppliers registered under Article 95. Products already available on the market via simplified authorization (Article 25 of the BPR) and marketing authorization: 112 lactic acid-based products are already on the market for PT1 (110 simplified authorisations and 2 Union authorisation)

Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Lactic acid as an effective active substance for PT1 hand hygiene products (hand disinfectant soaps, rinse-free hand disinfectant foams, and disinfectant wipes). These lactic acid-based products demonstrate efficacy against bacteria, yeasts, and enveloped viruses (including Influenza, Coronavirus, Vaccinia, etc.) with a contact time identical to alcohol-based solutions (30 seconds), and their effectiveness is validated by European authorities through simplified marketing authorizations. Furthermore, unlike alcohol-based disinfectants, lactic acid-based disinfectants are effective both in the absence and presence of organic soil on hands. While lactic acid products are not effective against most non-enveloped viruses with a compatible contact time for PT1 products, some have proven effective against Rotavirus. Additionally, some studies have shown that ethanol is not always effective (e.g., against Norovirus). However, the most common nosocomial infections and recent European outbreaks are caused by bacteria or enveloped viruses, which falls within the activity spectrum of lactic acid-based products. During the Covid-19 pandemic, both alcohol and lactic acid-based hand rubs significantly contributed to hand hygiene and were effective against coronavirus spread. Lactic acid stands out as a promising and readily available active substance for PT1 hand hygiene products. Its demonstrated efficacy against bacteria, yeasts, and enveloped viruses, coupled with its effectiveness even in the presence of organic soiling and validated by European authorities, positions it as a strong alternative to alcohol-based disinfectants. Furthermore, its economic advantages, favorable safety profile (non-flammable, no VOCs in formulations), comparable environmental impact to ethanol, and good tolerability on skin make lactic acid-based products a compelling solution for widespread use in various settings, contributing effectively to hand hygiene and infection control.
Information above is confidential	
Justification for confidentiality	
Other comments	Lactic acid-based solutions are a good alternative to ethanol for frequent use on sensitive skin, particularly in the workplace, such as in the cosmetics, hospital, and industrial settings, due to their good acceptability.

Information above is confidential	
Justification for confidentiality	
References	Ji-Hyoung et al., efficacy of chemical disinfectant compounds against Human Norovirus, 2015
Attachments (non-confidential information)	Efficacy of chemical disinfectant compounds against human norovirus.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 283	2025/04/29 20:12
Country	France
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	
Product Type	1,2,4
Alternative Identity and Properties	PT2 products with lactic acid as active substance. These products based on lactic acid show efficacy against bacteria yeasts and enveloped viruses with contact time from 2 minutes and efficacies are validated by European authorities thanks to simplified marketing authorisations. Moreover, unlike alcohol based disinfectants, lactic acid based disinfectants are efficient in absence and also in presence of organic soiled on surfaces. Concerning efficacy against non enveloped viruses like Noroviruses, some lactic acid disinfectant products have been proved to show efficacy against non enveloped viruses from 5 minutes of contact time according to EN14476 and from 15 minutes according to EN16777 when almost every ethanol disinfectant have no proved efficacy against EN16777 standards which is the most important test for virucidal efficacy as it shows real in use condition in the contrary to the standard EN14476.

Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Lactic acid is a biocidal active substance readily available on European territory with two major registered suppliers. Easily soluble in water, lactic acid makes it possible to obtain aqueous formulations applicable for PT2 for surface applications, both in the form of concentrates to be diluted by the end user (which is not possible with alcohol-based solutions that require a significantly higher concentration of active substances to demonstrate a biocidal effect) and ready-to-use solutions. The numerous products authorized throughout Europe in PT2 based on lactic acid include cleaning and disinfection solutions for surfaces suitable for the general public and professional sectors (communities, medical sector) and industrial sector (food processing, cosmetics, etc.). Lactic acid-based products comply with the regulatory requirements required for PT2 applications by the BPR Regulation with a very short contact time, starting from 2 minutes, more generally from 5 to 15 minutes. The available products have bactericidal and yeasticidal activity according to suspension standards (EN1276, EN13727, EN1650, EN13624) and according to application standards EN13697 and EN16615, as well as activity on all enveloped viruses (EN14476+A1) but also activity on non-enveloped viruses (see confidential document), covering a broad spectrum of micro-organisms involved in hygiene or epidemic issues, and at a level equivalent to ethanol-based solutions.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Lactic acid is a substance whose production and availability are guaranteed by a robust and established supply chain in Europe, ensuring sourcing independence for the European market. Two actors are currently listed on the Article 95 list of the BPR Regulation, and each has production units allowing for the placing on the market of several thousands tons of lactic acid per year. The main use of lactic acid in Europe is in the food industry (additive E270). Its use in the biocidal sector is relatively new and represents only a small share of actual production. Like ethanol, lactic acid is produced by the fermentation of sugar molasses residues, derived from corn, wheat, or beet from locally produced raw materials, close to the manufacturing sites. It perfectly

	aligns with the European Commission's desire for a circular economy. Its cost is estimated at around 1.4 – 2€ Eur/Kg, making it an affordable active substance. Furthermore, unlike ethanol, which requires a high concentration (more than 80% v/v) to demonstrate a biocidal effect on bacteria, yeasts, and viruses, lactic acid in the various dossiers under European authorizations is used at much lower concentrations (less than 2% w/w) and more particularly lower than 1% (w/w) for the majority of ready-to-use products for PT2. This use at low dosage makes it an economically advantageous solution as an alternative to various active substances, including alcohols.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Comparison of substance active hazards: Lactic acid: Physical hazards: None / Health hazards: Causes severe skin burns and eye damage and causes serious eye damage / Environmental hazards: none Ethanol: Physical hazards: Highly flammable liquid and vapour / Health hazards: Cause serious eye irritation / Environmental hazards: None Ethanol is considered as a VOC, whereas lactic acid is not. As a result, lactic acid-based products do not contain VOCs, with the exception of perfumes. Maximum hazards for concentrated products are only for corrosion and irritation. CLP-free products available, eligible for simplified authorisations (more than 200 products approved) No danger to the environment In view of the data available on the ECHA website on 23 April 2025, we have drawn up a comparison of the environmental profiles of these two substances. Lactic acid (CAS: 50-21-5, last modified : 04/01/2023) and ethanol (CAS : 64-17-5, last modified : 17/05/2023) both have similar ecotoxicological profiles. They both are highly mobile in aquatic environments, readily biodegradable and have a low bioaccumulation potential in addition to a low toxicity for aquatic environments. They are finally both not classified for environmental hazards. These two substances therefore both present an equivalent environmental risk. No toxic residues, substance used in the food industry (E270) : if ethanol is classified as CMR for ingestion, lactic acid is a good alternative because it is an endogenous substance. Reduced risk mitigation measures for the storage and use of products vs ethanol-based products

Information above is confidential	
Justification for confidentiality	
Availability	Readily available on the market, derived from the upcycling of sugar beet waste and corn syrup. Several suppliers registered under Article 95. Products already available on the market via marketing authorization and simplified authorization (Article 25 of the BPR): 1154 lactic acid-based products are already on the market for PT1 (139 simplified authorisations and 1015 marketing authorisation)
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Therefore, considering the data for PT2 products, lactic acid stands out as a robust and advantageous alternative to ethanol-based disinfectants for surface applications. Its proven efficacy against bacteria, yeasts, enveloped viruses with short contact times, and even certain non-enveloped viruses (including promising results against EN16777 standards where ethanol often falls short), coupled with its effectiveness in the presence of organic matter, highlights its strong disinfectant capabilities. Furthermore, its technical feasibility, economic benefits stemming from low production costs and low effective concentrations, reduced hazard profile (non-flammable, no VOCs), comparable environmental impact to ethanol, and readily available supply chain within Europe solidify its position. The added benefit of descaling properties further enhances its appeal for surface maintenance, making lactic acid a compelling and sustainable choice for a wide range of PT2 applications.
Information above is confidential	
Justification for confidentiality	
Other comments	Lactic acid provides a descaling benefit alongside its disinfectant properties, rendering it particularly advantageous for surface maintenance applications.
Information above is confidential	
Justification for confidentiality	

References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 284	2025/04/29 20:10
Country	Denmark
Name of organization/institution	ECA Consortium A/S
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	This hearing has been convened to evaluate and consider potential alternatives of ethanol in Product Type 2 (PT 2) biocidal products intended for private use and public health area, within the framework of European chemical legislation, specifically Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products (Biocidal Products Regulation, BPR). Ethanol is widely used as a biocidal active substance in surface disinfection, typically applied in liquid formulations without rinsing. Despite its proven efficacy, ethanol presents certain health and safety concerns, including its classification as flammable and its potential for adverse health effects depending on use and exposure. In alignment with the EU's commitment to the safe and sustainable use of chemicals, this hearing seeks to identify and assess viable alternatives that can meet hygiene requirements while reducing risk to human health and the environment. It should be noted that active chlorine released from hypochlorous acid (HOCl) is already available on the market as a biocidal active substance and has demonstrated high efficacy against bacteria, viruses, and fungi. HOCl is not classified as a carcinogen, mutagen, or reproductive toxin (CMR) and is widely used in medical, food, and public hygiene contexts. HOCl therefore represents a strong

	alternative to ethanol, given its existing authorization and established commercial use in various biocidal applications.
Product Type	1,2,4
Alternative Identity and Properties	Ethanol, while widely used as an active substance in biocidal products, presents notable safety concerns. It is classified as highly flammable, which poses significant hazards in environments such as military installations, industrial facilities, and healthcare settings, where strict safety protocols are essential. These flammability risks complicate the transport, storage, and on-site use of ethanol, especially in confined or high-risk areas. In addition, ethanol is subject to scrutiny under European chemical legislation due to its potential classification as a carcinogen, mutagen, or reproductive toxin (CMR) under certain conditions of use and concentration. This raises further concerns about its long-term safety, particularly with frequent or occupational exposure. By contrast, hypochlorous acid (HOCl) offers a significantly safer profile. It is non-flammable, making it more suitable for transport and use in sensitive or high-security environments. Moreover, HOCl is not classified as a CMR substance, and its use does not carry the same toxicological concerns associated with ethanol. With established biocidal efficacy and a favorable safety profile, HOCl represents a strong alternative in surface disinfection applications.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Hypochlorous acid (HOCl) offers significant potential as a biocidal alternative, with its stability and efficacy in use largely dependent on its degradation rate over time. Under current ECHA guidelines, biocidal products are required to maintain no more than a 10% degradation over their shelf life. While this standard presents an opportunity for further optimization, ensuring HOCl formulations remain within this limit can be a focus for ongoing development, aiming to enhance their stability and biocidal performance. However, recent industry discussions have proposed increasing the allowable degradation threshold to 30%, which could significantly enhance the regulatory viability of HOCl. If accepted, this adjustment would offer more flexibility in shelf life management, making HOCl a more competitive and feasible substitute for ethanol in Product Type 2 biocidal applications.

Information above is confidential	
Justification for confidentiality	
Economic Feasibility	The economic feasibility of hypochlorous acid (HOCl) as a substitute for ethanol in biocidal applications depends on ensuring consistent manufacturing standards to maintain its efficacy across various uses. Reliable and standardized production is essential to guarantee the quality and performance of HOCl-based products in both large-scale and consumer settings. A key consideration in the economic evaluation of HOCl is the choice between on-site generation and pre-packaged bottled products. While bottled HOCl products can offer convenience and portability, on-site generators may be more cost-effective in large-scale disinfection operations, such as in industrial or healthcare environments. ECHA may favor the use of on-site HOCl generators due to their ability to provide fresh, on-demand production, which can ensure efficacy and reduce concerns about degradation over time. This shift towards on-site generation could make HOCl a more economically viable option in settings where large volumes of biocidal products are required, further enhancing its market potential. Switching to HOCl reduces CO₂ emissions associated with long-distance ethanol transportation. Local production and simplified logistics lower environmental impacts while boosting local employment and technological capabilities. Economically, HOCl-based disinfection products are cost-competitive and often more affordable than alcohol-based alternatives, particularly over time.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	While hypochlorous acid (HOCl) is a highly effective biocide, it poses certain hazards when handled improperly, particularly in its concentrated form. However, it is typically marketed in low concentrations in water or gel solutions maintaining its biocidal efficacy, which significantly reduces its risks in everyday use. In concentrated form, HOCl is corrosive and can cause severe irritation or burns to the skin, eyes, and mucous membranes. Inhalation of HOCl vapors or mist may irritate the respiratory system, leading to coughing and shortness of breath, especially in poorly ventilated environments. As a strong oxidizing agent, HOCl can react violently with incompatible substances, potentially releasing harmful gases or heat. Its use also carries

	potential environmental risks, particularly if improperly disposed of, as high concentrations can disrupt ecosystems. Additionally, when exposed to heat or light, HOCl may degrade into chlorine gas, which is toxic and can cause serious respiratory issues. Proper handling, storage, and disposal practices are essential to mitigate these risks, including using diluted solutions, ensuring adequate ventilation, and following safety protocols to prevent accidental exposure.
Information above is confidential	
Justification for confidentiality	
Availability	The production of hypochlorous acid (HOCl) is primarily based on salt and water, which undergo electrolysis to produce HOCl. This process, known as electrolytic generation, involves the use of simple, widely available materials. This makes HOCl an economically attractive option, as salt is a readily available, low-cost raw material sourced globally. Given the abundance of salt and its widespread availability, the production of HOCl can be achieved with minimal reliance on complex or scarce raw materials. This ensures supply chain stability and reduces exposure to significant price volatility or geopolitical constraints, as can sometimes affect more specialized chemicals. Additionally, this low-cost precursor contributes to the overall economic feasibility of HOCl-based products, especially when produced on-site for large-scale disinfection applications. The widespread availability of salt also supports decentralized production, making HOCl a highly flexible and scalable solution for both small-scale and large-scale operations. This flexibility is particularly valuable in settings where local generation of biocidal products is preferred, such as healthcare facilities or industrial plants. In contrast, ethanol production typically requires more complex raw materials, such as corn, sugarcane, or grain-based feedstocks, that must be fermented and distilled. These processes demand significant energy input and specialized equipment. Ethanol supply chains are also vulnerable to fluctuations in crop yields, climate variability, and geopolitical disruptions, leading to greater price volatility and potential supply chain instability. This is especially relevant in regions facing crop shortages or changing agricultural policies. The European Union's ethanol supply is particularly exposed to such vulnerabilities. It heavily depends on imports from third countries, including Pakistan, the United States, Brazil, and

	Peru. In 2023 alone, the EU imported over 2 billion litres of ethanol, placing critical public health infrastructure, such as hygiene and sanitation, at the mercy of global trade fluctuations and geopolitical risks. In contrast, HOCl can be produced locally across Europe, ensuring continuous availability and significantly reducing reliance on volatile global supply chains. Promoting local HOCl production enhances the EU's strategic autonomy, aligning with the objectives of the European Green Deal and the broader goal of open strategic autonomy. In terms of flexibility and scalability, HOCl production is particularly advantageous. The electrolytic generation process allows for decentralized, on-site production at the point of use. This enables scalable deployment in diverse environments, whether in healthcare facilities or industrial settings, and ensures fresh, on-demand production. It also reduces the logistics costs associated with transporting and storing bulk ethanol, which must be delivered in pre-packaged forms and requires more extensive infrastructure and distribution networks. Altogether, these features make HOCl a cost-effective, sustainable, and strategically resilient alternative to ethanol in biocidal applications.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Hypochlorous acid (HOCl) is a viable and promising alternative to ethanol in Product Type 2 biocidal products used in private and public health areas. Already commercially available, HOCl is effective against a broad spectrum of microorganisms, including bacteria, viruses, and fungi, making it highly suitable for disinfectants. Its non-flammable nature, favorable safety profile, and non-CMR classification offer key advantages over ethanol, particularly in settings like hospitals, schools, and public facilities where safety and ease of use are essential. Regulatory challenges remain due to HOCl's degradation over time, with current ECHA guidelines requiring less than 10% degradation over the product's shelf life. However, industry discussions about increasing this limit to 30% could significantly enhance HOCl's regulatory acceptance and competitiveness. From an economic perspective, HOCl's success depends on maintaining consistent manufacturing standards for stability and efficacy. The choice between on-site generation and pre-packaged products is central to its market positioning. On-site generation can reduce transport and storage needs, cut costs, ensure product freshness, and

	lower CO ₂ emissions tied to ethanol logistics. ECHA's potential preference for on-site HOCl production could further improve its economic feasibility, especially for large-scale use in hospitals and municipal operations. In summary, HOCl demonstrates strong potential as a safer, effective, and sustainable alternative to ethanol as a surface disinfectant for public and private health settings. While challenges such as product stability and regulatory alignment remain, ongoing developments and potential policy changes could strengthen HOCl's role in the market.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 285	2025/04/29 20:16
Country	Denmark
Name of organization/institution	ECA Consortium A/S
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Hypochlorous acid (HOCl) is a viable and promising alternative to ethanol in Product Type 2 biocidal products used in private and public health areas. Already

	commercially available, HOCl is effective against a broad spectrum of microorganisms, including bacteria, viruses, and fungi, making it highly suitable for disinfectants. Its non-flammable nature, favorable safety profile, and non-CMR classification offer key advantages over ethanol, particularly in settings like hospitals, schools, and public facilities where safety and ease of use are essential. Regulatory challenges remain due to HOCl's degradation over time, with current ECHA guidelines requiring less than 10% degradation over the product's shelf life. However, industry discussions about increasing this limit to 30% could significantly enhance HOCl's regulatory acceptance and competitiveness. From an economic perspective, HOCl's success depends on maintaining consistent manufacturing standards for stability and efficacy. The choice between on-site generation and pre-packaged products is central to its market positioning. On-site generation can reduce transport and storage needs, cut costs, ensure product freshness, and lower CO₂ emissions tied to ethanol logistics. ECHA's potential preference for on-site HOCl production could further improve its economic feasibility, especially for large-scale use in hospitals and municipal operations. In summary, HOCl demonstrates strong potential as a safer, effective, and sustainable alternative to ethanol as a surface disinfectant for public and private health settings. While challenges such as product stability and regulatory alignment remain, ongoing developments and potential policy changes could strengthen HOCl's role in the market.
Product Type	1,2,4
Alternative Identity and Properties	Ethanol, while widely used as an active substance in biocidal products, presents notable safety concerns. It is classified as highly flammable, which poses significant hazards in environments such as military installations, industrial facilities, and healthcare settings, where strict safety protocols are essential. These flammability risks complicate the transport, storage, and on-site use of ethanol, especially in confined or high-risk areas. In addition, ethanol is subject to scrutiny under European chemical legislation due to its potential classification as a carcinogen, mutagen, or reproductive toxin (CMR) under certain conditions of use and concentration. This raises further concerns about its long-term safety, particularly with frequent or occupational exposure. By contrast, hypochlorous acid (HOCl) offers a significantly safer profile. It is non-flammable, making it more suitable for transport and use in sensitive or high-security environments. Moreover, HOCl is not classified as a CMR substance, and its use does not carry the same

	toxicological concerns associated with ethanol. With established biocidal efficacy and a favorable safety profile, HOCl represents a strong alternative in human hygiene applications.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Hypochlorous acid (HOCl) offers significant potential as a biocidal alternative, with its stability and efficacy in use largely dependent on its degradation rate over time. Under current ECHA guidelines, biocidal products are required to maintain no more than a 10% degradation over their shelf life. While this standard presents an opportunity for further optimization, ensuring HOCl formulations remain within this limit can be a focus for ongoing development, aiming to enhance their stability and biocidal performance. However, recent industry discussions have proposed increasing the allowable degradation threshold to 30%, which could significantly enhance the regulatory viability of HOCl. If accepted, this adjustment would offer more flexibility in shelf life management, making HOCl a more competitive and feasible alternative to ethanol in Product Type 4 biocidal applications.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	The economic feasibility of hypochlorous acid (HOCl) as a substitute for ethanol in biocidal applications depends on ensuring consistent manufacturing standards to maintain its efficacy across various uses. Reliable and standardized production is essential to guarantee the quality and performance of HOCl-based products in both large-scale and consumer settings. A key consideration in the economic evaluation of HOCl is the choice between on-site generation and pre-packaged bottled products. While bottled HOCl products can offer convenience and portability, on-site generators may be more cost-effective in large-scale disinfection operations, such as in industrial or healthcare environments. ECHA may favor the use of on-site HOCl generators due to their ability to provide fresh, on-demand production, which can ensure efficacy and reduce concerns about degradation over time. This shift towards on-site generation could make HOCl a more economically viable option in settings where large volumes of biocidal products

	are required, further enhancing its market potential. Switching to HOCl reduces CO ₂ emissions associated with long-distance ethanol transportation. Local production and simplified logistics lower environmental impacts while boosting local employment and technological capabilities. Economically, HOCl-based disinfection products are cost-competitive and often more affordable than alcohol-based alternatives, particularly over time.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	While hypochlorous acid (HOCl) is a highly effective biocide, it poses certain hazards when handled improperly, particularly in its concentrated form. However, it is typically marketed in low concentrations in water or gel solutions maintaining its biocidal efficacy, which significantly reduces its risks in everyday use. In concentrated form, HOCl is corrosive and can cause severe irritation or burns to the skin, eyes, and mucous membranes. Inhalation of HOCl vapors or mist may irritate the respiratory system, leading to coughing and shortness of breath, especially in poorly ventilated environments. As a strong oxidizing agent, HOCl can react violently with incompatible substances, potentially releasing harmful gases or heat. Its use also carries potential environmental risks, particularly if improperly disposed of, as high concentrations can disrupt ecosystems. Additionally, when exposed to heat or light, HOCl may degrade into chlorine gas, which is toxic and can cause serious respiratory issues. Proper handling, storage, and disposal practices are essential to mitigate these risks, including using diluted solutions, ensuring adequate ventilation, and following safety protocols to prevent accidental exposure.
Information above is confidential	
Justification for confidentiality	
Availability	The production of hypochlorous acid (HOCl) is primarily based on salt and water, which undergo electrolysis to produce HOCl. This process, known as electrolytic generation, involves the use of simple, widely available materials. This makes HOCl an economically attractive option, as salt is a readily available, low-cost raw material sourced globally. Given the abundance of salt and its widespread availability, the production of HOCl can be

	achieved with minimal reliance on complex or scarce raw materials. This ensures supply chain stability and reduces exposure to significant price volatility or geopolitical constraints, as can sometimes affect more specialized chemicals. Additionally, this low-cost precursor contributes to the overall economic feasibility of HOCl-based products, especially when produced on-site for large-scale disinfection applications. The widespread availability of salt also supports decentralized production, making HOCl a highly flexible and scalable solution for both small-scale and large-scale operations. This flexibility is particularly valuable in settings where local generation of biocidal products is preferred, such as healthcare facilities or industrial plants. In contrast, ethanol production typically requires more complex raw materials, such as corn, sugarcane, or grain-based feedstocks, that must be fermented and distilled. These processes demand significant energy input and specialized equipment. Ethanol supply chains are also vulnerable to fluctuations in crop yields, climate variability, and geopolitical disruptions, leading to greater price volatility and potential supply chain instability. This is especially relevant in regions facing crop shortages or changing agricultural policies. The European Union's ethanol supply is particularly exposed to such vulnerabilities. It heavily depends on imports from third countries, including Pakistan, the United States, Brazil, and Peru. In 2023 alone, the EU imported over 2 billion litres of ethanol, placing critical public health infrastructure, such as hygiene and sanitation, at the mercy of global trade fluctuations and geopolitical risks. In contrast, HOCl can be produced locally across Europe, ensuring continuous availability and significantly reducing reliance on volatile global supply chains. Promoting local HOCl production enhances the EU's strategic autonomy, aligning with the objectives of the European Green Deal and the broader goal of open strategic autonomy. In terms of flexibility and scalability, HOCl production is particularly advantageous. The electrolytic generation process allows for decentralized, on-site production at the point of use. This enables scalable deployment in diverse environments, whether in healthcare facilities or industrial settings, and ensures fresh, on-demand production. It also reduces the logistics costs associated with transporting and storing bulk ethanol, which must be delivered in pre-packaged forms and requires more extensive infrastructure and distribution networks. Altogether, these features make HOCl a cost-effective, sustainable, and strategically resilient alternative to ethanol in biocidal applications.

Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Hypochlorous acid (HOCl) presents a viable and promising alternative to ethanol in Product Type 4 (PT 4) biocidal products used in food and feed areas. Commercially available and effective against a broad spectrum of microorganisms, including bacteria, viruses, and fungi, HOCl is well-suited for disinfecting surfaces in food processing, storage, and handling environments. Its non-flammable, non-toxic nature and non-CMR classification make it a safer option than ethanol, especially where food safety and human health are top priorities. Regulatory challenges remain, particularly regarding HOCl's degradation over time. Current ECHA guidelines cap degradation at 10% over a product's shelf life. However, discussions around increasing this threshold to 30% could improve regulatory acceptance, facilitating wider market access and making HOCl more competitive with ethanol-based products. Economically, HOCl's viability depends on consistent manufacturing to ensure product stability. A key factor is the choice between on-site generation and pre-packaged bottled solutions. On-site generation can reduce transport and storage costs, enhance freshness, and cut CO₂ emissions compared to ethanol logistics. These benefits are especially relevant in large-scale operations such as food processing plants and feed mills. If regulatory bodies like ECHA support on-site generation, HOCl's cost-effectiveness and scalability will be further strengthened. In conclusion, HOCl is a strong candidate to replace ethanol in PT 4 biocidal applications. Its proven efficacy, safety, and environmental benefits make it well-suited for use in food and feed areas. While regulatory and production challenges exist, ongoing developments and potential policy changes could enhance HOCl's market position as a safe, effective, and sustainable disinfectant.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	

References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 286	2025/04/29 20:17
Country	France
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	
Product Type	1,2,4
Alternative Identity and Properties	PT4 products with lactic acid as active substance. These products based on lactic acid show efficacy against bacteria yeasts and enveloped viruses with contact time from 2 minutes and efficacies are validated by European authorities thanks to simplified marketing authorisations. Moreover, unlike alcohol based disinfectants, lactic acid based disinfectants are efficient in absence and also in presence of organic soiled on surfaces. Concerning efficacy against non enveloped viruses like Noroviruses, some lactic acid disinfectant products have been proved to show efficacy against non enveloped viruses from 5 minutes of contact time according to EN14476 and from 15 minutes according to EN16777 when almost every ethanol disinfectant have no proved efficacy against EN16777 standards which is the most important test for virucidal efficacy as it shows real in use condition in the contrary to the standard EN14476. Moreover, Lactic acid is registered as a food additive (E270) and so fully compliant for food contact. Lactic acid approved for use as a food additive (E270) according Regulation (EU) No. 1333/2008. Lactic acid meets the

	specifications for purity laid down in Regulation (EU) No. 231/2012. Lactic acid is present in a variety of foods, like yogurt containing 9 g/kg (Simpson BK., 2012), traditional cheese with 8 g/kg (Dolci P., 2008) and beef meat with a content of 1.4-5.0 g/kg (Nassos PS., 1988). Lactate is an endogenous substance (in carbohydrate and amino acid metabolism) and a natural component of very many foods, in particular fruits and fermented milk products. Lactic acid also occurs naturally in meats, fruits, tomato juice, beer, wine, molasses, blood and muscles of animals, and in the soil. Lactic acid has been approved in the EU as a food additive without an ADI or upper limit (Directive 95/2/EC), as a cosmetics ingredient, and as veterinary medicinal product without the requirement for MRL setting (EMA 2008)
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Lactic acid is an active substance readily available on European territory with 2 major registered suppliers. Lactic acid is registered as a food additive (E270), therefore perfectly suited for use on surfaces in contact with food. Easily soluble in water, lactic acid makes it possible to obtain aqueous formulations applicable for PT4 for surface applications, both in the form of concentrates to be diluted by the end user (which is not possible with alcohol-based solutions that require a significant concentration of active substances to have a biocidal effect) and ready-to-use solutions. The numerous products authorized throughout Europe in PT4 based on lactic acid include cleaning and disinfection solutions for surfaces suitable for the general public and professional sectors (communities, catering) and the food processing industry. Lactic acid-based products comply with the regulatory requirements required for PT4 applications by the BPR Regulation with a very short contact time, starting from 2 minutes, more generally 5 to 15 minutes. The available products have bactericidal and yeasticidal activity according to suspension standards (EN1276, EN1650) and according to application standards EN13697 and EN16615, as well as activity on all enveloped viruses (EN14476+A1) but also activity on non-enveloped viruses (see confidential document), covering a broad spectrum of micro-organisms to prevent hygiene issues, and at a level equivalent to ethanol-based solutions.

Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Lactic acid is a substance whose production and availability are guaranteed by a robust and established supply chain in Europe, ensuring sourcing independence for the European market. Two actors are currently listed on the Article 95 list of the BPR Regulation, and each has production units allowing for the placing on the market of several thousands tons of lactic acid per year. The main use of lactic acid in Europe is in the food industry (additive E270). Its use in the biocidal sector is relatively new and represents only a small share of actual production. Like ethanol, lactic acid is produced by the fermentation of sugar molasses residues, derived from corn, wheat, or beet from locally produced raw materials, close to the manufacturing sites. It perfectly aligns with the European Commission's desire for a circular economy. Its cost is estimated at around 1.4 – 2 €/Kg, making it an affordable active substance. Furthermore, unlike ethanol, which requires a high concentration (more than 80% v/v) to demonstrate a biocidal effect on bacteria, yeasts, and viruses, lactic acid in the various dossiers under European authorizations is used at much lower concentrations (less than 2% w/w) and more particularly lower than 1% (w/w) for the majority of ready-to-use products for PT2. This use at low dosage makes it an economically advantageous solution as an alternative to various active substances, including alcohols.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Comparison of substance active hazards: Lactic acid: Physical hazards: None / Health hazards: Causes severe skin burns and eye damage and causes serious eye damage / Environmental hazards: None Ethanol Physical hazards: Highly flammable liquid and vapour / Health hazards: Cause serious eye irritation / Environmental hazards: None Ethanol is considered as a VOC, whereas lactic acid is not. As a result, lactic acid-based products do not contain VOCs, with the exception of perfumes. Maximum hazards for concentrated products is only for corrosion and irritation. CLP-free products available, eligible for simplified authorisations (more than 200 products approved) No danger to the environment In view of the data available on the ECHA website on 23 April 2025, we have drawn up a

	comparison of the environmental profiles of these two substances. Lactic acid (CAS: 50-21-5, last modified : 04/01/2023) and ethanol (CAS : 64-17-5, last modified : 17/05/2023) both have similar ecotoxicological profiles. They both are highly mobile in aquatic environments, readily biodegradable and have a low bioaccumulation potential in addition to a low toxicity for aquatic environments. They are finally both not classified for environmental hazards. These two substances therefore both present an equivalent environmental risk. No toxic residues, substance used in the food industry (E270) : if ethanol is classified as CMR for ingestion, lactic acid is a good alternative because it is an endogenous substance. Reduced risk mitigation measures for the storage and use of products vs ethanol-based products
Information above is confidential	
Justification for confidentiality	
Availability	Readily available on the market, derived from the upcycling of sugar beet waste and corn syrup. Several suppliers registered under Article 95. Products already available on the market via AMM and simplified authorization (Article 25 of the BPR): 1155 lactic acid-based products are already on the market for PT1 (119 simplified authorisations and 1036 marketing authorisation
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	In conclusion, lactic acid stands out as a highly promising active substance for PT4 surface disinfectant products. Its proven efficacy against bacteria, yeasts, and enveloped viruses with short contact times, coupled with emerging evidence of effectiveness against non-enveloped viruses under relevant real-world testing conditions, offers a significant advantage over many ethanol-based disinfectants. Furthermore, its food additive status (E270) and natural presence in food underscore its safety and suitability for food contact surfaces. Technically feasible with readily available and biodegradable sources, economically competitive due to low concentrations required, and presenting a more favorable hazard profile than ethanol (non-flammable, no VOCs), lactic acid offers a sustainable and effective solution for a wide range of surface disinfection needs, further enhanced by its descaling

	properties. Its established supply chain in Europe and growing market presence solidify its position as a compelling alternative in the disinfectant
Information above is confidential	
Justification for confidentiality	
Other comments	Lactic acid provides a descaling benefit alongside its disinfectant properties, rendering it particularly advantageous for surface maintenance applications in particular in the milk industries.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 287	2025/04/29 20:23
Country	Germany
Name of organization/institution	Kao Manufacturing Germany GmbH
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	
Product Type	1,2,4
Alternative Identity and Properties	Isopropanol

Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Easy to implement
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	We expect significant price increases for isopropanol if ethanol is no longer available as a hand sanitizer. For our company, this will probably mean a doubling of our previous expenditure on hand sanitizers.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	no increased risks
Information above is confidential	
Justification for confidentiality	
Availability	We anticipate difficulties in availability and procurement following a ban on ethanol.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	If isopropanol is no longer available, this poses a risk to the production of hygiene-sensitive products for our company (approx. 20% of total sales)
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	

Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 288	2025/04/29 20:58
Country	Germany
Name of organization/institution	Bundesverband Medizintechnologie BVMed e.V.
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	BVMed represents over 300 industrial and commercial companies as well as suppliers in the medical technology sector. The 20 largest medical device manufacturers worldwide are organised in BVMed. The crucial role of medical technology in healthcare shows the importance and that medical devices are indispensable on the prevention of health threats in Europe and over the world. The sector and its products are essential for civil defence and public emergency response, from infection control, wound management, trauma surgery, surgical equipment and many more. Medical technology solutions must be considered humanitarian goods. As the leading association of the medical device industry in Germany, BVMed comments on the current classification procedure and the call for alternatives to ethanol within PT 1 and PT2 formulation as follows: Ethanol in the industrial health economy and health care systems Alcohol-based hygienic disinfectants have long been established as one of the most important measures to prevent and control infections inside and outside of healthcare institutions. Ethanol plays therefore an important role not only in hand disinfection but also in surface disinfection and in addition to that also in production processes especially within the health care

	industry. In contrast to other chemicals used for disinfection (isopropanol and hydrogen peroxide), it shows an unbeatable combination of fast, broad-spectrum antimicrobial activity against bacteria and viruses and a favourable exposure profile in various products that is unmatched by available alternatives and has a relatively low hazard potential. Furthermore, the substance is safe and biodegradable. Ethanol acts specifically and without alternative against non-enveloped viruses such as poliovirus. The prevalence of nosocomial infections has also been reduced through the use of alcohol-based hand sanitisers. The World Health Organisation (WHO) has therefore classified hand disinfectants containing ethanol as indispensable (1). Ethanol is readily and quickly available, and any necessary upscaling of production capacity can be achieved quickly, as has been demonstrated during the Covid-19 pandemic. It was shown that infection-chains could be safely and quickly interrupted by disinfection measures. Manufacturers were able to cover the exceptionally high demand for disinfectants during the pandemic mainly through available ethanol. The data used for the risk assessment and the proposed classification of ethanol as potentially reprotoxic or carcinogenic are based primarily on the (abusive) oral intake of alcoholic beverages. These data are in no way relevant for the intended use in the field of hygiene, in particular because denatured alcohol is used in these applications. Other exposures (inhalation, dermal) result in low blood levels comparable with endogenous formation or uptake via food. Even though this consultation and the current classification refers to BPR processes, we would like to refer to the CLP guidances. They define 'reasonably foreseeable use' as, among other things, occupational and non-occupational uses, including reasonably foreseeable accidental exposure, but not misuse. A CMR classification as class 1 substance would constitute in a de facto ban and has far-reaching consequences for the use of ethanol-containing disinfectants in the whole society not only in the healthcare sector and the health industry. In particular, it could significantly impair the necessary widespread use of these disinfectants but also the production of lifesaving products like medical devices, IVDs and medicinal products. In addition to consequences within the worker safety legislation, a classification as reproduction toxic with an effect on/through lactation would result in a work ban for women of childbearing age under German labour law. It is evident that the automatic linkage of classification according to the BPR or CLP Regulation and the associated regulations without further risk assessment does not serve to protect human

	health and the environment. Even with derogations, the availability of ethanol will be severely restricted due to local regulations. We also want to refer to Annex 1 No 3.6.2.1 CLP Regulation which states that the classification as carcinogenic should only be made according to one exposure pathway if it is proven that there is no risk in the other exposure pathways. Accordingly, ethanol would only have to be classified as carcinogenic via the oral exposure pathway. There is no intended oral exposure to ethanol within the scope of substance legislation. The classification of ethanol as a CMR substance class 1 in the BPR/CLH process has massive economic and legal impacts and must be stopped immediately.
Product Type	1,2,4
Alternative Identity and Properties	Particularly in its effect against non-enveloped viruses, ethanol is indispensable (1). Also, the German "Robert Koch Institute" recommends the use of Ethanol as it is more effective against viruses than propyl alcohols (2). Chlorhexidine digluconate, octenidine hydrochloride, polihexanide, quaternary ammonium compounds, ampholytes, phenol derivatives and triclosan do not enhance the effect of alcoholic disinfectants when added, but depending on the active ingredient, there is a increased hazardous profile and the risk of intolerance or the development of resistance. The use of polyvinylpyrrolidone (PVP) iodine products is limited by iodine absorption. Aqueous solutions based on chlorinated solvents, PVP iodine or peroxides are not an alternative to alcohol-based hand disinfectants in healthcare facilities due to their lower efficacy, poorer skin tolerance than alcohol-based products, due to their poorer spreading behaviour on the skin and longer evaporation time, are not an alternative to the use of alcohol-based hand disinfectants in healthcare facilities (3). Other alternatives would be isopropanol and hydrogen peroxide. All potential substitutes show a significantly higher hazardous profile and jeopardise the necessary compliance in hygiene within the healthcare sector since ethanol-based disinfectants show a very high level of acceptance among healthcare professionals.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	From a procedural perspective every replacement of disinfectants needs to be tested according to the state of the art (pharmacopoe and standards) to ensure the efficacy.

	The implementation of replacements includes rationales for substitution, efficacy validation, protocol and procedure adjustments as well as staff training and lasts at least 6-9 months. In case of non-biocidal uses of ethanol additional sectoral legislation (e.g. for medical devices, IVD or medicinal products) has to be taken into account.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Compared to possible substitutes the economic advantages of Ethanol are given as available, scalable and cheap. Especially the Covid-19 pandemic showed the fast upscale possibilities in case of urgent need for disinfectants. The market for hand disinfectants in Germany is already at a three-digit million level. All relevant virucidal products are ethanol-based, while the spectrum of other common disinfectants is limited. (4). Substitution with more expensive but less effective substances would place an unnecessary financial burden on the healthcare system, which is already under severe strain in many European countries, even though the risk potential of ethanol in these applications does not correspond to oral abuse and would lead to an increased infection potential. The implementation of necessary infection control measures can help to reduce additional burden on the healthcare system and the economy caused by preventable infections. Hand disinfectants and surface disinfectants are risk-minimising biocides, medical devices and technologies. When used continuously, they can help to prevent infections (5). According to the Robert Koch Institute, approximately 600,000 nosocomial infections in Germany lead to up to 20,000 deaths every year (6). The length of hospital stays increases due to an infection. This leads to additional costs for the healthcare system. A cost-benefit analysis concludes that a variety of 'Infection Protection and Control (IPC)' programmes are cost-effective (7). These programmes also include hand hygiene, for which the relevant hand disinfectants are required (8). The results show how essential it is to maintain and strengthen preventive measures against nosocomial infections. These include hand disinfectants and surface disinfectants. A classification as required in this procedure would endanger the protection against (nosocomial) infections to an unimaginable extent. Disinfectants are often placed on the market as dual use products under the BPR and the medical device regulation (MDR; Reg 2017/745). A change in the main active

	ingredient requires extensive and resource-intensive testing and approval processes under both regulations. To place a medical device on the market the development and approval process lasts at least 7 years. Additional to the approval processes also indirect expenses within the use and application have to be considered e.g. employee training, disinfection protocols and SOPs and the modification of inventory management systems.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Possible alternatives of Ethanol show different hazards and risks depending on the specific substance. The profiles of in the section 1 mentioned substances are well known within the European Chemical Agency and therefore we want to highlight only a few arguments: Isopropanol shows a comparable hazard and risk profile to Ethanol. Besides the chemical properties also the higher skin dryness caused by isopropanol has to be considered. The hazardous profile of other alternatives like hydrogen peroxide is significant different and show characteristics like corrosion, possible eye and skin damage.
Information above is confidential	
Justification for confidentiality	
Availability	Possible alternatives are available in principle, but scaling the production volume is not possible in the short or medium term. Strict planning rules and limit thresholds for industrial plants have always been part of everyday life for the chemical industry. Especially for chemicals such as hydrogen peroxide, authorisation procedures for plants are necessary due to the potential risk. Isopropanol has a petrochemical origin and considerable environmental drawbacks due to the energy intensive production must be taken into account.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol is recommended for hygienic uses by the WHO and the German RKI and is safely used for over 75 year worldwide even Islamic countries (9) (10). Since 2005,

	hand sanitiser dispensers have been installed in numerous healthcare facilities in Saudi Arabia (11). Ahmed et al. (2006) report that alcohol has long been a component of household cleaners and other materials for public use by Muslims. Since 2003, the use of alcohol-based hand sanitizers has been permitted in hospitals of the Saudi Arabian National Guard (SANG-HA) (12). The planned classification of Ethanol is mainly based on data from the - abusive - oral intake of alcoholic beverages. This hazard-based classification does not reflect use and exposure in hygienic applications and would have a huge impact to the healthcare system. BVMed therefore urgently request that the planned classification be stopped immediately and for only exposure-relevant data to be included within the assessment. This would avoid serious consequences for the industrial health sector, which would severely restrict or even ban the availability and use of ethanol as the main or auxiliary active ingredient in products such as hand disinfectants, surface disinfectants and in various production and hygiene processes.
Information above is confidential	
Justification for confidentiality	
Other comments	Within classification processes, substance authorisations and product approvals the regulatory complexity must be considered. A possible classification of Ethanol as CMR 1A/1B have a huge impact on other legislations. Among other product legislations its mainly the MDR (especially Annex 1, section 10.4.1), but also occupational safety law and maternity protection law. Especially in the women dominated field of health care this would lead to restrictions in the use of the chemical for example by women of childbearing age or breastfeeding women. We therefore urge for a proper impact assessment within BPR and CLP processes to avoid dramatic consequences.
Information above is confidential	
Justification for confidentiality	
References	(1) Kramer, A., Arvand, M., Christiansen, B. et al. (2022). Ethanol is indispensable for virucidal hand antisepsis: memorandum from the alcohol-based hand rub (ABHR) Task Force, WHO Collaborating Centre on Patient Safety, and the Commission for Hospital Hygiene and Infection Prevention (KRINKO), Robert Koch Institute,

	Berlin, Germany: https://pubmed.ncbi.nlm.nih.gov/35794648/ (2) Anforderungen an die Hygiene bei der Reinigung und Desinfektion von Flächen Empfehlung der Kommission für Krankenhaushygiene und Infektionsprävention (KRINKO) beim Robert Koch-Institut Bundesgesundheitsbl 2022 · 65:1074–1115 https://doi.org/10.1007/s00103-022-03576-1; Springer-Verlag GmbH Deutschland Including Erratum zu: Anforderungen an die Hygiene bei der Reinigung und Desinfektion von Flächen Bundesgesundheitsbl2023· 66:1302–1303 https://doi.org/10.1007/s00103-023-03770-9; Springer-Verlag GmbH Deutschland (3) Händehygiene in Einrichtungen des Gesundheitswesens: Empfehlung der Kommission für Krankenhaushygiene und Infektionsprävention (KRINKO) beim Robert Koch-Institut (RKI) https://www.rki.de/DE/Themen/Infektionskrankheiten/Krankenhaushygiene/KRINKO/Empfehlungen-der-KRINKO/Basishygiene/Downloads/Haendehyg_Rili.pdf?__blob=publicationFile&v=6 (4) Auswirkungen der Einstufung nach der CLP-Verordnung auf das nachgeschaltete Regelwerk am Beispiel Ethanol https://www.bayerische-chemieverbaende.de/wp-content/uploads/2015/03/vci-position-zu-den-rechtsfolgen-einer-harmonisierten-einstufung-etha-.pdf (5) BVMed web site Infection prevention https://www.bvmed.de/themen/infektionsschutz (6) German Ministry of Health, Hospital hygiene: https://www.bundesgesundheitsministerium.de/krankenhaushygiene.html (7) Dick A, Perencevich E, Pogorzelska-Maziarz M, Zwanziger J, Larson E, Stone P: A decade of investment in infection prevention: A cost effectiveness analysis https://pmc.ncbi.nlm.nih.gov/articles/PMC4743241/ (8) WHO Infection prevention and control: https://www.who.int/health-topics/infection-prevention-and-control#tab=tab_1 (9) Kirschner MH, Lang RA, Breuer B, Breuer M, Gronover CS, Zwingers T, Böttlich JG, Arndt A, Brauer U, Hintzpeter M, Burmeister MA, Fauteck JD.: Transdermal resorption of an ethanol and 2-propanol-containing skin disinfectant: https://pubmed.ncbi.nlm.nih.gov/17989993/ (10) Stellungnahme der Deutschen Gesellschaft für Allgemeine und Krankenhaus-Hygiene e.V. Ethanol darf nicht als CMR eingestuft werden; https://www.krankenhaushygiene.de/pdfdata/177_178_DGKH_Stellungnahme_Ethanol_HM_9_24.pdf (11) Allegranzi B, MD, Memish Z A, MD, Donaldson L, MD, Pittet D, MD, MS, (2013) for the World Health Organization Global Patient Safety Challenge Task Force on Religious and Cultural

	Aspects of Hand Hygiene (lead, D. Pittet), World Alliance for Patient Safety; “Religion and culture: Potential undercurrents influencing hand hygiene promotion in health care”; Geneva, Switzerland, and Riyadh, Saudi Arabia; P. 5 (12) Ahmed Q A, Memish Z A, Allegranzi B, Pittet D, on behalf of the WHO Global Patient Safety Challenge; “Muslim health-care workers and alcohol-based handrubs”; P. 2
Attachments (non-confidential information)	250430_BVMed_Positions_Ethanol_PT1+2_final.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 289	2025/04/29 21:00
Country	Germany
Name of organization/institution	Bundesverband Medizintechnologie BVMed e.V.
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	BVMed represents over 300 industrial and commercial companies as well as suppliers in the medical technology sector. The 20 largest medical device manufacturers worldwide are organised in BVMed. The crucial role of medical technology in healthcare shows the importance and that medical devices are indispensable on the prevention of health threats in Europe and over the world. The sector and its products are essential for civil defence and public emergency response, from infection control, wound management, trauma surgery, surgical equipment and many more. Medical technology solutions must be considered humanitarian goods. As the leading association of the medical device industry in Germany, BVMed comments on the current classification procedure and the call for alternatives to ethanol within PT 1 and PT2 formulation as follows: Ethanol in the industrial health economy and health care systems Alcohol-based hygienic disinfectants have long been established as one of the most important measures to prevent and control infections inside

	and outside of healthcare institutions. Ethanol plays therefore an important role not only in hand disinfection but also in surface disinfection and in addition to that also in production processes especially within the health care industry. In contrast to other chemicals used for disinfection (isopropanol and hydrogen peroxide), it shows an unbeatable combination of fast, broad-spectrum antimicrobial activity against bacteria and viruses and a favourable exposure profile in various products that is unmatched by available alternatives and has a relatively low hazard potential. Furthermore, the substance is safe and biodegradable. Ethanol acts specifically and without alternative against non-enveloped viruses such as poliovirus. The prevalence of nosocomial infections has also been reduced through the use of alcohol-based hand sanitisers. The World Health Organisation (WHO) has therefore classified hand disinfectants containing ethanol as indispensable (1). Ethanol is readily and quickly available, and any necessary upscaling of production capacity can be achieved quickly, as has been demonstrated during the Covid-19 pandemic. It was shown that infection-chains could be safely and quickly interrupted by disinfection measures. Manufacturers were able to cover the exceptionally high demand for disinfectants during the pandemic mainly through available ethanol. The data used for the risk assessment and the proposed classification of ethanol as potentially reprotoxic or carcinogenic are based primarily on the (abusive) oral intake of alcoholic beverages. These data are in no way relevant for the intended use in the field of hygiene, in particular because denatured alcohol is used in these applications. Other exposures (inhalation, dermal) result in low blood levels comparable with endogenous formation or uptake via food. Even though this consultation and the current classification refers to BPR processes, we would like to refer to the CLP guidances. They define 'reasonably foreseeable use' as, among other things, occupational and non-occupational uses, including reasonably foreseeable accidental exposure, but not misuse. A CMR classification as class 1 substance would constitute in a de facto ban and has far-reaching consequences for the use of ethanol-containing disinfectants in the whole society not only in the healthcare sector and the health industry. In particular, it could significantly impair the necessary widespread use of these disinfectants but also the production of lifesaving products like medical devices, IVDs and medicinal products. In addition to consequences within the worker safety legislation, a classification as reproduction toxic with an effect on/through lactation would result in a work ban for women of

	childbearing age under German labour law. It is evident that the automatic linkage of classification according to the BPR or CLP Regulation and the associated regulations without further risk assessment does not serve to protect human health and the environment. Even with derogations, the availability of ethanol will be severely restricted due to local regulations. We also want to refer to Annex 1 No 3.6.2.1 CLP Regulation which states that the classification as carcinogenic should only be made according to one exposure pathway if it is proven that there is no risk in the other exposure pathways. Accordingly, ethanol would only have to be classified as carcinogenic via the oral exposure pathway. There is no intended oral exposure to ethanol within the scope of substance legislation. The classification of ethanol as a CMR substance class 1 in the BPR/CLH process has massive economic and legal impacts and must be stopped immediately.
Product Type	1,2,4
Alternative Identity and Properties	Particularly in its effect against non-enveloped viruses, ethanol is indispensable (1). Also, the German "Robert Koch Institute" recommends the use of Ethanol as it is more effective against viruses than propyl alcohols (2). Chlorhexidine digluconate, octenidine hydrochloride, polihexanide, quaternary ammonium compounds, ampholytes, phenol derivatives and triclosan do not enhance the effect of alcoholic disinfectants when added, but depending on the active ingredient, there is a increased hazardous profile and the risk of intolerance or the development of resistance. The use of polyvinylpyrrolidone (PVP) iodine products is limited by iodine absorption. Aqueous solutions based on chlorinated solvents, PVP iodine or peroxides are not an alternative to alcohol-based hand disinfectants in healthcare facilities due to their lower efficacy, poorer skin tolerance than alcohol-based products, due to their poorer spreading behaviour on the skin and longer evaporation time, are not an alternative to the use of alcohol-based hand disinfectants in healthcare facilities (3). Other alternatives would be isopropanol and hydrogen peroxide. All potential substitutes show a significantly higher hazardous profile and jeopardise the necessary compliance in hygiene within the healthcare sector since ethanol-based disinfectants show a very high level of acceptance among healthcare professionals.
Information above is confidential	

Justification for confidentiality	
Technical Feasibility	From a procedural perspective every replacement of disinfectants needs to be tested according to the state of the art (pharmacopoe and standards) to ensure the efficacy. The implementation of replacements includes rationales for substitution, efficacy validation, protocol and procedure adjustments as well as staff training and lasts at least 6-9 months. In case of non-biocidal uses of ethanol additional sectoral legislation (e.g. for medical devices, IVD or medicinal products) has to be taken into account.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Compared to possible substitutes the economic advantages of Ethanol are given as available, scalable and cheap. Especially the Covid-19 pandemic showed the fast upscale possibilities in case of urgent need for disinfectants. The market for hand disinfectants in Germany is already at a three-digit million level. All relevant virucidal products are ethanol-based, while the spectrum of other common disinfectants is limited. (4). Substitution with more expensive but less effective substances would place an unnecessary financial burden on the healthcare system, which is already under severe strain in many European countries, even though the risk potential of ethanol in these applications does not correspond to oral abuse and would lead to an increased infection potential. The implementation of necessary infection control measures can help to reduce additional burden on the healthcare system and the economy caused by preventable infections. Hand disinfectants and surface disinfectants are risk-minimising biocides, medical devices and technologies. When used continuously, they can help to prevent infections (5). According to the Robert Koch Institute, approximately 600,000 nosocomial infections in Germany lead to up to 20,000 deaths every year (6). The length of hospital stays increases due to an infection. This leads to additional costs for the healthcare system. A cost-benefit analysis concludes that a variety of 'Infection Protection and Control (IPC)' programmes are cost-effective (7). These programmes also include hand hygiene, for which the relevant hand disinfectants are required (8). The results show how essential it is to maintain and strengthen preventive measures against nosocomial infections. These include hand disinfectants and surface disinfectants. A classification as

	required in this procedure would endanger the protection against (nosocomial) infections to an unimaginable extent. Disinfectants are often placed on the market as dual use products under the BPR and the medical device regulation (MDR; Reg 2017/745). A change in the main active ingredient requires extensive and resource-intensive testing and approval processes under both regulations. To place a medical device on the market the development and approval process lasts at least 7 years. Additional to the approval processes also indirect expenses within the use and application have to be considered e.g. employee training, disinfection protocols and SOPs and the modification of inventory management systems.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Possible alternatives of Ethanol show different hazards and risks depending on the specific substance. The profiles of in the section 1 mentioned substances are well known within the European Chemical Agency and therefore we want to highlight only a few arguments: Isopropanol shows a comparable hazard and risk profile to Ethanol. Besides the chemical properties also the higher skin dryness caused by isopropanol has to be considered. The hazardous profile of other alternatives like hydrogen peroxide is significant different and show characteristics like corrosion, possible eye and skin damage.
Information above is confidential	
Justification for confidentiality	
Availability	Possible alternatives are available in principle, but scaling the production volume is not possible in the short or medium term. Strict planning rules and limit thresholds for industrial plants have always been part of everyday life for the chemical industry. Especially for chemicals such as hydrogen peroxide, authorisation procedures for plants are necessary due to the potential risk. Isopropanol has a petrochemical origin and considerable environmental drawbacks due to the energy intensive production must be taken into account.
Information above is confidential	

Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol is recommended for hygienic uses by the WHO and the German RKI and is safely used for over 75 year worldwide even Islamic countries (9) (10). Since 2005, hand sanitiser dispensers have been installed in numerous healthcare facilities in Saudi Arabia (11). Ahmed et al. (2006) report that alcohol has long been a component of household cleaners and other materials for public use by Muslims. Since 2003, the use of alcohol-based hand sanitizers has been permitted in hospitals of the Saudi Arabian National Guard (SANG-HA) (12). The planned classification of Ethanol is mainly based on data from the - abusive - oral intake of alcoholic beverages. This hazard-based classification does not reflect use and exposure in hygienic applications and would have a huge impact to the healthcare system. BVMed therefore urgently request that the planned classification be stopped immediately and for only exposure-relevant data to be included within the assessment. This would avoid serious consequences for the industrial health sector, which would severely restrict or even ban the availability and use of ethanol as the main or auxiliary active ingredient in products such as hand disinfectants, surface disinfectants and in various production and hygiene processes.
Information above is confidential	
Justification for confidentiality	
Other comments	Within classification processes, substance authorisations and product approvals the regulatory complexity must be considered. A possible classification of Ethanol as CMR 1A/1B have a huge impact on other legislations. Among other product legislations its mainly the MDR (especially Annex 1, section 10.4.1), but also occupational safety law and maternity protection law. Especially in the women dominated field of health care this would lead to restrictions in the use of the chemical for example by women of childbearing age or breastfeeding women. We therefore urge for a proper impact assessment within BPR and CLP processes to avoid dramatic consequences.
Information above is confidential	
Justification for confidentiality	

References	(1) Kramer, A., Arvand, M., Christiansen, B. et al. (2022). Ethanol is indispensable for virucidal hand antisepsis: memorandum from the alcohol-based hand rub (ABHR) Task Force, WHO Collaborating Centre on Patient Safety, and the Commission for Hospital Hygiene and Infection Prevention (KRINKO), Robert Koch Institute, Berlin, Germany: https://pubmed.ncbi.nlm.nih.gov/35794648/ (2) Anforderungen an die Hygiene bei der Reinigung und Desinfektion von Flächen Empfehlung der Kommission für Krankenhaushygiene und Infektionsprävention (KRINKO) beim Robert Koch-Institut Bundesgesundheitsbl 2022 · 65:1074–1115 https://doi.org/10.1007/s00103-022-03576-1; Springer-Verlag GmbH Deutschland Including Erratum zu: Anforderungen an die Hygiene bei der Reinigung und Desinfektion von Flächen Bundesgesundheitsbl2023· 66:1302–1303 https://doi.org/10.1007/s00103-023-03770-9; Springer-Verlag GmbH Deutschland (3) Händehygiene in Einrichtungen des Gesundheitswesens: Empfehlung der Kommission für Krankenhaushygiene und Infektionsprävention (KRINKO) beim Robert Koch-Institut (RKI) https://www.rki.de/DE/Themen/Infektionskrankheiten/Krankenhaushygiene/KRINKO/Empfehlungen-der-KRINKO/Basishygiene/Downloads/Haendehyg_Rili.pdf?__blob=publicationFile&v=6 (4) Auswirkungen der Einstufung nach der CLP-Verordnung auf das nachgeschaltete Regelwerk am Beispiel Ethanol https://www.bayerische-chemieverbaende.de/wp-content/uploads/2015/03/vci-position-zu-den-rechtsfolgen-einer-harmonisierten-einstufung-etha-.pdf (5) BVMed web site Infection prevention https://www.bvmed.de/themen/infektionsschutz (6) German Ministry of Health, Hospital hygiene: https://www.bundesgesundheitsministerium.de/krankenhaushygiene.html (7) Dick A, Perencevich E, Pogorzelska-Maziarz M, Zwanziger J, Larson E, Stone P: A decade of investment in infection prevention: A cost effectiveness analysis https://pmc.ncbi.nlm.nih.gov/articles/PMC4743241/ (8) WHO Infection prevention and control: https://www.who.int/health-topics/infection-prevention-and-control#tab=tab_1 (9) Kirschner MH, Lang RA, Breuer B, Breuer M, Gronover CS, Zwingers T, Böttlich JG, Arndt A, Brauer U, Hintzpeter M, Burmeister MA, Fauteck JD.: Transdermal resorption of an ethanol and 2-propanol-containing skin disinfectant: https://pubmed.ncbi.nlm.nih.gov/17989993/ (10) Stellungnahme der Deutschen Gesellschaft für Allgemeine und Krankenhaus-Hygiene e.V. Ethanol darf

	nicht als CMR eingestuft werden; https://www.krankenhaushygiene.de/pdfdata/177_178_DG_KH_Stellungnahme_Ethanol_HM_9_24.pdf (11) Allegranzi B, MD, Memish Z A, MD, Donaldson L, MD, Pittet D, MD, MS, (2013) for the World Health Organization Global Patient Safety Challenge Task Force on Religious and Cultural Aspects of Hand Hygiene (lead, D. Pittet), World Alliance for Patient Safety; "Religion and culture: Potential undercurrents influencing hand hygiene promotion in health care"; Geneva, Switzerland, and Riyadh, Saudi Arabia; P. 5 (12) Ahmed Q A, Memish Z A, Allegranzi B, Pittet D, on behalf of the WHO Global Patient Safety Challenge; "Muslim health-care workers and alcohol-based handrubs"; P. 2
Attachments (non-confidential information)	250430_BVMed_Positions_Ethanol_PT1+2_final.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 290	2025/04/29 21:20
Country	Belgium
Name of organization/institution	European Association of Hospital Pharmacists (EAHP)
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	The European Association of Hospital Pharmacists (EAHP) represents over 29,000 hospital pharmacists across 36 member countries. EAHP represents and develops the hospital pharmacy profession within Europe in order to ensure the continuous improvement of care and outcomes for patients in the hospital setting. This is achieved through science, research, education, practice, as well as sharing best-practice and responsibility with other healthcare professionals.
Product Type	1,2,4

Alternative Identity and Properties	There are currently no alternative substances suitable for use in handrubs that demonstrate comparable efficacy and properties against hydrophilic non-enveloped viruses.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	We are not aware of biocidal products approved as PT1 possessing virucidal activity.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Alternative substances generally demonstrate a narrower spectrum of activity, reduced effectiveness against viruses, lower skin tolerability, or higher toxicity compared to Ethanol. For instance, chlorine-based disinfectants are characterised by a high instability and skin irritation potential; the peracetic acid is irritant and with worse organoleptic properties; propanol is more volatile, it has less surface contact time so less effective action time. Additionally, some substances indicated as potential alternatives are not virucidals. This may cause the development of antimicrobial resistance.
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	In multiple EU Countries, ethanol-based hand disinfectants are important for the compounding activity in hospital pharmacies. Indeed, hospital pharmacies prepare and

	dispense disinfectants, and hospital pharmacists are often involved in their tendering process at the local and/or national level. Additionally, in some countries, Hospital pharmacists use ethanol for cleaning the laminar flow cabinets used for compounding oncological drugs. In aseptic processes in many hospital pharmacies, ethanol is currently the most important product and benefits outweigh the risks. Ethanol is an essential product and the erection of additional barriers could negatively impact availability and costs. The WHO listed Ethanol among the essential antiseptics and disinfectants. Furthermore it is a component of the WHO-recommended handrub formulation, recognised for its effectiveness against non-enveloped viruses, and it is currently available in adequate supply throughout Europe and worldwide. Hand hygiene has been recognised as a crucial element of infection prevention and control. Alcohol-based handrubs are the preferred choice, with only ethanol-based formulations showing virucidal properties (https://cdn.who.int/media/docs/default-source/integrated-health-services-(ihs)/ipc/ipc-global-action-plan/who_gampf_w_annexes.pdf?sfvrsn=aef723f7_3). The proposed alternatives present several disadvantages and multiple risks, ranging from increased toxicity, instability, and potential irritation, to reduced efficacy against certain pathogens, which could lead to the development of resistance and pose health risks to healthcare professionals and patients. For the above mentioned reasons, EAHP considers that ethanol continues to be essential and irreplaceable as a virucidal active ingredient.
Information above is confidential	
Justification for confidentiality	
Other comments	Ethanol was assessed as a biocidal substance using data related to oral intake and alcohol misuse. Nonetheless, in the context of its use in biocidal products (PT1, PT2, PT4), ethanol is not intended for consumption as a food or beverage but is instead meant for application on the skin or on surfaces.
Information above is confidential	
Justification for confidentiality	
References	

Attachments (non-confidential information)	Ethanol Reclassification BPR.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 291	2025/04/29 21:23
Country	Germany
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	To protect biosecurity on farms, we urgently need an effective hand sanitiser against non-enveloped viruses in the future! If the active ingredient ethanol is banned for hand sanitiser, there will no longer be an effective hand sanitiser available for agriculture and forestry. In view of the strong globalisation in the world the risk of spreading disease-causing pathogens increases not only for humans but also for farm animals. Epidemics are only the top of the mountain, the introduction of new pathogens and the spread of known pathogens is a constant threat to animal husbandry. In Germany, preventive hygiene measures are mandatory for farmers. Hand sanitisation is an essential part of the extensive hygiene measures to break chains of infection.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	

Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	There is no product for hand disinfection available against non-enveloped viruses for farmers and foresters in cases of animal diseases such as the current outbreak of the foot-and-mouth disease (FMD) in Germany, Hungary, Slovenia.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	At the beginning of the year, there was a case of foot-and-mouth disease FMD (caused by an unenveloped virus) in Germany. This animal disease is fatal in its effects because it can affect many different animal species (including cattle, pigs, wild boar, sheep, goats, wild animals), the unenveloped virus is very resistant and long-lived in the environment and causes severe health problems in the animals. All (!) animals on an affected farm are culled. There are currently numerous outbreaks of FMD in Hungary and Slovenia. In 2011, there were 12 outbreaks in Bulgaria. FMD is endemic in Turkey and numerous cases are reported every year. There are also repeated outbreaks in Asian and African countries. The authorities are calling for absolute vigilance and urgently recommending that all possible biosecurity measures be implemented on farms. Hand disinfection is an absolute must! In order to contain FMD (and future epidemics), very effective hand sanitisers, also against non-enveloped viruses, are absolutely essential in agriculture (and forestry). If the active ingredient ethanol were banned, an effective product would no longer be

	available. Other non-enveloped viruses and diseases in livestock that can cause enormous economic damage through loss of performance and even death are, for example Circo virus in pigs, Porcine parvovirus in pigs Rota viruses in calves Swine vesicular disease
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	Cases of the Foot-and-mouth disease (FMD) in the world: https://wahis.woah.org/#/dashboards/country-or-disease-dashboard Federal Research Institute of Animal Health, Friedrich Löffler Institute, https://www.fli.de/en/news/animal-disease-situation/foot-and-mouth-disease/
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 292	2025/04/29 21:28
Country	Belgium
Name of organization/institution	European Association of Hospital Pharmacists (EAHP)
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	The European Association of Hospital Pharmacists (EAHP) represents over 29,000 hospital pharmacists across 36 member countries. EAHP represents and develops the

	hospital pharmacy profession within Europe in order to ensure the continuous improvement of care and outcomes for patients in the hospital setting. This is achieved through science, research, education, practice, as well as sharing best-practice and responsibility with other healthcare professionals.
Product Type	1,2,4
Alternative Identity and Properties	There are currently no alternative substances suitable for use in handrubs that demonstrate comparable efficacy and properties against hydrophilic non-enveloped viruses.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	No alternatives approved as PT1 appear to possess virucidal activity.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Alternative substances generally demonstrate a narrower spectrum of activity, reduced effectiveness against viruses, lower skin tolerability, or higher toxicity compared to Ethanol. For instance, chlorine-based disinfectants are characterised by a high instability and skin irritation potential; the peracetic acid is irritant and with worse organoleptic properties; propanol is more volatile, it has less surface contact time so less effective action time. Additionally, some substances indicated as potential alternatives are not virucidals. This may cause the development of antimicrobial resistance.
Information above is confidential	
Justification for confidentiality	
Availability	

Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	In multiple EU Countries, ethanol-based hand disinfectants are important for the compounding activity in hospital pharmacies. Indeed, hospital pharmacies prepare and dispense disinfectants, and hospital pharmacists are often involved in their tendering process at the local and/or national level. Additionally, in some countries, Hospital pharmacists use ethanol for cleaning the laminar flow cabinets used for compounding oncological drugs. In aseptic processes in many hospital pharmacies, ethanol is currently the most important product and benefits outweigh the risks. Ethanol is an essential product and the erection of additional barriers could negatively impact availability and costs. The WHO listed Ethanol among the essential antiseptics and disinfectants. Furthermore it is a component of the WHO-recommended handrub formulation, recognised for its effectiveness against non-enveloped viruses, and it is currently available in adequate supply throughout Europe and worldwide. Hand hygiene has been recognised as a crucial element of infection prevention and control. Alcohol-based handrubs are the preferred choice, with only ethanol-based formulations showing virucidal properties (https://cdn.who.int/media/docs/default-source/integrated-health-services-(ihs)/ipc/ipc-global-action-plan/who_gampf_w_annexes.pdf?sfvrsn=aef723f7_3). The proposed alternatives present several disadvantages and multiple risks, ranging from increased toxicity, instability, and potential irritation, to reduced efficacy against certain pathogens, which could lead to the development of resistance and pose health risks to healthcare professionals and patients. For the above mentioned reasons, EAHP considers that ethanol continues to be essential and irreplaceable as a virucidal active ingredient.
Information above is confidential	
Justification for confidentiality	
Other comments	Ethanol was assessed as a biocidal substance using data related to oral intake and alcohol misuse. Nonetheless, in the context of its use in biocidal products (PT1, PT2, PT4), ethanol is not intended for consumption as a food or beverage but is instead meant for application on the skin or on surfaces.

Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	Ethanol Reclassification BPR.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 293	2025/04/29 21:52
Country	United Kingdom
Name of organization/institution	[REDACTED]
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	This document presents a justification for maintaining the current classification of ethanol and opposing the proposed new CMR (Carcinogenic, Mutagenic, and/or Toxic to Reproduction) classifications. We acknowledge ECHA's role in safeguarding human health and the environment, but we believe that the proposed reclassification of ethanol is not supported by a comprehensive and balanced evaluation of the scientific evidence, and may have significant negative consequences across various sectors due to shortages of available, suitable alternatives on the market. Ethanol is a vital component of hand sanitisers, which play a crucial role in public health and hygiene, especially for our customers in healthcare, food manufacturing, and childcare as examples, where controlling organism transmission is paramount. Ethanol's effectiveness against a broad spectrum of microorganisms has been well-established.
Product Type	1,2,4
Alternative Identity and Properties	Ethanol is a critical component of some hand sanitisers, playing a vital role in public health and hygiene. In

	particular, for some of our customers, good workplace hygiene is paramount, especially in those customers where the risk of organism transmission must be controlled, e.g. healthcare facilities, food manufacturing, childcare facilities. Its effectiveness against a broad spectrum of microorganisms, including bacteria, viruses, and fungi, is well-established. There is a wealth of evidence showing ethanol (64 g / 100 g) preparation efficacy according to EN 1500, 13624, 13727, 14476 with full virucidal activity against Noro, Adeno and Polio viruses as example. Ethanol plays a critical role in many applications where its unique properties are essential, and suitable alternatives are not readily available. Most important is the lack of efficacy for non-enveloped viruses of all possible alternatives of ethanol. This means that it is not possible to prevent the spreading of diseases by non-enveloped viruses like Polio, Norovirus (Kramer, 2022). Ethanol is comparatively cheap to other active substances, generally available, easy and fast to produce ensuring a constant supply, green and sustainable. As a candidate for substitution ethanol will no longer be available for use by the general public. This is particularly critical for an outbreak or pandemic situation.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	We do not believe that a suitable technical alternative exists for all our usage cases.
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Justification for confidentiality	
Economic Feasibility	If ethanol is classified as a CMR (Carcinogenic, Mutagenic, or Reprotoxic) substance, the impact on both direct and indirect costs associated with hand sanitisers would be significant. Direct costs would increase due to the need to reformulate products with alternative active ingredients. These alternatives have different efficacy profiles and may be more expensive to source and produce. Manufacturers would also incur expenses related to research and development, new safety testing to ensure the efficacy and safety of alternative formulations, and changes in labeling and packaging to comply with new regulations and inform consumers. This we already see with the current changing landscape within the EU that label updates, SDS updates, horizon mapping for classification changes all have a

	financial impact on industry. The removal of ethanol from hand sanitisers could lead to several indirect costs. A primary concern is the potential decrease in public health efficacy, as ethanol is a broad-spectrum virucidal agent effective against pathogens like poliovirus and norovirus (Kampf (2018)). This could necessitate the use of alternative disinfectants, some of which may have limitations in efficacy, particularly against non-enveloped viruses, potentially leading to an increased risk of infections and higher healthcare costs. Additionally, the need for extensive research and development to find and validate effective, sustainable alternatives could strain resources and delay the availability of suitable replacements.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Ethanol plays a critical role in many applications where its unique properties are essential, and suitable alternatives are not readily available. Most important is the lack of efficacy for non enveloped viruses of all possible alternatives of ethanol. This means, it is not possible to prevent the spreading of diseases by non-enveloped virus's like Polio and Norovirus (Kramer, 2022). Ethanol is comparatively cheap to other active substances, generally available, easy and fast to produce ensuring a constant supply, green and sustainable. As a candidate for substitution ethanol will no longer be available for use by the general public. This is particularly critical for pandemic situations. Currently available options to us and their issues which we must manage: Propan-1-ol (CAS: 71-23-8) and Propan-2-ol (CAS: 67-63-0) : Lack of full virucidal activity, they do not provide the level of coverage that is required especially in those customers who require focus on reducing virus bioburden at their sites. Not sufficiently available in the EU with continuous supply also not as available as ethanol. No sustainable production is in place. Higher risk of accidental poisoning. Chlorhexidine Digluconate (CAS: 55-56-01) No full virucidal activity, residues, not fast efficacy action. Known sensitivity to Chlorhexidine products. Under review for increased hazard classifications Residue forming on surfaces due to cationic nature. Lactic Acid (CAS: 79-33-4) Not fully virucidal. Odour formation is strong and repellent. Can damage surfaces. Phenoxyethanol (CAS: 122-99-6) Not fully virucidal. Higher risk of accidental poisoning. Various Quats Quats can cause skin irritation, dryness, and allergic

	reactions in some individuals. Overuse of quats may contribute to the development of antimicrobial resistance in bacteria, potentially leading to the emergence of "superbugs" that are resistant to both quats and antibiotics. Quats can persist in the environment and may be found in water supplies, raising concerns about their long-term ecological effects. In some situations, quats may not be as effective as other hand sanitizer ingredients, such as alcohol, particularly against certain types of viruses. As a public health partner to our customers, hand sanitising products containing alcohols react mainly by denaturing cell membranes and proteins and other cellular components. Due to the unspecific mode of action of the alcohols, there is low risk of resistance phenomena. We have a number of customers in key healthcare environments where microbial resistance is a real and persistent threat with no replacement options available. The proposed CMR classification would have a disproportionate impact on various sectors, leading to: Increased costs for reformulation and substitution. Reduced product efficacy and performance. Potential negative impacts on public health (e.g., reduced efficacy of disinfectants). Unnecessary disruption to supply chains and economic activity.
Information above is confidential	
Justification for confidentiality	
Availability	Ethanol is readily and sustainably available for hand sanitiser production due to its efficient production process and renewable sources. It is primarily produced through the fermentation of sugars or starches from various feedstocks like corn, sugarcane, and other biomass, which are renewable. The widespread availability of these feedstocks, coupled with established production infrastructure, ensures a stable supply of ethanol. This process not only provides a sustainable alternative to fossil fuels but also supports a circular economy by utilising agricultural byproducts and waste materials. As a result, ethanol can be produced in large quantities, making it a cost-effective and accessible option for use in hand sanitisers, and its production often involves processes that reduce greenhouse gas emissions compared to traditional fossil fuels. This availability was critical to us during the pandemic when our suppliers could leverage a number of different raw material stocks to ensure as full a manufacturing programme as possible. While propan-2-ol is also a common alcohol used in hand sanitisers, its supply chain is generally not considered as

	sustainable as that of ethanol. Propan-2-ol is typically derived from propylene, a fossil fuel byproduct, through energy-intensive chemical processes. Propylene is obtained from crude oil, a non-renewable resource, and its conversion to propan-2-ol involves multiple energy-intensive steps, contributing to greenhouse gas emissions. The reliance on fossil fuels and energy-intensive production makes propan-2-ol less environmentally sustainable compared to ethanol, which benefits from renewable feedstocks and a lower carbon footprint. No other alternative has the same global platform, and as a company we have a footprint in over 90 countries. This global network helps to reduce reliance on global shipping and transport requirements of other active ingredients. Again, providing another rationale to the sustainable nature of ethanol.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol's unique combination of efficacy, availability, and sustainability makes it difficult to replace within hand sanitiser formulations. Its broad-spectrum antimicrobial activity ensures effectiveness against a wide range of pathogens, including both enveloped and non-enveloped viruses, which is a quality not consistently matched by alternatives. The following points highlight summarise our perspective : Efficacy and Public Health: Ethanol-based hand sanitisers have been proven to significantly reduce the transmission of infectious diseases, including those caused by enveloped and non-enveloped viruses. The COVID-19 pandemic further underscored the essential role of these products in preventing the spread of pathogens. Exposure Scenario: The typical use of hand sanitisers involves topical application of a small amount of ethanol, which rapidly evaporates. Dermal absorption of ethanol from hand sanitisers is minimal, resulting in negligible systemic exposure. Studies have shown that blood ethanol levels following recommended use of hand sanitisers remain well below those associated with any toxic effects (Gorolski et al. (2025); Leeper et al. (2020); Kirshcher et al. (2007)). Several sources emphasize that the exposure to ethanol from topical application in hand sanitisers results in low or insignificant blood alcohol concentrations. The World Health Organization (WHO) specifically states that for hand hygiene, "due to the limited time of exposure alcohol is not absorbed in measurable quantities" (WHO). The benefits of

	using ethanol-based hand sanitisers in preventing infectious disease transmission far outweigh the negligible risks associated with their proper use. Restricting or eliminating ethanol in these products would have significant negative consequences for public health, especially with those alternatives with no activity against viruses, which can be easily spread within a contained population, such as healthcare facilities or nurseries.
Information above is confidential	
Justification for confidentiality	
Other comments	Arguments Against the Proposed CMR Classification The primary data supporting the CMR classification are derived from studies on the chronic and excessive consumption of alcoholic beverages. These exposure scenarios are fundamentally different from the controlled and limited exposure associated with ethanol's use in healthcare, personal care, and industrial applications. Extrapolating the risks from one scenario to another is scientifically unsound and leads to an overestimation of risk. The available data from oral route does not represent a 'reasonably expected use' for ethanol as chemical in related uses and exposure according to Art. 5 of the CLP. The 'reasonably expected use' is defined in the CLP Guidance: Any process, including production, handling, maintenance, storage, transport or disposal. All technical operations/manufacturing activities like e.g. spraying, filing, and sawing. Any putative consumer contact through e.g. do-it-yourself or household chemicals. All professional and non-professional uses include reasonably foreseeable accidental exposure, but not abuse such as criminal or suicidal uses. Therefore, human data on adverse effects should obviously be related to the sector of chemical substances (e.g. occupational data and data from accident databases). Other human data, e.g. from oral intake except accidental intake does not fit for purpose with the CLP Regulation and the definition of 'reasonably expected use'. For occupational and consumer exposure to biocidal products, it has to be taken into account that oral intake is prevented by denaturants, and should be considered as misuse. In their conclusion on the harmonised classification and labelling of acetaldehyde, the Risk Assessment Committee (RAC101) also followed this approach and did not consider effects of oral intake in humans of ethanol from consumption of alcoholic beverages. Weight of Evidence: A comprehensive assessment of ethanol requires a weight-of-evidence

	approach. This approach considers all available scientific data, including epidemiological studies, animal studies, and mechanistic data, in the context of relevant exposure scenarios. Many studies demonstrate the safety of ethanol in its typical applications, with minimal systemic exposure and negligible risk of CMR effects. This evidence should be given due consideration. Exposure Scenarios and Risk Assessment: Exposure to ethanol via application to the skin (dermal exposure) or by breathing in ethanol in the air (inhalation), being the two potential routes of exposure from the production or use of biocidal products, does not result in levels of ethanol in the human body that have been shown to cause cancer and/or have adverse effects, indeed absorption is low of ethanol (Gorolski et al. (2025). Ethanol evaporates rapidly from the skin. Intake via the dermal route is low. Occupational inhalation does not lead to a significant increase in the concentration of ethanol in the blood. Atmospheric concentrations of ethanol in workplaces where it is used are generally well below (6 to 20 times) national occupational exposure limits over an eight-hour period (ANSES (2013). Risk is a function of both hazard and exposure. While ethanol may exhibit hazardous properties under conditions of chronic and excessive ingestion, the risk associated with typical applications is low due to limited exposure. For instance: Healthcare: Topical application of ethanol-based disinfectants results in minimal systemic absorption (Gorolski et al. (2025); Leeper et al. (2020); Kirshcher et al. (2007). Personal Care: Ethanol concentrations in cosmetics are generally low, and dermal absorption is limited. Fragrance products, or fragrance products exposure criteria via inhalation are below national guidelines. Industry: Repeated occupational exposure is controlled through safety measures, such as ventilation and personal protective equipment and risk assessments where required for our in the field Service Technicians.
Information above is confidential	
Justification for confidentiality	
References	A.I.S.E. (2025). A CMR classification of ethanol would have critical consequences for public health. [Press release]. Available at: https://aise.eu/app/uploads/2025-04-03-The-impact-of-a-ban-on-ethanol-AISE-press-release.pdf ANSES (2013) Assessing the Risks of Ethanol. [Online] Available at: https://www.anses.fr/en/content/assessing-risks-ethanol (Accessed: 18 April 2025). Blue Frog Scientific. (n.d.). Ethanol's Regulatory Challenges & CMR Classification.

	Retrieved from https://bluefrogscientific.com/chemical-regulatory-news-and-views/ethanols-regulatory-challenges-cmr-classification Goralski, K. B., Westerlund, J., & Hallmans, G. (2005). Ethanol absorption after use of a hand disinfectant. American Journal of Infection Control, 33(9), 607-609. Leeper, C. et al. (2020) 'Is Alcohol in Hand sanitisers Absorbed Through the Skin or Lungs? Implications for Disulfiram Treatment', Alcohol and Alcoholism, 55(6), pp. 603–607. Available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC7454269/ (Accessed: 18 April 2025). Kirschner, S. et al. (2007) 'Transdermal resorption of an ethanol- and 2-propanol-containing skin disinfectant' [Transdermale Resorption eines ethanol- und 2-propanolhaltigen Hautdesinfektionsmittels], Gefahrstoffe - Reinhaltung der Luft, 67(7/8), pp. 289–294. Kumar et al. (n.d.). Analysis of Alcohol Concentration and Cost Variation of Different Laboratory Made and Commercially Available Hand Sanitizers Used in Corona Virus Disease Pandemic. Kramer, A. et al. (2022) 'Ethanol is indispensable for virucidal hand antisepsis: memorandum from the alcohol-based hand rub (ABHR) Task Force, WHO Collaborating Centre on Patient Safety, and the Commission for Hospital Hygiene and Infection Prevention (KRINKO), Robert Koch Institute, Berlin, Germany', GMS Hygiene and Infection Control, 17, p. Doc05. Available at: https://pubmed.ncbi.nlm.nih.gov/35794648/ (Accessed: 18 April 2025). WHO (n.d.). Infection prevention and control: Alcohol-based handrub risks and hazards. [online] Available at: https://www.who.int/news-room/questions-and-answers/item/alcohol-based-handrub-risks-hazards (Accessed: 29 April 2025).
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Attachments (confidential information)	
Justification for confidential attachment	

Comment 294	2025/04/29 22:15
Country	United Kingdom
Name of organization/institution	[REDACTED]

I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	This document presents a justification for maintaining the current classification of ethanol and opposing the proposed new CMR (Carcinogenic, Mutagenic, and/or Toxic to Reproduction) classifications. We acknowledge ECHA's role in safeguarding human health and the environment, but we believe that the proposed reclassification of ethanol is not supported by a comprehensive and balanced evaluation of the scientific evidence, and would have significant negative consequences across various sectors due to shortages of available, suitable alternatives on the market. Ethanol is a vital component of some surface sanitisers which play a crucial role in public health and hygiene, especially for our customers in healthcare, food manufacturing, and childcare as examples, where controlling organism transmission is paramount whilst leaving no taint or taste, or residue on surfaces. Ethanol's effectiveness against a broad spectrum of microorganisms has been well-established.
Product Type	1,2,4
Alternative Identity and Properties	Ethanol is a critical component of surface sanitisers, playing a vital role in public health and hygiene. In particular, for some customers, good workplace hygiene is paramount, especially in those customers where the risk of organism transmission must be controlled, e.g. healthcare facilities, food manufacturing, childcare facilities. Its effectiveness against a broad spectrum of microorganisms, including bacteria, viruses, and fungi, is well-established. There is a wealth of evidence showing ethanol (64 g / 100 g) preparation efficacy according to EN 1500, 13624, 13727, 14476 with full virucidal activity against Noro, Adeno and Polio viruses as example. While some of these evaluations are used on the hands it highlights the wealth of evidence available for ethanol as a sanitiser. This level of efficacy is critical for customers and we do not think that the alternatives have the versatility that ethanol has and is a critical component in reducing bioburden without providing resistance pressure.
Information above is confidential	
Justification for confidentiality	

Technical Feasibility	While there are a number of available active ingredients as replacement for ethanol in hand sanitising, its key benefits are what drives its need to be retained in the suite of actives for microbial control. This ability to effectively inactivate challenging viruses, combined with its rapid evaporation and minimal residue, positions ethanol as a valuable tool for surface disinfection in environments where swift and thorough pathogen elimination is essential. Most importantly, ethanol is recognised for its broad-spectrum virucidal activity, which is crucial in surface disinfection, including effectiveness against non-enveloped viruses like poliovirus and norovirus, known for their resilience to many disinfectants (Kampf (2018)). Ethanol's mechanism of action involves denaturing the protein capsid, disrupting the virus's structure and rendering it non-infectious (Golin et al., 2020). Studies have demonstrated ethanol's efficacy against norovirus, with concentrations between 62.4% and 85.8% shown to be effective in inactivating the virus within short exposure times (Kampf (2018)).
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	If ethanol is classified as a CMR (Carcinogenic, Mutagenic, or Reprotoxic) substance, the impact on both direct and indirect costs associated with surface sanitisers would be significant. Direct costs would increase due to the need to reformulate products with alternative active ingredients. These alternatives have different efficacy profiles and may be more expensive to source and produce. Manufacturers would also incur expenses related to research and development, new safety testing to ensure the efficacy and safety of alternative formulations, and changes in labeling and packaging to comply with new regulations and inform consumers. This we already see with the current changing landscape within the EU that label updates, SDS updates, horizon mapping for classification changes all have a financial impact on industry. The removal of ethanol from surface sanitisers could lead to several indirect costs. A primary concern is the potential decrease in public health efficacy, as ethanol is a broad-spectrum virucidal agent effective against pathogens like poliovirus and norovirus (Kampf (2018)). This could necessitate the use of alternative disinfectants, some of which may have limitations in efficacy, particularly against non-enveloped viruses, potentially leading to an increased risk of infections and higher healthcare costs. Additionally, the need for

	extensive research and development to find and validate effective, sustainable alternatives could strain resources and delay the availability of suitable replacements.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Ethanol plays a critical role in many applications where its unique properties are essential, and suitable alternatives are not readily available. Most important is the lack of efficacy for non enveloped viruses of all possible alternatives of ethanol. This means, it is not possible to prevent the spreading of diseases by non-enveloped virus's like Polio and Norovirus (Kramer, 2022). Currently available options to us and their issues which we must manage: Propan-2-ol (CAS: 67-63-0) : Lack of full virucidal activity, they do not provide the level of coverage that is required especially in those customers who require focus on reducing virus bioburden at their sites. Not sufficiently available in the EU with continuous supply also not as available as ethanol. No sustainable production is in place. Higher risk of accidental poisoning. Peracetic acid (CAS: 79-21-0) : Corrosive. Longevity of efficacy not sufficient. Reactivity with other chemicals in product formulations. Higher safety standards for workers and higher storage standards. Higher risk of accidental poisoning. Sodium Hypochlorite (CAS: 7681-52-0): No evaporation required to wait for surfaces to dry, this is important in customer facilities where the environmental temperatures may be cooler, Longevity of efficacy not sufficient Corrosive Reactivity with other standard cleaning chemicals a real risk Can produce disinfection by products which is a risk to our customers and Service Technicians. Higher risk of accidental poisoning. Hydrogen Peroxide (CAS: 7722-84-1) Micro lesions on skin. Not fast efficacy action. No evaporation. Longevity is not sufficient. Corrosive. Not efficacious at low concentrations and ambient temperatures. Higher safety standards for workers and higher requirements. Stability and storage requirements can be a challenge through industrial supply chains. Phenoxyethanol (CAS: 122-99-6) Not fully virucidal. Higher risk of accidental poisoning. Various Quats Quats can cause skin irritation, dryness, and allergic reactions in some individuals. Overuse of quats may contribute to the development of antimicrobial resistance in bacteria, potentially leading to the emergence of "superbugs" that are resistant to both quats and antibiotics. Quats can persist in the environment and may be found in

	water supplies, raising concerns about their long-term ecological effects. In some situations, quats may not be as effective as other hand sanitizer ingredients, such as alcohol, particularly against certain types of viruses. As a public health partner to our customers, surface sanitising products containing alcohols react mainly by denaturing cell membranes and proteins and other cellular components. Due to the unspecific mode of action of the alcohols, there is low risk of resistance phenomena. We have a number of customers in key healthcare environments where microbial resistance is a real and persistent threat. Ethanol is comparatively cheap to other active substances, generally available, easy and fast to produce ensuring a constant supply, green and sustainable. As a candidate for substitution ethanol will no longer be available for use by the general public. This is particularly critical for an outbreak or pandemic situation.
Information above is confidential	
Justification for confidentiality	
Availability	Ethanol is readily and sustainably available for surface sanitiser production due to its efficient production process and renewable sources. It is primarily produced through the fermentation of sugars or starches from various feedstocks like corn, sugarcane, and other biomass, which are renewable. The widespread availability of these feedstocks, coupled with established production infrastructure, ensures a stable supply of ethanol. This process not only provides a sustainable alternative to fossil fuels but also supports a circular economy by utilising agricultural byproducts and waste materials. As a result, ethanol can be produced in large quantities, making it a cost-effective and accessible option for use in surface sanitisers, and its production often involves processes that reduce greenhouse gas emissions compared to traditional fossil fuels. This availability was critical to us during the pandemic when our suppliers could leverage a number of different raw material stocks to ensure as full a manufacturing programme as possible. While propan-2-ol is also a common alcohol used in surface sanitisers, its supply chain is generally not considered as sustainable as that of ethanol. Propan-2-ol is typically derived from propylene, a fossil fuel byproduct, through energy-intensive chemical processes. Propylene is obtained from crude oil, a non-renewable resource, and its conversion to propan-2-ol involves multiple energy-intensive steps, contributing to greenhouse gas emissions.

	The reliance on fossil fuels and energy-intensive production makes propan-2-ol less environmentally sustainable compared to ethanol, which benefits from renewable feedstocks and a lower carbon footprint. No other alternative has the same global platform, and as a company we have a foot print in over 90 countries. This global network helps to reduce reliance on global shipping and transport requirements of other active ingredients. Again, providing another rationale to the sustainable nature of ethanol.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol is a critical component of surface sanitisers, playing a vital role in public health and hygiene. In particular, for some of our customers, good workplace hygiene is paramount, especially in those customers where the risk of organism transmission must be controlled, e.g. healthcare facilities, food manufacturing, childcare facilities. The following points highlight the importance of ethanol in this application to further support the argument against the proposed CMR classification: Efficacy on Surfaces: Ethanol effectively disinfects hard, non-porous surfaces, reducing the number of viable microorganisms, including bacteria, viruses, and fungi. This is critical in various settings, including healthcare facilities, food processing plants, and public spaces. Exposure Scenario: Exposure to ethanol from surface sanitisers primarily occurs through inhalation and dermal contact. However, when used as directed, the levels of exposure are generally low and well-controlled. Furthermore, the rapid evaporation of ethanol minimises prolonged contact. Risk Assessment: Risk assessments for ethanol in surface sanitisers, considering the typical exposure routes and levels, indicate that the potential for CMR effects is negligible. The concentrations used, the frequency of application, and the engineering controls in place (e.g., ventilation) contribute to a low-risk profile. Essential for Hygiene: Ethanol-based surface sanitisers are essential for maintaining hygiene and preventing the spread of infections in various settings. Restricting their use could compromise public health and safety, particularly in environments where vulnerable populations are present. Lack of Suitable Alternatives: While alternative surface sanitising agents exist, ethanol's rapid action, broad-spectrum efficacy, and residue-free properties make it a preferred choice in many situations. Finding equally

	effective, safe substitutes, that can be used on a multitude of surfaces can be challenging.
Information above is confidential	
Justification for confidentiality	
Other comments	The primary data supporting the CMR classification are derived from studies on the chronic and excessive consumption of alcoholic beverages. These exposure scenarios are fundamentally different from the controlled and limited exposure associated with ethanol's use in healthcare, personal care, and industrial applications. Extrapolating the risks from one scenario to another is scientifically unsound and leads to an overestimation of risk. The available data from oral route does not represent a 'reasonably expected use' for ethanol as chemical in related uses and exposure according to Art. 5 of the CLP. The 'reasonably expected use' is defined in the CLP Guidance: Any process, including production, handling, maintenance, storage, transport or disposal. All technical operations/manufacturing activities like e.g. spraying, filing, and sawing. Any putative consumer contact through e.g. do-it-yourself or household chemicals. All professional and non-professional uses include reasonably foreseeable accidental exposure, but not abuse such as criminal or suicidal uses. Therefore, human data on adverse effects should obviously be related to the sector of chemical substances (e.g. occupational data and data from accident databases). Other human data, e.g. from oral intake except accidental intake does not fit for purpose with the CLP Regulation and the definition of 'reasonably expected use'. For occupational and consumer exposure to biocidal products, it has to be taken into account that oral intake is prevented by denaturants, and should be considered as misuse. In their conclusion on the harmonised classification and labelling of acetaldehyde, the Risk Assessment Committee (RAC101) also followed this approach and did not consider effects of oral intake in humans of ethanol from consumption of alcoholic beverages. Weight of Evidence: A comprehensive assessment of ethanol requires a weight-of-evidence approach. This approach considers all available scientific data, including epidemiological studies, animal studies, and mechanistic data, in the context of relevant exposure scenarios. Many studies demonstrate the safety of ethanol in its typical applications, with minimal systemic exposure and negligible risk of CMR effects. This evidence should be given due consideration. Exposure Scenarios and

	Risk Assessment: Exposure to ethanol via application to the skin (dermal exposure) or by breathing in ethanol in the air (inhalation), being the two potential routes of exposure from the production or use of biocidal products, does not result in levels of ethanol in the human body that have been shown to cause cancer and/or have adverse effects, indeed absorption is low of ethanol (Gorolski et al. (2025)). Ethanol evaporates rapidly from the skin. Intake via the dermal route is low. Occupational inhalation does not lead to a significant increase in the concentration of ethanol in the blood. Atmospheric concentrations of ethanol in workplaces where it is used are generally well below (6 to 20 times) national occupational exposure limits over an eight-hour period (ANSES (2013)). Risk is a function of both hazard and exposure. While ethanol may exhibit hazardous properties under conditions of chronic and excessive ingestion, the risk associated with typical applications is low due to limited exposure
Information above is confidential	
Justification for confidentiality	
References	ANSES (2013) Assessing the Risks of Ethanol. [Online] Available at: https://www.anses.fr/en/content/assessing-risks-ethanol (Accessed: 18 April 2025). Golin, A.P., Choi, D. & Ghahary, A. (2020) 'Hand sanitizers: A review of ingredients, mechanisms of action, modes of delivery, and efficacy against coronaviruses', American Journal of Infection Control, 48(9), 1062-1075. Goralski, K. B., Westerlund, J., & Hallmans, G. (2005). Ethanol absorption after use of a hand disinfectant. American Journal of Infection Control, 33(9), 607-609. Kampf G. Efficacy of ethanol against viruses in hand disinfection. J Hosp Infect. 2018 Apr;98(4):331-338. doi: 10.1016/j.jhin.2017.08.025. Epub 2017 Sep 5. PMID: 28882643; PMCID: PMC7132458.
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 295	2025/04/29 22:36

Country	Poland
Name of organization/institution	Polish Chamber of Biofuels
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Ethanol meets all the requirements for effective biocides: it shows high biocidal activity while being safe in use, minimal impact on the environment and available. It does not cause microbial resistance, which is a problem when using some synthetic biocides. Ethanol production ensures stable supply chains, unlike other biocides, the production of which may require more complex technological processes generating higher costs, which in turn may cause availability problems. Although ethanol in alcoholic beverages has been classified as a carcinogen (Group 1 according to IARC), the use of ethanol in disinfectants and cosmetic products does not pose a confirmed carcinogenic risk under typical conditions of use. The EU's proposed classification of ethanol as a CMR substance (carcinogenic, mutagenic, reproductive toxicity) mainly concerns cases of long-term and intense industrial exposure is still at the stage of discussion, but there are no clear grounds for such a classification. There is no scientific evidence to consider ethanol used in biocidal products to be mutagenic under conditions of typical use. Ethanol itself is not a mutagen, only its metabolite, acetaldehyde, exhibits mutagenic properties, but mainly after alcohol consumption. When properly managed, ethanol-based disinfectants pose minimal risk to the environment, making them an appropriate choice for sustainable infection control. No other biocide than ethanol offers the same effectiveness, environmental safety and availability. Therefore, continued authorization of ethanol as a biocide is crucial for both public health and economic stability. The considered classification of ethanol as CMR could introduce unjustified restrictions on its use as a biocide, despite the lack of any real threat when used correctly. Implementing appropriate risk management measures and ensuring effective disposal practices consistent with environmental standards will allow the safe use of ethanol as a biocide.
Product Type	1,2,4
Alternative Identity and Properties	In the case of applications in the scope of PT2, including disinfection of surfaces in various environments, such as schools, workplaces, hospitals, the pharmaceutical industry

	and public spaces (For the use of ethanol in disinfectants and algaecides not intended for direct application to humans or animals (Product Type 2) (Version:3.0. - FINAL PUBLIC version)), the biocide should have a broad spectrum of activity, including effectiveness against enveloped and non-enveloped viruses and rapid effectiveness disinfection. In this regard, the proposed ethanol substitutes are propan-1-ol, propan-2-ol, citric acid, peracetic acid, copper sulfate pentahydrate and sterilization with UV-C radiation and steam. Based on the analyses, none of the above-mentioned alternatives was considered suitable as a replacement for ethanol-based products because they do not meet the critical effectiveness criteria: • propanols, although they offer some disinfection effectiveness, evaporate slower and have narrower antimicrobial activity spectra; • Citric acid and copper sulfate pentahydrate, although useful in niche applications, do not have the required speed of action and effectiveness for disinfecting surfaces in healthcare facilities. • pure peracetic acid (PAA), a strong oxidizing agent with a broad spectrum of activity, including some virucidal activity, but corrosive and highly irritating, requiring the use of strict personal protective equipment and limiting the ease of use in PT2 applications (material compatibility). The potential of PAA is significant in aquaculture as an alternative to less environmentally friendly practices. PAA poses no carcinogenic risk to humans (unlike formalin), has negligible harmful by-products (unlike chlorine-based disinfectants), and with appropriate precautions, the risk of causing serious harm to human health is easier to control than ozone. The effective concentration of PAA against many fish pathogens is usually below 2 mg L⁻¹, which is tolerated by most fish and has a very low risk to the environment due to rapid degradation. However, such degradation and hydrodynamics in production-scale aquaculture systems complicate the practical use of PAA. Moreover, in concentrations safe for fish, PAA only limits the growth of microorganisms without eliminating them, which in the long term may lead to the development of resistance to oxidation for generations. To avoid this risk, complete microbiological inactivation during production breaks is strongly recommended [Liu et al. 2024].
Information above is confidential	
Justification for confidentiality	Physical methods, i.e. UV-C sterilization and steam, although promising as complementary measures, cannot replace ethanol as the main disinfectant due to high costs,

	limited usefulness and slower action. In the case of the use of ethanol and its potential substitutes in PT4 applications (Product Type 4), i.e. for surface disinfection in the food and feed sectors, including cleaning and disinfection of surfaces, equipment and containers in food processing plants, warehouses and feed production areas (For the use of ethanol as disinfectant in the food and feed area (Product Type 4)), 85 active substances were assessed, 3 of which were identified as potential substitutes due to their functionality and similarity to ethanol-based products, i.e.: L-(+)-lactic acid, propan-1-ol, propan-2-ol. These substances demonstrate some level of surface disinfection effectiveness, but are not as good as ethanol in several key aspects.
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	As with PT2 applications, physical disinfection methods, i.e., UV-C radiation and steam sterilization, have significant limitations of an economic nature (requires specialized equipment, unprofitable for many food and feed companies) and technical limitations (not suitable for some porous or complex surfaces that are common in food processing and storage plants, limited scalability - not suitable for high-throughput operations) compared to ethanol.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Propan-1-ol and propan-2-ol (as already mentioned in PT2 applications) have biocidal activity against bacteria and fungi, but have limited virucidal activity, especially against non-enveloped viruses. Additionally, propan-1-ol's classification as an H318 substance prevents its use by non-professionals, making it less suitable for broad PT4 applications. However, in the case of propa-2-ol, its slower evaporation rate compared to ethanol causes residues to remain on food contact surfaces longer, which reduces operational efficiency.
Information above is confidential	

Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	To sum up, ethanol meets all the requirements for effective biocides: it shows high biocidal activity while being safe in use, minimal impact on the environment and available. It does not cause microbial resistance, which is a problem when using some synthetic biocides. Ethanol production ensures stable supply chains, unlike other biocides, the production of which may require more complex technological processes generating higher costs, which in turn may cause availability problems. Although ethanol in alcoholic beverages has been classified as a carcinogen (Group 1 according to IARC), the use of ethanol in disinfectants and cosmetic products does not pose a confirmed carcinogenic risk under typical conditions of use. The EU's proposed classification of ethanol as a CMR substance (carcinogenic, mutagenic, reproductive toxicity) mainly concerns cases of long-term and intense industrial exposure is still at the stage of discussion, but there are no clear grounds for such a classification. There is no scientific evidence to consider ethanol used in biocidal products to be mutagenic under conditions of typical use. Ethanol itself is not a mutagen, only its metabolite, acetaldehyde, exhibits mutagenic properties, but mainly after alcohol consumption. When properly managed, ethanol-based disinfectants pose minimal risk to the environment, making them an appropriate choice for sustainable infection control. No other biocide than ethanol offers the same effectiveness, environmental safety and availability. Therefore, continued authorization of ethanol as a biocide is crucial for both public health and economic stability. The considered classification of ethanol as CMR could introduce unjustified restrictions on its use as a biocide, despite the lack of any real threat when used correctly. Implementing appropriate risk management measures and ensuring effective disposal practices consistent with environmental standards will allow the safe use of ethanol as a biocide.
Information above is confidential	
Justification for confidentiality	

Other comments	
Information above is confidential	
Justification for confidentiality	
References	1. Bevan, R. J., Slack, R. J., Holmes, P., & Levy, L. S. (2009). An assessment of potential cancer risk following occupational exposure to ethanol. <i>Journal of Toxicology and Environmental Health, Part B</i>, 12(3), 188-205. 2. Caslin, B., Mohler, K., Thiagarajan, S., & Melamed, E. (2021). Alcohol as friend or foe in autoimmune diseases: a role for gut microbiome? <i>Gut Microbes</i>, 13(1). https://doi.org/10.1080/19490976.2021.1916278 3. Đurđević-Milošević, D., Petrović, A., Kalaba, V., Stijepić, M., & Jovanović, G. (2024). Selected aspects of the antibacterial use of lactic acid in food processing. <i>Engineering Proceedings</i>, 67(1), 2. 4. Kampf, G., & Löffler, H. (2003). Dermatological aspects of a successful introduction and continuation of alcohol-based hand rubs for hygienic hand disinfection. <i>Journal of Hospital Infection</i>, 55(1), 1-7. 5. Liu, D., Straus, D. L., Pedersen, L. F., Good, C., Lazado, C. C., & Meinelt, T. (2024). Towards sustainable water disinfection with peracetic acid in aquaculture: A review. <i>Reviews in Aquaculture</i>, 16(4), 1621-1646. 6. Mahmood, A., Egan, M., Pervez, S., Alghamdi, H. A., Tabinda, A. B., Yasar, A., ... & Pugazhendhi, A. (2020). COVID-19 and frequent use of hand sanitizers; human health and environmental hazards by exposure pathways. <i>Science of the Total Environment</i>, 742, 140561. 7. BS EN 1276:2019 - Chemical Disinfectants and Antiseptics.
Attachments (non-confidential information)	KIB position paper public consultation on ethanol.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 296	2025/04/29 22:57
Country	Belgium
Name of organization/institution	ePURE - European renewable ethanol association

I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	ePURE represents the interests of European renewable ethanol producers from crops, wastes and residues, speaking for 43 member companies and associations, with around 50 plants across the EU and UK, accounting for about 85% of EU renewable ethanol production. The organisation, established in 2010, promotes the beneficial uses of ethanol throughout Europe. The EU ethanol market can be roughly split into three segments: potable, industrial and fuel. • Potable: Ethanol can also be used to produce spirit drinks, such as vodka or gin, as a food additive, for the extraction of aromas, for food preservation and the production of white vinegar. • Industrial: Ethanol is an essential renewable chemical component in various products (e.g. sanitising products, cosmetics, pharmaceuticals, detergents, solvents, paints, printing inks and de-icing fluids) to ensure hygiene and safety, as well as a renewable feedstock for bio-based chemical production (e.g. bio-ethylene). • Fuel: Ethanol is used as an additive in petrol, or as an alternative fuel. E10 is a type of petrol grade, which contains up to 10% ethanol, and can be used in most of today's internal combustion engines and hybrid vehicles, significantly lowering transport greenhouse gas emissions. Bioethanol is manufactured in European biorefineries by fermenting sugars into alcohol. In the EU, these sugars typically come from a variety of agricultural sources such as wheat, corn, barley, rye, triticale, sugar beet and a wide range of waste and residues stemming from the transformation of cereals and sugar beets into respectively starch and sugar. While the feedstock used varies depending on market conditions, the majority of European renewable ethanol biorefineries are built to specifically process either grains or sugar beets. In 2023, ePURE members and other European producers of renewable ethanol produced 6.44 billion litres of ethanol for all uses, operating at 80% of their 8.05 billion litres of installed capacity.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	

Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	The human drinking data considered by the biocidal competent authorities is not scientifically suitable for classification. Using abusive drinking data is not relevant for biocidal applications not only because the exposure routes are extremely different but also because customs and fiscal legislation requires the addition of denaturing agents to alcohol for non-beverage uses in order to keep it separate from the beverage market. Without an evaluation of appropriate and accurate data related specifically to the impacts of alcohol via skin contact and inhalation, a hazard assessment is impossible. Because extrapolating epidemiological drink data to worker/consumer exposure is scientifically invalid, the scientific basis to classify a substance under biocidal legislation as a Cat. 1 Carcinogenic and Toxic for Reproduction substance using results from intake data of foodstuffs is unsound and inappropriate. Ethanol is a unique case, being one of the most widely used basic chemicals in numerous applications worldwide. A BPC recommendation for a CMR classification leading to exclusion or substitution criteria will: Prevent the usage of

	Ethanol by the general public (hand gels) and professional users (hospitals) where no suitable alternatives exist that are effective against non-enveloped viruses, as demonstrated by the Assessment of Alternatives; Impact various industries beyond biocidal applications linked to cosmetic products, chemical agents at work, food contact materials, EU Ecolabel, waste, medical devices, and general food law; Such a classification would bring no health benefit at all but would create severe health issues and would have severe socio-economic consequences for many industries that would be left with no alternative.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	250429 DEF PP - ePURE's reply to the ECHA public consultation on biocidal uses of ethanol.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 297	2025/04/29 23:01
Country	Belgium
Name of organization/institution	ePURE - European renewable ethanol association
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	ePURE represents the interests of European renewable ethanol producers from crops, wastes and residues,

	speaking for 43 member companies and associations, with around 50 plants across the EU and UK, accounting for about 85% of EU renewable ethanol production. The organisation, established in 2010, promotes the beneficial uses of ethanol throughout Europe. The EU ethanol market can be roughly split into three segments: potable, industrial and fuel. • Potable: Ethanol can also be used to produce spirit drinks, such as vodka or gin, as a food additive, for the extraction of aromas, for food preservation and the production of white vinegar. • Industrial: Ethanol is an essential renewable chemical component in various products (e.g. sanitising products, cosmetics, pharmaceuticals, detergents, solvents, paints, printing inks and de-icing fluids) to ensure hygiene and safety, as well as a renewable feedstock for bio-based chemical production (e.g. bio-ethylene). • Fuel: Ethanol is used as an additive in petrol, or as an alternative fuel. E10 is a type of petrol grade, which contains up to 10% ethanol, and can be used in most of today's internal combustion engines and hybrid vehicles, significantly lowering transport greenhouse gas emissions. Bioethanol is manufactured in European biorefineries by fermenting sugars into alcohol. In the EU, these sugars typically come from a variety of agricultural sources such as wheat, corn, barley, rye, triticale, sugar beet and a wide range of waste and residues stemming from the transformation of cereals and sugar beets into respectively starch and sugar. While the feedstock used varies depending on market conditions, the majority of European renewable ethanol biorefineries are built to specifically process either grains or sugar beets. In 2023, ePURE members and other European producers of renewable ethanol produced 6.44 billion litres of ethanol for all uses, operating at 80% of their 8.05 billion litres of installed capacity.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	

Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	The human drinking data considered by the biocidal competent authorities is not scientifically suitable for classification. Using abusive drinking data is not relevant for biocidal applications not only because the exposure routes are extremely different but also because customs and fiscal legislation requires the addition of denaturing agents to alcohol for non-beverage uses in order to keep it separate from the beverage market. Without an evaluation of appropriate and accurate data related specifically to the impacts of alcohol via skin contact and inhalation, a hazard assessment is impossible. Because extrapolating epidemiological drink data to worker/consumer exposure is scientifically invalid, the scientific basis to classify a substance under biocidal legislation as a Cat. 1 Carcinogenic and Toxic for Reproduction substance using results from intake data of foodstuffs is unsound and inappropriate. Ethanol is a unique case, being one of the most widely used basic chemicals in numerous applications worldwide. A BPC recommendation for a CMR classification leading to exclusion or substitution criteria will: Prevent the usage of Ethanol by the general public (hand gels) and professional users (hospitals) where no suitable alternatives exist that are effective against non-enveloped viruses, as demonstrated by the Assessment of Alternatives; Impact various industries beyond biocidal applications linked to cosmetic products, chemical agents at work, food contact

	materials, EU Ecolabel, waste, medical devices, and general food law; Such a classification would bring no health benefit at all but would create severe health issues and would have severe socio-economic consequences for many industries that would be left with no alternative.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	250429 DEF PP - ePURE's reply to the ECHA public consultation on biocidal uses of ethanol.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 298	2025/04/29 23:05
Country	Belgium
Name of organization/institution	ePURE - European renewable ethanol association
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	ePURE represents the interests of European renewable ethanol producers from crops, wastes and residues, speaking for 43 member companies and associations, with around 50 plants across the EU and UK, accounting for about 85% of EU renewable ethanol production. The organisation, established in 2010, promotes the beneficial uses of ethanol throughout Europe. The EU ethanol market can be roughly split into three segments: potable, industrial

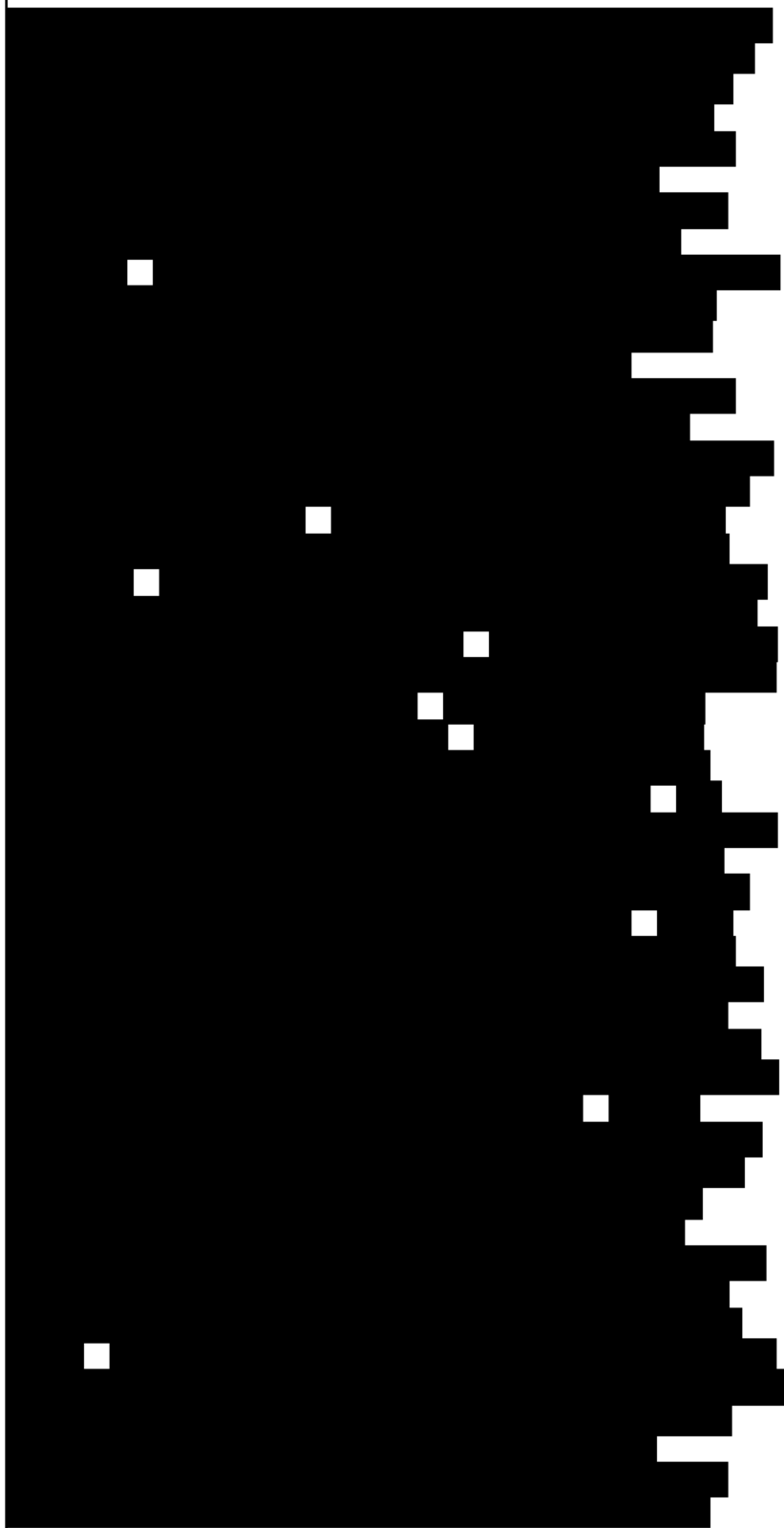
	and fuel. • Potable: Ethanol can also be used to produce spirit drinks, such as vodka or gin, as a food additive, for the extraction of aromas, for food preservation and the production of white vinegar. • Industrial: Ethanol is an essential renewable chemical component in various products (e.g. sanitising products, cosmetics, pharmaceuticals, detergents, solvents, paints, printing inks and de-icing fluids) to ensure hygiene and safety, as well as a renewable feedstock for bio-based chemical production (e.g. bio-ethylene). • Fuel: Ethanol is used as an additive in petrol, or as an alternative fuel. E10 is a type of petrol grade, which contains up to 10% ethanol, and can be used in most of today's internal combustion engines and hybrid vehicles, significantly lowering transport greenhouse gas emissions. Bioethanol is manufactured in European biorefineries by fermenting sugars into alcohol. In the EU, these sugars typically come from a variety of agricultural sources such as wheat, corn, barley, rye, triticale, sugar beet and a wide range of waste and residues stemming from the transformation of cereals and sugar beets into respectively starch and sugar. While the feedstock used varies depending on market conditions, the majority of European renewable ethanol biorefineries are built to specifically process either grains or sugar beets. In 2023, ePURE members and other European producers of renewable ethanol produced 6.44 billion litres of ethanol for all uses, operating at 80% of their 8.05 billion litres of installed capacity.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	

Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	The human drinking data considered by the biocidal competent authorities is not scientifically suitable for classification. Using abusive drinking data is not relevant for biocidal applications not only because the exposure routes are extremely different but also because customs and fiscal legislation requires the addition of denaturing agents to alcohol for non-beverage uses in order to keep it separate from the beverage market. Without an evaluation of appropriate and accurate data related specifically to the impacts of alcohol via skin contact and inhalation, a hazard assessment is impossible. Because extrapolating epidemiological drink data to worker/consumer exposure is scientifically invalid, the scientific basis to classify a substance under biocidal legislation as a Cat. 1 Carcinogenic and Toxic for Reproduction substance using results from intake data of foodstuffs is unsound and inappropriate. Ethanol is a unique case, being one of the most widely used basic chemicals in numerous applications worldwide. A BPC recommendation for a CMR classification leading to exclusion or substitution criteria will: Prevent the usage of Ethanol by the general public (hand gels) and professional users (hospitals) where no suitable alternatives exist that are effective against non-enveloped viruses, as demonstrated by the Assessment of Alternatives; Impact various industries beyond biocidal applications linked to cosmetic products, chemical agents at work, food contact materials, EU Ecolabel, waste, medical devices, and general food law; Such a classification would bring no health benefit at all but would create severe health issues and would have severe socio-economic consequences for many industries that would be left with no alternative.

Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	250429 DEF PP - ePURE's reply to the ECHA public consultation on biocidal uses of ethanol.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 299	2025/04/29 23:06
Country	Germany
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	We are a start-up company specializing in the production of a biodegradable, natural plastic substitute derived from agricultural residues. Our innovation contributes to a circular bioeconomy by converting renewable raw materials into sustainable alternatives to conventional plastics. Ethanol plays a critical role in our production process as a solvent used in a closed-loop system, ensuring minimal emissions and efficient resource use. It enables the extraction and processing of raw biomass into high-purity products used as feed (by-product), food ingredients, and food contact material, including sustainable packaging solutions. Our process supports EU climate and sustainability goals by reducing plastic pollution, lowering dependence on fossil resources, and creating value from

Technical Feasibility



Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Substitution of ethanol would impose substantial financial burdens on our company. As a start-up, our capital is allocated toward scaling a validated process, not re-engineering it around unproven alternatives. Estimated impacts include: - Time and financial resources in process redesign, validation, and regulatory costs - Delays of 2–4 years in commercialization - Increased operational expenditures due to inefficient alternatives - Potential loss of investor confidence and competitive positioning In short, substitution would make our process economically less viable at this stage and potentially uncompetitive in the long term.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Most proposed alternatives pose greater health and environmental risks compared to ethanol when used under our current safety measures: Isopropanol, for example, has a lower occupational exposure limit and higher fire hazard. Many alternatives lack clear approval for food contact or feed-related use. Several show reduced biodegradability and increased risk of environmental persistence. Handling risks would require stricter containment, ventilation, and training protocols. By contrast, ethanol—particularly when used in a closed system—has a well-characterized risk profile and is manageable through standard occupational safety practices already in place.
Information above is confidential	
Justification for confidentiality	
Availability	

Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Based on our technical evaluations and process requirements, no suitable or available alternatives to ethanol exist that can fulfill its role in our production process without significant trade-offs in safety, sustainability, and feasibility. Alternative substances either fail to meet the necessary performance criteria or introduce greater hazards, higher emissions, and major economic burdens – particularly for a start-up in the scale-up phase. Ethanol, especially in its bio-based form and used within our closed-loop system, enables the safe and efficient production of biodegradable materials derived from agricultural residues. It supports EU priorities such as the Green Deal and the Chemicals Strategy for Sustainability by reducing fossil dependence and promoting circularity. Replacing ethanol would not only delay market entry but also is a high risk to the viability of our innovation, to our business plan and with that to our financing strategy. We therefore conclude that ethanol remains the only technically, economically, and strategically viable substance for the specified use.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 300	2025/04/29 23:13
Country	Portugal
Name of organization/institution	AISDPCL
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	AISDPCL is the Portuguese association representing the detergents, disinfectants and maintenance products, and is a member of A.I.S.E. Ethanol is an indispensable ingredient in a broad range of household, professional and industrial products, namely in biocidal products (use as active substance in disinfectants and use as co-formulant in insecticides and repellents) and in cleaning products such as hand dish washing liquids, laundry detergents and surface cleaners, where it is used for its solvent properties. Ethanol shows a unique combination of rapid, broad-spectrum antimicrobial activity and a favourable exposure profile in PT1, PT2 and PT4 formulations that is unmatched by available alternatives. It has a broad-spectrum efficacy against bacteria, fungi, and both enveloped and non-enveloped viruses, and this within very short contact times. Its use in biocidal applications, whether as a hand disinfectant or a surface disinfectant—is essential for maintaining public health, particularly in high-risk environments. Reclassification that compromises these applications would jeopardize effective infection control and could lead to significant safety and supply challenges. In fact, Ethanol is critical for human health and safety. More than 3.5 million cases of Health Acquired Infections (HAI) are estimated to occur in the EU/EEA each year, leading to more than 90 thousand deaths. Ethanol is endorsed by the WHO. It is known to be the most effective substance in the fight against HAIs and the only substance effective against viruses like polio. Ethanol is a vital ingredient in various cleaning and household products, such as surface disinfectants and skin repellents. Restaurants use ethanol-based products to prevent the spread of salmonella, ensuring food safety and public health. It is also a skin repellent essential since vector borne diseases are rising due to climate change in Europe. In many use cases, substitutes are either non-existent or less effective: o In terms of HAIs, there is no alternative for fighting polio and other non-enveloped viruses. o No other substance

	matches ethanol's efficacy, skin tolerability, and safety profile for point-of-care hand hygiene. Other substances are known to dry and irritate the skin. The absence of an effective substitute could lead to increased infection rates and higher healthcare costs. (Hand sanitizers in hospitals are used by nurses between 60 to 100 times per day, and insect repellents are applied to the skin). o The absence of an effective substitute could lead to increased infection rates and higher healthcare costs. A recent study found that ethanol at a 70% concentration had a stronger effect on coronaviruses, with a contact time of just one minute, compared to 0.06% sodium hypochlorite. Ethanol was critical in combating COVID-19: it was widely available and cost-effective, unlike propanol and other alternatives. The industry was able to ramp up production and meet government requirements. In a world of geopolitical uncertainty and climate related disasters, ethanol-based hand disinfectants are a key tool in preventing the spread of disease in war torn and disaster areas, refugee camps and during rural outbreaks of deadly viruses such as Ebola when water and proper handwashing is inaccessible. Ethanol is safe for the environment: it mainly comes from renewable sources, it is fully biodegradable compared to its alternatives, it leaves no residue on surfaces, it evaporates quickly, and it is generally more sustainable than other options. When used as a co-formulant in insecticides and repellents, ethanol presents unique solvency properties, helps control viscosity and is highly compatible with the other formulation's ingredients.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	

Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol's reclassification means a de facto ban and would have massive consequences not only on European industry, but also on society as a whole, while not bringing any benefit to human health or the environment. Even with derogations, the availability of ethanol will be severely restricted due to local regulations. Authorities will have to face a host of (unintended) consequences including a change in infection patterns as well as higher costs. The sector believes that the proposed reclassification of ethanol is based on very flawed assumptions: it considers the effects of the substance after oral intake of high doses, in other words utilising data on the adverse effects of (excessive) drinking of alcoholic beverages. This is not based on the typical uses of ethanol in biocidal products. It also does not take into account mitigation strategies used in industry to provide safe products, such as denaturation of ethanol to prevent drinking of ethanol-containing products. The uptake of ethanol after skin contact or inhalation is negligible and better comparable to the intake of ethanol in non-alcoholic products such as apple juice, where ethanol occurs naturally. The sector calls on the European authorities to recognise the essential role of ethanol. Ethanol should remain classified based on its real-world, biocidal use, rather than being inaccurately compared to alcohol consumption. Recognising ethanol's essential role in infection control and public health is vital for maintaining effective and safe disinfecting practices. Finally, the sector calls on the European Commission to fully assess the consequences of reclassifying ethanol on public health, healthcare costs and economic stability. A thorough impact

	assessment will provide a clear understanding of the potential ramifications and help guide informed decisions.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	2025-04-29 AISDPCL Annex Comments to PC ethanol.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 301	2025/04/30 02:11
Country	Netherlands
Name of organization/institution	Ethanol REACH Association
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Ethanol REACH Association, on behalf of the European producers of ethanol, hereby comments on the ongoing public consultation regarding the planned classification of ethanol as carcinogenic and toxic for reproduction category 1 and the possible classification as mutagenic in the context of the authorisation procedure under the Biocidal Products Regulation (EU) No 528/2012. The example of ethanol makes it particularly clear that a differentiated consideration of the relevant areas of application and the resulting risk that the use of an active substance entails is essential. The

	consequences of such a disproportionate categorisation of ethanol would be serious at this point and under these circumstances would not only fail to reduce the risks to human health, but would actually have catastrophic consequences for many health and economic sectors as well as for security of supply.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	The classification of ethanol as carcinogenic and toxic to reproduction category 1 as well as the possible classification as mutagenic with regard to the occupational health and safety precautions to be taken in the workplace will lead to significant additional costs in the production of ethanol. Fulfilment of the increased safety requirements, such as the additional installation of exhaust air systems, will have a price-driving effect on the residual quantity of ethanol produced. A similar price-driving effect is likely to be felt in logistics, as it additional safety requirements would also be required. In addition to the reorganisation of long-established supply chains, the logistics sector would therefore be subject to increased cost pressure, which will be reflected in higher prices for customers. In principle, it can be assumed that there would be plant closures in the ethanol production sector following ruinous price competition. Developments in the logistics sector must be characterised by a high degree of uncertainty. In addition, these disruptions in the economic structure are also likely to lead to upheavals on the labour market, although these cannot be reliably estimated in the short term.
Information above is confidential	
Justification for confidentiality	

Hazards and Risks of the Alternative	Ethanol, applied to hands or surfaces, is characterised by rapid and residue-free evaporation, so that the actual exposure after use of the active ingredient is only a few minutes. This time is sufficient to develop a biocidal effect against viruses, bacteria and microorganisms, while not causing any harmful effects in humans. This property is the main reason why ethanol is used as a biocide for surface cleaning in food and animal feed production. Another decisive advantage here is that the use of ethanol-based biocidal products does not lead to the formation of disinfection by-products or other toxicological chemical compounds that are harmful to human health or the environment. Substituting ethanol as a biocidal active ingredient would have fatal consequences for healthcare: no known substitute has the broad virucidal spectrum of activity and all the substitutes under consideration have a worse toxicity profile than ethanol. Accordingly, the increased use of disinfectants with a weaker effect would lead to higher microbial resistance. Furthermore, possible alternatives are not available in the required quantities either in the short or long term and would also be significantly more expensive than ethanol. The resulting reduction in the availability of effective disinfectants would drastically increase infection rates in healthcare, food processing and public hygiene, posing a significant risk to public health. It is therefore imperative that the appropriateness of the planned categorisation takes into account the actual risk in real-life application scenarios.
Information above is confidential	
Justification for confidentiality	
Availability	Substituting ethanol as a biocidal active ingredient would also have drastic economic consequences. At present, there are no correspondingly large production capacities for any of the possible substitutes, meaning that the construction of such large-scale plants would involve immense investment costs. At the same time, reliable supply chains would have to be established in order to start up and maintain production at the plants. It is also worth noting that the construction of production facilities for the manufacture of alternative biocides would take several years, during which a shortage of disinfectants is likely. On the ethanol production side, on the other hand, there would be opposing developments: existing plants would suddenly lose value due to the drop in demand and the resulting lower ethanol prices, while the loss of established supply chains would

	also cause price distortions on the markets for agricultural raw materials across Europe. As the production of ethanol is accompanied by the creation of co-products, it is to be expected that undersupply and market imbalances may also occur in these areas. This would primarily affect the animal feed sector, but also the food sector, which is currently supplied with biogenic carbon dioxide. The decline in the supply of protein-rich animal feed is particularly in conflict with the European Protein Strategy, which aims to make the EU's supply of plant-based protein sources (especially for animal feed, but also for food) more sustainable, independent and diverse.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol REACH Association strongly opposes the proposed CMR classification of ethanol. According to scientific knowledge, this classification for the use of ethanol as a biocidal active substance is inappropriate and not justified.
Information above is confidential	
Justification for confidentiality	
Other comments	The World Health Organisation (WHO) has long listed ethanol as an "essential medicine" and the active ingredient has been established as an indispensable disinfectant for decades. The use of alcohol-based hand sanitisers based on ethanol has been a matter of course in different countries in Europe since the 1950s. Ethanol is used worldwide as a biocide and has been able to establish itself due to its excellent effectiveness, despite strict alcohol bans even in Muslim countries. [1] [2] Ethanol has a unique and incomparably broad spectrum of antivirucidal activity. Only ethanol is effective against non-enveloped viruses such as adenoviruses, poliovirus, human enteroviruses, echoviruses and various coxsackieviruses. [3] [4] This effectiveness is a key component of infection control and is indispensable for breaking chains of infection during pandemic outbreaks and other waves of disease. Studies published in the Lancet, one of the oldest and most renowned medical journals in the world, in 2000 prove the efficiency of the biocidal effect of ethanol: when using alcohol-based hand sanitisers, compliance with hand disinfection was increased from 48% to 66% and the prevalence of nosocomial infections was reduced from 17% to 10%. [5] Ethanolic hand sanitisers

	were and still are an indispensable protection for staff and patients in medical care. To date, no comparable, reliable and safe alternatives with similarly good skin compatibility and rapid efficacy are available or known. Recommendations from the Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute (RKI) show that the tissue compatibility [6] of ethanol is significantly better than that of propanol, a frequently mentioned substitute, even when ethanol is used in higher concentrations than propanol.[7] The inhalation toxicity of ethanol is also much lower than that of propanol. It should be emphasised in particular that there would also be a regulatory contradiction when considering different areas of application: as foodstuffs are exempt from the CLP Regulation, ethanol in alcoholic beverages would remain freely available for sale, while the same substance in a disinfectant would be categorised as hazardous and heavily regulated. This regulatory inconsistency cannot be justified on the basis of the data used for the assessment and robs the entire regulatory system of its credibility.
Information above is confidential	
Justification for confidentiality	
References	1. Allegranzi, B. et al: Global implementation of WHO's multimodal strategy for improvement of hand hygiene: a quasi-experimental study. Lancet Infect Dis 2013, 13, 843-851. DOI: 10.1016/S1473-3099(13)70163-4 2. Hübner, N.-O. et al: Haben wir seine Botschaft verstanden? – Ein Abriss zur Geschichte der Händehygiene anlässlich des 200. Geburtstages von Ignaz Philipp Semmelweis (Have we understood his message? - An outline of the history of hand hygiene on the occasion of the 200th birthday of Ignaz Philipp Semmelweis). Epidem Bull No. 18/2018, 3 May 2018. 3. Kramer, A. et al: Ethanol is indispensable for virucidal hand antisepsis: memorandum from the alcohol-based hand rub (ABHR) Task Force, WHO Collaborating Centre on Patient Safety, and the Commission for Hospital Hygiene and Infection Prevention (KRINKO), Robert Koch Institute, Berlin, Germany. Antimicrobial Resistance & Infection Control 2022, 11, 93. DOI: 10.1186/s13756-022-01134-7 4. VAH: Ethanol is indispensable as a biocidal agent for hygienic hand disinfection. Hyg Med 2020, 45, 194-200. 5. Pittet, D. et al: Effectiveness of a hospital-wide programme to improve compliance with hand hygiene. Lancet 2000, 356, 1307-1312. DOI: 10.1016/s0140-6736(00)02814-2 6. Kramer, A. et al: Explantationstest mit

	Haut und Peritoneum der neonatalen Ratte als Voraussagetest zur Verträglichkeit lokaler Antiinfektiva für Wunden und Körperhöhlen (Explantation test with skin and peritoneum of the neonatal rat as a preliminary test for the tolerance of local anti-infectives for wounds and body cavities) Chirurg 1998, 69, 840–845. DOI: 10.1007/s001040050498 7. KRINKO/Robert-Koch Institut: Händehygiene in Einrichtungen des Gesundheitswesens (Hand hygiene in healthcare facilities of the health care system) Bundesgesundheitsbl 2016 - 59:1189-1220, DOI 10.1007/s00103-016-2416-6
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 302	2025/04/30 02:14
Country	Netherlands
Name of organization/institution	Ethanol REACH Association
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Ethanol REACH Association, on behalf of the European producers and importers of ethanol, hereby comments on the ongoing public consultation regarding the planned classification of ethanol as carcinogenic and toxic for reproduction category 1 and the possible classification as mutagenic in the context of the authorisation procedure under the Biocidal Products Regulation (EU) No 528/2012. The example of ethanol makes it particularly clear that a differentiated consideration of the relevant areas of application and the resulting risk that the use of an active substance entails is essential. The consequences of such a disproportionate categorisation of ethanol would be serious at this point and under these circumstances would not only fail to reduce the risks to human health, but would actually

	have catastrophic consequences for many health and economic sectors as well as for security of supply.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	The classification of ethanol as carcinogenic and toxic to reproduction category 1 as well as the possible classification as mutagenic with regard to the occupational health and safety precautions to be taken in the workplace will lead to significant additional costs in the production of ethanol. Fulfilment of the increased safety requirements, such as the additional installation of exhaust air systems, will have a price-driving effect on the residual quantity of ethanol produced. A similar price-driving effect is likely to be felt in logistics, as it additional safety requirements would also be required. In addition to the reorganisation of long-established supply chains, the logistics sector would therefore be subject to increased cost pressure, which will be reflected in higher prices for customers. In principle, it can be assumed that there would be plant closures in the ethanol production sector following ruinous price competition. Developments in the logistics sector must be characterised by a high degree of uncertainty. In addition, these disruptions in the economic structure are also likely to lead to upheavals on the labour market, although these cannot be reliably estimated in the short term.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Ethanol, applied to hands or surfaces, is characterised by rapid and residue-free evaporation, so that the actual exposure after use of the active ingredient is only a few

	minutes. This time is sufficient to develop a biocidal effect against viruses, bacteria and microorganisms, while not causing any harmful effects in humans. This property is the main reason why ethanol is used as a biocide for surface cleaning in food and animal feed production. Another decisive advantage here is that the use of ethanol-based biocidal products does not lead to the formation of disinfection by-products or other toxicological chemical compounds that are harmful to human health or the environment. Substituting ethanol as a biocidal active ingredient would have fatal consequences for healthcare: no known substitute has the broad virucidal spectrum of activity and all the substitutes under consideration have a worse toxicity profile than ethanol. Accordingly, the increased use of disinfectants with a weaker effect would lead to higher microbial resistance. Furthermore, possible alternatives are not available in the required quantities either in the short or long term and would also be significantly more expensive than ethanol. The resulting reduction in the availability of effective disinfectants would drastically increase infection rates in healthcare, food processing and public hygiene, posing a significant risk to public health. It is therefore imperative that the appropriateness of the planned categorisation takes into account the actual risk in real-life application scenarios.
Information above is confidential	
Justification for confidentiality	
Availability	Substituting ethanol as a biocidal active ingredient would also have drastic economic consequences. At present, there are no correspondingly large production capacities for any of the possible substitutes, meaning that the construction of such large-scale plants would involve immense investment costs. At the same time, reliable supply chains would have to be established in order to start up and maintain production at the plants. It is also worth noting that the construction of production facilities for the manufacture of alternative biocides would take several years, during which a shortage of disinfectants is likely. On the ethanol production side, on the other hand, there would be opposing developments: existing plants would suddenly lose value due to the drop in demand and the resulting lower ethanol prices, while the loss of established supply chains would also cause price distortions on the markets for agricultural raw materials across Europe. As the production of ethanol is accompanied by the creation of co-products, it is to be

	expected that undersupply and market imbalances may also occur in these areas. This would primarily affect the animal feed sector, but also the food sector, which is currently supplied with biogenic carbon dioxide. The decline in the supply of protein-rich animal feed is particularly in conflict with the European Protein Strategy, which aims to make the EU's supply of plant-based protein sources (especially for animal feed, but also for food) more sustainable, independent and diverse.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol REACH Association strongly opposes the proposed CMR classification of ethanol. According to scientific knowledge, this classification for the use of ethanol as a biocidal active substance is inappropriate and not justified.
Information above is confidential	
Justification for confidentiality	
Other comments	The World Health Organisation (WHO) has long listed ethanol as an "essential medicine" and the active ingredient has been established as an indispensable disinfectant for decades. The use of alcohol-based hand sanitisers based on ethanol has been a matter of course in different countries in Europe since the 1950s. Ethanol is used worldwide as a biocide and has been able to establish itself due to its excellent effectiveness, despite strict alcohol bans even in Muslim countries. [1] [2] Ethanol has a unique and incomparably broad spectrum of antivirucidal activity. Only ethanol is effective against non-enveloped viruses such as adenoviruses, poliovirus, human enteroviruses, echoviruses and various coxsackieviruses. [3] [4] This effectiveness is a key component of infection control and is indispensable for breaking chains of infection during pandemic outbreaks and other waves of disease. Studies published in the Lancet, one of the oldest and most renowned medical journals in the world, in 2000 prove the efficiency of the biocidal effect of ethanol: when using alcohol-based hand sanitisers, compliance with hand disinfection was increased from 48% to 66% and the prevalence of nosocomial infections was reduced from 17% to 10%. [5] Ethanolic hand sanitisers were and still are an indispensable protection for staff and patients in medical care. To date, no comparable, reliable and safe alternatives with similarly good skin compatibility

	and rapid efficacy are available or known. Recommendations from the Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute (RKI) show that the tissue compatibility [6] of ethanol is significantly better than that of propanol, a frequently mentioned substitute, even when ethanol is used in higher concentrations than propanol.[7] The inhalation toxicity of ethanol is also much lower than that of propanol. It should be emphasised in particular that there would also be a regulatory contradiction when considering different areas of application: as foodstuffs are exempt from the CLP Regulation, ethanol in alcoholic beverages would remain freely available for sale, while the same substance in a disinfectant would be categorised as hazardous and heavily regulated. This regulatory inconsistency cannot be justified on the basis of the data used for the assessment and robs the entire regulatory system of its credibility.
Information above is confidential	
Justification for confidentiality	
References	1. Allegranzi, B. et al: Global implementation of WHO's multimodal strategy for improvement of hand hygiene: a quasi-experimental study. Lancet Infect Dis 2013, 13, 843-851. DOI: 10.1016/S1473-3099(13)70163-4 2. Hübner, N.-O. et al: Haben wir seine Botschaft verstanden? – Ein Abriss zur Geschichte der Händehygiene anlässlich des 200. Geburtstages von Ignaz Philipp Semmelweis (Have we understood his message? - An outline of the history of hand hygiene on the occasion of the 200th birthday of Ignaz Philipp Semmelweis). Epidem Bull No. 18/2018, 3 May 2018. 3. Kramer, A. et al: Ethanol is indispensable for virucidal hand antisepsis: memorandum from the alcohol-based hand rub (ABHR) Task Force, WHO Collaborating Centre on Patient Safety, and the Commission for Hospital Hygiene and Infection Prevention (KRINKO), Robert Koch Institute, Berlin, Germany. Antimicrobial Resistance & Infection Control 2022, 11, 93. DOI: 10.1186/s13756-022-01134-7 4. VAH: Ethanol is indispensable as a biocidal agent for hygienic hand disinfection. Hyg Med 2020, 45, 194-200. 5. Pittet, D. et al: Effectiveness of a hospital-wide programme to improve compliance with hand hygiene. Lancet 2000, 356, 1307-1312. DOI: 10.1016/S0140-6736(00)02814-2 6. Kramer, A. et al: Explantationstest mit Haut und Peritoneum der neonatalen Ratte als Voraussagetest zur Verträglichkeit lokaler Antiinfektiva für Wunden und Körperhöhlen (Explantation test with skin and

	peritoneum of the neonatal rat as a preliminary test for the tolerance of local anti-infectives for wounds and body cavities) Chirurg 1998, 69, 840–845. DOI: 10.1007/s001040050498 7. KRINKO/Robert-Koch Institut: Händehygiene in Einrichtungen des Gesundheitswesens (Hand hygiene in healthcare facilities of the health care system) Bundesgesundheitsbl 2016 - 59:1189-1220, DOI 10.1007/s00103-016-2416-6
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 303	2025/04/30 02:16
Country	Netherlands
Name of organization/institution	Ethanol REACH Association
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Ethanol REACH Association, on behalf of the European producers and importers of ethanol, hereby comments on the ongoing public consultation regarding the planned classification of ethanol as carcinogenic and toxic for reproduction category 1 and the possible classification as mutagenic in the context of the authorisation procedure under the Biocidal Products Regulation (EU) No 528/2012. The example of ethanol makes it particularly clear that a differentiated consideration of the relevant areas of application and the resulting risk that the use of an active substance entails is essential. The consequences of such a disproportionate categorisation of ethanol would be serious at this point and under these circumstances would not only fail to reduce the risks to human health, but would actually have catastrophic consequences for many health and economic sectors as well as for security of supply.
Product Type	1,2,4

Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	The classification of ethanol as carcinogenic and toxic to reproduction category 1 as well as the possible classification as mutagenic with regard to the occupational health and safety precautions to be taken in the workplace will lead to significant additional costs in the production of ethanol. Fulfilment of the increased safety requirements, such as the additional installation of exhaust air systems, will have a price-driving effect on the residual quantity of ethanol produced. A similar price-driving effect is likely to be felt in logistics, as it additional safety requirements would also be required. In addition to the reorganisation of long-established supply chains, the logistics sector would therefore be subject to increased cost pressure, which will be reflected in higher prices for customers. In principle, it can be assumed that there would be plant closures in the ethanol production sector following ruinous price competition. Developments in the logistics sector must be characterised by a high degree of uncertainty. In addition, these disruptions in the economic structure are also likely to lead to upheavals on the labour market, although these cannot be reliably estimated in the short term.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Ethanol, applied to hands or surfaces, is characterised by rapid and residue-free evaporation, so that the actual exposure after use of the active ingredient is only a few minutes. This time is sufficient to develop a biocidal effect against viruses, bacteria and microorganisms, while not causing any harmful effects in humans. This property is the main reason why ethanol is used as a biocide for surface cleaning in food and animal feed production. Another

	decisive advantage here is that the use of ethanol-based biocidal products does not lead to the formation of disinfection by-products or other toxicological chemical compounds that are harmful to human health or the environment. Substituting ethanol as a biocidal active ingredient would have fatal consequences for healthcare: no known substitute has the broad virucidal spectrum of activity and all the substitutes under consideration have a worse toxicity profile than ethanol. Accordingly, the increased use of disinfectants with a weaker effect would lead to higher microbial resistance. Furthermore, possible alternatives are not available in the required quantities either in the short or long term and would also be significantly more expensive than ethanol. The resulting reduction in the availability of effective disinfectants would drastically increase infection rates in healthcare, food processing and public hygiene, posing a significant risk to public health. It is therefore imperative that the appropriateness of the planned categorisation takes into account the actual risk in real-life application scenarios.
Information above is confidential	
Justification for confidentiality	
Availability	Substituting ethanol as a biocidal active ingredient would also have drastic economic consequences. At present, there are no correspondingly large production capacities for any of the possible substitutes, meaning that the construction of such large-scale plants would involve immense investment costs. At the same time, reliable supply chains would have to be established in order to start up and maintain production at the plants. It is also worth noting that the construction of production facilities for the manufacture of alternative biocides would take several years, during which a shortage of disinfectants is likely. On the ethanol production side, on the other hand, there would be opposing developments: existing plants would suddenly lose value due to the drop in demand and the resulting lower ethanol prices, while the loss of established supply chains would also cause price distortions on the markets for agricultural raw materials across Europe. As the production of ethanol is accompanied by the creation of co-products, it is to be expected that undersupply and market imbalances may also occur in these areas. This would primarily affect the animal feed sector, but also the food sector, which is currently supplied with biogenic carbon dioxide. The decline in the supply of protein-rich animal feed is particularly in conflict

	with the European Protein Strategy, which aims to make the EU's supply of plant-based protein sources (especially for animal feed, but also for food) more sustainable, independent and diverse.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol REACH Association strongly opposes the proposed CMR classification of ethanol. According to scientific knowledge, this classification for the use of ethanol as a biocidal active substance is inappropriate and not justified.
Information above is confidential	
Justification for confidentiality	
Other comments	The World Health Organisation (WHO) has long listed ethanol as an "essential medicine" and the active ingredient has been established as an indispensable disinfectant for decades. The use of alcohol-based hand sanitisers based on ethanol has been a matter of course in different countries in Europe since the 1950s. Ethanol is used worldwide as a biocide and has been able to establish itself due to its excellent effectiveness, despite strict alcohol bans even in Muslim countries. [1] [2] Ethanol has a unique and incomparably broad spectrum of antivirucidal activity. Only ethanol is effective against non-enveloped viruses such as adenoviruses, poliovirus, human enteroviruses, echoviruses and various coxsackieviruses. [3] [4] This effectiveness is a key component of infection control and is indispensable for breaking chains of infection during pandemic outbreaks and other waves of disease. Studies published in the Lancet, one of the oldest and most renowned medical journals in the world, in 2000 prove the efficiency of the biocidal effect of ethanol: when using alcohol-based hand sanitisers, compliance with hand disinfection was increased from 48% to 66% and the prevalence of nosocomial infections was reduced from 17% to 10%. [5] Ethanol hand sanitisers were and still are an indispensable protection for staff and patients in medical care. To date, no comparable, reliable and safe alternatives with similarly good skin compatibility and rapid efficacy are available or known. Recommendations from the Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute (RKI) show that the tissue compatibility [6] of ethanol is significantly better than that of propanol, a

	frequently mentioned substitute, even when ethanol is used in higher concentrations than propanol.[7] The inhalation toxicity of ethanol is also much lower than that of propanol. It should be emphasised in particular that there would also be a regulatory contradiction when considering different areas of application: as foodstuffs are exempt from the CLP Regulation, ethanol in alcoholic beverages would remain freely available for sale, while the same substance in a disinfectant would be categorised as hazardous and heavily regulated. This regulatory inconsistency cannot be justified on the basis of the data used for the assessment and robs the entire regulatory system of its credibility.
Information above is confidential	
Justification for confidentiality	
References	1. Allegranzi, B. et al: Global implementation of WHO's multimodal strategy for improvement of hand hygiene: a quasi-experimental study. Lancet Infect Dis 2013, 13, 843-851. DOI: 10.1016/S1473-3099(13)70163-4 2. Hübner, N.-O. et al: Haben wir seine Botschaft verstanden? – Ein Abriss zur Geschichte der Händehygiene anlässlich des 200. Geburtstages von Ignaz Philipp Semmelweis (Have we understood his message? - An outline of the history of hand hygiene on the occasion of the 200th birthday of Ignaz Philipp Semmelweis). Epidem Bull No. 18/2018, 3 May 2018. 3. Kramer, A. et al: Ethanol is indispensable for virucidal hand antisepsis: memorandum from the alcohol-based hand rub (ABHR) Task Force, WHO Collaborating Centre on Patient Safety, and the Commission for Hospital Hygiene and Infection Prevention (KRINKO), Robert Koch Institute, Berlin, Germany. Antimicrobial Resistance & Infection Control 2022, 11, 93. DOI: 10.1186/s13756-022-01134-7 4. VAH: Ethanol is indispensable as a biocidal agent for hygienic hand disinfection. Hyg Med 2020, 45, 194-200. 5. Pittet, D. et al: Effectiveness of a hospital-wide programme to improve compliance with hand hygiene. Lancet 2000, 356, 1307-1312. DOI: 10.1016/s0140-6736(00)02814-2 6. Kramer, A. et al: Explantationstest mit Haut und Peritoneum der neonatalen Ratte als Voraussagetest zur Verträglichkeit lokaler Antiinfektiva für Wunden und Körperhöhlen (Explantation test with skin and peritoneum of the neonatal rat as a preliminary test for the tolerance of local anti-infectives for wounds and body cavities) Chirurg 1998, 69, 840–845. DOI: 10.1007/s001040050498 7. KRINKO/Robert-Koch Institut: Händehygiene in Einrichtungen des Gesundheitswesens

	(Hand hygiene in healthcare facilities of the health care system) Bundesgesundheitsbl 2016 - 59:1189-1220, DOI 10.1007/s00103-016-2416-6
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 304	2025/04/30 07:40
Country	Sweden
Name of organization/institution	Sanify AB
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Proposal for substitution
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	

Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	See attachment
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	Archive.zip
Attachments (confidential information)	
Justification for confidential attachment	

Comment 305	2025/04/30 10:54
Country	Belgium
Name of organization/institution	MedTech Europe

I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	MedTech Europe, the European trade association representing manufacturers of medical technologies, including medical devices (MDs) and in vitro diagnostic medical devices (IVDs), including Research Use Only (RUO) products, welcomes the opportunity to contribute to the European Chemicals Agency's consultation on the availability of alternatives for ethanol in product types 1, 2, and 4. The feasibility of substituting ethanol within the medical technology sector is highly dependent on its specific applications within companies. In healthcare and specifically, the medical technology sector, ethanol is widely used in disinfection and sterilization processes, including surface cleaners, hand sanitizers, and ophthalmic instrument cleaning. Additionally, it serves as a solvent and stabilizing agent in medical formulations, including ophthalmic solutions and reagents, as well as a general-purpose solvent for application of coatings and cleaner widely used by medical device manufacturers. Ethanol can also be found in inks, degreasers, dyes and lubricants, which are used to manufacture a variety of medical devices, from orthopedic instruments to ophthalmic implants and neurovascular catheters. As a key active ingredient in disinfectants, ethanol is particularly effective against bacteria and viruses while also being safe and biodegradable. The World Health Organization (WHO) has classified ethanol-based hand disinfectants as indispensable, given their unique efficacy, particularly against non-enveloped viruses such as polioviruses. Moreover, ethanol's role in maintaining contamination-free environment, such as in semiconductor manufacturing, is critical due to its high purity and rapid evaporation properties. We note that the current classification proposal subject to this consultation is on the basis of the hazard of ingestion. However, if the administration route is considered in this evaluation, we invite ECHA to take into account that for hazard characterization, in the medical technology sector, Ethanol is used on skin and (device) surfaces – for disinfection and sterilization, respectively. Therefore, in the context of medical technology applications, ethanol is employed as a biocidal agent via dermal and inhalation routes, rather than through oral exposure. In the context of medical device manufacturing, it is widely used as a solvent for coating and cleaning applications. Consequently, toxicity assessments based primarily on chronic repeated dose oral exposure data

	may not be representative of the actual risk profile associated with its use in this sector. As highlighted in the Analysis of Alternatives , exposure levels via biocidal applications are considered negligible, further stressing the importance of route-specific risk evaluation. The COVID-19 pandemic underscored the essential role of ethanol-based disinfection in breaking infection chains effectively and rapidly. During this period, manufacturers successfully met the unprecedented demand for disinfectants by leveraging available ethanol supplies and adapting production capabilities. In contrast, alternative substances do not offer the same flexibility or scalability, and do not have such widely known and available toxicity information. Furthermore, in hygiene and other professional applications, only denatured ethanol is used to prevent oral consumption. Any potential classification of ethanol as CMR 1A/1B under the Biocidal Product Regulation (EU) No 528/2012 would have significant consequences for its use in healthcare settings and medical device manufacturing. In healthcare settings, such a classification could severely restrict the availability of ethanol-based disinfectants, drive up production costs, and create strong incentives for manufacturers to relocate production outside the EU. In manufacturing settings, such a classification would severely restrict available components such as inks and coatings that use ethanol as a solvent, and would push manufacturers to rely on cleaning solvents with less favourable toxicological properties. MedTech Europe urges careful consideration of these critical factors in assessing the continued use of ethanol within the medical technology sector. We remain committed to collaborating with regulatory bodies to ensure safe, effective, and practical solutions for healthcare and hygiene applications.
Product Type	1,2,4
Alternative Identity and Properties	Depending on the specific applications of ethanol in healthcare and medical technology, potential substitutes must be carefully assessed to ensure they meet safety, efficacy, and regulatory requirements especially under the EU sectoral legislation (Medical Device Regulation 2017/745 and In Vitro Diagnostic Devices 2017/746). Key factors influencing their suitability include antimicrobial potency, evaporation rate, material compatibility, and toxicity. 1. For disinfection and sterilization uses, possible alternatives include Isopropanol (IPA) (EC 200-661-7, CAS 67-63-0) and Hydrogen Peroxide (H₂O₂) (EC 231-765-0, CAS 7722-84-1). □ Isopropanol (IPA) (EC 200-661-7, CAS 67-63-0) is a volatile, colourless alcohol with similar solvent and

	disinfectant properties to ethanol. Both ethanol and IPA share similar mechanisms of action, and effectiveness against microorganisms depending on concentration and formulation. However, ethanol possesses a more favourable toxicological profile that is well studied and documented in both animals and humans. Ethanol is preferred from a functionality perspective for its rapid evaporation, which minimizes residue, while IPA's slower evaporation rate allows for extended surface contact time, potentially enhancing its antimicrobial efficacy. However, Isopropanol falls short of ethanol in the pathogen range efficacy; in particular, it lacks sufficient efficacy against non-enveloped viruses, supporting ethanol's essentiality for high-hygiene environments. □ Hydrogen Peroxide (H₂O₂) (EC 231-765-0, CAS 7722-84-1) is a strong oxidizer that decomposes into water and oxygen, making it an effective sterilizing agent. While not a direct solvent substitute, it is widely used for high-level disinfection and sterilization purposes. It should be noted that this chemical is also undergoing potential regulation and the restriction on either or both Ethanol and Hydrogen Peroxide, may lead to regrettable substitution. 2. For solvent applications, possible alternatives include Propylene Glycol (PG) (EC 200-338-0, CAS 57-55-6) and Glycerol (EC 200-289-5, CAS 56-81-5). □ Propylene Glycol (PG) (EC 200-338-0, CAS 57-55-6) is a colourless, odourless liquid commonly used as a solvent and excipient in pharmaceutical and ophthalmic formulations. While it can serve as an alternative solvent to ethanol, it has different viscosity and evaporation characteristics that may impact its suitability for specific applications. □ Glycerol (EC 200-289-5, CAS 56-81-5) is used in ophthalmic formulations as both a solvent and humectant, though it does not serve as a direct replacement for ethanol in disinfection applications.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	The replacement of ethanol with isopropanol (IPA) as a surface disinfectant in a manufacturing environment is technically feasible but presents several challenges. While IPA offers similar antimicrobial properties and is widely used for disinfection, its efficacy against non-enveloped viruses is lower than ethanol. This limitation must be addressed through disinfection efficacy testing in accordance with USP '1072' to confirm compliance with microbial reduction standards. Additionally, implementing this transition

	requires adherence to regulatory change control procedures. A formal change control document must detail the rationale for substitution, efficacy validation, protocol adjustments, and staff training updates. The scope of testing and documentation complexity will depend on the range of surfaces treated, with an estimated transition period of 6–9 months. Despite the technical feasibility, practical constraints such as higher costs, supply chain limitations, and reduced efficacy against certain pathogens make IPA a less optimal choice for frequent surface disinfection. Other alternatives, such as propylene glycol (PG), may be suitable for ophthalmic applications but are not viable replacements for ethanol in manufacturing disinfection. Hydrogen peroxide (H₂O₂) remains effective for sterilization but does not serve as a direct solvent substitute. Thus, while ethanol alternatives exist, their implementation may result in reduced functionality, lowered performance, and logistical challenges, limiting their practicality for widespread use in manufacturing environments.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	The economic impact of replacing ethanol with alternative disinfectants in a manufacturing environment depends on several factors, including material costs, regulatory compliance, and operational adjustments. When comparing the costs of alternative disinfectants, isopropanol (IPA) is slightly more expensive than ethanol but remains widely available and generally cost-effective. However, its higher price, supply chain limitations, and reduced efficacy against non-enveloped viruses make it less practical for frequent surface disinfection. Hydrogen peroxide (H₂O₂) is a relatively affordable alternative, but its strict handling and storage requirements introduce additional compliance and logistical costs. Meanwhile, propylene glycol (PG) is more expensive than ethanol, limiting its economic viability except for specialized formulations where its unique properties are necessary. Transitioning from ethanol to isopropanol (IPA) for surface disinfection involves significant regulatory and operational costs, including disinfection efficacy testing under USP '1072' , which is estimated at 130,000 euros per site. This cost covers laboratory testing, materials, and compliance documentation. Additionally, indirect expenses arise from training employees on new disinfection protocols, revising standard operating procedures, modifying inventory management systems, and

	managing temporary productivity losses due to process adjustments. These factors contribute to increased labour costs and potential operational disruptions, with the full transition expected to take 6–9 months. A forced switch to less effective alternatives could significantly raise production costs, impacting a broad range of products. This shift could incentivize companies to relocate manufacturing operations outside the EU, where regulatory restrictions may be less stringent. Additionally, classifying ethanol under CMR 1A/1B could trigger further legislative constraints in different Members States, affecting compliance with local laws leading to consequences across multiple industries through increasing operational burdens.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	When considering substitutes for ethanol in disinfection and solvent applications, it is crucial to assess their associated hazards and risks. While some alternatives share similar safety profiles with ethanol, others present distinct challenges that could impact workplace safety, material compatibility, and infection control. Isopropanol is widely used as a disinfectant and solvent, carrying many of the same hazards as ethanol, but at lower exposure doses. It is highly flammable, posing an ignition risk from sparks, open flames, or static electricity. Vapor inhalation can cause dizziness, headaches, and respiratory irritation, especially in confined or poorly ventilated areas. Skin and eye contact may lead to dryness, irritation, dermatitis, or eye discomfort. Additionally, IPA can degrade certain plastics, rubbers, and coatings, like ethanol. While it evaporates quickly, improper application may reduce contact time, potentially affecting disinfection efficacy. Despite these risks, IPA is generally considered a low-risk alternative to ethanol for antiseptic and disinfectant applications due to its similar volatility and lack of ingestion concerns. In addition, Isopropanol, as a petrochemical derivative, presents considerable environmental drawbacks due to its energy-intensive production process, which relies on non-renewable resources. While Hydrogen Peroxide is an effective sterilizing agent, its hazards differ significantly from ethanol and IPA. At high concentrations, it is highly corrosive, capable of causing severe skin and eye damage. It also requires strict handling and storage precautions due to its oxidative properties. Additionally, H₂O₂ can degrade metals and organic materials, limiting its practical use in certain

	environments. Propylene Glycol is Generally Recognized as Safe (GRAS) and is commonly used in ophthalmic formulations. It has low toxicity and does not pose significant health hazards under normal use. However, unlike ethanol or IPA, PG lacks broad-spectrum antimicrobial activity, making it unsuitable as a disinfectant. While valuable as a solvent, it does not serve as a direct replacement for ethanol in disinfection applications. Replacing ethanol with less effective but partly more hazardous alternatives such as Isopropanol or Hydrogen Peroxide in healthcare environments could increase infection risks for workers and patients over time. The long-term costs of weaker infection prevention—including higher rates of hospital-acquired infections (HAIs) and associated healthcare expenses—are difficult to quantify but could outweigh the benefits of switching. When evaluating ethanol alternatives, additional factors beyond efficacy, cost, and availability must be considered. Isopropanol (IPA) is widely used in disinfection and laboratory cleaning but can be more drying to the skin compared to ethanol. Hydrogen peroxide (H₂O₂) is more effective for sterilization but is not directly interchangeable with ethanol in formulations. Propylene glycol (PG), while not a direct disinfectant, provides moisturizing benefits, making it a suitable alternative in ophthalmic solutions. Furthermore, ethanol's widespread use in food and beverages contributes to its well-established safety profile, making it more acceptable for many applications compared to IPA. Lastly, it is essential to recognize that toxicological risk is not absolute; both dose and route of exposure are critical determinants of harm. In the context of medical technology, ethanol is used almost exclusively via dermal and inhalation routes at low exposure levels, which differ significantly from the oral exposure data upon which current classifications are largely based. The current CMR classification framework does not account for this route- and dose-dependent nuance, nor does it align with patient safety considerations. Regulatory approaches should emphasize actual patient risk, reinforcing toxicological principles such as “the dose makes the poison,” which is overlooked in current interpretations of General Safety and Performance Requirements (GSPR) outlined in Annex I of the EU Medical Device Regulation (MDR) 2017/745. There are no known less-toxic alternatives to ethanol for its biocidal role, and comparative toxicity assessments based on No Observed Adverse Effect Levels (NOAELs) suggest ethanol performs similarly or better than substitutes such as isopropanol.

Information above is confidential	
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Availability	The availability of ethanol alternatives varies depending on industry demand, production capacity, and handling requirements. Isopropanol (IPA) is widely available and commonly used across the medical, pharmaceutical, and laboratory sectors. Similarly, hydrogen peroxide (H₂O₂) is readily accessible but requires careful handling and concentration control, which can limit its practicality for certain applications. Propylene glycol (PG) is commonly found in pharmaceutical and cosmetic industries, particularly in ophthalmic products. While possible alternatives are globally available, ethanol remains the most accessible option. During the COVID-19 pandemic, many companies were able to rapidly scale ethanol production to meet surging demand, a level of flexibility that would not be possible for the proposed alternative substances as highlighted in the findings of the Analysis of Alternatives for the use of Ethanol in product-types 1 and 2.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	As highlighted in this document and supported by ECHA's reports, there are currently no viable alternatives that fully match ethanol's broad-spectrum antimicrobial activity, rapid evaporation, and material compatibility. Isopropanol is overall less effective, with slower evaporation and a narrower antimicrobial spectrum and less sustainable due to its higher production cost and environmental drawbacks. Other proposed alternatives are more suitable for niche applications and cannot meet the industrial and healthcare sector's high-volume demands. A substitution of ethanol would not only compromise effectiveness in critical applications but also lead to increased costs, potentially incentivizing companies to relocate production outside the EU, and risk leading to ineffective disinfection and sterilization processes, jeopardizing patient safety. A ban of ethanol under BPR would lead to uncertainties regarding the continuity of supply of ethanol for critical, non-biocidal applications and impair access to critical medical technologies, impacting patient health and safety. Given ethanol's proven safety profile in controlled applications, the proportionality of such regulatory measures must be carefully evaluated. Regulatory decisions should balance risk

	assessment with practical impact, ensuring that essential industrial and healthcare functions remain both effective and economically sustainable.
Information above is confidential	
Justification for confidentiality	
Other comments	One key point that needs to be considered is the regulatory complexity of a potential restriction of Ethanol under BPR and/or CMR 1A/1B classification under CLH. Any CMR 1A/1B classification under CLH would then trigger requirements under a lot of sectoral rules for example the Medical Devices Regulation (MDR), Section 10.4.1). Considering sectoral legislation is crucial within a proper impact assessment. This was also shown within the last years during the discussion of substance approval of ethylene oxide under the BPR. The non approval of ethylene oxide, which is already decided but not published yet, according to its CMR classification bore the risk that a sterilisation process for medical devices and other products without an alternative could no longer be available. This shows that the classification processes under BPR and also CLP must undergo a critical review to avoid long term negative consequences. Especially the exposure of substances must be taken into account while assessing the risks and hazards. We would also like to note that any restriction of Ethanol would lead to severe socio-economic consequences for healthcare and patients across Europe: ☐ The COVID-19 pandemic clearly highlighted the critical role of ethanol in supporting national crisis preparedness and response efforts. Its widespread use in disinfectants, sanitizers, and medical applications underscored the need for secure, reliable access to ethanol in the event of future public health emergencies or pandemics. ☐ A matter of particular concern arises in relation to the continuity of supply of ethanol for critical, non-biocidal applications. In the potential scenario in which ethanol manufacturers or suppliers, currently operating under a transitional provision outlined in article 89 of the Biocidal Products Regulation (BPR), are not granted the Union BPR approval, it remains uncertain whether these manufacturers would continue producing ethanol for non-biocidal applications—such as its use in inks, degreasers, and other formulations—where the primary mode of action is solvency rather than biocidal activity. This uncertainty is especially relevant where non-biocidal uses constitute only a small fraction of overall market demand. Understanding whether continued production for these uses would remain

	viable is essential, as the consequences of a withdrawal could be far-reaching. Should ethanol no longer be available for such non-biocidal purposes, suitable alternatives would need to be identified and subjected to rigorous qualification, verification, and validation processes. For medical devices, this includes extensive testing and the need to obtain new regulatory approvals, which—particularly for Class III implantable devices—can take more than a decade. If a BPR-driven restriction or ban were to reduce or eliminate ethanol supply before such redesign efforts are completed, access to critical medical technologies used for example in orthopaedic, ophthalmic, and neurovascular surgery could be severely impacted, posing potential risks to patient health and safety. Additionally, there are broader industrial and economic implications. For instance, an EU-based ink manufacturer reliant on domestic ethanol supply may face difficult strategic choices if its supplier ceases production due to regulatory constraints. This could lead to a shift toward sourcing ethanol from outside the EU (e.g., China or the United States), or even relocation of manufacturing operations closer to alternative sources. Such downstream effects, while indirect, could result in reduced EU industrial capacity and loss of taxable economic activity, even in cases where the non-biocidal uses themselves are not subject to restriction under the BPR. These facts are especially relevant as substances which are classified as CMR class 1 will need special approvals for production sites according to certain national laws. □ The potential CMR classification has also a direct impact on (national) occupational safety laws and leads to potential restrictions in the use of the chemical, for example by women of childbearing age or breastfeeding women. We therefore urge that these potential impacts—particularly on the continuity of supply for critical, non-biocidal applications—be fully assessed and taken into account as part of the regulatory decision-making process.
Information above is confidential	
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References	
Attachments (non-confidential information)	250422_MTE_Response_Ethanol AoA Consultation_FINAL.pdf
Attachments (confidential information)	

Justification for confidential attachment	

Comment 306	2025/04/30 11:01
Country	Belgium
Name of organization/institution	MedTech Europe
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	MedTech Europe, the European trade association representing manufacturers of medical technologies, including medical devices (MDs) and in vitro diagnostic medical devices (IVDs), including Research Use Only (RUO) products, welcomes the opportunity to contribute to the European Chemicals Agency's consultation on the availability of alternatives for ethanol in product types 1, 2, and 4. The feasibility of substituting ethanol within the medical technology sector is highly dependent on its specific applications within companies. In healthcare and specifically, the medical technology sector, ethanol is widely used in disinfection and sterilization processes, including surface cleaners, hand sanitizers, and ophthalmic instrument cleaning. Additionally, it serves as a solvent and stabilizing agent in medical formulations, including ophthalmic solutions and reagents, as well as a general-purpose solvent for application of coatings and cleaner widely used by medical device manufacturers. Ethanol can also be found in inks, degreasers, dyes and lubricants, which are used to manufacture a variety of medical devices, from orthopedic instruments to ophthalmic implants and neurovascular catheters. As a key active ingredient in disinfectants, ethanol is particularly effective against bacteria and viruses while also being safe and biodegradable. The World Health Organization (WHO) has classified ethanol-based hand disinfectants as indispensable, given their unique efficacy, particularly against non-enveloped viruses such as polioviruses. Moreover, ethanol's role in maintaining contamination-free environment, such as in semiconductor manufacturing, is critical due to its high purity and rapid evaporation properties. We note that the current classification proposal subject to this consultation is on the basis of the hazard of ingestion. However, if the

	administration route is considered in this evaluation, we invite ECHA to take into account that for hazard characterization, in the medical technology sector, Ethanol is used on skin and (device) surfaces – for disinfection and sterilization, respectively. Therefore, in the context of medical technology applications, ethanol is employed as a biocidal agent via dermal and inhalation routes, rather than through oral exposure. In the context of medical device manufacturing, it is widely used as a solvent for coating and cleaning applications. Consequently, toxicity assessments based primarily on chronic repeated dose oral exposure data may not be representative of the actual risk profile associated with its use in this sector. As highlighted in the Analysis of Alternatives , exposure levels via biocidal applications are considered negligible, further stressing the importance of route-specific risk evaluation. The COVID-19 pandemic underscored the essential role of ethanol-based disinfection in breaking infection chains effectively and rapidly. During this period, manufacturers successfully met the unprecedented demand for disinfectants by leveraging available ethanol supplies and adapting production capabilities. In contrast, alternative substances do not offer the same flexibility or scalability, and do not have such widely known and available toxicity information. Furthermore, in hygiene and other professional applications, only denatured ethanol is used to prevent oral consumption. Any potential classification of ethanol as CMR 1A/1B under the Biocidal Product Regulation (EU) No 528/2012 would have significant consequences for its use in healthcare settings and medical device manufacturing. In healthcare settings, such a classification could severely restrict the availability of ethanol-based disinfectants, drive up production costs, and create strong incentives for manufacturers to relocate production outside the EU. In manufacturing settings, such a classification would severely restrict available components such as inks and coatings that use ethanol as a solvent, and would push manufacturers to rely on cleaning solvents with less favourable toxicological properties. MedTech Europe urges careful consideration of these critical factors in assessing the continued use of ethanol within the medical technology sector. We remain committed to collaborating with regulatory bodies to ensure safe, effective, and practical solutions for healthcare and hygiene applications.
Product Type	1,2,4
Alternative Identity and Properties	Depending on the specific applications of ethanol in healthcare and medical technology, potential substitutes

	must be carefully assessed to ensure they meet safety, efficacy, and regulatory requirements especially under the EU sectoral legislation (Medical Device Regulation 2017/745 and In Vitro Diagnostic Devices 2017/746). Key factors influencing their suitability include antimicrobial potency, evaporation rate, material compatibility, and toxicity. 1. For disinfection and sterilization uses, possible alternatives include Isopropanol (IPA) (EC 200-661-7, CAS 67-63-0) and Hydrogen Peroxide (H₂O₂) (EC 231-765-0, CAS 7722-84-1). □ Isopropanol (IPA) (EC 200-661-7, CAS 67-63-0) is a volatile, colourless alcohol with similar solvent and disinfectant properties to ethanol. Both ethanol and IPA share similar mechanisms of action, and effectiveness against microorganisms depending on concentration and formulation. However, ethanol possesses a more favourable toxicological profile that is well studied and documented in both animals and humans. Ethanol is preferred from a functionality perspective for its rapid evaporation, which minimizes residue, while IPA's slower evaporation rate allows for extended surface contact time, potentially enhancing its antimicrobial efficacy. However, Isopropanol falls short of ethanol in the pathogen range efficacy; in particular, it lacks sufficient efficacy against non-enveloped viruses, supporting ethanol's essentiality for high-hygiene environments. □ Hydrogen Peroxide (H₂O₂) (EC 231-765-0, CAS 7722-84-1) is a strong oxidizer that decomposes into water and oxygen, making it an effective sterilizing agent. While not a direct solvent substitute, it is widely used for high-level disinfection and sterilization purposes. It should be noted that this chemical is also undergoing potential regulation and the restriction on either or both Ethanol and Hydrogen Peroxide, may lead to regrettable substitution. 2. For solvent applications, possible alternatives include Propylene Glycol (PG) (EC 200-338-0, CAS 57-55-6) and Glycerol (EC 200-289-5, CAS 56-81-5). □ Propylene Glycol (PG) (EC 200-338-0, CAS 57-55-6) is a colourless, odourless liquid commonly used as a solvent and excipient in pharmaceutical and ophthalmic formulations. While it can serve as an alternative solvent to ethanol, it has different viscosity and evaporation characteristics that may impact its suitability for specific applications. □ Glycerol (EC 200-289-5, CAS 56-81-5) is used in ophthalmic formulations as both a solvent and humectant, though it does not serve as a direct replacement for ethanol in disinfection applications.
Information above is confidential	

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Technical Feasibility	The replacement of ethanol with isopropanol (IPA) as a surface disinfectant in a manufacturing environment is technically feasible but presents several challenges. While IPA offers similar antimicrobial properties and is widely used for disinfection, its efficacy against non-enveloped viruses is lower than ethanol. This limitation must be addressed through disinfection efficacy testing in accordance with USP '1072' to confirm compliance with microbial reduction standards. Additionally, implementing this transition requires adherence to regulatory change control procedures. A formal change control document must detail the rationale for substitution, efficacy validation, protocol adjustments, and staff training updates. The scope of testing and documentation complexity will depend on the range of surfaces treated, with an estimated transition period of 6–9 months. Despite the technical feasibility, practical constraints such as higher costs, supply chain limitations, and reduced efficacy against certain pathogens make IPA a less optimal choice for frequent surface disinfection. Other alternatives, such as propylene glycol (PG), may be suitable for ophthalmic applications but are not viable replacements for ethanol in manufacturing disinfection. Hydrogen peroxide (H₂O₂) remains effective for sterilization but does not serve as a direct solvent substitute. Thus, while ethanol alternatives exist, their implementation may result in reduced functionality, lowered performance, and logistical challenges, limiting their practicality for widespread use in manufacturing environments.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	The economic impact of replacing ethanol with alternative disinfectants in a manufacturing environment depends on several factors, including material costs, regulatory compliance, and operational adjustments. When comparing the costs of alternative disinfectants, isopropanol (IPA) is slightly more expensive than ethanol but remains widely available and generally cost-effective. However, its higher price, supply chain limitations, and reduced efficacy against non-enveloped viruses make it less practical for frequent surface disinfection. Hydrogen peroxide (H₂O₂) is a relatively affordable alternative, but its strict handling and storage requirements introduce additional compliance and logistical costs. Meanwhile, propylene glycol (PG) is more

	expensive than ethanol, limiting its economic viability except for specialized formulations where its unique properties are necessary. Transitioning from ethanol to isopropanol (IPA) for surface disinfection involves significant regulatory and operational costs, including disinfection efficacy testing under USP '1072' , which is estimated at 130,000 euros per site. This cost covers laboratory testing, materials, and compliance documentation. Additionally, indirect expenses arise from training employees on new disinfection protocols, revising standard operating procedures, modifying inventory management systems, and managing temporary productivity losses due to process adjustments. These factors contribute to increased labour costs and potential operational disruptions, with the full transition expected to take 6–9 months. A forced switch to less effective alternatives could significantly raise production costs, impacting a broad range of products. This shift could incentivize companies to relocate manufacturing operations outside the EU, where regulatory restrictions may be less stringent. Additionally, classifying ethanol under CMR 1A/1B could trigger further legislative constraints in different Members States, affecting compliance with local laws leading to consequences across multiple industries through increasing operational burdens.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	When considering substitutes for ethanol in disinfection and solvent applications, it is crucial to assess their associated hazards and risks. While some alternatives share similar safety profiles with ethanol, others present distinct challenges that could impact workplace safety, material compatibility, and infection control. Isopropanol is widely used as a disinfectant and solvent, carrying many of the same hazards as ethanol, but at lower exposure doses. It is highly flammable, posing an ignition risk from sparks, open flames, or static electricity. Vapor inhalation can cause dizziness, headaches, and respiratory irritation, especially in confined or poorly ventilated areas. Skin and eye contact may lead to dryness, irritation, dermatitis, or eye discomfort. Additionally, IPA can degrade certain plastics, rubbers, and coatings, like ethanol. While it evaporates quickly, improper application may reduce contact time, potentially affecting disinfection efficacy. Despite these risks, IPA is generally considered a low-risk alternative to ethanol for antiseptic and disinfectant applications due to its

similar volatility and lack of ingestion concerns. In addition, Isopropanol, as a petrochemical derivative, presents considerable environmental drawbacks due to its energy-intensive production process, which relies on non-renewable resources. While Hydrogen Peroxide is an effective sterilizing agent, its hazards differ significantly from ethanol and IPA. At high concentrations, it is highly corrosive, capable of causing severe skin and eye damage. It also requires strict handling and storage precautions due to its oxidative properties. Additionally, H_2O_2 can degrade metals and organic materials, limiting its practical use in certain environments. Propylene Glycol is Generally Recognized as Safe (GRAS) and is commonly used in ophthalmic formulations. It has low toxicity and does not pose significant health hazards under normal use. However, unlike ethanol or IPA, PG lacks broad-spectrum antimicrobial activity, making it unsuitable as a disinfectant. While valuable as a solvent, it does not serve as a direct replacement for ethanol in disinfection applications. Replacing ethanol with less effective but partly more hazardous alternatives such as Isopropanol or Hydrogen Peroxide in healthcare environments could increase infection risks for workers and patients over time. The long-term costs of weaker infection prevention—including higher rates of hospital-acquired infections (HAIs) and associated healthcare expenses—are difficult to quantify but could outweigh the benefits of switching. When evaluating ethanol alternatives, additional factors beyond efficacy, cost, and availability must be considered. Isopropanol (IPA) is widely used in disinfection and laboratory cleaning but can be more drying to the skin compared to ethanol. Hydrogen peroxide (H_2O_2) is more effective for sterilization but is not directly interchangeable with ethanol in formulations. Propylene glycol (PG), while not a direct disinfectant, provides moisturizing benefits, making it a suitable alternative in ophthalmic solutions. Furthermore, ethanol's widespread use in food and beverages contributes to its well-established safety profile, making it more acceptable for many applications compared to IPA. Lastly, it is essential to recognize that toxicological risk is not absolute; both dose and route of exposure are critical determinants of harm. In the context of medical technology, ethanol is used almost exclusively via dermal and inhalation routes at low exposure levels, which differ significantly from the oral exposure data upon which current classifications are largely based. The current CMR classification framework does not account for this route- and dose-dependent nuance, nor does it align with patient safety considerations. Regulatory approaches should emphasize actual patient

	risk, reinforcing toxicological principles such as “the dose makes the poison,” which is overlooked in current interpretations of General Safety and Performance Requirements (GSPR) outlined in Annex I of the EU Medical Device Regulation (MDR) 2017/745. There are no known less-toxic alternatives to ethanol for its biocidal role, and comparative toxicity assessments based on No Observed Adverse Effect Levels (NOAELs) suggest ethanol performs similarly or better than substitutes such as isopropanol.
Information above is confidential	
Justification for confidentiality	
Availability	The availability of ethanol alternatives varies depending on industry demand, production capacity, and handling requirements. Isopropanol (IPA) is widely available and commonly used across the medical, pharmaceutical, and laboratory sectors. Similarly, hydrogen peroxide (H₂O₂) is readily accessible but requires careful handling and concentration control, which can limit its practicality for certain applications. Propylene glycol (PG) is commonly found in pharmaceutical and cosmetic industries, particularly in ophthalmic products. While possible alternatives are globally available, ethanol remains the most accessible option. During the COVID-19 pandemic, many companies were able to rapidly scale ethanol production to meet surging demand, a level of flexibility that would not be possible for the proposed alternative substances as highlighted in the findings of the Analysis of Alternatives for the use of Ethanol in product-types 1 and 2.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	As highlighted in this document and supported by ECHA's reports, there are currently no viable alternatives that fully match ethanol's broad-spectrum antimicrobial activity, rapid evaporation, and material compatibility. Isopropanol is overall less effective, with slower evaporation and a narrower antimicrobial spectrum and less sustainable due to its higher production cost and environmental drawbacks. Other proposed alternatives are more suitable for niche applications and cannot meet the industrial and healthcare sector's high-volume demands. A substitution of ethanol would not only compromise effectiveness in critical applications but also lead to increased costs, potentially

	incentivizing companies to relocate production outside the EU, and risk leading to ineffective disinfection and sterilization processes, which would jeopardize patient safety. A ban or restriction of ethanol under BPR would lead to uncertainties regarding the continuity of supply of ethanol for critical, non-biocidal applications and consequently impair access to critical medical technologies, impacting patient health and safety. Given ethanol's proven safety profile in controlled applications, the proportionality of such regulatory measures must be carefully evaluated. Regulatory decisions should balance risk assessment with practical impact, ensuring that essential industrial and healthcare functions remain both effective and economically sustainable.
Information above is confidential	
Justification for confidentiality	
Other comments	One key point that needs to be considered is the regulatory complexity of a potential restriction of Ethanol under BPR and/or CMR 1A/1B classification under CLH. Any CMR 1A/1B classification under CLH would then trigger requirements under a lot of sectoral rules for example the Medical Devices Regulation (MDR), Section 10.4.1). Considering sectoral legislation is crucial within a proper impact assessment. This was also shown within the last years during the discussion of substance approval of ethylene oxide under the BPR. The non approval of ethylene oxide, which is already decided but not published yet, according to its CMR classification bore the risk that a sterilisation process for medical devices and other products without an alternative could no longer be available. This shows that the classification processes under BPR and also CLP must undergo a critical review to avoid long term negative consequences. Especially the exposure of substances must be taken into account while assessing the risks and hazards. We would also like to note that any restriction of Ethanol would lead to severe socio-economic consequences for healthcare and patients across Europe: ☐ The COVID-19 pandemic clearly highlighted the critical role of ethanol in supporting national crisis preparedness and response efforts. Its widespread use in disinfectants, sanitizers, and medical applications underscored the need for secure, reliable access to ethanol in the event of future public health emergencies or pandemics. ☐ A matter of particular concern arises in relation to the continuity of supply of ethanol for critical, non-biocidal applications. In the potential scenario in which

	ethanol manufacturers or suppliers, currently operating under a transitional provision outlined in article 89 of the Biocidal Products Regulation (BPR), are not granted the Union BPR approval, it remains uncertain whether these manufacturers would continue producing ethanol for non-biocidal applications—such as its use in inks, degreasers, and other formulations—where the primary mode of action is solvency rather than biocidal activity. This uncertainty is especially relevant where non-biocidal uses constitute only a small fraction of overall market demand. Understanding whether continued production for these uses would remain viable is essential, as the consequences of a withdrawal could be far-reaching. Should ethanol no longer be available for such non-biocidal purposes, suitable alternatives would need to be identified and subjected to rigorous qualification, verification, and validation processes. For medical devices, this includes extensive testing and the need to obtain new regulatory approvals, which—particularly for Class III implantable devices—can take more than a decade. If a BPR-driven restriction or ban were to reduce or eliminate ethanol supply before such redesign efforts are completed, access to critical medical technologies used for example in orthopaedic, ophthalmic, and neurovascular surgery could be severely impacted, posing potential risks to patient health and safety. Additionally, there are broader industrial and economic implications. For instance, an EU-based ink manufacturer reliant on domestic ethanol supply may face difficult strategic choices if its supplier ceases production due to regulatory constraints. This could lead to a shift toward sourcing ethanol from outside the EU (e.g., China or the United States), or even relocation of manufacturing operations closer to alternative sources. Such downstream effects, while indirect, could result in reduced EU industrial capacity and loss of taxable economic activity, even in cases where the non-biocidal uses themselves are not subject to restriction under the BPR. These facts are especially relevant as substances which are classified as CMR class 1 will need special approvals for production sites according to certain national laws. □ The potential CMR classification has also a direct impact on (national) occupational safety laws and leads to potential restrictions in the use of the chemical, for example by women of childbearing age or breastfeeding women. We therefore urge that these potential impacts—particularly on the continuity of supply for critical, non-biocidal applications—be fully assessed and taken into account as part of the regulatory decision-making process.

Information above is confidential	
Justification for confidentiality	
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Attachments (non-confidential information)	250422_MTE_Response_Ethanol AoA Consultation_FINAL.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 307	2025/04/30 11:21

Country	France
Name of organization/institution	NOVAMEX
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	We are using ethanol in our detergent and cosmetic products ECOLABEL certified, as a solvent, solubilizer, coformulant, for it degreasing proprieties, and to adjust viscosity. We don't use it as biocide. For us, Ethanol is not avoidable and meet many advantages, in term of proprieties, environmental impact and health impact compared to bioased or non biobased alternatives. If Ethanol is CMR classified, it will be no longer used in our formulas, and not authorized anymore on ECOLABEL certified products. All the alternative we studied don't meet the same proprieties, advantages and reduced environment/health impact.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	

Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	For now, we don't see suitable alternative to this multi benefits ingredient, and we claim to keep the actual classification in order to continue to use it on detergent and cosmetics products.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	Contribution Ethanol NOVAMEX.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 308	2025/04/30 11:39
Country	Poland
Name of organization/institution	Polish Association of the Cosmetic and Detergent Industry
I do not wish the name of my organisation/institution to be	

published on the ECHA website.	
General information	In the context of the ongoing assessment of ethyl alcohol as an active substance in biocidal products (Product Types 1, 2, and 4), pursuant to the exclusion criteria laid down in Article 5(1) of Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products (Biocidal Products Regulation, BPR), the Polish Association of the Cosmetic and Detergent Industry (PACDI) hereby expresses its deep concern regarding the current direction of the proposed regulatory actions aimed at the reclassification of ethanol. The Association further deems it essential to underscore the potentially far-reaching and adverse implications such a reclassification could entail for the healthcare sector and a wide array of industrial domains. In PACDI's view, this substance may be eligible for derogation under Article 5(2) of the BPR.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Currently, no alternative substances demonstrate comparable efficacy in infection control. Substitutes such as isopropanol (IPA) or n-propanol (NPA) are significantly less available, more irritating to the skin, and less effective microbiologically, especially against non-enveloped viruses. Moreover, these alternatives are supported by fewer safety data.

Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol is considered environmentally safe, predominantly derived from renewable resources. It is fully biodegradable, evaporates rapidly without leaving residues, and its environmental profile is consistent with high sustainability standards. Currently, no alternative substances demonstrate comparable efficacy in infection control. Substitutes such as isopropanol (IPA) or n-propanol (NPA) are significantly less available, more irritating to the skin, and less effective microbiologically, especially against non-enveloped viruses. Moreover, these alternatives are supported by fewer safety data.
Information above is confidential	
Justification for confidentiality	
Other comments	Worker and Consumer Safety: The proposed reclassification of ethanol is based on data derived from the consumption of alcoholic beverages, without consideration of the typical exposure to ethanol via dermal or inhalation routes resulting from the use of biocidal products. Moreover, it disregards mitigating factors such as the denaturation of ethanol, which renders it unfit for consumption. Available toxicological studies indicate that ethanol possesses carcinogenic and reproductive toxicity potential. However, these findings are based on oral exposure from alcohol consumption. Extrapolation of this epidemiological data to assess the risks to workers and consumers fails to take into account the actual routes of exposure in the context of chemical use. The levels of ethanol to which individuals are exposed in occupational or consumer settings are minimal in comparison to those ingested through even moderate alcohol consumption. Therefore, exposure arising from non-ingestive uses of ethanol is negligible, and dermal or inhalation exposure results in internal doses far below critical thresholds. It should further be noted that ethanol used across numerous industrial sectors is denatured and

	unsuitable for ingestion, thereby eliminating any risk to consumers associated with oral intake. As such, CMR properties based on ingestion of the pure substance appear irrelevant in this context. Environmental Safety: Ethanol is considered environmentally safe, predominantly derived from renewable resources. It is fully biodegradable, evaporates rapidly without leaving residues, and its environmental profile is consistent with high sustainability standards. II. ESSENTIALITY FOR THE PREVENTION OF SERIOUS HAZARDS Protection of Health and Infection Control: Ethanol is a critical component in disinfectant products employed in households, hospitals, the food industry, and pharmaceutical manufacturing. It is a highly effective biocide with broad-spectrum efficacy, including against hard-to-inactivate non-enveloped viruses such as poliovirus. This efficacy is essential for infection prevention and control. Due to its high effectiveness, ethanol was widely used as a key active substance during the COVID-19 pandemic to combat SARS-CoV-2. Limiting the availability of ethanol-based disinfectants for both consumers and institutional settings could lead to an increase in infections. The unavailability of such effective, affordable, and safe hygiene products would pose a threat to public health. Furthermore, due to the low likelihood of microbial resistance, ethanol remains one of the most effective and accessible disinfectants in combating healthcare-associated infections, which account for tens of thousands of deaths annually within the EU and result in considerable economic costs. Its role in infection control within healthcare settings is irreplaceable. The World Health Organization (WHO) recognises ethanol-based hand disinfectants as the gold standard in healthcare hand hygiene and has actively promoted their use through initiatives such as the Safe Hands Challenge since 2020. Alternative Substances: Currently, no alternative substances demonstrate comparable efficacy in infection control. Substitutes such as isopropanol (IPA) or n-propanol (NPA) are significantly less available, more irritating to the skin, and less effective microbiologically, especially against non-enveloped viruses. Moreover, these alternatives are supported by fewer safety data. III. DISPROPORTIONATE NEGATIVE IMPACT ON SOCIETY Beyond fulfilling the exemption criteria under the BPR, it is important to consider the implications of a potential CMR Category 1 classification under the REACH Regulation, which would prohibit the placing on the market of such mixtures for consumer use. Should ethanol be classified accordingly, numerous widely used product categories—such as hand and surface disinfectants, automotive windshield washer fluids, and glass cleaners—

	would be banned from consumer markets, despite posing minimal risk to human health. This would lead to a substantial reduction in ethanol use across healthcare and hygiene-related applications, forcing reliance on alternative substances that are often less effective and may pose greater risks. Ethanol also serves as a widely used solvent with unique properties that are irreplaceable in various formulations. In the cosmetics industry, it is employed to dissolve active ingredients and enhance product performance. Owing to its antibacterial properties, ethanol also supports preservative systems—reducing the required concentration of conventional preservatives—and helps prevent microbial contamination in final products. These antibacterial properties are utilized in products such as mouthwashes and deodorants. Restricting the use of ethanol in consumer products, including cosmetics, despite the lack of health risks associated with its presence, could result in the withdrawal of numerous essential hygiene and personal care products from the EU market. The use of ethanol in cosmetics is widely regarded as safe, with the levels absorbed by the body being insignificant in relation to the thresholds for adverse effects. CONCLUSION: In the opinion of the Polish Association of the Cosmetic and Detergent Industry (PACDI), the proposed reclassification of ethanol appears inconsistent with the principles of Better Regulation as outlined by the European Commission. Such a classification would be disproportionate and would exert a profoundly negative impact across multiple sectors—including cosmetics, detergents, and biocidal products—where ethanol constitutes a key ingredient, particularly in consumer-facing formulations. This reclassification would result in substantial socio-economic consequences for European industry, the economy, and society as a whole, while failing to yield any clear public health or safety benefits for consumers or workers. It may also lead to the withdrawal of numerous essential consumer products from the EU market and curtail the use of ethanol-based disinfectants in healthcare and public sectors. Finally, such action could lead to confusion among consumers and undermine the credibility of the EU chemical regulatory framework, especially given that ethanol in alcoholic beverages would remain outside the scope of this regulation.
Information above is confidential	
Justification for confidentiality	

References	
Attachments (non-confidential information)	PSPKD_Stalowisko ws nowej klasyfikacja etanolu_30.04.2025.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 309	2025/04/30 12:14
Country	Slovakia
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	
Product Type	1,2,4
Alternative Identity and Properties	There are no suitable alternatives for ethanol due to its unique combination of effectiveness, safety, and practicality. Ethanol is highly effective against a broad spectrum of microorganisms, including bacteria, viruses, and fungi, making it a reliable disinfectant and preservative. It evaporates quickly, leaving minimal residue, and poses low long-term exposure risks when used appropriately. Ethanol achieves its antimicrobial action in low concentrations, requiring smaller quantities compared to many alternatives. Other substances like isopropanol, formaldehyde, or quaternary ammonium compounds may be less effective, more toxic, or cause greater environmental harm. Ethanol requires fewer safety measures to protect human health and the environment compared to many chemical alternatives, making it a safer and more sustainable option overall.
Information above is confidential	
Justification for confidentiality	

Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	The use of alternatives to ethanol, such as isopropanol, formaldehyde, or quaternary ammonium compounds, is associated with increased risks to human health and the environment. These substances have higher toxicity, greater potential for bioaccumulation, and require more stringent protective measures. For example, formaldehyde is a known carcinogen, while quats may cause skin sensitisation and aquatic toxicity. Substitution would likely increase overall risk, not reduce it. In comparing risks, a qualitative assessment based on literature review and available toxicological, environmental, and use data was conducted. Limitations include data gaps in long-term exposure and environmental fate for some alternatives. The methodology accounted for hazard classification, exposure potential, required concentrations, and downstream impacts, such as increased energy use for manufacturing and waste treatment. Overall, ethanol remains the safer and more sustainable option when considering human and environmental health.
Information above is confidential	
Justification for confidentiality	
Availability	There are no suitable alternatives to ethanol that match its effectiveness, safety profile, and availability. While other substances like isopropanol or quaternary ammonium compounds exist, they either pose higher risks to human health and the environment, or lack the broad-spectrum efficacy of ethanol. Availability of these alternatives in the required quantities is also uncertain, especially without significant lead time and investment in production capacity. This could lead to supply disruptions and reduced effectiveness in critical applications.

Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	After a thorough assessment, it is clear that no alternative substance matches ethanol in terms of effectiveness, safety, and availability. Potential alternatives, such as isopropanol or quaternary ammonium compounds, present greater risks to human health and the environment, and may not be available in sufficient quantities without significant delay or investment. Additionally, the substitution would not reduce overall risks but rather increase them, compromising both human and environmental safety. Data sources used for this analysis — including peer-reviewed studies, REACH dossiers, and ECHA substance databases — are of high quality and reliability. Although some uncertainties exist, particularly regarding long-term effects of alternatives, these do not affect the overall conclusion. Thus, ethanol remains the most suitable and readily available option for its current applications, and no viable alternative is currently identified that would justify substitution.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 310	2025/04/30 12:39
Country	France

Name of organization/institution	FHER
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Fédération de l'Hygiène et de l'Entretien Responsable, FHER représente en France les entreprises qui formulent, fabriquent et commercialisent les produits destinés à laver, nettoyer et entretenir le linge, la vaisselle et l'ensemble des surfaces que ce soit dans les foyers, dans les collectivités, les services de santé ou dans l'industrie. FHER fédère 80 % des entreprises du secteur, TPE, PME ou grands groupes de dimension internationale. La reclassification de l'éthanol implique une interdiction de fait et aurait des conséquences considérables non seulement sur l'industrie européenne, mais aussi sur la société dans son ensemble, sans apporter aucun bénéfice pour la santé humaine ni pour l'environnement. Même avec des dérogations, la disponibilité de l'éthanol sera sévèrement limitée par les réglementations locales. Les autorités devront faire face à de nombreuses conséquences (imprévues), notamment une modification des schémas d'infection et une hausse des coûts. Ainsi qu'à une complexification des utilisations notamment au niveau national via le Décret du 4 avril 2024 fixant de nouvelles valeurs limites d'exposition professionnelles contraignantes et introduisant de nouvelles dispositions pour établir la traçabilité de l'exposition. On peut citer comme exemple la législation sur la sécurité des travailleurs, qui vise à protéger les travailleurs contre les substances dangereuses, en accordant une attention particulière aux groupes de travailleurs susceptibles d'être exposés à un risque accru, comme les femmes enceintes ou allaitantes et les jeunes. • Les directives européennes générales définissent des exigences minimales et des principes fondamentaux pour la sécurité des travailleurs (par exemple, la directive 98/24/CE (directive sur les agents chimiques) et la directive 2004/34/CE (directive sur les substances cancérigènes, mutagènes ou toxiques pour la reproduction). Cela inclut des exigences en matière d'évaluation et de prévention des risques, ainsi que la définition des responsabilités des employeurs et des salariés. Les États membres ont transposé le contenu de ces directives en droit national et sont libres d'adopter des règles plus strictes pour la protection des travailleurs. Ainsi, les exigences en matière de sécurité des travailleurs peuvent être plus strictes dans certains États membres et

	moins strictes dans d'autres. • Cependant, indépendamment de ces différences, la classification proposée de l'éthanol comme substance toxique pour la reproduction de catégorie 1A ou 1B et comme substance cancérigène de catégorie 1A ou 1B peut être considérée comme équivalant à une interdiction de l'utilisation de l'éthanol comme substance active biocide ou substance chimique par les travailleurs en Europe. • La classification de substances/produits comme CMR (cancérogènes, mutagènes ou toxiques pour la reproduction) déclenche des procédures d'évaluation des risques approfondies et des mesures de précaution, comme indiqué ci-dessous (toutes ces exigences peuvent ne pas être remplies). Applicable dans tous les États membres) : • Le risque associé à l'exposition à une substance/un produit CMR doit être soit éliminé (obligation de substituer une substance/un produit chaque fois que possible en modifiant un procédé ou de la remplacer par des alternatives non dangereuses ou moins dangereuses), soit réduit autant que possible l'exposition. Cette mesure générale d'atténuation des risques est mise en œuvre sous le nom de principe STOP dans les législations nationales relatives à la sécurité des travailleurs et les lignes directrices relatives aux activités de sécurité des travailleurs. • STOP signifie "Substitution, Technical measures, organizational measures, personal protective equipment". Ce principe doit être appliqué selon une approche progressive et doit s'appliquer à toutes les substances dangereuses. Selon le pays européen concerné et l'interprétation des employeurs, ce principe peut être appliqué uniquement selon une approche fondée sur le danger (par exemple, au Danemark) ou selon une approche fondée sur le risque, où l'exposition potentielle à une substance et la gravité des effets (par exemple, les substances classées comme irritantes pour la peau sont considérées comme associées à un risque moindre pour le travailleur) sont également prises en compte (par exemple, en Allemagne). Toutefois, pour les substances/produits classés CMR, la substitution par une substance/un produit moins dangereux est obligatoire, dans la mesure du possible, dans tous les États membres. • Les outils d'évaluation des risques professionnels généralement utilisés (par exemple, le Système de contrôle des substances dangereuses sur le lieu de travail (EMKG), Baua, Allemagne) prescrivent le port de gants de protection par les travailleurs/femmes enceintes ou allaitantes en cas de contact avec des substances classées comme cancérigènes, mutagènes ou toxiques pour la reproduction. Cette disposition est incompatible avec l'utilisation de désinfectants cutanés à base d'éthanol : o Le confinement

	du processus d'émission est obligatoire si cela est techniquement possible. Les limites d'exposition sur le lieu de travail et les mesures des concentrations d'éthanol dans l'air doivent être strictement respectées. o L'accès des travailleurs aux zones où des substances CMR sont utilisées doit être restreint. o Des activités de surveillance sanitaire obligatoires – examens médicaux réguliers (par exemple, Allemagne, France, Norvège, Grèce, Italie, Espagne) o Une formation et une information approfondies des travailleurs doivent être mises en place. o Des procédures d'urgence doivent être établies en cas d'incident impliquant des substances CMR. o Rapports et documentation : signaler tout incident ou problème de santé lié à l'exposition aux CMR aux autorités compétentes et documenter toutes les mesures de sécurité et tous les incidents. o Des dossiers détaillés sur l'exposition des travailleurs sont nécessaires ; une notification aux registres nationaux peut être nécessaire (par exemple, en Pologne, en Autriche et en Roumanie).
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	

Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Les désinfectants pour les mains à base d'éthanol sont essentiels à la prévention et au contrôle des infections, que ce soit dans les établissements de santé ou dans la vie quotidienne. L'éthanol est aujourd'hui la seule substance active biocide capable d'inactiver efficacement en quelques secondes un large spectre de virus, incluant les virus non enveloppés (norovirus, entérovirus, adénovirus), mais aussi les virus enveloppés comme le SARS-CoV-2. Cette rapidité d'action permet de réduire les temps de contact et la quantité de produit utilisé, ce qui simplifie les flux de travail dans les environnements critiques comme les hôpitaux. L'Organisation mondiale de la santé (OMS) reconnaît l'importance des désinfectants à base d'éthanol, les ayant inscrits sur la Liste des médicaments essentiels. Elle souligne également que les campagnes d'hygiène des mains, fondées sur l'utilisation de ces désinfectants, ont permis de réduire de moitié le nombre d'infections associées aux soins (IAS) en Europe au cours de la dernière décennie. Pourtant, les IAS continuent de représenter un fardeau sanitaire considérable, avec plus de 4,3 millions de cas chaque année dans l'Union européenne et l'Espace économique européen (UE/EEE), dont 37 000 décès directement attribuables, 16 millions de jours d'hospitalisation supplémentaires, et jusqu'à 110 000 décès annuels. Si l'éthanol était classé comme substance CMR, ces produits seraient interdits dans les hôpitaux, compromettant gravement la prévention des IAS. Aucun substitut ne présente une efficacité équivalente, en particulier contre les virus non enveloppés pour lesquels aucun vaccin n'existe. Face à la résurgence de virus comme le norovirus ou le poliovirus, maintenir l'utilisation de l'éthanol est une priorité de santé publique.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	

Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 311	2025/04/30 12:52
Country	France
Name of organization/institution	Tereos France
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Tereos is a key player in ethanol production, with a significant portion of our traditional alcohol utilized in biocides. We produce ethanol from a variety of agricultural sources such as beets, corn and wheat. Our ethanol serves as an active substance in PT 1, PT 2 & PT 4. Additionally, we use products containing ethanol, such as cleaning agents and denaturants for industrial alcohol, which are essential for ensuring the cleanliness and safety of our premises as well as compliance with legal requirements. Specifically, we utilize Biocidal Products containing ethanol PT 4 in our facilities for the production of ingredients for food and feedstuff, pharmaceuticals, and cosmetics. Therefore, the classification of ethanol would have a critical impact on our operations. Currently, we do not have alternative solutions. Ethanol is a very specific substance because of the diversity of its uses including food, industrial and fuel that leads to extremely different routes and levels of exposure for human body. Because potable alcohol is kept entirely separate from other end-uses through customs regulations, and because levels of alcohol in blood from ingestion is much higher than through inhalation or skin contact, data from abuse of alcohol as a beverage cannot be used to classify ethanol as a CMR 1 for non-beverage uses such as biocides. In

	addition, classification of ethanol as carcinogenic or toxic to reproduction would be detrimental to many biocidal products, create a lack of alternatives and have critical consequences for public health. It would also have knock-on effects on other end-uses through linkages between regulations and reputation.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol is an essential biocidal active substance with proven efficacy and safety. The lack of viable alternatives makes ethanol particularly indispensable for infection control. The human drinking data considered by the biocidal competent authorities is not scientifically appropriate for classification.

	Using data from abusive drinking is not a reliable method for biocidal applications, not only because the exposure routes differ significantly but also because customs and fiscal legislation mandate the addition of denaturing agents to alcohol for non-beverage uses in order to keep it separate from the beverage market. Without evaluating relevant data specifically related to the impacts of alcohol via skin contact and inhalation, a hazard assessment is impossible. Extrapolating epidemiological drinking data to worker/consumer exposure is scientifically invalid, making the classification of a substance under biocidal legislation as Category 1 CMR based on food intake data unsound and inappropriate. Ethanol is unique, being one of the most widely used basic chemicals in numerous applications worldwide. A BPC recommendation for CMR classification leading to exclusion or substitution criteria will •Prevent the usage of ethanol by the general public and professional users where no suitable alternatives exist that are effective against non-enveloped viruses, as demonstrated by the Assessment of Alternatives. •Impact various industries beyond biocidal applications linked to cosmetic products, chemical agents at work, food contact materials, EU Ecolabel and general food law. Such a classification would bring no health benefit at all but would create severe health issues and would have severe socio-economic consequences for our industry that would be left with no alternative. Considering the complexity of the discussion around classification and its significant consequences, the RAC under the CLP framework, not the BPC, should address the harmonized classification discussion.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	202504_BPR Public Consultation_ TEREOS.pdf
Attachments (confidential information)	

Justification for confidential attachment	

Comment 312	2025/04/30 12:54
Country	France
Name of organization/institution	Tereos France
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Tereos is a key player in ethanol production, with a significant portion of our traditional alcohol utilized in biocides. We produce ethanol from a variety of agricultural sources such as beets, corn and wheat. Our ethanol serves as an active substance in PT 1, PT 2 & PT 4. Additionally, we use products containing ethanol, such as cleaning agents and denaturants for industrial alcohol, which are essential for ensuring the cleanliness and safety of our premises as well as compliance with legal requirements. Specifically, we utilize Biocidal Products containing ethanol PT 4 in our facilities for the production of ingredients for food and feedstuff, pharmaceuticals, and cosmetics. Therefore, the classification of ethanol would have a critical impact on our operations. Currently, we do not have alternative solutions. Ethanol is a very specific substance because of the diversity of its uses including food, industrial and fuel that leads to extremely different routes and levels of exposure for human body. Because potable alcohol is kept entirely separate from other end-uses through customs regulations, and because levels of alcohol in blood from ingestion is much higher than through inhalation or skin contact, data from abuse of alcohol as a beverage cannot be used to classify ethanol as a CMR 1 for non-beverage uses such as biocides. In addition, classification of ethanol as carcinogenic or toxic to reproduction would be detrimental to many biocidal products, create a lack of alternatives and have critical consequences for public health. It would also have knock-on effects on other end-uses through linkages between regulations and reputation.
Product Type	1,2,4

Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol is an essential biocidal active substance with proven efficacy and safety. The lack of viable alternatives makes ethanol particularly indispensable for infection control. The human drinking data considered by the biocidal competent authorities is not scientifically appropriate for classification. Using data from abusive drinking is not a reliable method for biocidal applications, not only because the exposure routes differ significantly but also because customs and fiscal legislation mandate the addition of denaturing agents to alcohol for non-beverage uses in order to keep it separate from the beverage market. Without evaluating relevant data specifically related to the impacts of alcohol via skin contact and inhalation, a hazard assessment is impossible. Extrapolating epidemiological drinking data to

	worker/consumer exposure is scientifically invalid, making the classification of a substance under biocidal legislation as Category 1 CMR based on food intake data unsound and inappropriate. Ethanol is unique, being one of the most widely used basic chemicals in numerous applications worldwide. A BPC recommendation for CMR classification leading to exclusion or substitution criteria will •Prevent the usage of ethanol by the general public and professional users where no suitable alternatives exist that are effective against non-enveloped viruses, as demonstrated by the Assessment of Alternatives. •Impact various industries beyond biocidal applications linked to cosmetic products, chemical agents at work, food contact materials, EU Ecolabel and general food law. Such a classification would bring no health benefit at all but would create severe health issues and would have severe socio-economic consequences for our industry that would be left with no alternative. Considering the complexity of the discussion around classification and its significant consequences, the RAC under the CLP framework, not the BPC, should address the harmonized classification discussion.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	202504_BPR Public Consultation_ TEREOS.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 313	2025/04/30 12:56
Country	France

Name of organization/institution	Tereos France
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Tereos is a key player in ethanol production, with a significant portion of our traditional alcohol utilized in biocides. We produce ethanol from a variety of agricultural sources such as beets, corn and wheat. Our ethanol serves as an active substance in PT 1, PT 2 & PT 4. Additionally, we use products containing ethanol, such as cleaning agents and denaturants for industrial alcohol, which are essential for ensuring the cleanliness and safety of our premises as well as compliance with legal requirements. Specifically, we utilize Biocidal Products containing ethanol PT 4 in our facilities for the production of ingredients for food and feedstuff, pharmaceuticals, and cosmetics. Therefore, the classification of ethanol would have a critical impact on our operations. Currently, we do not have alternative solutions. Ethanol is a very specific substance because of the diversity of its uses including food, industrial and fuel that leads to extremely different routes and levels of exposure for human body. Because potable alcohol is kept entirely separate from other end-uses through customs regulations, and because levels of alcohol in blood from ingestion is much higher than through inhalation or skin contact, data from abuse of alcohol as a beverage cannot be used to classify ethanol as a CMR 1 for non-beverage uses such as biocides. In addition, classification of ethanol as carcinogenic or toxic to reproduction would be detrimental to many biocidal products, create a lack of alternatives and have critical consequences for public health. It would also have knock-on effects on other end-uses through linkages between regulations and reputation.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	

Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol is an essential biocidal active substance with proven efficacy and safety. The lack of viable alternatives makes ethanol particularly indispensable for infection control. The human drinking data considered by the biocidal competent authorities is not scientifically appropriate for classification. Using data from abusive drinking is not a reliable method for biocidal applications, not only because the exposure routes differ significantly but also because customs and fiscal legislation mandate the addition of denaturing agents to alcohol for non-beverage uses in order to keep it separate from the beverage market. Without evaluating relevant data specifically related to the impacts of alcohol via skin contact and inhalation, a hazard assessment is impossible. Extrapolating epidemiological drinking data to worker/consumer exposure is scientifically invalid, making the classification of a substance under biocidal legislation as Category 1 CMR based on food intake data unsound and inappropriate. Ethanol is unique, being one of the most widely used basic chemicals in numerous applications worldwide. A BPC recommendation for CMR classification leading to exclusion or substitution criteria will •Prevent the usage of ethanol by the general public and professional users where no suitable alternatives exist that are effective

	against non-enveloped viruses, as demonstrated by the Assessment of Alternatives. •Impact various industries beyond biocidal applications linked to cosmetic products, chemical agents at work, food contact materials, EU Ecolabel and general food law. Such a classification would bring no health benefit at all but would create severe health issues and would have severe socio-economic consequences for our industry that would be left with no alternative. Considering the complexity of the discussion around classification and its significant consequences, the RAC under the CLP framework, not the BPC, should address the harmonized classification discussion.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	202504_BPR Public Consultation_ TEREOS.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 314	2025/04/30 13:00
Country	France
Name of organization/institution	FHER
I do not wish the name of my organisation/institution to be published on the ECHA website.	

General information	Fédération de l'Hygiène et de l'Entretien Responsable, FHER représente en France les entreprises qui formulent, fabriquent et commercialisent les produits destinés à laver, nettoyer et entretenir le linge, la vaisselle et l'ensemble des surfaces que ce soit dans les foyers, dans les collectivités, les services de santé ou dans l'industrie. FHER fédère 80 % des entreprises du secteur, TPE, PME ou grands groupes de dimension internationale. La reclassification de l'éthanol implique une interdiction de fait et aurait des conséquences considérables non seulement sur l'industrie européenne, mais aussi sur la société dans son ensemble, sans apporter aucun bénéfice pour la santé humaine ni pour l'environnement. Même avec des dérogations, la disponibilité de l'éthanol sera sévèrement limitée par les réglementations locales. Les autorités devront faire face à de nombreuses conséquences (imprévues), notamment une modification des schémas d'infection et une hausse des coûts. Ainsi qu'à une complexification des utilisations notamment au niveau national via le Décret du 4 avril 2024 fixant de nouvelles valeurs limites d'exposition professionnelles contraignantes et introduisant de nouvelles dispositions pour établir la traçabilité de l'exposition. On peut citer comme exemple la législation sur la sécurité des travailleurs, qui vise à protéger les travailleurs contre les substances dangereuses, en accordant une attention particulière aux groupes de travailleurs susceptibles d'être exposés à un risque accru, comme les femmes enceintes ou allaitantes et les jeunes. • Les directives européennes générales définissent des exigences minimales et des principes fondamentaux pour la sécurité des travailleurs (par exemple, la directive 98/24/CE (directive sur les agents chimiques) et la directive 2004/34/CE (directive sur les substances cancérigènes, mutagènes ou toxiques pour la reproduction). Cela inclut des exigences en matière d'évaluation et de prévention des risques, ainsi que la définition des responsabilités des employeurs et des salariés. Les États membres ont transposé le contenu de ces directives en droit national et sont libres d'adopter des règles plus strictes pour la protection des travailleurs. Ainsi, les exigences en matière de sécurité des travailleurs peuvent être plus strictes dans certains États membres et moins strictes dans d'autres. • Cependant, indépendamment de ces différences, la classification proposée de l'éthanol comme substance toxique pour la reproduction de catégorie 1A ou 1B et comme substance cancérigène de catégorie 1A ou 1B peut être considérée comme équivalant à une interdiction de l'utilisation de l'éthanol comme substance active biocide ou substance chimique par les travailleurs en Europe. • La classification

	de substances/produits comme CMR (cancérogènes, mutagènes ou toxiques pour la reproduction) déclenche des procédures d'évaluation des risques approfondies et des mesures de précaution, comme indiqué ci-dessous (toutes ces exigences peuvent ne pas être remplies). Applicable dans tous les États membres) : • Le risque associé à l'exposition à une substance/un produit CMR doit être soit éliminé (obligation de substituer une substance/un produit chaque fois que possible en modifiant un procédé ou de la remplacer par des alternatives non dangereuses ou moins dangereuses), soit réduit autant que possible l'exposition. Cette mesure générale d'atténuation des risques est mise en œuvre sous le nom de principe STOP dans les législations nationales relatives à la sécurité des travailleurs et les lignes directrices relatives aux activités de sécurité des travailleurs. • STOP signifie "Substitution, Technical measures, organizational measures, personal protective equipment". Ce principe doit être appliqué selon une approche progressive et doit s'appliquer à toutes les substances dangereuses. Selon le pays européen concerné et l'interprétation des employeurs, ce principe peut être appliqué uniquement selon une approche fondée sur le danger (par exemple, au Danemark) ou selon une approche fondée sur le risque, où l'exposition potentielle à une substance et la gravité des effets (par exemple, les substances classées comme irritantes pour la peau sont considérées comme associées à un risque moindre pour le travailleur) sont également prises en compte (par exemple, en Allemagne). Toutefois, pour les substances/produits classés CMR, la substitution par une substance/un produit moins dangereux est obligatoire, dans la mesure du possible, dans tous les États membres. • Les outils d'évaluation des risques professionnels généralement utilisés (par exemple, le Système de contrôle des substances dangereuses sur le lieu de travail (EMKG), Baua, Allemagne) prescrivent le port de gants de protection par les travailleurs/femmes enceintes ou allaitantes en cas de contact avec des substances classées comme cancérigènes, mutagènes ou toxiques pour la reproduction. Cette disposition est incompatible avec l'utilisation de désinfectants cutanés à base d'éthanol : - o Le confinement du processus d'émission est obligatoire si cela est techniquement possible. Les limites d'exposition sur le lieu de travail et les mesures des concentrations d'éthanol dans l'air doivent être strictement respectées. - o L'accès des travailleurs aux zones où des substances CMR sont utilisées doit être restreint. - o Des activités de surveillance sanitaire obligatoires – examens médicaux réguliers (par exemple, Allemagne, France, Norvège, Grèce, Italie, Espagne) o

	Une formation et une information approfondies des travailleurs doivent être mises en place. o Des procédures d'urgence doivent être établies en cas d'incident impliquant des substances CMR. o Rapports et documentation : signaler tout incident ou problème de santé lié à l'exposition aux CMR aux autorités compétentes et documenter toutes les mesures de sécurité et tous les incidents. o Des dossiers détaillés sur l'exposition des travailleurs sont nécessaires ; une notification aux registres nationaux peut être nécessaire (par exemple, en Pologne, en Autriche et en Roumanie).
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	

Conclusion on suitability and availability of the alternative	L'éthanol reste la substance active la plus efficace pour la désinfection, notamment dans les environnements où les surfaces sont fréquemment touchées, tels que les hôpitaux, les établissements industriels, d'enseignement et de garde d'enfants. Aucune autre substance active du TP2 ne combine aussi bien spectre d'efficacité, action rapide, compatibilité avec les surfaces et profil de sécurité. D'autres alcools, comme les propanols, présentent une activité virucide plus limitée, en particulier contre les virus non enveloppés. L'acide peracétique, bien que plus puissant, est corrosif, ce qui limite son utilisation, notamment dans les établissements de santé où la compatibilité avec les équipements sensibles est primordiale. L'éthanol, quant à lui, offre une désinfection à large spectre, essentielle à la prévention des infections. Il est efficace contre les bactéries, virus et champignons, et son usage dans les nettoyeurs multi-usages garantit une action nettoyante et désinfectante dans un seul produit. Recommandé par de nombreuses agences de santé publique et respectant les normes environnementales, l'éthanol est également reconnu par le Centre européen de prévention et de contrôle des maladies, notamment pour son efficacité contre le coronavirus. En tant que solvant, l'éthanol dissout efficacement saleté, graisse et matières organiques, ce qui en fait un ingrédient clé dans les nettoyeurs destinés aux zones difficiles à nettoyer, comme les cuisines et salles de bains. Il possède un profil de sécurité élevé et se décompose en sous-produits non toxiques, ce qui le rend sûr pour les surfaces en contact avec les aliments. Comparé à d'autres désinfectants chimiques, l'éthanol est moins irritant pour la peau, ce qui le rend adapté à un usage domestique, y compris pour les peaux sensibles. Il désinfecte une grande variété de surfaces sans les endommager, contrairement à l'hypochlorite de sodium qui peut corroder certaines surfaces.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	

Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 315	2025/04/30 13:05
Country	France
Name of organization/institution	FHER
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Fédération de l'Hygiène et de l'Entretien Responsable, FHER représente en France les entreprises qui formulent, fabriquent et commercialisent les produits destinés à laver, nettoyer et entretenir le linge, la vaisselle et l'ensemble des surfaces que ce soit dans les foyers, dans les collectivités, les services de santé ou dans l'industrie. FHER fédère 80 % des entreprises du secteur, TPE, PME ou grands groupes de dimension internationale. La reclassification de l'éthanol implique une interdiction de fait et aurait des conséquences considérables non seulement sur l'industrie européenne, mais aussi sur la société dans son ensemble, sans apporter aucun bénéfice pour la santé humaine ni pour l'environnement. Même avec des dérogations, la disponibilité de l'éthanol sera sévèrement limitée par les réglementations locales. Les autorités devront faire face à de nombreuses conséquences (imprévues), notamment une modification des schémas d'infection et une hausse des coûts. Ainsi qu'à une complexification des utilisations notamment au niveau national via le Décret du 4 avril 2024 fixant de nouvelles valeurs limites d'exposition professionnelles contraignantes et introduisant de nouvelles dispositions pour établir la traçabilité de l'exposition. On peut citer comme exemple la législation sur la sécurité des travailleurs, qui vise à protéger les travailleurs contre les substances dangereuses, en accordant une attention particulière aux groupes de travailleurs susceptibles d'être exposés à un risque accru, comme les femmes enceintes ou

	allaitantes et les jeunes. • Les directives européennes générales définissent des exigences minimales et des principes fondamentaux pour la sécurité des travailleurs (par exemple, la directive 98/24/CE (directive sur les agents chimiques) et la directive 2004/34/CE (directive sur les substances cancérigènes, mutagènes ou toxiques pour la reproduction). Cela inclut des exigences en matière d'évaluation et de prévention des risques, ainsi que la définition des responsabilités des employeurs et des salariés. Les États membres ont transposé le contenu de ces directives en droit national et sont libres d'adopter des règles plus strictes pour la protection des travailleurs. Ainsi, les exigences en matière de sécurité des travailleurs peuvent être plus strictes dans certains États membres et moins strictes dans d'autres. • Cependant, indépendamment de ces différences, la classification proposée de l'éthanol comme substance toxique pour la reproduction de catégorie 1A ou 1B et comme substance cancérigène de catégorie 1A ou 1B peut être considérée comme équivalant à une interdiction de l'utilisation de l'éthanol comme substance active biocide ou substance chimique par les travailleurs en Europe. • La classification de substances/produits comme CMR (cancérogènes, mutagènes ou toxiques pour la reproduction) déclenche des procédures d'évaluation des risques approfondies et des mesures de précaution, comme indiqué ci-dessous (toutes ces exigences peuvent ne pas être remplies). Applicable dans tous les États membres) : • Le risque associé à l'exposition à une substance/un produit CMR doit être soit éliminé (obligation de substituer une substance/un produit chaque fois que possible en modifiant un procédé ou de la remplacer par des alternatives non dangereuses ou moins dangereuses), soit réduit autant que possible l'exposition. Cette mesure générale d'atténuation des risques est mise en œuvre sous le nom de principe STOP dans les législations nationales relatives à la sécurité des travailleurs et les lignes directrices relatives aux activités de sécurité des travailleurs. • STOP signifie "Substitution, Technical measures, organizational measures, personal protective equipment". Ce principe doit être appliqué selon une approche progressive et doit s'appliquer à toutes les substances dangereuses. Selon le pays européen concerné et l'interprétation des employeurs, ce principe peut être appliqué uniquement selon une approche fondée sur le danger (par exemple, au Danemark) ou selon une approche fondée sur le risque, où l'exposition potentielle à une substance et la gravité des effets (par exemple, les substances classées comme irritantes pour la peau sont considérées comme associées à un risque moindre pour le

	travailleur) sont également prises en compte (par exemple, en Allemagne). Toutefois, pour les substances/produits classés CMR, la substitution par une substance/un produit moins dangereux est obligatoire, dans la mesure du possible, dans tous les États membres. • Les outils d'évaluation des risques professionnels généralement utilisés (par exemple, le Système de contrôle des substances dangereuses sur le lieu de travail (EMKG), Baua, Allemagne) prescrivent le port de gants de protection par les travailleurs/femmes enceintes ou allaitantes en cas de contact avec des substances classées comme cancérogènes, mutagènes ou toxiques pour la reproduction. Cette disposition est incompatible avec l'utilisation de désinfectants cutanés à base d'éthanol : - o Le confinement du processus d'émission est obligatoire si cela est techniquement possible. Les limites d'exposition sur le lieu de travail et les mesures des concentrations d'éthanol dans l'air doivent être strictement respectées. - o L'accès des travailleurs aux zones où des substances CMR sont utilisées doit être restreint. - o Des activités de surveillance sanitaire obligatoires – examens médicaux réguliers (par exemple, Allemagne, France, Norvège, Grèce, Italie, Espagne) - o Une formation et une information approfondies des travailleurs doivent être mises en place. - o Des procédures d'urgence doivent être établies en cas d'incident impliquant des substances CMR. - o Rapports et documentation : signaler tout incident ou problème de santé lié à l'exposition aux CMR aux autorités compétentes et documenter toutes les mesures de sécurité et tous les incidents. - o Des dossiers détaillés sur l'exposition des travailleurs sont nécessaires ; une notification aux registres nationaux peut être nécessaire (par exemple, en Pologne, en Autriche et en Roumanie).
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	

Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	L'utilisation de désinfectants TP4, notamment ceux à base d'éthanol, est essentielle pour maintenir des normes d'hygiène strictes dans le secteur agroalimentaire. L'éthanol combine un large spectre d'efficacité, une action antimicrobienne rapide, un profil de sécurité élevé et une évaporation rapide, ce qui en fait un choix irremplaçable. Aucune autre substance active TP4 ne réunit ces avantages. Les alternatives, comme les propanols, sont moins efficaces, surtout contre les virus non enveloppés, et s'évaporent plus lentement, prolongeant le contact avec les surfaces. Cela est problématique dans des environnements où des désinfections fréquentes sont nécessaires, comme dans les installations agroalimentaires. Limiter l'utilisation d'éthanol compromettrait la sécurité alimentaire. À la ferme, où l'accès à l'eau et au lavage est souvent limité, les désinfectants à base d'éthanol évitent la transmission d'agents pathogènes tels que l'hépatite A, le norovirus et la salmonelle aux aliments prêts à consommer, comme les salades ou les fruits rouges. Dans la chaîne d'approvisionnement, de la ferme à la table, l'éthanol prévient la contamination croisée des aliments pendant la transformation, la distribution et la vente. Dans l'industrie agroalimentaire, les désinfectants à base d'éthanol sont essentiels pour éviter la contamination croisée, notamment dans les usines produisant des aliments sensibles comme les préparations pour nourrissons, les produits laitiers secs et les céréales. Leur efficacité à désinfecter sans compromettre la qualité des produits est cruciale pour

	garantir la sécurité contre des pathogènes comme E. coli et Salmonella. Enfin, dans les supermarchés et restaurants, l'éthanol assure une désinfection rapide et efficace des surfaces en contact avec les aliments, contribuant ainsi à des conditions sanitaires optimales.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 316	2025/04/30 13:12
Country	Germany
Name of organization/institution	Martin Bauer GmbH & Co. KG
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	MartinBauer is a leading developer, producer and supplier of teas, botanicals, extracts and powders for the food, tea, phytopharmaceutical and animal nutrition industries. As a fourth-generation family business, we have worked hard for decades for business partners, customers and employees to place their faith in our value-driven, long-range corporate strategy. To manufacture food and feed safely, we use ethanol-based disinfectants within the scope of our HACCP

	concept. Besides using ethanol as a biocidal agent, we also use ethanol as an extraction solvent for the manufacturing of plant extracts and as a carrier substance for flavors. We consider ethanol as an essential and irreplaceable substance, both as disinfectant and for use in food and feed.
Product Type	1,2,4
Alternative Identity and Properties	In theory isopropyl alcohol and quaternary ammonium compounds can be considered in the sector of hand disinfection as an active ingredient. In practice these substances can not be used as a the (sole) active ingredient, as they are not completely virucidal. However, in order to produce safe food, it is a basic requirement to eliminate also non-enveloped viruses. In addition, residues of both mentioned alternative active ingredients are critical in food, not legally authorized and undesirable, in contrast to ethanol.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	The application of active ingredients other than ethanol for hand disinfection results in a high contamination risk for the products. Residues of ethanol on the hands evaporate extremely fast (and would not be critical in case of trace contamination in the product). Residues of alternative active ingredients are less or not at all volatile and a contamination from hand to product is possible.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Ethanol is in a financial point of view more favorable than the theoretical alternatives. It can be produced quickly and easily in large quantities. Ethanol is a natural product that is formed as a 'down streaming product', e.g., in the manufacturing of non-alcoholic wine or beer, and is used as a long-established active ingredient in disinfectants.
Information above is confidential	
Justification for confidentiality	

Hazards and Risks of the Alternative	We see many risks with an exclusive application of alternative active ingredients. Our highest priority is the manufacturing of safe food. We see high risks for the safety of our manufactured products with the application of alternative active ingredients for hand disinfection that have been proved as not (completely) virucidal and therefore cannot eliminate noroviruses, for example. As this could result in a damage to the consumer's health, we believe that consumer protection is not guaranteed. Furthermore, this can also harm the image of our well-established company and may cause an existence threatening situation. In addition, it is questionable if the employees will have the same acceptance towards the alternatives (in this case less established and less well-studied). These can also feel different and smell unpleasant. Furthermore, we fear the risks of sensory impairments in the end product through unintentional, inevitable contamination of the product and the consequence of low acceptance by the end consumer. In addition, the availability of alternatives is clearly lower than that of ethanol, which in a crisis - such as a pandemic - can be critical.
Information above is confidential	
Justification for confidentiality	
Availability	Ethanol is better available than alternative active ingredients. It does not depend on supply chains and is convenient to produce, furthermore, it arises naturally in food production. Ethanol is obtained as an agricultural raw material and there is no chemical needed as starting material (however this is the case for the alternative active ingredients) for its production. This means that the use of ethanol as an active ingredient for disinfectants is more sustainable and environmentally friendly in comparison to the alternatives, which is supported by MartinBauer as a trailblazer for natural solutions.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Since decades, ethanol is a widespread and well-established disinfectant. Ethanol is the only entirely effective disinfectant in the food industry and cannot be fully replaced or substituted. The alternatives are not process-validated (efficacy tests – huge amount of work). Risks for our products as 'safe food' are to be expected. We urgently

	request to consider the classification of ethanol in an appropriate approach – the subject is not ethanol as a stimulant but the dermal/inhalative exposition to ethanol. In our opinion and according to many years of experience, there is no safe alternative for the application of ethanol in disinfection or in food itself.
Information above is confidential	
Justification for confidentiality	
Other comments	The debate around the classification of ethanol as CMR-substance is based on the data for oral exposure to ethanol –in other words, the widespread and well-known damage of alcohol abuse. However, as a biocidal active ingredient in this sector for categories PT 1 and PT4, dermal and inhalation contact occurs. Ethanol in disinfectants is denatured and uneatable for the human consumption, an oral ingestion does not happen. The CMR classification in the BPC process will force a harmonised classification within the framework of the CLP regulation. This could cause devastating and disproportionate effects on work safety, food- and feed industries and its use as food as well. This would result in great uncertainty among end consumers and certainly in an exceeding activism of consumer protection organisations. A factor to be considered absolutely is the fact that there is no entry in the list of illnesses related to occupation (Nationale Berufskrankheiten-Verordnung, BKV) in connection with the handling of ethanol (via inhalative or dermal exposition), (the list of occupational diseases exists since 1990 – see attachments please), while other solvents are definitely mentioned. For this reason, we consider a CMR classification of ethanol for the application as disinfectant as disproportional.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	Annexes ECHA Consultation MartinBauer.zip
Attachments (confidential information)	

Justification for confidential attachment	

Comment 317	2025/04/30 13:17
Country	Finland
Name of organization/institution	██████████
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	Ethanol is the cornerstone of infection prevention control. During COVID-19 pandemic ethanol was required all over the world to save lives and enable normal life as we know it. Currently AMR (Antimicrobial resistance) is one of the biggest challenge for humans according to WHO. Hygiene measures including ethanol disinfectants in healthcare settings are cost-effective and practical and WHO recommended procedures to prevent AMR and deaths that it causes. In addition, in a world of geopolitical uncertainty, the healthcare sector has to be well equipped with effective hygiene products. Ethanol CMR properties exist via oral route, it has been known for ages. Disinfectants are not for drinking, the ethanol containing chemicals are additionally denaturized to prevent misuse.
Product Type	1,2,4
Alternative Identity and Properties	The only potential alternatives are 1-propanol and 2-propanol. Like ethanol, they are H225 flammable liquids. Like ethanol, 2-propanol is H319 eye irritant, but 1-propanol is worse, H318 eye damaging. Propanols are also H336 drowsiness or dizziness causing substances. Propanols are not effective against non-enveloped viruses like noro, adeno and polio, while ethanol is effective. Propanols evaporate slower than ethanol, so they stay longer on skin leading to longer dermal exposure. It is also a harm for a healthcare worker to wait for a hand rub to dry longer. And the most important thing: there is not enough data on propanol hazards via oral route, since it has not been drunk loads as ethanol has been drunk during ages. It is known that propanols are acutely more dangerous to human health via oral route than ethanol. Assessing the chemistry of alcohols,

	propanols should also be classified as CMR substances via oral route.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Propanols are H336 drowsiness or dizziness causing substances, this has to be considered during manufacturing the products.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Propanols are more expensive than ethanol and propanols are not widely available like ethanol is. The effect on raw material cost would be millions euros for a mid-size company. The increasing cost would be finally allocated for the healthcare sector and consumers.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Propanols as alcohols would have at least the same CMR effects via oral route (once it would have been investigated in detail) as ethanol. Propanols are not effective against non-enveloped viruses. Propanols would increase the cost of disinfection. This would obviously lead to reduced hygiene measures. At the end we would have less effective products with propanols, they wouldn't be better for human health, and they would cost more and be less sustainable. Hygiene would decrease, AMR would increase, and we would get more diseases and deaths.
Information above is confidential	
Justification for confidentiality	
Availability	Propanols are manufactured from non-renewable fossil resources, while ethanol is mostly manufactured from renewable, sustainable sources. Propanols are not widely available, and it is expensive compared to ethanol.
Information above is confidential	

Justification for confidentiality	
Conclusion on suitability and availability of the alternative	The only potential alternatives are 1-propanol and 2-propanol. Propanols are not effective against non-enveloped viruses like noro, adeno and polio. Propanols as alcohols would have at least the same CMR effects via oral route (once it would have been investigated in detail) as ethanol. At the end we would have less effective products with propanols, they wouldn't be better for human health, and they would cost more and be less sustainable. Hygiene would decrease, AMR would increase, and we would get more diseases and deaths.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 318	2025/04/30 13:18
Country	Belgium
Name of organization/institution	CEBP (craft bakers and confectioners)
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	

Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Socio-economic effects must be taken into account in ongoing procedures. Legislative proposals must be postponed to avoid major negative effects on crafts and industry, especially as long as alternatives are not available.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	The assessment of the reproductive toxicity of ethanol is based on experience from the misuse of alcoholic beverages, i.e. exclusively on oral intake. When used as a chemical, this is not comparable and the risks should not be considered the same for occupational hazards. Ethanol is typically used in denatured form to prevent oral uptake.
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol-based disinfectants have clear advantages over alternatives in ensuring a high level of health protection and were irreplaceable, especially during the Covid pandemic.

Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 319	2025/04/30 13:29
Country	France
Name of organization/institution	BIOETHANOL FRANCE
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Bioethanol France represents French producers of bioethanol (ethyl alcohol produced from biomass). France is the first bioethanol producer in Europe and represents around 20% of the European production. The French bioethanol industry accounts for around 12 000 direct, indirect and induced jobs (Full time equivalent), from agriculture to industry and services. Bioethanol is produced in French biorefineries by fermenting sugars into alcohol. These sugars typically come from a variety of agricultural sources such as wheat, corn and sugar beet and a wide range of waste and residues stemming from the transformation of cereals and sugar beets into respectively starch and sugar.

Product Type	1,2,4
Alternative Identity and Properties	There is no suitable alternative to ethanol as a biocidal active substance with equal efficacy against non-enveloped viruses. As demonstrated by the Assessment of Alternatives by the Alcohol Task Force for all three product types in question (P1, PT2 and PT4) there is by far no better alternative to ethanol for disinfection against non-enveloped viruses, which form a majority of the human infecting-viruses.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	For the proposed classification of ethanol under the Biocide Regulation, competent authorities took into account mainly data on alcohol consumption in humans which are not scientifically appropriate for classification purposes. Ethanol for biocidal applications is systematically denatured with the addition of denaturing agents. This denaturation is required

	by tax and customs regulations. Article 27 of Directive 92/83/EEC on excise duties on alcohol and alcoholic beverages states that in order to benefit from the excise duty exemption, alcohol not intended for human consumption must be denatured in accordance to required methods laid down at national level. (source : https://taxation-customs.ec.europa.eu/taxation/excise-taxes/excise-duties-alcohol/denatured-alcohol_en) Ethanol is a unique case as it is one of the few molecules to have both food and non-food uses although these two categories are legally and practically kept entirely separate through systematic implementation of custom regulations throughout the EU. A BPC recommendation for CMR classification leading to exclusion or substitution criteria would: - o prevent the use of ethanol by the general public (hydroalcoholic hand sanitizers) and professional users (hospitals) whereas there are no suitable alternatives effective against non-enveloped viruses, as demonstrated by the evaluation of alternatives. - o impact on various industries not covered by the Biocide Regulation, such as cosmetics, workplace chemicals, food contact materials, EU eco-labels, waste, medical devices and general food legislation. Such a classification would bring no health benefits but would on the contrary create serious health problems and have serious socio-economic consequences for many industries. Given the complexity of the classification debate and its far-reaching consequences, it is the CLP Risk Assessment Committee (RAC), and not the Biocidal Products Committee (BPC), which should address the issue of harmonized classification.
Information above is confidential	
Justification for confidentiality	
Other comments	The use of data on the abusive consumption of undenatured alcohol beverages is not a reliable method that can be reasonably expected for biocidal classification and cannot be extrapolated to exposure of workers/consumers through inhalation or skin contact. Without appropriate and accurate data specifically concerning the effects of alcohol the latter routes of exposure , it is impossible to carry out a risk assessment. hence scientific basis for classifying a substance under biocidal legislation as a category 1 carcinogen and health toxicant is unfounded and inappropriate.

Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	Bioethanol France reply to ECHA public consultation on biocidal uses of ethanol - final.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 320	2025/04/30 13:40
Country	France
Name of organization/institution	BIOETHANOL FRANCE
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Bioethanol France represents French producers of bioethanol (ethyl alcohol produced from biomass). France is the first bioethanol producer in Europe and represents around 20% of the European production. The French bioethanol industry accounts for around 12 000 direct, indirect and induced jobs, from agriculture to industry and services. Bioethanol is produced in French biorefineries by fermenting sugars into alcohol. These sugars typically come from a variety of agricultural sources such as wheat, corn and sugar beet and a wide range of waste and residues stemming from the transformation of cereals and sugar beets into respectively starch and sugar.
Product Type	1,2,4
Alternative Identity and Properties	There is no substitute biocidal active substance with equal efficacy against non-enveloped viruses. As demonstrated by the Assessment of Alternatives by the Alcohol Task Force for all three product types in question (P1, PT2 and PT4) there is by far no better alternative to ethanol for disinfection

	against non-enveloped viruses, which form a majority of the human infecting-viruses.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	For the proposed classification of ethanol under the Biocide Regulation, competent authorities took into account mainly data on alcohol consumption in humans which are not scientifically appropriate for classification purposes. Ethanol for biocidal applications is systematically denatured with the addition of denaturing agents. This denaturation is required by tax and customs regulations. Ethanol is unique as it is one of the most widely used basic chemicals in many applications worldwide. Moreover, it is one of the few molecules to have both food and non-food uses although these two categories are legally and practically kept entirely separate through systematic implementation of custom regulations throughout the EU. A BPC recommendation for CMR classification leading to exclusion or substitution

	criteria would: o prevent the use of ethanol by the general public (hydroalcoholic hand sanitizers) and professional users (hospitals) without suitable alternatives effective against non-enveloped viruses, as demonstrated by the evaluation of alternatives. o impact on various industries not covered by the Biocide Regulation, such as cosmetics, workplace chemicals, food contact materials, EU eco-labels, waste, medical devices and general food legislation. Such a classification would bring no health benefits but would on the contrary create serious health problems and have serious socio-economic consequences for many industries. Given the complexity of the classification debate and its far-reaching consequences, it is the CLP Risk Assessment Committee (RAC), and not the Biocidal Products Committee (BPC), which should address the issue of harmonized classification.
Information above is confidential	
Justification for confidentiality	
Other comments	The use of data on the abusive consumption of undenatured alcohol beverages is not a reliable method that can be reasonably expected for biocidal classification and cannot be extrapolated to exposure of workers/consumers through inhalation or skin contact. Without appropriate and accurate data specifically concerning the effects of alcohol the latter routes of exposure , it is impossible to carry out a risk assessment. hence scientific basis for classifying a substance under biocidal legislation as a category 1 carcinogen and health toxicant is unfounded and inappropriate. Article 27 of Directive 92/83/EEC on excise duties on alcohol and alcoholic beverages states that in order to benefit from the excise duty exemption, alcohol not intended for human consumption must be denatured in accordance to required methods laid down at national level. (source : https://taxation-customs.ec.europa.eu/taxation/excise-taxes/excise-duties-alcohol/denatured-alcohol_en)
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	Bioethanol France reply to ECHA public consultation on biocidal uses of ethanol - final.pdf

Attachments (confidential information)	
Justification for confidential attachment	

Comment 321	2025/04/30 13:43
Country	France
Name of organization/institution	BIOETHANOL FRANCE
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Bioethanol France represents French producers of bioethanol (ethyl alcohol produced from biomass). France is the first bioethanol producer in Europe and represents around 20% of the European production. The French bioethanol industry accounts for around 12 000 direct, indirect and induced jobs (Full time equivalent), from agriculture to industry and services. Bioethanol is produced in French biorefineries by fermenting sugars into alcohol. These sugars typically come from a variety of agricultural sources such as wheat, corn and sugar beet and a wide range of waste and residues stemming from the transformation of cereals and sugar beets into respectively starch and sugar.
Product Type	1,2,4
Alternative Identity and Properties	There is no suitable alternative to ethanol as a biocidal active substance with equal efficacy against non-enveloped viruses. As demonstrated by the Assessment of Alternatives by the Alcohol Task Force for all three product types in question (P1, PT2 and PT4) there is by far no better alternative to ethanol for disinfection against non-enveloped viruses, which form a majority of the human infecting-viruses.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	

Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	For the proposed classification of ethanol under the Biocide Regulation, competent authorities took into account mainly data on alcohol consumption in humans which are not scientifically appropriate for classification purposes. Ethanol for biocidal applications is systematically denatured with the addition of denaturing agents. This denaturation is required by tax and customs regulations. Ethanol is unique as it is one of the most widely used basic chemicals in many applications worldwide. Moreover, it is one of the few molecules to have both food and non-food uses although these two categories are legally and practically kept entirely separate through systematic implementation of custom regulations throughout the EU. A BPC recommendation for CMR classification leading to exclusion or substitution criteria would: - o prevent the use of ethanol by the general public (hydroalcoholic hand sanitizers) and professional users (hospitals) without suitable alternatives effective against non-enveloped viruses, as demonstrated by the evaluation of alternatives. - o impact on various industries not covered by the Biocide Regulation, such as cosmetics, workplace chemicals, food contact materials, EU eco-labels, waste, medical devices and general food legislation. Such a classification would bring no health

	benefits but would on the contrary create serious health problems and have serious socio-economic consequences for many industries. Given the complexity of the classification debate and its far-reaching consequences, it is the CLP Risk Assessment Committee (RAC), and not the Biocidal Products Committee (BPC), which should address the issue of harmonized classification.
Information above is confidential	
Justification for confidentiality	
Other comments	The use of data on the abusive consumption of undenatured alcohol beverages is not a reliable method that can be reasonably expected for biocidal classification and cannot be extrapolated to exposure of workers/consumers through inhalation or skin contact. Without appropriate and accurate data specifically concerning the effects of alcohol the latter routes of exposure , it is impossible to carry out a risk assessment. hence scientific basis for classifying a substance under biocidal legislation as a category 1 carcinogen and health toxicant is unfounded and inappropriate. Article 27 of Directive 92/83/EEC on excise duties on alcohol and alcoholic beverages states that in order to benefit from the excise duty exemption, alcohol not intended for human consumption must be denatured in accordance to required methods laid down at national level. (source : https://taxation-customs.ec.europa.eu/taxation/excise-taxes/excise-duties-alcohol/denatured-alcohol_en)
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	Bioethanol France reply to ECHA public consultation on biocidal uses of ethanol - final.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 322	2025/04/30 13:53
Country	Finland
Name of organization/institution	██████████
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	Ethanol is the cornerstone of infection prevention control. During COVID-19 pandemic ethanol was required all over the world to save lives and enable normal life as we know it. Currently AMR (Antimicrobial resistance) is one of the biggest challenge for humans according to WHO. Hygiene measures including ethanol disinfectants in healthcare settings are cost-effective and practical and WHO recommended procedures to prevent AMR and deaths that it causes. In addition, in a world of geopolitical uncertainty, the healthcare sector has to be well equipped with effective hygiene products. Ethanol CMR properties exist via oral route, it has been known for ages. Disinfectants are not for drinking, the ethanol containing chemicals are additionally denaturized to prevent misuse.
Product Type	1,2,4
Alternative Identity and Properties	The potential alternatives are 1-propanol and 2-propanol. Like ethanol, they are H225 flammable liquids. Like ethanol, 2-propanol is H319 eye irritant, but 1-propanol is worse, H318 eye damaging. Propanols are also H336 drowsiness or dizziness causing substances. Propanols are not effective against non-enveloped viruses like noro, adeno and polio, while ethanol is effective. Propanols evaporate slower than ethanol, so they stay longer on surfaces leading to longer material exposure. And the most important thing: there is no enough data on propanol hazards via oral route, since it has not been drunk loads as ethanol has been drunk during ages. It is known that propanols are acutely more dangerous to human health via oral route than ethanol. Assessing the chemistry of alcohols, propanols should also be classified as CMR substances via oral route.
Information above is confidential	
Justification for confidentiality	

Technical Feasibility	Propanols are H336 drowsiness or dizziness causing substances, this has to be considered during manufacturing the products.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Propanols are more expensive than ethanol and propanols are not widely available like ethanol is. The effect on raw material cost would be millions euros for a mid-size company. The increasing cost would be finally allocated for the healthcare sector and consumers.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Propanols as alcohols would have at least the same CMR effects via oral route (once it would have been investigated in detail) as ethanol. Propanols are not effective against non-enveloped viruses. Propanols would increase the cost of disinfection. This would obviously lead to reduced hygiene measures. At the end we would have less effective products with propanols, they wouldn't be better for human health, and they would cost more and be less sustainable. Hygiene would decrease, AMR would increase, and we would get more diseases and deaths.
Information above is confidential	
Justification for confidentiality	
Availability	Propanols are manufactured from non-renewable fossil resources, while ethanol is mostly manufactured from renewable, sustainable sources. Propanols are not widely available, and it is expensive compared to ethanol.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	The potential alternatives are 1-propanol and 2-propanol. Propanols are not effective against non-enveloped viruses like noro, adeno and polio. Propanols as alcohols would have at least the same CMR effects via oral route (once it would have been investigated in detail) as ethanol. At the

	end we would have less effective products with propanols, they wouldn't be better for human health, and they would cost more and be less sustainable.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	Ethanol ECHA 2025 other sectors.docx
Attachments (confidential information)	
Justification for confidential attachment	

Comment 323	2025/04/30 14:02
Country	Finland
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	Ethanol is the cornerstone of infection prevention control. During COVID-19 pandemic ethanol was required all over the world to save lives and enable normal life as we know it. Ethanol CMR properties exist via oral route, it has been known for ages. Disinfectants are not for drinking, the ethanol containing chemicals are additionally denaturized to prevent misuse.
Product Type	1,2,4

Alternative Identity and Properties	The potential alternatives are 1-propanol and 2-propanol. Like ethanol, they are H225 flammable liquids. Like ethanol, 2-propanol is H319 eye irritant, but 1-propanol is worse, H318 eye damaging. Propanols are also H336 drowsiness or dizziness causing substances. Propanols are not effective against non-enveloped viruses like noro, while ethanol is effective. Noro-virus is one of the main pathogens on food and feed area. Propanols evaporate slower than ethanol, so they stay longer on surfaces leading to longer material exposure. And the most important thing: there is not enough data on propanol hazards via oral route, since it has not been drunk loads as ethanol has been drunk during ages. It is known that propanols are acutely more dangerous to human health via oral route than ethanol. Assessing the chemistry of alcohols, propanols should also be classified as CMR substances via oral route.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Propanols are H336 drowsiness or dizziness causing substances, this has to be considered during manufacturing the products.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Propanols are more expensive than ethanol and propanols are not widely available like ethanol is.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Propanols as alcohols would have at least the same CMR effects via oral route (once it would have been investigated in detail) as ethanol. Propanols are not effective against non-enveloped viruses. Propanols would increase the cost of disinfection. This would obviously lead to reduced hygiene measures. At the end we would have less effective products with propanols, they wouldn't be better for human health, and they would cost more and be less sustainable.
Information above is confidential	

Justification for confidentiality	
Availability	Propanols are manufactured from non-renewable fossil resources, while ethanol is mostly manufactured from renewable, sustainable sources. Propanols are not widely available, and it is expensive compared to ethanol.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	The potential alternatives are 1-propanol and 2-propanol. Propanols are not effective against non-enveloped viruses like noro, which is very important pathogen in food and feed sector. Propanols as alcohols would have at least the same CMR effects via oral route (once it would have been investigated in detail) as ethanol. At the end we would have less effective products with propanols, they wouldn't be better for human health, and they would cost more and be less sustainable.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 324	2025/04/30 15:46
Country	Germany

Name of organization/institution	Martin Bauer GmbH & Co. KG
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	MartinBauer is a leading developer, producer and supplier of teas, botanicals, extracts and powders for the food, tea, phytopharmaceutical and animal nutrition industries. As a fourth-generation family business, we have worked hard for decades for business partners, customers and employees to place their faith in our value-driven, long-range corporate strategy. To manufacture food and feed safely, we used ethanol based disinfectants within the scope of our HACCP concept. Besides using ethanol as a biocidal agent, we also use ethanol as an extraction solvent for the manufacturing of plant extracts and as a carrier substance for flavors. We consider ethanol as an essential and irreplaceable substance, both as disinfectant and for use in food and feed.
Product Type	1,2,4
Alternative Identity and Properties	In theory hydrogen peroxide, hypochlorite, isopropyl alcohol and lactic acid can be considered in the sector of plant-/surface disinfection as an active ingredient. However, these substances are partly unstable, less volatile in contrast to ethanol, taste differently and lead to organoleptic adverse effects. Furthermore, these substances are not (completely) virucidal. However, in order to produce safe food, it is a basic requirement to eliminate also non-enveloped viruses. In addition, residues of the mentioned alternative active ingredients are critical in food, not legally authorized and undesirable, in contrast to ethanol.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	The application of active ingredients other than ethanol for hand disinfection results in a high contamination risk for the products. Residues of ethanol evaporate extremely fast (and would not be critical in case of trace contamination in the product). Residues of alternative active ingredients do not evaporate so quickly or are not volatile at all, respectively, and a contamination from hand to product is possible. It may also be necessary to rinse the alternative

	disinfectant out of/from the production plant, which can cause microbiological issues on one hand, and on the other hand unnecessarily uses/wastes water as a resource and pollutes the wastewater treatment plant and the environment (especially water bodies).
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Ethanol is in a financial point of view more favorable than the theoretical alternatives. It can be produced quickly and easily in large quantities. Ethanol is a natural product that is formed as a 'down streaming product', e.g., in the manufacturing of non-alcoholic wine or beer and is used as a long-established active ingredient in disinfectants. The sustainable use of this by-product from natural resources is expressly supported by our MartinBauer philosophy.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	We see many risks with an exclusive application of alternative active ingredients. Our highest priority is the manufacturing of safe food. We see high risks for the safety of our manufactured products with the application of alternative active ingredients that have been proved as not (completely) virucidal and therefore cannot eliminate noroviruses, for example. We also see a microbiological risk if the production plant needs to be rinsed. This could result in damage to the consumer's health, and we believe that consumer protection is not guaranteed. Furthermore, this can also harm the image of our well-established company and may cause an existence threatening situation. Moreover, this may also result in an undesirable reduction in the shelf life of the manufactured products. In addition, it is questionable if the employees will have the same acceptance towards the alternatives (in this case less established and less well-studied). These can also feel different and smell unpleasant. Furthermore, we fear the risks of sensory impairments in the end product through unintentional, inevitable contamination of the product and the consequence of low acceptance by the end consumer. In addition, the availability of alternatives is clearly lower than that of ethanol, which in a crisis - such as a pandemic - can be critical.

Information above is confidential	
Justification for confidentiality	
Availability	Ethanol is better available than alternative active ingredients. It does not depend on supply chains and is convenient to produce, furthermore, it arises naturally in food production. Ethanol is obtained as an agricultural raw material and there is no chemical needed as starting material (however this is the case for the alternative active ingredients) for its production. This means that the use of ethanol as an active ingredient for disinfectants is more sustainable and environmentally friendly in comparison with the alternatives, which is supported by MartinBauer as a pioneer for natural solutions.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Since decades, ethanol is a widespread and well-established disinfectant. Ethanol is the only entirely effective disinfectant in the food industry and cannot be fully replaced or substituted. The alternatives are not process-validated (efficient tests – huge amount of work). Risks for our products as 'safe food' are to be expected. We urgently request to consider the classification of ethanol in an appropriate approach – the subject is not ethanol as a stimulant but the dermal/inhalative exposition to ethanol. In our opinion and according to many years of experience, there is no safe alternative for the application of ethanol in disinfection or in food itself (as solvent, carrier substance, etc).
Information above is confidential	
Justification for confidentiality	
Other comments	The debate around the classification of ethanol as CMR-substance is based on the data for oral exposure to ethanol – in other words, the widespread and well known damage of alcohol abuse. However, as a biocidal active ingredient in this sector for the category PT4, dermal and inhalation contact occurs. Ethanol in disinfectants is denatured and uneatable for the human consumption, an oral ingestion does not happen. The CMR classification in the BPC process will force a harmonised classification within the framework

	of the CLP regulation. This could cause devastating and disproportionate effects on work safety, food- and feed industries and its use as food as well. This would result in great uncertainty among end consumers and certainly in an exceeding activism of consumer protection organisations. A factor to be considered absolutely is the fact that there is no entry in the list of illnesses related to occupation (Nationale Berufskrankheiten-Verordnung, BKV) in connection with the handling of ethanol (via inhalative or dermal exposition), (the list of occupational diseases exists since 1990 – see attachments please), while other solvents are definitely mentioned. For this reason, we consider a CMR classification of ethanol for the application as disinfectant as disproportional.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	Annexes ECHA Consultation MartinBauer.zip
Attachments (confidential information)	
Justification for confidential attachment	

Comment 325	2025/04/30 16:02
Country	Finland
Name of organization/institution	Kosmetiikka- ja hygieniateollisuus ry (The Finnish Cosmetic and Hygiene Industry Association)
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Ethanol is widely used in biocidal product groups PT1, PT2, and PT4. It is an effective and safe biocidal active substance. Ethanol evaporates quickly, making it skin-friendly and leaving negligible residues on surfaces. It is also an environmentally friendly option because it is mainly produced from renewable sources and is biodegradable.

	Ethanol is harmful when alcohol is consumed excessively. Exposure through disinfectants occurs through the skin and/or respiratory tract, which cannot be compared to drinking. In this assessment, it is important to examine the actual exposure routes in the biocidal use of ethanol.
Product Type	1,2,4
Alternative Identity and Properties	No other active substance offers similar good disinfection properties with as few side effects as ethanol. Ethanol is effective against a wide range of microorganisms, from bacteria to non-enveloped viruses. For example, isopropanol is not as effective and at the same time it is worse for the skin. Ethanol is also used as an excipient in pharmaceutical and food industry processes, and there are no alternatives for it.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	In usage situations, the superiority of ethanol comes from its smooth use. It evaporates quickly from the skin and surfaces, resulting in minimal skin irritation and negligible residues on surfaces. For hand disinfectants, rapid evaporation is important so that professional use can proceed without unnecessary waiting and consumer use does not leave the product unused due to uncomfortable waiting. Ethanol is a key active substance in disinfectants - a key factor in infection prevention and control.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Ethanol is mainly produced from renewable sources and its availability can be considered good. Evidence of this is the joint effort during the COVID-19 pandemic, where the availability of ethanol was successfully increased to meet demand. According to our knowledge, there is no competitive alternative to ethanol in this regard either. The World Health Organization (WHO) has recommended ethanol-based hand disinfectants for areas where water is not available for hand hygiene.
Information above is confidential	

Justification for confidentiality	
Hazards and Risks of the Alternative	Ethanol substitutes are in many ways worse alternatives than ethanol. Ethanol is completely biodegradable compared to alternatives, it evaporates quickly and is generally a more sustainable option compared to possible alternative active substances. Overall, it is good to remember that the reported dangers and risks of ethanol are related to excessive drinking. For this reason, it would be a poor choice to abandon a functional and safe biocidal active substance due to secondary harms related to biocidal use.
Information above is confidential	
Justification for confidentiality	
Availability	Ethanol is mainly produced from renewable sources and its availability can be considered good. Evidence of this is the joint effort during the COVID-19 pandemic, where the availability of ethanol was successfully increased to meet demand. Since ethanol is used in many industries, alternative producers can also be utilized in possible crisis situations. This should be taken into account, among other things, from the perspective of climate change and the geopolitical situation. Climate change increases the spread of diseases, making effective and available hygiene practices vital. The same applies to other undesirable crisis situations. In the globally worsening antibiotic resistance situation, the use of ethanol is one of the key means both in healthcare and in preventing water- and food-borne microbial contaminations.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol is an effective and safe active substance for biocidal product groups PT1, PT2, and PT4. It is a key substance in infection prevention and hygiene practices. Human exposure routes in these uses are via skin or respiratory tract. Its replacement with other active substances should not be discussed based on the toxicological harms caused by excessive drinking. Ethanol is a special case chemically and an essential substance socially, and it is not suitable for routine handling in the evaluation of biocidal active substances. The consequences of possible actions should be carefully assessed from the perspective of public health, healthcare costs, and economic sustainability.

Information above is confidential	
Justification for confidentiality	
Other comments	In biocidal use, ethanol is a key substance in healthcare, food production, and pharmaceutical industry. The CMR classification of ethanol would practically mean a ban on its use in many applications in addition to disinfectants. It is used for example in surface cleaners, air fresheners, cosmetics, medical devices, medicines, windshield washer fluids, and antifreeze products.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 327	2025/04/30 16:58
Country	Italy
Name of organization/institution	Federchimica
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	
Product Type	1,2,4
Alternative Identity and Properties	

Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Federchimica supports the AoA made by the consultant of the Alcohol Task Force which highlights how in none of the types of products under analysis as disinfectant there are equally effective alternatives. Essentially, no other substance currently equals ethanol's effectiveness in infection control. Ethanol is valued for: - its broad-spectrum of activity and efficacy against bacteria, fungi and virus (particularly for non-enveloped viruses) - its compatibility with a wide range of formulations and it is a versatile solvent - it has the best cost-effectiveness profile as it is widely available, easy to produce - no long-term environmental risks have been identified Furthermore, we know the global impact beyond the mere field of biocides if it will be confirmed the stricter classification. Therefore, it is important that the essential role of ethanol in different areas of use is recognized and, most importantly, in order to obtain a proper hazard classification, consider realistic

	routes of exposure through a risk assessment that should distinguish between ingestion and dermal/inhalation exposure. In this regard, it would be desirable to bring forward the hazard assessment in order to achieve harmonized classification and labelling under the CLP Regulation, in line with the 'one substance - one assessment' approach, which aims to strengthen cooperation and consolidate the scientific and technical work of European agencies, while also awaiting the opinion of the Risk Assessment Committee (RAC) reviewing proposals.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	Federchimica- Public Consultation on Ethanol.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 326	2025/04/30 16:58
Country	Germany
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	In a current assessment procedure by the European Chemicals Agency (ECHA), the active substance ethanol is at risk of being classified as carcinogenic, mutagenic and/or

	toxic for reproduction (CMR). • The evaluation of ethanol as a biocidal active substance in hand and surface disinfectants for PT1, PT2 and PT4 is being conducted the Biocidal Products Directive (BPD, EU Directive 98/8/EC), making it a "backlog dossier". • In October 2024, the BPC Working Groups concluded that ethanol meets the exclusion criteria for carcinogenicity and reproductive toxicity but has not yet reached a decision on mutagenicity. Additionally, the classification of ethanol under category 1A or 1B for carcinogenicity and reprotoxicity remains unresolved, with further discussions planned. • It must be pointed out that the outcome of the BPC Working groups is predominately based on epidemiological data on the consumption of alcoholic beverages and alcohol abuse which is neither suitable for substance classification nor related to any biocidal uses: oral consumption is not a form that "can reasonably be foreseen" in biocidal applications. It is also explicitly excluded by adding denaturing agents. • Studies suggest that the dermal and inhaled absorption of ethanol when using ethanol-based handrubs is minor and results in blood and urine concentrations comparable with other widely used alcohol-containing products of daily life such as fruit juices, chocolate, mouthwash, aftershave, and other cosmetics contain appreciable amounts of ethanol.¹
Product Type	1,2,4
Alternative Identity and Properties	• Ethanol is promoted by WHO as an indispensable active substance ² for the use in ethanol-based handrubs.³ • Ethanol is used in hand and surface disinfection products to effectively prevent the spread of pathogens (including bacteria, viruses and fungi) and played a major role in the fight against SARS-CoV-2. • The AoA concluded that while alternatives exist, none offer the same level of performance or safety as ethanol when used in high-frequency applications, such as healthcare settings, where frequent hand hygiene disinfection is essential. Furthermore, the alternatives were not able to replicate the broad-spectrum efficacy or the skin-friendly properties of ethanol-based formulations, especially in intensive environments like hospitals and surgical settings. ⁴
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	• Moreover, ethanol is an inexpensive and widely available substance which can also be obtained from

	renewable sources and is biodegradable, respectively. • With ethanol being widely used across industries the classification as CMR category 1A or 1B will require significant investments in R&D, capital goods, driving up labor and production costs across sectors and ultimately, in healthcare.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	• An adverse CMR classification under BPR will unavoidably be translated into a harmonized classification under CLP Regulation which will have disproportionate socio-economic impacts far beyond Biocidal applications. If the BPC concludes that ethanol should be classified as a CMR Category 1A or 1B, negative consequences will not be restricted to Biocidal uses rather a negative cascade to all industry sectors where Ethanol is used directly or indirectly will be triggered, thus, will put the EU's competitiveness at risk. This assumption applies even more in times of fragile supply chains.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	• A CMR classification of ethanol would have far-reaching consequences for infection prevention and control, as the use of ethanol would be severely restricted or largely prevented. • The fast pandemic spread of SARS-CoV 2 led to the question of suitable protective measures in the medical and public sectors. Disinfection also became the focus of general interest. As a result, the demand for disinfectants rose sharply, not only in the medical sector but also in the public and private spheres.⁵ • According to a press release from the German Federal Statistical Office (Statistisches Bundesamt), the average production of disinfectants from January to September 2020 was 80% higher than in the same period of the previous year. ⁶ • • The supply of disinfectants is currently secured again and alternative products are no longer required. This is a fortunate circumstance and should not be taken for granted. It should also be borne in mind that in the case of SARS-CoV-2 as an enveloped virus, it was quite unproblematic to identify suitable products for safe inactivation. In the case of more stable pathogens and those for which hand washing and surface cleaning cannot achieve a sufficient effect, it is

	likely to be more difficult to identify and provide suitable products, as the demand is likely to be much greater again. 5 • With declining hand hygiene compliance rates following the pandemic both the high efficacy and skin-friendly properties of ethanol-based formulations help improve hand hygiene and thus, Infection prevention in health care facilities.
Information above is confidential	
Justification for confidentiality	
Availability	The pandemic situation clearly showed that the availability of disinfectants plays a pivotal role in preventing the infection from spreading, especially in the healthcare sector. This would not have been possible without ethanol that is available in large quantities and is also affordable, even in economically weaker countries.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	- A potential CMR classification of ethanol predominately based on human alcohol abuse is neither justified nor can reasonably be expected that ethanol-containing biocides are ingested due to the addition of a denaturing agent. - Overall, the findings suggest that the approval of ethanol remains crucial for the maintenance of current hygiene standards in healthcare. A non-approval of ethanol would likely result in increased reliance on less effective and potentially more costly alternatives, ultimately jeopardizing public health and disrupting established disinfection protocols. - The qualitative and economic impacts of a CMR classification of ethanol would lead to greater risks of healthcare-associated infections (HCAs), higher substitution costs, and a potential burden on healthcare systems, particularly during outbreaks or high-demand periods. Therefore, the approval of ethanol-based disinfectants without a CMR classification is essential to ensure effective and safe infection control across the EU. - A premature decision on the CMR properties under the BPR regime would pre-empt any decision making by the Risk Assessment Committee (RAC) as the competent body for taking a legally binding decision on the classification of Ethanol under the CLP Regulation. For this and the above-mentioned reasons, the BPC should not endorse the Human Health Working Group's proposal to classify Ethanol as a

	Carcinogenic and Reprotoxic substance of Category 1 in the BPC Opinion.
Information above is confidential	
Justification for confidentiality	
Other comments	• The biocidal evaluation process should not decide on a CMR classification: Discussions on classification should go through the CLP Regulation, a process which can allow a more comprehensive and dedicated discussion on this complex matter and the underlying data. • Given the far-reaching consequences of a CMR classification for ethanol under BPR, it should be RAC under the CLP Framework who should address the harmonized classification discussion based on the available data.
Information above is confidential	
Justification for confidentiality	
References	1 Pires et al. 2006 Ethanol-based handrubs: Safe for patients and health care workers - American Journal of Infection Control 2 WHO Model List of Essential Medicine: WHO EML 23rd List (2023) 3 WHO-recommended handrub formulation containing ethanol 80% v/v: WHO guidelines on hand hygiene in health care 4 ANALYSIS OF ALTERNATIVES for the use of Ethanol in Human hygiene products for the primary purpose of disinfecting the skin or scalp (Product Type 1) under the Biocidal Products Regulation Version: 3.0. – FINAL PUBLIC version (2025, 20th February) 5 Desinfektionsmittel in der COVID-19-Pandemie: eine Herausforderung, Bundesgesundheitsbl 2022 · 65:86–95, Eggers et al. 2022: https://doi.org/10.1007/s00103-021-03457-z 6 Produktion in Corona-Zeiten: 80 % mehr Desinfektionsmittel von Januar bis September 2020 gegenüber Vorjahreszeitraum - Statistisches Bundesamt: Produktion in Corona-Zeiten: 80 % mehr Desinfektionsmittel von Januar bis September 2020 gegenüber Vorjahreszeitraum - Statistisches Bundesamt
Attachments (non-confidential information)	
Attachments (confidential information)	

Justification for confidential attachment	

Comment 328	2025/04/30 16:59
Country	Italy
Name of organization/institution	Federchimica
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	

Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Federchimica supports the AoA made by the consultant of the Alcohol Task Force which highlights how in none of the types of products under analysis as disinfectant there are equally effective alternatives. Essentially, no other substance currently equals ethanol's effectiveness in infection control. Ethanol is valued for: - its broad-spectrum of activity and efficacy against bacteria, fungi and virus (particularly for non-enveloped viruses) - its compatibility with a wide range of formulations and it is a versatile solvent - it has the best cost-effectiveness profile as it is widely available, easy to produce - no long-term environmental risks have been identified Furthermore, we know the global impact beyond the mere field of biocides if it will be confirmed the stricter classification. Therefore, it is important that the essential role of ethanol in different areas of use is recognized and, most importantly, in order to obtain a proper hazard classification, consider realistic routes of exposure through a risk assessment that should distinguish between ingestion and dermal/inhalation exposure. In this regard, it would be desirable to bring forward the hazard assessment in order to achieve harmonized classification and labelling under the CLP Regulation, in line with the 'one substance - one assessment' approach, which aims to strengthen cooperation and consolidate the scientific and technical work of European agencies, while also awaiting the opinion of the Risk Assessment Committee (RAC) reviewing proposals.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	Federchimica- Public Consultation on Ethanol.pdf

Attachments (confidential information)	
Justification for confidential attachment	

Comment 329	2025/04/30 17:01
Country	Germany
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	• In a current assessment procedure by the European Chemicals Agency (ECHA), the active substance ethanol is at risk of being classified as carcinogenic, mutagenic and/or toxic for reproduction (CMR). • The evaluation of ethanol as a biocidal active substance in hand and surface disinfectants for PT1, PT2 and PT4 is being conducted the Biocidal Products Directive (BPD, EU Directive 98/8/EC), making it a "backlog dossier". • In October 2024, the BPC Working Groups concluded that ethanol meets the exclusion criteria for carcinogenicity and reproductive toxicity but has not yet reached a decision on mutagenicity. Additionally, the classification of ethanol under category 1A or 1B for carcinogenicity and reprotoxicity remains unresolved, with further discussions planned. • It must be pointed out that the outcome of the BPC Working groups is predominately based on epidemiological data on the consumption of alcoholic beverages and alcohol abuse which is neither suitable for substance classification nor related to any biocidal uses: oral consumption is not a form that "can reasonably be foreseen" in biocidal applications. It is also explicitly excluded by adding denaturing agents. • Studies suggest that the dermal and inhaled absorption of ethanol when using ethanol-based handrubs is minor and results in blood and urine concentrations comparable with other widely used alcohol-containing products of daily life such as fruit juices, chocolate, mouthwash, aftershave, and other cosmetics contain appreciable amounts of ethanol.¹
Product Type	1,2,4

Alternative Identity and Properties	• Ethanol is promoted by WHO as an indispensable active substance 2 for the use in ethanol-based handrubs.³ • Ethanol is used in hand and surface disinfection products to effectively prevent the spread of pathogens (including bacteria, viruses and fungi) and played a major role in the fight against SARS-CoV-2. • The AoA concluded that while alternatives exist, none offer the same level of performance or safety as ethanol when used in high-frequency applications, such as healthcare settings, where frequent hand hygiene disinfection is essential. Furthermore, the alternatives were not able to replicate the broad-spectrum efficacy or the skin-friendly properties of ethanol-based formulations, especially in intensive environments like hospitals and surgical settings. 4
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	• Moreover, ethanol is an inexpensive and widely available substance which can also be obtained from renewable sources and is biodegradable, respectively. • With ethanol being widely used across industries the classification as CMR category 1A or 1B will require significant investments in R&D, capital goods, driving up labor and production costs across sectors and ultimately, in healthcare.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	• An adverse CMR classification under BPR will unavoidably be translated into a harmonized classification under CLP Regulation which will have disproportionate socio-economic impacts far beyond Biocidal applications. If the BPC concludes that ethanol should be classified as a CMR Category 1A or 1B, negative consequences will not be restricted to Biocidal uses rather a negative cascade to all industry sectors where Ethanol is used directly or indirectly will be triggered, thus, will put the EU's competitiveness at risk. This assumption applies even more in times of fragile supply chains.
Information above is confidential	
Justification for confidentiality	

Hazards and Risks of the Alternative	• A CMR classification of ethanol would have far-reaching consequences for infection prevention and control, as the use of ethanol would be severely restricted or largely prevented. • The fast pandemic spread of SARS-CoV 2 led to the question of suitable protective measures in the medical and public sectors. Disinfection also became the focus of general interest. As a result, the demand for disinfectants rose sharply, not only in the medical sector but also in the public and private spheres.⁵ • According to a press release from the German Federal Statistical Office (Statistisches Bundesamt), the average production of disinfectants from January to September 2020 was 80% higher than in the same period of the previous year.⁶ • The supply of disinfectants is currently secured again and alternative products are no longer required. This is a fortunate circumstance and should not be taken for granted. It should also be borne in mind that in the case of SARS-CoV-2 as an enveloped virus, it was quite unproblematic to identify suitable products for safe inactivation. In the case of more stable pathogens and those for which hand washing and surface cleaning cannot achieve a sufficient effect, it is likely to be more difficult to identify and provide suitable products, as the demand is likely to be much greater again.⁵
Information above is confidential	
Justification for confidentiality	
Availability	• The pandemic situation clearly showed that the availability of disinfectants plays a pivotal role in preventing the infection from spreading, especially in the healthcare sector. This would not have been possible without ethanol that is available in large quantities and is also affordable, even in economically weaker countries.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	• A potential CMR classification of ethanol predominately based on human alcohol abuse is neither justified nor can reasonably be expected that ethanol-containing biocides are ingested due to the addition of a denaturing agent. • Overall, the findings suggest that the approval of ethanol remains crucial for the maintenance of current hygiene standards in healthcare. A non-approval of ethanol would likely result in increased reliance on less

	effective and potentially more costly alternatives, ultimately jeopardizing public health and disrupting established disinfection protocols. • The qualitative and economic impacts of a CMR classification of ethanol would lead to greater risks of healthcare-associated infections (HCAIs), higher substitution costs, and a potential burden on healthcare systems, particularly during outbreaks or high-demand periods. Therefore, the approval of ethanol-based disinfectants without a CMR classification is essential to ensure effective and safe infection control across the EU. • A premature decision on the CMR properties under the BPR regime would pre-empt any decision making by the Risk Assessment Committee (RAC) as the competent body for taking a legally binding decision on the classification of Ethanol under the CLP Regulation. For this and the above-mentioned reasons, the BPC should not endorse the Human Health Working Group's proposal to classify Ethanol as a Carcinogenic and Reprotoxic substance of Category 1 in the BPC Opinion.
Information above is confidential	
Justification for confidentiality	
Other comments	• The biocidal evaluation process should not decide on a CMR classification: Discussions on classification should go through the CLP Regulation, a process which can allow a more comprehensive and dedicated discussion on this complex matter and the underlying data. • Given the far-reaching consequences of a CMR classification for ethanol under BPR, it should be RAC under the CLP Framework who should address the harmonized classification discussion based on the available data.
Information above is confidential	
Justification for confidentiality	
References	1 Pires et al. 2006 Ethanol-based handrubs: Safe for patients and health care workers - American Journal of Infection Control 2 WHO Model List of Essential Medicine: WHO EML 23rd List (2023) 3 WHO-recommended handrub formulation containing ethanol 80% v/v: WHO guidelines on hand hygiene in health care 4 ANALYSIS OF ALTERNATIVES for the use of Ethanol in Human hygiene products for the primary purpose of disinfecting the skin or scalp (Product Type 1) under the Biocidal Products Regulation Version: 3.0. – FINAL PUBLIC version (2025,

	20th February) 5 Desinfektionsmittel in der COVID-19-Pandemie: eine Herausforderung, Bundesgesundheitsbl 2022 · 65:86–95, Eggers et al. 2022: https://doi.org/10.1007/s00103-021-03457-z 6 Produktion in Corona-Zeiten: 80 % mehr Desinfektionsmittel von Januar bis September 2020 gegenüber Vorjahreszeitraum - Statistisches Bundesamt: Produktion in Corona-Zeiten: 80 % mehr Desinfektionsmittel von Januar bis September 2020 gegenüber Vorjahreszeitraum - Statistisches Bundesamt
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 330	2025/04/30 17:00
Country	Italy
Name of organization/institution	Federchimica
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	

Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Federchimica supports the AoA made by the consultant of the Alcohol Task Force which highlights how in none of the types of products under analysis as disinfectant there are equally effective alternatives. Essentially, no other substance currently equals ethanol's effectiveness in infection control. Ethanol is valued for: - its broad-spectrum of activity and efficacy against bacteria, fungi and virus (particularly for non-enveloped viruses) - its compatibility with a wide range of formulations and it is a versatile solvent - it has the best cost-effectiveness profile as it is widely available, easy to produce - no long-term environmental risks have been identified Furthermore, we know the global impact beyond the mere field of biocides if it will be confirmed the stricter classification. Therefore, it is important that the essential role of ethanol in different areas of use is recognized and, most importantly, in order to obtain a proper hazard classification, consider realistic routes of exposure through a risk assessment that should distinguish between ingestion and dermal/inhalation exposure. In this regard, it would be desirable to bring forward the hazard assessment in order to achieve harmonized classification and labelling under the CLP Regulation, in line with the 'one substance - one assessment' approach, which aims to strengthen cooperation and consolidate the scientific and technical work of European agencies, while also awaiting the opinion of the Risk Assessment Committee (RAC) reviewing proposals.

Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	Federchimica- Public Consultation on Ethanol.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 331	2025/04/30 17:20
Country	Spain
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	
Product Type	1,2,4
Alternative Identity and Properties	Identity of the Active Substance Chemical Name: Propan-1-ol Synonyms: n-Propanol, n-PrOH, propyl alcohol, ethyl carbinol CAS Number: 71-23-8 Molecular Formula: C₃H₈O EC Number: 200-746-9 IUPAC Name: Propan-1-ol UN Number: 1274 GHS Classification: Flammable liquid (Category 2), Serious eye damage (Category 1), Specific target organ toxicity – single exposure (Category 3) Physical and Chemical Properties Appearance: Colourless, clear liquid Odour: Mild, alcohol-like Melting Point: –127 °C Boiling Point: 97 °C Density: 0.804 g/cm³ at 25 °C

	Solubility: Completely miscible with water Vapour Pressure: 19.3 hPa at 20 °C Flash Point: 22 °C (closed cup) Autoignition Temperature: 400 °C Explosive Limits: Lower: 2.1%, Upper: 13.7% (v/v) Partition Coefficient (log P): 0.2 at 25 °C Viscosity: 2.21 mPa·s at 20 °C Refractive Index: 1.384 at 20 °C pH: 8.5 at 200 g/L in water at 20 °C Physical Hazards and Respective Characteristics Flammability: Highly flammable liquid and vapour Explosive Potential: Vapours can form explosive mixtures with air Autoignition Temperature: 400 °C Vapour Density: 2.07 (heavier than air), posing a risk of accumulation in low-lying areas Reactivity: Reacts exothermically with alkaline earth metals and alkali metals, releasing hydrogen; violent reactions possible with strong oxidising agents Methods of Detection and Identification Analytical Techniques: Gas Chromatography (GC) High-Performance Liquid Chromatography (HPLC) Infrared (IR) Spectroscopy Nuclear Magnetic Resonance (NMR) Spectroscopy Detection Limits: The odour threshold is approximately 0.094 ppm, facilitating detection by smell at low concentrations Effectiveness Against Target Organisms Antimicrobial Activity: Exhibits broad-spectrum antimicrobial properties, effective against bacteria, fungi, and viruses Applications: Hand Sanitisers: Effective in reducing microbial load Surface Disinfectants: Used in various concentrations for decontamination Industrial Cleaning: Employed in cleaning and degreasing processes Efficacy Considerations: The effectiveness can be influenced by concentration, contact time, and presence of organic matter Intended Uses and Exposure Primary Uses: Solvent in pharmaceuticals and cosmetics Intermediate in chemical synthesis Antiseptic in healthcare settings Cleaning agent in industrial applications Exposure Routes: Occupational: Inhalation, dermal contact, and accidental ingestion during manufacturing and application General Population: Inhalation of vapours, dermal contact with consumer products, and ingestion through contaminated food or beverages Exposure Limits: NIOSH REL: TWA 200 ppm (500 mg/m³), STEL 250 ppm (625 mg/m³) [skin] OSHA PEL: TWA 200 ppm (500 mg/m³) Measures Necessary to Protect Humans, Animals, and the Environment Personal Protective Equipment (PPE): Respiratory Protection: Use of appropriate respirators when concentrations exceed occupational exposure limits Skin Protection: Protective gloves and clothing to prevent dermal exposure Eye Protection: Safety goggles or face shields to prevent eye contact Environmental Protection: Prevent release into water bodies to avoid aquatic toxicity Implement spill containment and clean-up procedures First Aid Measures: Inhalation: Move to fresh air; seek medical

	attention if symptoms persist Skin Contact: Wash with soap and water; remove contaminated clothing Eye Contact: Rinse immediately with plenty of water for at least 15 minutes; seek medical attention Ingestion: Do not induce vomiting; seek medical attention immediately Classification, Labelling, and Packaging GHS Classification: Flammable Liquids: Category 2 Serious Eye Damage/Eye Irritation: Category 1 Specific Target Organ Toxicity – Single Exposure: Category 3 (Central Nervous System) Signal Word: Danger Hazard Statements: H225: Highly flammable liquid and vapour H318: Causes serious eye damage H336: May cause drowsiness or dizziness Precautionary Statements: P210: Keep away from heat/sparks/open flames/hot surfaces. — No smoking. P233: Keep container tightly closed. P280: Wear protective gloves/protective clothing/eye protection/face protection. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Packaging Group: II (Moderate danger) Transport Information: UN Number: 1274 Hazard Class: 3 Packing Group: II
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Spectrum and Efficacy: propanols offer limited effectiveness against a wide range of pathogens for which ethanol provides superior efficacy, including non-enveloped viruses such as Murine Norovirus, Poliovirus type 1, and Adenoviruses. This makes propanols less relevant compared to ethanol, which remains indispensable in high-hygiene settings.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	: Ethanol remains highly cost-effective due to its widespread availability, ease of production from renewable resources, and scalability. On the other hand, propan-1-ol and propan-2-ol have higher production costs and are less widely available, making them less cost-effective. Ethanol's established supply chain ensures stability, particularly during periods of crisis, such as the COVID-19 pandemic.
Information above is confidential	

Justification for confidentiality	
Hazards and Risks of the Alternative	Propan-1-ol is restricted due to its classification as H318 (serious eye damage), limiting its use in non-professional settings. Ethanol however is suitable for use in both professional and private environments. Propanols can increase skin irritation with frequent use due to slower evaporation rates, making them less suitable than ethanol for repeated disinfection in healthcare, education, and other public environments.
Information above is confidential	
Justification for confidentiality	
Availability	In terms of availability and supply chain, ethanol propanols have few suppliers, particularly propan-1-ol, which has a limited number of suppliers under PT1, raising concerns about their ability to meet high demand during critical times, as opposed to ethanol benefits from a well-established, diversified supply network across the EU, which ensures stable and reliable access.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Larger, diversified companies are better equipped to adapt to ethanol restrictions, with resources for R&D, alternative formulations, and regulatory compliance. Smaller or niche businesses, however, would face disproportionate financial and operational burdens, potentially leading to market exits or consolidations. Regulatory uncertainty—especially from the CLP classification process—may erode confidence in ethanol-based products among consumers, healthcare providers, and industry users. This could reduce usage, compromise hygiene standards, and heighten infection risks, particularly in critical sectors. Wider Socioeconomic Impacts on Third Countries Non-approval of ethanol in the EU would also impact third countries, especially emerging economies like India, Brazil, South Africa, Argentina, and Kenya, which rely on EU exports for hygiene and infection control. The EU supplies high-quality, cost-effective ethanol products. Disruptions would: • Break global supply chains, forcing reliance on costlier or less effective alternatives. • Increase trade barriers for low-income countries unable to quickly adapt. • Undermine public health, especially during pandemics, where ethanol is vital for disinfection. • Raise

	prices and reduce availability, hitting vulnerable populations hardest. Sectors such as healthcare, tourism, and public services would face increased costs and reduced hygiene capacity. The combined impact could deepen global health inequalities, underscoring the need for coordinated international responses.
Information above is confidential	
Justification for confidentiality	
Other comments	The ethanol-based disinfectant industry is a well-established and growing sector within the European Economic Area (EEA), supporting: • Thousands of jobs, particularly in SMEs. • A resilient regional supply chain spanning production, formulation, packaging, and distribution. • A strong export and intra-EU trade network, particularly in medical and hygiene-related products. Restricting ethanol would result in: • Disruption of production lines, as companies would be forced to seek, validate, and integrate less effective or more expensive alternatives. • Increased operational costs, with knock-on effects for healthcare providers, food safety operators, and industrial facilities. • Barriers for SMEs, which may lack the resources to invest in reformulation or meet new compliance requirements, risking closures or market exit. The economic burden would ultimately be passed on to consumers, with higher retail prices for disinfectants and hygiene products, disproportionately affecting low-income populations. Public Perception and Regulatory Trust Ethanol enjoys high public acceptance due to its widespread use and proven track record, especially during the COVID-19 pandemic. A restriction or ban on ethanol in hygiene contexts, while its use in alcoholic beverages remains permitted, would appear contradictory to the public and risk: • Undermining trust in EU regulatory decisions. • Fostering confusion and skepticism about risk assessment processes. • Jeopardizing compliance with public health recommendations. This perceptual disconnect could have long-term impacts on public confidence in regulatory institutions and health guidance. Impact on the Market: EU Competition, Market Consolidation, and Market Disruption In the event of restrictions or non-approval of ethanol for biocidal use under PT1, PT2, and PT4, the EU market would likely experience significant structural changes. A key consequence would be market consolidation, as small and medium-sized enterprises (SMEs)—which make up a large portion of the ethanol-based product supply chain—may

	struggle to meet new regulatory requirements or absorb the costs of reformulation.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	A-Letter PT1.docx
Attachments (confidential information)	
Justification for confidential attachment	

Comment 332	2025/04/30 17:31
Country	Spain
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	
Product Type	1,2,4
Alternative Identity and Properties	Identity of the Active Substance Chemical Name: Propan-1-ol Synonyms: n-Propanol, n-PrOH, propyl alcohol, ethyl carbinol CAS Number: 71-23-8 Molecular Formula: C₃H₈O EC Number: 200-746-9 IUPAC Name: Propan-1-ol UN Number: 1274 GHS Classification: Flammable liquid (Category 2), Serious eye damage (Category 1), Specific target organ toxicity – single exposure (Category 3) Physical and Chemical Properties Appearance: Colourless, clear liquid Odour: Mild, alcohol-like Melting Point: –127 °C Boiling Point: 97 °C Density: 0.804 g/cm³ at 25 °C Solubility: Completely miscible with water Vapour Pressure: 19.3 hPa at 20 °C Flash Point: 22 °C (closed cup) Autoignition Temperature: 400 °C Explosive Limits: Lower: 2.1%, Upper: 13.7% (v/v) Partition Coefficient (log P): 0.2

	at 25 °C Viscosity: 2.21 mPa·s at 20 °C Refractive Index: 1.384 at 20 °C pH: 8.5 at 200 g/L in water at 20 °C Physical Hazards and Respective Characteristics Flammability: Highly flammable liquid and vapour Explosive Potential: Vapours can form explosive mixtures with air Autoignition Temperature: 400 °C Vapour Density: 2.07 (heavier than air), posing a risk of accumulation in low-lying areas Reactivity: Reacts exothermically with alkaline earth metals and alkali metals, releasing hydrogen; violent reactions possible with strong oxidising agents Methods of Detection and Identification Analytical Techniques: Gas Chromatography (GC) High-Performance Liquid Chromatography (HPLC) Infrared (IR) Spectroscopy Nuclear Magnetic Resonance (NMR) Spectroscopy Detection Limits: The odour threshold is approximately 0.094 ppm, facilitating detection by smell at low concentrations Effectiveness Against Target Organisms Antimicrobial Activity: Exhibits broad-spectrum antimicrobial properties, effective against bacteria, fungi, and viruses Applications: Hand Sanitisers: Effective in reducing microbial load Surface Disinfectants: Used in various concentrations for decontamination Industrial Cleaning: Employed in cleaning and degreasing processes Efficacy Considerations: The effectiveness can be influenced by concentration, contact time, and presence of organic matter Intended Uses and Exposure Primary Uses: Solvent in pharmaceuticals and cosmetics Intermediate in chemical synthesis Antiseptic in healthcare settings Cleaning agent in industrial applications Exposure Routes: Occupational: Inhalation, dermal contact, and accidental ingestion during manufacturing and application General Population: Inhalation of vapours, dermal contact with consumer products, and ingestion through contaminated food or beverages Exposure Limits: NIOSH REL: TWA 200 ppm (500 mg/m³), STEL 250 ppm (625 mg/m³) [skin] OSHA PEL: TWA 200 ppm (500 mg/m³) Measures Necessary to Protect Humans, Animals, and the Environment Personal Protective Equipment (PPE): Respiratory Protection: Use of appropriate respirators when concentrations exceed occupational exposure limits Skin Protection: Protective gloves and clothing to prevent dermal exposure Eye Protection: Safety goggles or face shields to prevent eye contact Environmental Protection: Prevent release into water bodies to avoid aquatic toxicity Implement spill containment and clean-up procedures First Aid Measures: Inhalation: Move to fresh air; seek medical attention if symptoms persist Skin Contact: Wash with soap and water; remove contaminated clothing Eye Contact: Rinse immediately with plenty of water for at least 15 minutes; seek medical attention Ingestion: Do not induce

	vomiting; seek medical attention immediately Classification, Labelling, and Packaging GHS Classification: Flammable Liquids: Category 2 Serious Eye Damage/Eye Irritation: Category 1 Specific Target Organ Toxicity – Single Exposure: Category 3 (Central Nervous System) Signal Word: Danger Hazard Statements: H225: Highly flammable liquid and vapour H318: Causes serious eye damage H336: May cause drowsiness or dizziness Precautionary Statements: P210: Keep away from heat/sparks/open flames/hot surfaces. — No smoking. P233: Keep container tightly closed. P280: Wear protective gloves/protective clothing/eye protection/face protection. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Packaging Group: II (Moderate danger) Transport Information: UN Number: 1274 Hazard Class: 3 Packing Group: II ---- Identity of the Active Substance Chemical Name: Propan-1-ol Synonyms: n-Propanol, n-PrOH, propyl alcohol, ethyl carbinol CAS Number: 71-23-8 Molecular Formula: C₃H₈O EC Number: 200-746-9 IUPAC Name: Propan-1-ol UN Number: 1274 GHS Classification: Flammable liquid (Category 2), Serious eye damage (Category 1), Specific target organ toxicity – single exposure (Category 3) Physical and Chemical Properties Appearance: Colourless, clear liquid Odour: Mild, alcohol-like Melting Point: –127 °C Boiling Point: 97 °C Density: 0.804 g/cm³ at 25 °C Solubility: Completely miscible with water Vapour Pressure: 19.3 hPa at 20 °C Flash Point: 22 °C (closed cup) Autoignition Temperature: 400 °C Explosive Limits: Lower: 2.1%, Upper: 13.7% (v/v) Partition Coefficient (log P): 0.2 at 25 °C Viscosity: 2.21 mPa·s at 20 °C Refractive Index: 1.384 at 20 °C pH: 8.5 at 200 g/L in water at 20 °C Physical Hazards and Respective Characteristics Flammability: Highly flammable liquid and vapour Explosive Potential: Vapours can form explosive mixtures with air Autoignition Temperature: 400 °C Vapour Density: 2.07 (heavier than air), posing a risk of accumulation in low-lying areas Reactivity: Reacts exothermically with alkaline earth metals and alkali metals, releasing hydrogen; violent reactions possible with strong oxidising agents Methods of Detection and Identification Analytical Techniques: Gas Chromatography (GC) High-Performance Liquid Chromatography (HPLC) Infrared (IR) Spectroscopy Nuclear Magnetic Resonance (NMR) Spectroscopy Detection Limits: The odour threshold is approximately 0.094 ppm, facilitating detection by smell at low concentrations Effectiveness Against Target Organisms Antimicrobial Activity: Exhibits broad-spectrum antimicrobial properties, effective against bacteria, fungi, and viruses

	Applications: Hand Sanitisers: Effective in reducing microbial load Surface Disinfectants: Used in various concentrations for decontamination Industrial Cleaning: Employed in cleaning and degreasing processes Efficacy Considerations: The effectiveness can be influenced by concentration, contact time, and presence of organic matter Intended Uses and Exposure Primary Uses: Solvent in pharmaceuticals and cosmetics Intermediate in chemical synthesis Antiseptic in healthcare settings Cleaning agent in industrial applications Exposure Routes: Occupational: Inhalation, dermal contact, and accidental ingestion during manufacturing and application General Population: Inhalation of vapours, dermal contact with consumer products, and ingestion through contaminated food or beverages Exposure Limits: NIOSH REL: TWA 200 ppm (500 mg/m³), STEL 250 ppm (625 mg/m³) [skin] OSHA PEL: TWA 200 ppm (500 mg/m³) Measures Necessary to Protect Humans, Animals, and the Environment Personal Protective Equipment (PPE): Respiratory Protection: Use of appropriate respirators when concentrations exceed occupational exposure limits Skin Protection: Protective gloves and clothing to prevent dermal exposure Eye Protection: Safety goggles or face shields to prevent eye contact Environmental Protection: Prevent release into water bodies to avoid aquatic toxicity Implement spill containment and clean-up procedures First Aid Measures: Inhalation: Move to fresh air; seek medical attention if symptoms persist Skin Contact: Wash with soap and water; remove contaminated clothing Eye Contact: Rinse immediately with plenty of water for at least 15 minutes; seek medical attention Ingestion: Do not induce vomiting; seek medical attention immediately Classification, Labelling, and Packaging GHS Classification: Flammable Liquids: Category 2 Serious Eye Damage/Eye Irritation: Category 1 Specific Target Organ Toxicity – Single Exposure: Category 3 (Central Nervous System) Signal Word: Danger Hazard Statements: H225: Highly flammable liquid and vapour H318: Causes serious eye damage H336: May cause drowsiness or dizziness Precautionary Statements: P210: Keep away from heat/sparks/open flames/hot surfaces. — No smoking. P233: Keep container tightly closed. P280: Wear protective gloves/protective clothing/eye protection/face protection. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Packaging Group: II (Moderate danger) Transport Information: UN Number: 1274 Hazard Class: 3 Packing Group: II

Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Spectrum and Efficacy: propanols offer limited effectiveness against a wide range of pathogens for which ethanol provides superior efficacy, including non-enveloped viruses such as Murine Norovirus, Poliovirus type 1, and Adenoviruses. This makes propanols less relevant compared to ethanol, which remains indispensable in high-hygiene settings. Propan-1-ol is approved under the BPR, thus an alternative for PT2 uses. However, its flammability (H225) and potential for causing eye damage (H318) must be carefully managed, especially when used in non-professional uses. The biocidal products for the non-professional use are restricted to pre-soaked wipes.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Ethanol remains highly cost-effective due to its widespread availability, ease of production from renewable resources, and scalability. On the other hand, propan-1-ol and propan-2-ol have higher production costs and are less widely available, making them less cost-effective. Ethanol's established supply chain ensures stability, particularly during periods of crisis, such as the COVID-19 pandemic.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Propan-1-ol is restricted due to its classification as H318 (serious eye damage), limiting its use in non-professional settings. Ethanol however is suitable for use in both professional and private environments. Propanols can increase skin irritation with frequent use due to slower evaporation rates, making them less suitable than ethanol for repeated disinfection in healthcare, education, and other public environments.
Information above is confidential	
Justification for confidentiality	

Availability	In terms of availability and supply chain, ethanol propanols have few suppliers, particularly propan-1-ol, which has a limited number of suppliers, raising concerns about their ability to meet high demand during critical times, as opposed to ethanol benefits from a well-established, diversified supply network across the EU, which ensures stable and reliable access.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Larger, diversified companies are better equipped to adapt to ethanol restrictions, with resources for R&D, alternative formulations, and regulatory compliance. Smaller or niche businesses, however, would face disproportionate financial and operational burdens, potentially leading to market exits or consolidations. Regulatory uncertainty—especially from the CLP classification process—may erode confidence in ethanol-based products among consumers, healthcare providers, and industry users. This could reduce usage, compromise hygiene standards, and heighten infection risks, particularly in critical sectors. Wider Socioeconomic Impacts on Third Countries Non-approval of ethanol in the EU would also impact third countries, especially emerging economies like India, Brazil, South Africa, Argentina, and Kenya, which rely on EU exports for hygiene and infection control. The EU supplies high-quality, cost-effective ethanol products. Disruptions would: • Break global supply chains, forcing reliance on costlier or less effective alternatives. • Increase trade barriers for low-income countries unable to quickly adapt. • Undermine public health, especially during pandemics, where ethanol is vital for disinfection. • Raise prices and reduce availability, hitting vulnerable populations hardest. Sectors such as healthcare, tourism, and public services would face increased costs and reduced hygiene capacity. The combined impact could deepen global health inequalities, underscoring the need for coordinated international responses.
Information above is confidential	
Justification for confidentiality	
Other comments	The ethanol-based disinfectant industry is a well-established and growing sector within the European Economic Area (EEA), supporting: • Thousands of jobs, particularly in SMEs. • A resilient regional supply chain spanning

	production, formulation, packaging, and distribution. • A strong export and intra-EU trade network, particularly in medical and hygiene-related products. Restricting ethanol would result in: • Disruption of production lines, as companies would be forced to seek, validate, and integrate less effective or more expensive alternatives. • Increased operational costs, with knock-on effects for healthcare providers, food safety operators, and industrial facilities. • Barriers for SMEs, which may lack the resources to invest in reformulation or meet new compliance requirements, risking closures or market exit. The economic burden would ultimately be passed on to consumers, with higher retail prices for disinfectants and hygiene products, disproportionately affecting low-income populations. *Public Perception and Regulatory Trust Ethanol enjoys high public acceptance due to its widespread use and proven track record, especially during the COVID-19 pandemic. A restriction or ban on ethanol in hygiene contexts, while its use in alcoholic beverages remains permitted, would appear contradictory to the public and risk: • Undermining trust in EU regulatory decisions. • Fostering confusion and skepticism about risk assessment processes. • Jeopardizing compliance with public health recommendations. This perceptual disconnect could have long-term impacts on public confidence in regulatory institutions and health guidance. *Impact on the Market: EU Competition, Market Consolidation, and Market Disruption In the event of restrictions or non-approval of ethanol for biocidal use under PT1, PT2, and PT4, the EU market would likely experience significant structural changes. A key consequence would be market consolidation, as small and medium-sized enterprises (SMEs)—which make up a large portion of the ethanol-based product supply chain—may struggle to meet new regulatory requirements or absorb the costs of reformulation.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	

Justification for confidential attachment	

Comment 333	2025/04/30 17:41
Country	Spain
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	
Product Type	1,2,4
Alternative Identity and Properties	Identity of the Active Substance Chemical Name: Propan-1-ol Synonyms: n-Propanol, n-PrOH, propyl alcohol, ethyl carbinol CAS Number: 71-23-8 Molecular Formula: C₃H₈O EC Number: 200-746-9 IUPAC Name: Propan-1-ol UN Number: 1274 GHS Classification: Flammable liquid (Category 2), Serious eye damage (Category 1), Specific target organ toxicity – single exposure (Category 3) Physical and Chemical Properties Appearance: Colourless, clear liquid Odour: Mild, alcohol-like Melting Point: –127 °C Boiling Point: 97 °C Density: 0.804 g/cm³ at 25 °C Solubility: Completely miscible with water Vapour Pressure: 19.3 hPa at 20 °C Flash Point: 22 °C (closed cup) Autoignition Temperature: 400 °C Explosive Limits: Lower: 2.1%, Upper: 13.7% (v/v) Partition Coefficient (log P): 0.2 at 25 °C Viscosity: 2.21 mPa·s at 20 °C Refractive Index: 1.384 at 20 °C pH: 8.5 at 200 g/L in water at 20 °C Physical Hazards and Respective Characteristics Flammability: Highly flammable liquid and vapour Explosive Potential: Vapours can form explosive mixtures with air Autoignition Temperature: 400 °C Vapour Density: 2.07 (heavier than air), posing a risk of accumulation in low-lying areas Reactivity: Reacts exothermically with alkaline earth metals and alkali metals, releasing hydrogen; violent reactions possible with strong oxidising agents Methods of Detection and Identification Analytical Techniques: Gas Chromatography (GC) High-Performance Liquid Chromatography (HPLC) Infrared (IR) Spectroscopy Nuclear Magnetic Resonance (NMR) Spectroscopy Detection Limits:

	The odour threshold is approximately 0.094 ppm, facilitating detection by smell at low concentrations Effectiveness Against Target Organisms Antimicrobial Activity: Exhibits broad-spectrum antimicrobial properties, effective against bacteria, fungi, and viruses Applications: Hand Sanitisers: Effective in reducing microbial load Surface Disinfectants: Used in various concentrations for decontamination Industrial Cleaning: Employed in cleaning and degreasing processes Efficacy Considerations: The effectiveness can be influenced by concentration, contact time, and presence of organic matter Intended Uses and Exposure Primary Uses: Solvent in pharmaceuticals and cosmetics Intermediate in chemical synthesis Antiseptic in healthcare settings Cleaning agent in industrial applications Exposure Routes: Occupational: Inhalation, dermal contact, and accidental ingestion during manufacturing and application General Population: Inhalation of vapours, dermal contact with consumer products, and ingestion through contaminated food or beverages Exposure Limits: NIOSH REL: TWA 200 ppm (500 mg/m³), STEL 250 ppm (625 mg/m³) [skin] OSHA PEL: TWA 200 ppm (500 mg/m³) Measures Necessary to Protect Humans, Animals, and the Environment Personal Protective Equipment (PPE): Respiratory Protection: Use of appropriate respirators when concentrations exceed occupational exposure limits Skin Protection: Protective gloves and clothing to prevent dermal exposure Eye Protection: Safety goggles or face shields to prevent eye contact Environmental Protection: Prevent release into water bodies to avoid aquatic toxicity Implement spill containment and clean-up procedures First Aid Measures: Inhalation: Move to fresh air; seek medical attention if symptoms persist Skin Contact: Wash with soap and water; remove contaminated clothing Eye Contact: Rinse immediately with plenty of water for at least 15 minutes; seek medical attention Ingestion: Do not induce vomiting; seek medical attention immediately Classification, Labelling, and Packaging GHS Classification: Flammable Liquids: Category 2 Serious Eye Damage/Eye Irritation: Category 1 Specific Target Organ Toxicity – Single Exposure: Category 3 (Central Nervous System) Signal Word: Danger Hazard Statements: H225: Highly flammable liquid and vapour H318: Causes serious eye damage H336: May cause drowsiness or dizziness Precautionary Statements: P210: Keep away from heat/sparks/open flames/hot surfaces. — No smoking. P233: Keep container tightly closed. P280: Wear protective gloves/protective clothing/eye protection/face protection. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and

	easy to do. Continue rinsing. Packaging Group: II (Moderate danger) Transport Information: UN Number: 1274 Hazard Class: 3 Packing Group: II
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Spectrum and Efficacy: propanols offer limited effectiveness against a wide range of pathogens for which ethanol provides superior efficacy, including non-enveloped viruses such as Murine Norovirus, Poliovirus type 1, and Adenoviruses. This makes propanols less relevant compared to ethanol, which remains indispensable in high-hygiene settings. Slower evaporation times of propanols are also a technical hindrance in PT4 applications
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Small producers that rely on ethanol as a core product face considerable challenges. Transition costs and loss of market share to larger companies with established production capabilities for alternatives could threaten their business viability. In some cases, companies may be forced to exit the market due to the technical and economic infeasibility of substitution. Overall, the substitution of ethanol is expected to require an investment ranging from €1.25 million to several million euros per company, excluding the costs of active substance R&D, which are often in the millions as well. The high costs, combined with lengthy timelines, highlight the complexity of transitioning away from ethanol in biocidal products. •The transition to alternative substances often requires substantial investments to adapt manufacturing facilities. For example, converting tank systems to handle new substances can cost up to €500,000. In cases where entirely new production sites are needed, the costs can increase significantly, potentially exceeding several million euros.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Propan-1-ol is restricted due to its classification as H318 (serious eye damage), limiting its use in non-professional

	settings. Ethanol however is suitable for use in both professional and private environments. Propanols can increase skin irritation with frequent use due to slower evaporation rates, making them less suitable than ethanol for repeated disinfection in healthcare, education, and other public environments.
Information above is confidential	
Justification for confidentiality	
Availability	In terms of availability and supply chain, propanols have few suppliers, particularly propan-1-ol, raising concerns about their ability to meet high demand during critical times. On the other hand, ethanol benefits from a well-established, diversified supply network across the EU, which ensures stable and reliable access. Propanols have few suppliers, particularly propan-1-ol, which has a limited number of suppliers under PT1, raising concerns about their ability to meet high demand during critical times. Propanols have higher production costs and are less widely available, making them less cost-effective. Ethanol's established supply chain ensures stability, particularly during periods of crisis, such as the COVID-19 pandemic.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Larger, diversified companies are better equipped to adapt to ethanol restrictions, with resources for R&D, alternative formulations, and regulatory compliance. Smaller or niche businesses, however, would face disproportionate financial and operational burdens, potentially leading to market exits or consolidations. Regulatory uncertainty—especially from the CLP classification process—may erode confidence in ethanol-based products among consumers, healthcare providers, and industry users. This could reduce usage, compromise hygiene standards, and heighten infection risks, particularly in critical sectors. Wider Socioeconomic Impacts on Third Countries Non-approval of ethanol in the EU would also impact third countries, especially emerging economies like India, Brazil, South Africa, Argentina, and Kenya, which rely on EU exports for hygiene and infection control. The EU supplies high-quality, cost-effective ethanol products. Disruptions would: • Break global supply chains, forcing reliance on costlier or less effective alternatives. • Increase trade barriers for low-income countries unable to

	quickly adapt. • Undermine public health, especially during pandemics, where ethanol is vital for disinfection. • Raise prices and reduce availability, hitting vulnerable populations hardest. Sectors such as healthcare, tourism, and public services would face increased costs and reduced hygiene capacity. The combined impact could deepen global health inequalities, underscoring the need for coordinated international responses.
Information above is confidential	
Justification for confidentiality	
Other comments	The ethanol-based disinfectant industry is a well-established and growing sector within the European Economic Area (EEA), supporting: • Thousands of jobs, particularly in SMEs. • A resilient regional supply chain spanning production, formulation, packaging, and distribution. • A strong export and intra-EU trade network, particularly in medical and hygiene-related products. Restricting ethanol would result in: • Disruption of production lines, as companies would be forced to seek, validate, and integrate less effective or more expensive alternatives. • Increased operational costs, with knock-on effects for healthcare providers, food safety operators, and industrial facilities. • Barriers for SMEs, which may lack the resources to invest in reformulation or meet new compliance requirements, risking closures or market exit. The economic burden would ultimately be passed on to consumers, with higher retail prices for disinfectants and hygiene products, disproportionately affecting low-income populations. Public Perception and Regulatory Trust Ethanol enjoys high public acceptance due to its widespread use and proven track record, especially during the COVID-19 pandemic. A restriction or ban on ethanol in hygiene contexts, while its use in alcoholic beverages remains permitted, would appear contradictory to the public and risk: • Undermining trust in EU regulatory decisions. • Fostering confusion and skepticism about risk assessment processes. • Jeopardizing compliance with public health recommendations. This perceptual disconnect could have long-term impacts on public confidence in regulatory institutions and health guidance. Impact on the Market: EU Competition, Market Consolidation, and Market Disruption In the event of restrictions or non-approval of ethanol for biocidal use under PT1, PT2, and PT4, the EU market would likely experience significant structural changes. A key consequence would be market consolidation, as small and

	medium-sized enterprises (SMEs)—which make up a large portion of the ethanol-based product supply chain—may struggle to meet new regulatory requirements or absorb the costs of reformulation.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	A-Letter Pt4.docx
Attachments (confidential information)	
Justification for confidential attachment	

Comment 334	2025/04/30 17:45
Country	Spain
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	
Product Type	1,2,4
Alternative Identity and Properties	Identity of the Active Substance Chemical Name: Propan-2-ol Synonyms: Isopropyl alcohol, 2-propanol, i-PrOH, sec-propyl alcohol CAS Number: 67-63-0 Molecular Formula: C₃H₈O EC Number: 200-661-7 IUPAC Name: Propan-2-ol UN Number: 1219 3. Physical and Chemical Properties Appearance: Colourless, clear liquid Odour: Mild, characteristic alcoholic odour Melting Point: –89 °C Boiling Point: 82.6 °C Density: 0.786 g/cm³ at 20 °C Solubility: Completely miscible with water, ethanol, acetone, chloroform, and benzene Flash Point: 12 °C (closed cup) Autoignition Temperature: 399 °C Explosive Limits: Lower: 2%, Upper: 12.7% (v/v) Vapour Pressure: 42.6 hPa at

	20 °C Refractive Index: 1.379 at 20 °C 4. Physical Hazards and Respective Characteristics Flammability: Highly flammable liquid and vapour Explosive Potential: Vapours can form explosive mixtures with air Reactivity: Reacts exothermically with alkaline earth metals and alkali metals, releasing hydrogen; violent reactions possible with strong oxidising agents 5. Methods of Detection and Identification Analytical Techniques: Gas Chromatography (GC) High-Performance Liquid Chromatography (HPLC) Infrared (IR) Spectroscopy Nuclear Magnetic Resonance (NMR) Spectroscopy Detection Limits: The odour threshold is approximately 0.04 ppm, facilitating detection by smell at low concentrations 6. Effectiveness Against Target Organisms Antimicrobial Activity: Exhibits broad-spectrum antimicrobial properties, effective against bacteria, fungi, and viruses Applications: Hand Sanitisers: Effective in reducing microbial load Surface Disinfectants: Used in various concentrations for decontamination Industrial Cleaning: Employed in cleaning and degreasing processes Efficacy Considerations: The effectiveness can be influenced by concentration, contact time, and presence of organic matter 7. Intended Uses and Exposure Primary Uses: Solvent in pharmaceuticals and cosmetics Intermediate in chemical synthesis Antiseptic in healthcare settings Cleaning agent in industrial applications Exposure Routes: Occupational: Inhalation, dermal contact, and accidental ingestion during manufacturing and application General Population: Inhalation of vapours, dermal contact with consumer products, and ingestion through contaminated food or beverages Exposure Limits: NIOSH REL: TWA 400 ppm (980 mg/m³), STEL 500 ppm (1,225 mg/m³) OSHA PEL: TWA 400 ppm (980 mg/m³) 11. Measures Necessary to Protect Humans, Animals, and the Environment Personal Protective Equipment (PPE): Respiratory Protection: Use of appropriate respirators when concentrations exceed occupational exposure limits Skin Protection: Protective gloves and clothing to prevent dermal exposure Eye Protection: Safety goggles or face shields to prevent eye contact Environmental Protection: Prevent release into water bodies to avoid aquatic toxicity Implement spill containment and clean-up procedures First Aid Measures: Inhalation: Move to fresh air; seek medical attention if symptoms persist Skin Contact: Wash with soap and water; remove contaminated clothing Eye Contact: Rinse immediately with plenty of water for at least 15 minutes; seek medical attention Ingestion: Do not induce vomiting; seek medical attention immediately 12. Classification, Labelling, and Packaging GHS Classification: Flammable Liquids: Category 2 Serious Eye Damage/Eye Irritation:

	Category 2 Specific Target Organ Toxicity – Single Exposure: Category 3 (Central Nervous System) Signal Word: Danger Hazard Statements: H225: Highly flammable liquid and vapour H319: Causes serious eye irritation H336: May cause drowsiness or dizziness Precautionary Statements: P210: Keep away from heat/sparks/open flames/hot surfaces. — No smoking. P233: Keep container tightly closed. P280: Wear protective gloves/protective clothing/eye protection/face protection. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Packaging Group: II (Moderate danger) Transport Information: UN Number: 1219 Hazard Class: 3 Packing Group: II
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Spectrum and Efficacy: propanols offer limited effectiveness against a wide range of pathogens for which ethanol provides superior efficacy, including non-enveloped viruses such as Murine Norovirus, Poliovirus type 1, and Adenoviruses. This makes propanols less relevant compared to ethanol, which remains indispensable in high-hygiene settings. Application Versatility: Propan-1-ol is restricted due to its classification as H318 (serious eye damage), limiting its use in non-professional settings. Ethanol however is suitable for use in both professional and private environments. User Safety and Skin Tolerance: propanols can increase skin irritation with frequent use due to slower evaporation rates, making them less suitable than ethanol for repeated disinfection in healthcare, education, and other public environments.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Small producers that rely on ethanol as a core product face considerable challenges. Transition costs and loss of market share to larger companies with established production capabilities for alternatives could threaten their business viability. In some cases, companies may be forced to exit the market due to the technical and economic infeasibility of substitution. Overall, the substitution of ethanol is expected to require an investment ranging from €1.25 million to several million euros per company, excluding the costs of

	active substance R&D, which are often in the millions as well. The high costs, combined with lengthy timelines, highlight the complexity of transitioning away from ethanol in biocidal products. •The transition to alternative substances often requires substantial investments to adapt manufacturing facilities. For example, converting tank systems to handle new substances can cost up to €500,000. In cases where entirely new production sites are needed, the costs can increase significantly, potentially exceeding several million euros.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Propanols can increase skin irritation with frequent use due to slower evaporation rates, making them less suitable than ethanol for repeated disinfection in healthcare, education, and other public environments.
Information above is confidential	
Justification for confidentiality	
Availability	In terms of availability and supply chain, propanols have few suppliers, particularly propan-1-ol, which has a limited number of suppliers under PT1, raising concerns about their ability to meet high demand during critical times. On the other hand, ethanol benefits from a well-established, diversified supply network across the EU, which ensures stable and reliable access. Propanols have higher production costs and are less widely available, making them less cost-effective. Ethanol's established supply chain ensures stability, particularly during periods of crisis, such as the COVID-19 pandemic.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Larger, diversified companies are better equipped to adapt to ethanol restrictions, with resources for R&D, alternative formulations, and regulatory compliance. Smaller or niche businesses, however, would face disproportionate financial and operational burdens, potentially leading to market exits or consolidations. Regulatory uncertainty—especially from the CLP classification process—may erode confidence in

	ethanol-based products among consumers, healthcare providers, and industry users. This could reduce usage, compromise hygiene standards, and heighten infection risks, particularly in critical sectors. Wider Socioeconomic Impacts on Third Countries Non-approval of ethanol in the EU would also impact third countries, especially emerging economies like India, Brazil, South Africa, Argentina, and Kenya, which rely on EU exports for hygiene and infection control. The EU supplies high-quality, cost-effective ethanol products. Disruptions would: • Break global supply chains, forcing reliance on costlier or less effective alternatives. • Increase trade barriers for low-income countries unable to quickly adapt. • Undermine public health, especially during pandemics, where ethanol is vital for disinfection. • Raise prices and reduce availability, hitting vulnerable populations hardest. Sectors such as healthcare, tourism, and public services would face increased costs and reduced hygiene capacity. The combined impact could deepen global health inequalities, underscoring the need for coordinated international responses.
Information above is confidential	
Justification for confidentiality	
Other comments	The ethanol-based disinfectant industry is a well-established and growing sector within the European Economic Area (EEA), supporting: • Thousands of jobs, particularly in SMEs. • A resilient regional supply chain spanning production, formulation, packaging, and distribution. • A strong export and intra-EU trade network, particularly in medical and hygiene-related products. Restricting ethanol would result in: • Disruption of production lines, as companies would be forced to seek, validate, and integrate less effective or more expensive alternatives. • Increased operational costs, with knock-on effects for healthcare providers, food safety operators, and industrial facilities. • Barriers for SMEs, which may lack the resources to invest in reformulation or meet new compliance requirements, risking closures or market exit. The economic burden would ultimately be passed on to consumers, with higher retail prices for disinfectants and hygiene products, disproportionately affecting low-income populations. Public Perception and Regulatory Trust Ethanol enjoys high public acceptance due to its widespread use and proven track record, especially during the COVID-19 pandemic. A restriction or ban on ethanol in hygiene contexts, while its use in alcoholic beverages remains permitted, would appear

	contradictory to the public and risk: • Undermining trust in EU regulatory decisions. • Fostering confusion and skepticism about risk assessment processes. • Jeopardizing compliance with public health recommendations. This perceptual disconnect could have long-term impacts on public confidence in regulatory institutions and health guidance. Impact on the Market: EU Competition, Market Consolidation, and Market Disruption In the event of restrictions or non-approval of ethanol for biocidal use under PT1, PT2, and PT4, the EU market would likely experience significant structural changes. A key consequence would be market consolidation, as small and medium-sized enterprises (SMEs)—which make up a large portion of the ethanol-based product supply chain—may struggle to meet new regulatory requirements or absorb the costs of reformulation.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	A-Letter PT1.docx
Attachments (confidential information)	
Justification for confidential attachment	

Comment 335	2025/04/30 17:49
Country	Spain
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	
Product Type	1,2,4

Alternative Identity and Properties	Identity of the Active Substance Chemical Name: Propan-2-ol Synonyms: Isopropyl alcohol, 2-propanol, i-PrOH, sec-propyl alcohol CAS Number: 67-63-0 Molecular Formula: C₃H₈O EC Number: 200-661-7 IUPAC Name: Propan-2-ol UN Number: 1219 3. Physical and Chemical Properties Appearance: Colourless, clear liquid Odour: Mild, characteristic alcoholic odour Melting Point: –89 °C Boiling Point: 82.6 °C Density: 0.786 g/cm³ at 20 °C Solubility: Completely miscible with water, ethanol, acetone, chloroform, and benzene Flash Point: 12 °C (closed cup) Autoignition Temperature: 399 °C Explosive Limits: Lower: 2%, Upper: 12.7% (v/v) Vapour Pressure: 42.6 hPa at 20 °C Refractive Index: 1.379 at 20 °C 4. Physical Hazards and Respective Characteristics Flammability: Highly flammable liquid and vapour Explosive Potential: Vapours can form explosive mixtures with air Reactivity: Reacts exothermically with alkaline earth metals and alkali metals, releasing hydrogen; violent reactions possible with strong oxidising agents 5. Methods of Detection and Identification Analytical Techniques: Gas Chromatography (GC) High-Performance Liquid Chromatography (HPLC) Infrared (IR) Spectroscopy Nuclear Magnetic Resonance (NMR) Spectroscopy Detection Limits: The odour threshold is approximately 0.04 ppm, facilitating detection by smell at low concentrations 6. Effectiveness Against Target Organisms Antimicrobial Activity: Exhibits broad-spectrum antimicrobial properties, effective against bacteria, fungi, and viruses Applications: Hand Sanitisers: Effective in reducing microbial load Surface Disinfectants: Used in various concentrations for decontamination Industrial Cleaning: Employed in cleaning and degreasing processes Efficacy Considerations: The effectiveness can be influenced by concentration, contact time, and presence of organic matter 7. Intended Uses and Exposure Primary Uses: Solvent in pharmaceuticals and cosmetics Intermediate in chemical synthesis Antiseptic in healthcare settings Cleaning agent in industrial applications Exposure Routes: Occupational: Inhalation, dermal contact, and accidental ingestion during manufacturing and application General Population: Inhalation of vapours, dermal contact with consumer products, and ingestion through contaminated food or beverages Exposure Limits: NIOSH REL: TWA 400 ppm (980 mg/m³), STEL 500 ppm (1,225 mg/m³) OSHA PEL: TWA 400 ppm (980 mg/m³) 11. Measures Necessary to Protect Humans, Animals, and the Environment Personal Protective Equipment (PPE): Respiratory Protection: Use of appropriate respirators when concentrations exceed occupational exposure limits Skin Protection: Protective gloves and clothing to prevent dermal exposure Eye

	Protection: Safety goggles or face shields to prevent eye contact Environmental Protection: Prevent release into water bodies to avoid aquatic toxicity Implement spill containment and clean-up procedures First Aid Measures: Inhalation: Move to fresh air; seek medical attention if symptoms persist Skin Contact: Wash with soap and water; remove contaminated clothing Eye Contact: Rinse immediately with plenty of water for at least 15 minutes; seek medical attention Ingestion: Do not induce vomiting; seek medical attention immediately 12. Classification, Labelling, and Packaging GHS Classification: Flammable Liquids: Category 2 Serious Eye Damage/Eye Irritation: Category 2 Specific Target Organ Toxicity – Single Exposure: Category 3 (Central Nervous System) Signal Word: Danger Hazard Statements: H225: Highly flammable liquid and vapour H319: Causes serious eye irritation H336: May cause drowsiness or dizziness Precautionary Statements: P210: Keep away from heat/sparks/open flames/hot surfaces. — No smoking. P233: Keep container tightly closed. P280: Wear protective gloves/protective clothing/eye protection/face protection. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Packaging Group: II (Moderate danger) Transport Information: UN Number: 1219 Hazard Class: 3 Packing Group: II
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Spectrum and Efficacy: propanols offer limited effectiveness against a wide range of pathogens for which ethanol provides superior efficacy, including non-enveloped viruses such as Murine Norovirus, Poliovirus type 1, and Adenoviruses. This makes propanols less relevant compared to ethanol, which remains indispensable in high-hygiene settings.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Small producers that rely on ethanol as a core product face considerable challenges. Transition costs and loss of market share to larger companies with established production capabilities for alternatives could threaten their business viability. In some cases, companies may be forced to exit

	the market due to the technical and economic infeasibility of substitution. Overall, the substitution of ethanol is expected to require an investment ranging from €1.25 million to several million euros per company, excluding the costs of active substance R&D, which are often in the millions as well. The high costs, combined with lengthy timelines, highlight the complexity of transitioning away from ethanol in biocidal products. •The transition to alternative substances often requires substantial investments to adapt manufacturing facilities. For example, converting tank systems to handle new substances can cost up to €500,000. In cases where entirely new production sites are needed, the costs can increase significantly, potentially exceeding several million euros.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	In terms of availability and supply chain, ethanol propanols have few suppliers, raising concerns about their ability to meet high demand during critical times, as opposed to ethanol benefits from a well-established, diversified supply network across the EU, which ensures stable and reliable access.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Larger, diversified companies are better equipped to adapt to ethanol restrictions, with resources for R&D, alternative formulations, and regulatory compliance. Smaller or niche businesses, however, would face disproportionate financial and operational burdens, potentially leading to market exits or consolidations. Regulatory uncertainty—especially from the CLP classification process—may erode confidence in ethanol-based products among consumers, healthcare providers, and industry users. This could reduce usage, compromise hygiene standards, and heighten infection

	risks, particularly in critical sectors. Wider Socioeconomic Impacts on Third Countries Non-approval of ethanol in the EU would also impact third countries, especially emerging economies like India, Brazil, South Africa, Argentina, and Kenya, which rely on EU exports for hygiene and infection control. The EU supplies high-quality, cost-effective ethanol products. Disruptions would: • Break global supply chains, forcing reliance on costlier or less effective alternatives. • Increase trade barriers for low-income countries unable to quickly adapt. • Undermine public health, especially during pandemics, where ethanol is vital for disinfection. • Raise prices and reduce availability, hitting vulnerable populations hardest. Sectors such as healthcare, tourism, and public services would face increased costs and reduced hygiene capacity. The combined impact could deepen global health inequalities, underscoring the need for coordinated international responses.
Information above is confidential	
Justification for confidentiality	
Other comments	The ethanol-based disinfectant industry is a well-established and growing sector within the European Economic Area (EEA), supporting: • Thousands of jobs, particularly in SMEs. • A resilient regional supply chain spanning production, formulation, packaging, and distribution. • A strong export and intra-EU trade network, particularly in medical and hygiene-related products. Restricting ethanol would result in: • Disruption of production lines, as companies would be forced to seek, validate, and integrate less effective or more expensive alternatives. • Increased operational costs, with knock-on effects for healthcare providers, food safety operators, and industrial facilities. • Barriers for SMEs, which may lack the resources to invest in reformulation or meet new compliance requirements, risking closures or market exit. The economic burden would ultimately be passed on to consumers, with higher retail prices for disinfectants and hygiene products, disproportionately affecting low-income populations. Public Perception and Regulatory Trust Ethanol enjoys high public acceptance due to its widespread use and proven track record, especially during the COVID-19 pandemic. A restriction or ban on ethanol in hygiene contexts, while its use in alcoholic beverages remains permitted, would appear contradictory to the public and risk: • Undermining trust in EU regulatory decisions. • Fostering confusion and skepticism about risk assessment

	processes. • Jeopardizing compliance with public health recommendations. This perceptual disconnect could have long-term impacts on public confidence in regulatory institutions and health guidance. Impact on the Market: EU Competition, Market Consolidation, and Market Disruption In the event of restrictions or non-approval of ethanol for biocidal use under PT1, PT2, and PT4, the EU market would likely experience significant structural changes. A key consequence would be market consolidation, as small and medium-sized enterprises (SMEs)—which make up a large portion of the ethanol-based product supply chain—may struggle to meet new regulatory requirements or absorb the costs of reformulation.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	A-Letter Pt2.docx
Attachments (confidential information)	
Justification for confidential attachment	

Comment 336	2025/04/30 17:54
Country	Spain
Name of organization/institution	Alcoholes Montplet S.A.U.
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	
Product Type	1,2,4
Alternative Identity and Properties	Identity of the Active Substance Chemical Name: Propan-2-ol Synonyms: Isopropyl alcohol, 2-propanol, i-PrOH, sec-propyl alcohol CAS Number: 67-63-0 Molecular Formula:

	<chem>C3H8O</chem> EC Number: 200-661-7 IUPAC Name: Propan-2-ol UN Number: 1219 3. Physical and Chemical Properties Appearance: Colourless, clear liquid Odour: Mild, characteristic alcoholic odour Melting Point: -89°C Boiling Point: 82.6°C Density: 0.786 g/cm^3 at 20°C Solubility: Completely miscible with water, ethanol, acetone, chloroform, and benzene Flash Point: 12°C (closed cup) Autoignition Temperature: 399°C Explosive Limits: Lower: 2%, Upper: 12.7% (v/v) Vapour Pressure: 42.6 hPa at 20°C Refractive Index: 1.379 at 20°C 4. Physical Hazards and Respective Characteristics Flammability: Highly flammable liquid and vapour Explosive Potential: Vapours can form explosive mixtures with air Reactivity: Reacts exothermically with alkaline earth metals and alkali metals, releasing hydrogen; violent reactions possible with strong oxidising agents 5. Methods of Detection and Identification Analytical Techniques: Gas Chromatography (GC) High- Performance Liquid Chromatography (HPLC) Infrared (IR) Spectroscopy Nuclear Magnetic Resonance (NMR) Spectroscopy Detection Limits: The odour threshold is approximately 0.04 ppm, facilitating detection by smell at low concentrations 6. Effectiveness Against Target Organisms Antimicrobial Activity: Exhibits broad-spectrum antimicrobial properties, effective against bacteria, fungi, and viruses Applications: Hand Sanitisers: Effective in reducing microbial load Surface Disinfectants: Used in various concentrations for decontamination Industrial Cleaning: Employed in cleaning and degreasing processes Efficacy Considerations: The effectiveness can be influenced by concentration, contact time, and presence of organic matter 7. Intended Uses and Exposure Primary Uses: Solvent in pharmaceuticals and cosmetics Intermediate in chemical synthesis Antiseptic in healthcare settings Cleaning agent in industrial applications Exposure Routes: Occupational: Inhalation, dermal contact, and accidental ingestion during manufacturing and application General Population: Inhalation of vapours, dermal contact with consumer products, and ingestion through contaminated food or beverages Exposure Limits: NIOSH REL: TWA 400 ppm (980 mg/m^3), STEL 500 ppm ($1,225\text{ mg/m}^3$) OSHA PEL: TWA 400 ppm (980 mg/m^3) 11. Measures Necessary to Protect Humans, Animals, and the Environment Personal Protective Equipment (PPE): Respiratory Protection: Use of appropriate respirators when concentrations exceed occupational exposure limits Skin Protection: Protective gloves and clothing to prevent dermal exposure Eye Protection: Safety goggles or face shields to prevent eye contact Environmental Protection: Prevent release into water bodies to avoid aquatic toxicity Implement spill

	containment and clean-up procedures First Aid Measures: Inhalation: Move to fresh air; seek medical attention if symptoms persist Skin Contact: Wash with soap and water; remove contaminated clothing Eye Contact: Rinse immediately with plenty of water for at least 15 minutes; seek medical attention Ingestion: Do not induce vomiting; seek medical attention immediately 12. Classification, Labelling, and Packaging GHS Classification: Flammable Liquids: Category 2 Serious Eye Damage/Eye Irritation: Category 2 Specific Target Organ Toxicity – Single Exposure: Category 3 (Central Nervous System) Signal Word: Danger Hazard Statements: H225: Highly flammable liquid and vapour H319: Causes serious eye irritation H336: May cause drowsiness or dizziness Precautionary Statements: P210: Keep away from heat/sparks/open flames/hot surfaces. — No smoking. P233: Keep container tightly closed. P280: Wear protective gloves/protective clothing/eye protection/face protection. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Packaging Group: II (Moderate danger) Transport Information: UN Number: 1219 Hazard Class: 3 Packing Group: II
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Spectrum and Efficacy: propanols offer limited effectiveness against a wide range of pathogens for which ethanol provides superior efficacy, including non-enveloped viruses such as Murine Norovirus, Poliovirus type 1, and Adenoviruses. This makes propanols less relevant compared to ethanol, which remains indispensable in high-hygiene settings. Propanols have slower drying times than ethanol therefore posing greater challenges for food hygiene applications; in contrast, ethanol's quick evaporation and non-residual nature make it particularly efficient in food-contact environments, together with its broad-spectrum efficacy which allows for the use of a single disinfectant across multiple pathogens. In PT4 applications (food and feed), ethanol leaves no harmful residues, ensuring safe use on food-contact surfaces and compliance with EU regulations and HACCP protocols
Information above is confidential	
Justification for confidentiality	

Economic Feasibility	Small producers that rely on ethanol as a core product face considerable challenges. Transition costs and loss of market share to larger companies with established production capabilities for alternatives could threaten their business viability. In some cases, companies may be forced to exit the market due to the technical and economic infeasibility of substitution. Overall, the substitution of ethanol is expected to require an investment ranging from €1.25 million to several million euros per company, excluding the costs of active substance R&D, which are often in the millions as well. The high costs, combined with lengthy timelines, highlight the complexity of transitioning away from ethanol in biocidal products. •The transition to alternative substances often requires substantial investments to adapt manufacturing facilities. For example, converting tank systems to handle new substances can cost up to €500,000. In cases where entirely new production sites are needed, the costs can increase significantly, potentially exceeding several million euros.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Propanols can increase skin irritation with frequent use due to slower evaporation rates, making them less suitable than ethanol for repeated disinfection in healthcare, education, and other public environments. Ethanol however is suitable for use in both professional and private environments.
Information above is confidential	
Justification for confidentiality	
Availability	In terms of availability and supply chain, propanols have few suppliers, raising concerns about their ability to meet high demand during critical times. On the other hand, ethanol benefits from a well-established, diversified supply network across the EU, which ensures stable and reliable access. Propanols have higher production costs and are less widely available, making them less cost-effective. Ethanol's established supply chain ensures stability, particularly during periods of crisis, such as the COVID-19 pandemic.
Information above is confidential	
Justification for confidentiality	

Conclusion on suitability and availability of the alternative	Larger, diversified companies are better equipped to adapt to ethanol restrictions, with resources for R&D, alternative formulations, and regulatory compliance. Smaller or niche businesses, however, would face disproportionate financial and operational burdens, potentially leading to market exits or consolidations. Regulatory uncertainty—especially from the CLP classification process—may erode confidence in ethanol-based products among consumers, healthcare providers, and industry users. This could reduce usage, compromise hygiene standards, and heighten infection risks, particularly in critical sectors. Wider Socioeconomic Impacts on Third Countries Non-approval of ethanol in the EU would also impact third countries, especially emerging economies like India, Brazil, South Africa, Argentina, and Kenya, which rely on EU exports for hygiene and infection control. The EU supplies high-quality, cost-effective ethanol products. Disruptions would: • Break global supply chains, forcing reliance on costlier or less effective alternatives. • Increase trade barriers for low-income countries unable to quickly adapt. • Undermine public health, especially during pandemics, where ethanol is vital for disinfection. • Raise prices and reduce availability, hitting vulnerable populations hardest. Sectors such as healthcare, tourism, and public services would face increased costs and reduced hygiene capacity. The combined impact could deepen global health inequalities, underscoring the need for coordinated international responses.
Information above is confidential	
Justification for confidentiality	
Other comments	The ethanol-based disinfectant industry is a well-established and growing sector within the European Economic Area (EEA), supporting: • Thousands of jobs, particularly in SMEs. • A resilient regional supply chain spanning production, formulation, packaging, and distribution. • A strong export and intra-EU trade network, particularly in medical and hygiene-related products. Restricting ethanol would result in: • Disruption of production lines, as companies would be forced to seek, validate, and integrate less effective or more expensive alternatives. • Increased operational costs, with knock-on effects for healthcare providers, food safety operators, and industrial facilities. • Barriers for SMEs, which may lack the resources to invest in reformulation or meet new compliance requirements, risking closures or market exit. The economic burden would ultimately be passed on to

	consumers, with higher retail prices for disinfectants and hygiene products, disproportionately affecting low-income populations. Public Perception and Regulatory Trust Ethanol enjoys high public acceptance due to its widespread use and proven track record, especially during the COVID-19 pandemic. A restriction or ban on ethanol in hygiene contexts, while its use in alcoholic beverages remains permitted, would appear contradictory to the public and risk: • Undermining trust in EU regulatory decisions. • Fostering confusion and skepticism about risk assessment processes. • Jeopardizing compliance with public health recommendations. This perceptual disconnect could have long-term impacts on public confidence in regulatory institutions and health guidance. Impact on the Market: EU Competition, Market Consolidation, and Market Disruption In the event of restrictions or non-approval of ethanol for biocidal use under PT1, PT2, and PT4, the EU market would likely experience significant structural changes. A key consequence would be market consolidation, as small and medium-sized enterprises (SMEs)—which make up a large portion of the ethanol-based product supply chain—may struggle to meet new regulatory requirements or absorb the costs of reformulation.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	A-Letter Pt4.docx
Attachments (confidential information)	
Justification for confidential attachment	

Comment 337	2025/04/30 17:59
Country	Spain
Name of organization/institution	Alcoholes Montplet S.A.U.

I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	
Product Type	1,2,4
Alternative Identity and Properties	Effectiveness Against Target Organisms Antimicrobial Activity: Exhibits broad-spectrum antimicrobial properties, effective against bacteria, fungi, and viruses Applications: Hand Sanitisers: Effective in reducing microbial load Surface Disinfectants: Used in various concentrations for decontamination Industrial Cleaning: Employed in cleaning and degreasing processes Efficacy Considerations: The effectiveness can be influenced by concentration, contact time, and presence of organic matter Intended Uses and Exposure Primary Uses: Solvent in pharmaceuticals and cosmetics Intermediate in chemical synthesis Antiseptic in healthcare settings Cleaning agent in industrial applications Exposure Routes: Occupational: Inhalation, dermal contact, and accidental ingestion during manufacturing and application General Population: Inhalation of vapours, dermal contact with consumer products, and ingestion through contaminated food or beverages Exposure Limits: NIOSH REL: TWA 200 ppm (500 mg/m³), STEL 250 ppm (625 mg/m³) [skin] OSHA PEL: TWA 200 ppm (500 mg/m³) Measures Necessary to Protect Humans, Animals, and the Environment Personal Protective Equipment (PPE): Respiratory Protection: Use of appropriate respirators when concentrations exceed occupational exposure limits Skin Protection: Protective gloves and clothing to prevent dermal exposure Eye Protection: Safety goggles or face shields to prevent eye contact Environmental Protection: Prevent release into water bodies to avoid aquatic toxicity Implement spill containment and clean-up procedures First Aid Measures: Inhalation: Move to fresh air; seek medical attention if symptoms persist Skin Contact: Wash with soap and water; remove contaminated clothing Eye Contact: Rinse immediately with plenty of water for at least 15 minutes; seek medical attention Ingestion: Do not induce vomiting; seek medical attention immediately Classification, Labelling, and Packaging GHS Classification: Flammable Liquids: Category 2 Serious Eye Damage/Eye Irritation: Category 1 Specific Target Organ Toxicity – Single Exposure: Category 3 (Central Nervous System) Signal Word: Danger Hazard Statements: H225: Highly flammable liquid and vapour H318: Causes serious eye

	damage H336: May cause drowsiness or dizziness Precautionary Statements: P210: Keep away from heat/sparks/open flames/hot surfaces. — No smoking. P233: Keep container tightly closed. P280: Wear protective gloves/protective clothing/eye protection/face protection. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Packaging Group: II (Moderate danger) Transport Information: UN Number: 1274 Hazard Class: 3 Packing Group: II
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Spectrum and Efficacy: propanols offer limited effectiveness against a wide range of pathogens for which ethanol provides superior efficacy, including non-enveloped viruses such as Murine Norovirus, Poliovirus type 1, and Adenoviruses. This makes propanols less relevant compared to ethanol, which remains indispensable in high-hygiene settings.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Small producers that rely on ethanol as a core product face considerable challenges. Transition costs and loss of market share to larger companies with established production capabilities for alternatives could threaten their business viability. In some cases, companies may be forced to exit the market due to the technical and economic infeasibility of substitution. Overall, the substitution of ethanol is expected to require an investment ranging from €1.25 million to several million euros per company, excluding the costs of active substance R&D, which are often in the millions as well. The high costs, combined with lengthy timelines, highlight the complexity of transitioning away from ethanol in biocidal products. •The transition to alternative substances often requires substantial investments to adapt manufacturing facilities. For example, converting tank systems to handle new substances can cost up to €500,000. In cases where entirely new production sites are needed, the costs can increase significantly, potentially exceeding several million euros.

Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Propan-1-ol is restricted due to its classification as H318 (serious eye damage), limiting its use in non-professional settings. Ethanol however is suitable for use in both professional and private environments. Propanols can increase skin irritation with frequent use due to slower evaporation rates, making them less suitable than ethanol for repeated disinfection in healthcare, education, and other public environments.
Information above is confidential	
Justification for confidentiality	
Availability	In terms of availability and supply chain, propanols have few suppliers, raising concerns about their ability to meet high demand during critical times. On the other hand, ethanol benefits from a well-established, diversified supply network across the EU, which ensures stable and reliable access. Propanols have higher production costs and are less widely available, making them less cost-effective. Ethanol's established supply chain ensures stability, particularly during periods of crisis, such as the COVID-19 pandemic.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Larger, diversified companies are better equipped to adapt to ethanol restrictions, with resources for R&D, alternative formulations, and regulatory compliance. Smaller or niche businesses, however, would face disproportionate financial and operational burdens, potentially leading to market exits or consolidations. Regulatory uncertainty—especially from the CLP classification process—may erode confidence in ethanol-based products among consumers, healthcare providers, and industry users. This could reduce usage, compromise hygiene standards, and heighten infection risks, particularly in critical sectors. Wider Socioeconomic Impacts on Third Countries Non-approval of ethanol in the EU would also impact third countries, especially emerging economies like India, Brazil, South Africa, Argentina, and Kenya, which rely on EU exports for hygiene and infection control. The EU supplies high-quality, cost-effective ethanol

	products. Disruptions would: • Break global supply chains, forcing reliance on costlier or less effective alternatives. • Increase trade barriers for low-income countries unable to quickly adapt. • Undermine public health, especially during pandemics, where ethanol is vital for disinfection. • Raise prices and reduce availability, hitting vulnerable populations hardest. Sectors such as healthcare, tourism, and public services would face increased costs and reduced hygiene capacity. The combined impact could deepen global health inequalities, underscoring the need for coordinated international responses.
Information above is confidential	
Justification for confidentiality	
Other comments	The ethanol-based disinfectant industry is a well-established and growing sector within the European Economic Area (EEA), supporting: • Thousands of jobs, particularly in SMEs. • A resilient regional supply chain spanning production, formulation, packaging, and distribution. • A strong export and intra-EU trade network, particularly in medical and hygiene-related products. Restricting ethanol would result in: • Disruption of production lines, as companies would be forced to seek, validate, and integrate less effective or more expensive alternatives. • Increased operational costs, with knock-on effects for healthcare providers, food safety operators, and industrial facilities. • Barriers for SMEs, which may lack the resources to invest in reformulation or meet new compliance requirements, risking closures or market exit. The economic burden would ultimately be passed on to consumers, with higher retail prices for disinfectants and hygiene products, disproportionately affecting low-income populations. Public Perception and Regulatory Trust Ethanol enjoys high public acceptance due to its widespread use and proven track record, especially during the COVID-19 pandemic. A restriction or ban on ethanol in hygiene contexts, while its use in alcoholic beverages remains permitted, would appear contradictory to the public and risk: • Undermining trust in EU regulatory decisions. • Fostering confusion and skepticism about risk assessment processes. • Jeopardizing compliance with public health recommendations. This perceptual disconnect could have long-term impacts on public confidence in regulatory institutions and health guidance. Impact on the Market: EU Competition, Market Consolidation, and Market Disruption In the event of restrictions or non-approval of ethanol for

	biocidal use under PT1, PT2, and PT4, the EU market would likely experience significant structural changes. A key consequence would be market consolidation, as small and medium-sized enterprises (SMEs)—which make up a large portion of the ethanol-based product supply chain—may struggle to meet new regulatory requirements or absorb the costs of reformulation.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	A-Letter PT1.docx
Attachments (confidential information)	
Justification for confidential attachment	

Comment 338	2025/04/30 18:05
Country	Spain
Name of organization/institution	Alcoholos Montplet S.A.U.
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	
Product Type	1,2,4
Alternative Identity and Properties	Identity of the Active Substance Chemical Name: Propan-1-ol Synonyms: n-Propanol, n-PrOH, propyl alcohol, ethyl carbinol CAS Number: 71-23-8 Molecular Formula: C ₃ H ₈ O EC Number: 200-746-9 IUPAC Name: Propan-1-ol UN Number: 1274 GHS Classification: Flammable liquid (Category 2), Serious eye damage (Category 1), Specific target organ toxicity – single exposure (Category 3) Physical and Chemical Properties Appearance: Colourless, clear liquid Odour: Mild, alcohol-like Melting Point: –127 °C

	Boiling Point: 97 °C Density: 0.804 g/cm³ at 25 °C Solubility: Completely miscible with water Vapour Pressure: 19.3 hPa at 20 °C Flash Point: 22 °C (closed cup) Autoignition Temperature: 400 °C Explosive Limits: Lower: 2.1%, Upper: 13.7% (v/v) Partition Coefficient (log P): 0.2 at 25 °C Viscosity: 2.21 mPa·s at 20 °C Refractive Index: 1.384 at 20 °C pH: 8.5 at 200 g/L in water at 20 °C Physical Hazards and Respective Characteristics Flammability: Highly flammable liquid and vapour Explosive Potential: Vapours can form explosive mixtures with air Autoignition Temperature: 400 °C Vapour Density: 2.07 (heavier than air), posing a risk of accumulation in low-lying areas Reactivity: Reacts exothermically with alkaline earth metals and alkali metals, releasing hydrogen; violent reactions possible with strong oxidising agents Methods of Detection and Identification Analytical Techniques: Gas Chromatography (GC) High-Performance Liquid Chromatography (HPLC) Infrared (IR) Spectroscopy Nuclear Magnetic Resonance (NMR) Spectroscopy Detection Limits: The odour threshold is approximately 0.094 ppm, facilitating detection by smell at low concentrations Effectiveness Against Target Organisms Antimicrobial Activity: Exhibits broad-spectrum antimicrobial properties, effective against bacteria, fungi, and viruses Applications: Hand Sanitisers: Effective in reducing microbial load Surface Disinfectants: Used in various concentrations for decontamination Industrial Cleaning: Employed in cleaning and degreasing processes Efficacy Considerations: The effectiveness can be influenced by concentration, contact time, and presence of organic matter Intended Uses and Exposure Primary Uses: Solvent in pharmaceuticals and cosmetics Intermediate in chemical synthesis Antiseptic in healthcare settings Cleaning agent in industrial applications Exposure Routes: Occupational: Inhalation, dermal contact, and accidental ingestion during manufacturing and application General Population: Inhalation of vapours, dermal contact with consumer products, and ingestion through contaminated food or beverages Exposure Limits: NIOSH REL: TWA 200 ppm (500 mg/m³), STEL 250 ppm (625 mg/m³) [skin] OSHA PEL: TWA 200 ppm (500 mg/m³) Measures Necessary to Protect Humans, Animals, and the Environment Personal Protective Equipment (PPE): Respiratory Protection: Use of appropriate respirators when concentrations exceed occupational exposure limits Skin Protection: Protective gloves and clothing to prevent dermal exposure Eye Protection: Safety goggles or face shields to prevent eye contact Environmental Protection: Prevent release into water bodies to avoid aquatic toxicity Implement spill containment and clean-up procedures First

	Aid Measures: Inhalation: Move to fresh air; seek medical attention if symptoms persist Skin Contact: Wash with soap and water; remove contaminated clothing Eye Contact: Rinse immediately with plenty of water for at least 15 minutes; seek medical attention immediately Ingestion: Do not induce vomiting; seek medical attention immediately Classification, Labelling, and Packaging GHS Classification: Flammable Liquids: Category 2 Serious Eye Damage/Eye Irritation: Category 1 Specific Target Organ Toxicity – Single Exposure: Category 3 (Central Nervous System) Signal Word: Danger Hazard Statements: H225: Highly flammable liquid and vapour H318: Causes serious eye damage H336: May cause drowsiness or dizziness Precautionary Statements: P210: Keep away from heat/sparks/open flames/hot surfaces. — No smoking. P233: Keep container tightly closed. P280: Wear protective gloves/protective clothing/eye protection/face protection. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Packaging Group: II (Moderate danger) Transport Information: UN Number: 1274 Hazard Class: 3 Packing Group: II
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Spectrum and Efficacy: propanols offer limited effectiveness against a wide range of pathogens for which ethanol provides superior efficacy, including non-enveloped viruses such as Murine Norovirus, Poliovirus type 1, and Adenoviruses. This makes propanols less relevant compared to ethanol, which remains indispensable in high-hygiene settings. Propan-1-ol is approved under the BPR, thus and alternative for PT2 uses. However, its flammability (H225) and potential for causing eye damage (H318) must be carefully managed, especially when used in non-professional uses. The biocidal products for the non-professional use are restricted to pre-soaked wipes.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Small producers that rely on ethanol as a core product face considerable challenges. Transition costs and loss of market share to larger companies with established production capabilities for alternatives could threaten their business

	viability. In some cases, companies may be forced to exit the market due to the technical and economic infeasibility of substitution. Overall, the substitution of ethanol is expected to require an investment ranging from €1.25 million to several million euros per company, excluding the costs of active substance R&D, which are often in the millions as well. The high costs, combined with lengthy timelines, highlight the complexity of transitioning away from ethanol in biocidal products. •The transition to alternative substances often requires substantial investments to adapt manufacturing facilities. For example, converting tank systems to handle new substances can cost up to €500,000. In cases where entirely new production sites are needed, the costs can increase significantly, potentially exceeding several million euros.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Propan-1-ol is restricted due to its classification as H318 (serious eye damage), limiting its use in non-professional settings. Ethanol however is suitable for use in both professional and private environments. Propanols can increase skin irritation with frequent use due to slower evaporation rates, making them less suitable than ethanol for repeated disinfection in healthcare, education, and other public environments.
Information above is confidential	
Justification for confidentiality	
Availability	In terms of availability and supply chain, propanols have few suppliers, raising concerns about their ability to meet high demand during critical times. On the other hand, ethanol benefits from a well-established, diversified supply network across the EU, which ensures stable and reliable access. Propanols have higher production costs and are less widely available, making them less cost-effective. Ethanol's established supply chain ensures stability, particularly during periods of crisis, such as the COVID-19 pandemic.
Information above is confidential	
Justification for confidentiality	

Conclusion on suitability and availability of the alternative	Larger, diversified companies are better equipped to adapt to ethanol restrictions, with resources for R&D, alternative formulations, and regulatory compliance. Smaller or niche businesses, however, would face disproportionate financial and operational burdens, potentially leading to market exits or consolidations. Regulatory uncertainty—especially from the CLP classification process—may erode confidence in ethanol-based products among consumers, healthcare providers, and industry users. This could reduce usage, compromise hygiene standards, and heighten infection risks, particularly in critical sectors. Wider Socioeconomic Impacts on Third Countries Non-approval of ethanol in the EU would also impact third countries, especially emerging economies like India, Brazil, South Africa, Argentina, and Kenya, which rely on EU exports for hygiene and infection control. The EU supplies high-quality, cost-effective ethanol products. Disruptions would: • Break global supply chains, forcing reliance on costlier or less effective alternatives. • Increase trade barriers for low-income countries unable to quickly adapt. • Undermine public health, especially during pandemics, where ethanol is vital for disinfection. • Raise prices and reduce availability, hitting vulnerable populations hardest. Sectors such as healthcare, tourism, and public services would face increased costs and reduced hygiene capacity. The combined impact could deepen global health inequalities, underscoring the need for coordinated international responses.
Information above is confidential	
Justification for confidentiality	
Other comments	The ethanol-based disinfectant industry is a well-established and growing sector within the European Economic Area (EEA), supporting: • Thousands of jobs, particularly in SMEs. • A resilient regional supply chain spanning production, formulation, packaging, and distribution. • A strong export and intra-EU trade network, particularly in medical and hygiene-related products. Restricting ethanol would result in: • Disruption of production lines, as companies would be forced to seek, validate, and integrate less effective or more expensive alternatives. • Increased operational costs, with knock-on effects for healthcare providers, food safety operators, and industrial facilities. • Barriers for SMEs, which may lack the resources to invest in reformulation or meet new compliance requirements, risking closures or market exit. The economic burden would ultimately be passed on to

	consumers, with higher retail prices for disinfectants and hygiene products, disproportionately affecting low-income populations. Public Perception and Regulatory Trust Ethanol enjoys high public acceptance due to its widespread use and proven track record, especially during the COVID-19 pandemic. A restriction or ban on ethanol in hygiene contexts, while its use in alcoholic beverages remains permitted, would appear contradictory to the public and risk: • Undermining trust in EU regulatory decisions. • Fostering confusion and skepticism about risk assessment processes. • Jeopardizing compliance with public health recommendations. This perceptual disconnect could have long-term impacts on public confidence in regulatory institutions and health guidance. Impact on the Market: EU Competition, Market Consolidation, and Market Disruption In the event of restrictions or non-approval of ethanol for biocidal use under PT1, PT2, and PT4, the EU market would likely experience significant structural changes. A key consequence would be market consolidation, as small and medium-sized enterprises (SMEs)—which make up a large portion of the ethanol-based product supply chain—may struggle to meet new regulatory requirements or absorb the costs of reformulation.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	A-Letter Pt2.docx
Attachments (confidential information)	
Justification for confidential attachment	

Comment 339	2025/04/30 18:08
Country	Spain
Name of organization/institution	

I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	
Product Type	1,2,4
Alternative Identity and Properties	Identity of the Active Substance Chemical Name: Propan-1-ol Synonyms: n-Propanol, n-PrOH, propyl alcohol, ethyl carbinol CAS Number: 71-23-8 Molecular Formula: C₃H₈O EC Number: 200-746-9 IUPAC Name: Propan-1-ol UN Number: 1274 GHS Classification: Flammable liquid (Category 2), Serious eye damage (Category 1), Specific target organ toxicity – single exposure (Category 3) Physical and Chemical Properties Appearance: Colourless, clear liquid Odour: Mild, alcohol-like Melting Point: –127 °C Boiling Point: 97 °C Density: 0.804 g/cm³ at 25 °C Solubility: Completely miscible with water Vapour Pressure: 19.3 hPa at 20 °C Flash Point: 22 °C (closed cup) Autoignition Temperature: 400 °C Explosive Limits: Lower: 2.1%, Upper: 13.7% (v/v) Partition Coefficient (log P): 0.2 at 25 °C Viscosity: 2.21 mPa·s at 20 °C Refractive Index: 1.384 at 20 °C pH: 8.5 at 200 g/L in water at 20 °C Physical Hazards and Respective Characteristics Flammability: Highly flammable liquid and vapour Explosive Potential: Vapours can form explosive mixtures with air Autoignition Temperature: 400 °C Vapour Density: 2.07 (heavier than air), posing a risk of accumulation in low-lying areas Reactivity: Reacts exothermically with alkaline earth metals and alkali metals, releasing hydrogen; violent reactions possible with strong oxidising agents Methods of Detection and Identification Analytical Techniques: Gas Chromatography (GC) High-Performance Liquid Chromatography (HPLC) Infrared (IR) Spectroscopy Nuclear Magnetic Resonance (NMR) Spectroscopy Detection Limits: The odour threshold is approximately 0.094 ppm, facilitating detection by smell at low concentrations Effectiveness Against Target Organisms Antimicrobial Activity: Exhibits broad-spectrum antimicrobial properties, effective against bacteria, fungi, and viruses Applications: Hand Sanitisers: Effective in reducing microbial load Surface Disinfectants: Used in various concentrations for decontamination Industrial Cleaning: Employed in cleaning and degreasing processes Efficacy Considerations: The effectiveness can be influenced by concentration, contact time, and presence of organic matter Intended Uses and Exposure Primary Uses: Solvent in pharmaceuticals and cosmetics Intermediate in

	chemical synthesis Antiseptic in healthcare settings Cleaning agent in industrial applications Exposure Routes: Occupational: Inhalation, dermal contact, and accidental ingestion during manufacturing and application General Population: Inhalation of vapours, dermal contact with consumer products, and ingestion through contaminated food or beverages Exposure Limits: NIOSH REL: TWA 200 ppm (500 mg/m³), STEL 250 ppm (625 mg/m³) [skin] OSHA PEL: TWA 200 ppm (500 mg/m³) Measures Necessary to Protect Humans, Animals, and the Environment Personal Protective Equipment (PPE): Respiratory Protection: Use of appropriate respirators when concentrations exceed occupational exposure limits Skin Protection: Protective gloves and clothing to prevent dermal exposure Eye Protection: Safety goggles or face shields to prevent eye contact Environmental Protection: Prevent release into water bodies to avoid aquatic toxicity Implement spill containment and clean-up procedures First Aid Measures: Inhalation: Move to fresh air; seek medical attention if symptoms persist Skin Contact: Wash with soap and water; remove contaminated clothing Eye Contact: Rinse immediately with plenty of water for at least 15 minutes; seek medical attention immediately Ingestion: Do not induce vomiting; seek medical attention immediately Classification, Labelling, and Packaging GHS Classification: Flammable Liquids: Category 2 Serious Eye Damage/Eye Irritation: Category 1 Specific Target Organ Toxicity – Single Exposure: Category 3 (Central Nervous System) Signal Word: Danger Hazard Statements: H225: Highly flammable liquid and vapour H318: Causes serious eye damage H336: May cause drowsiness or dizziness Precautionary Statements: P210: Keep away from heat/sparks/open flames/hot surfaces. — No smoking. P233: Keep container tightly closed. P280: Wear protective gloves/protective clothing/eye protection/face protection. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Packaging Group: II (Moderate danger) Transport Information: UN Number: 1274 Hazard Class: 3 Packing Group: II
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Spectrum and Efficacy: propanols offer limited effectiveness against a wide range of pathogens for which ethanol provides superior efficacy, including non-enveloped viruses

	such as Murine Norovirus, Poliovirus type 1, and Adenoviruses. This makes propanols less relevant compared to ethanol, which remains indispensable in high-hygiene settings.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Small producers that rely on ethanol as a core product face considerable challenges. Transition costs and loss of market share to larger companies with established production capabilities for alternatives could threaten their business viability. In some cases, companies may be forced to exit the market due to the technical and economic infeasibility of substitution. Overall, the substitution of ethanol is expected to require an investment ranging from €1.25 million to several million euros per company, excluding the costs of active substance R&D, which are often in the millions as well. The high costs, combined with lengthy timelines, highlight the complexity of transitioning away from ethanol in biocidal products. •The transition to alternative substances often requires substantial investments to adapt manufacturing facilities. For example, converting tank systems to handle new substances can cost up to €500,000. In cases where entirely new production sites are needed, the costs can increase significantly, potentially exceeding several million euros.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Propan-1-ol is restricted due to its classification as H318 (serious eye damage), limiting its use in non-professional settings. Ethanol however is suitable for use in both professional and private environments. Propanols can increase skin irritation with frequent use due to slower evaporation rates, making them less suitable than ethanol for repeated disinfection in healthcare, education, and other public environments.
Information above is confidential	
Justification for confidentiality	

Availability	In terms of availability and supply chain, propanols have few suppliers, raising concerns about their ability to meet high demand during critical times. on the other hand, ethanol benefits from a well-established, diversified supply network across the EU, which ensures stable and reliable access. Propanols have higher production costs and are less widely available, making them less cost-effective. Ethanol's established supply chain ensures stability, particularly during periods of crisis, such as the COVID-19 pandemic.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Larger, diversified companies are better equipped to adapt to ethanol restrictions, with resources for R&D, alternative formulations, and regulatory compliance. Smaller or niche businesses, however, would face disproportionate financial and operational burdens, potentially leading to market exits or consolidations. Regulatory uncertainty—especially from the CLP classification process—may erode confidence in ethanol-based products among consumers, healthcare providers, and industry users. This could reduce usage, compromise hygiene standards, and heighten infection risks, particularly in critical sectors. Wider Socioeconomic Impacts on Third Countries Non-approval of ethanol in the EU would also impact third countries, especially emerging economies like India, Brazil, South Africa, Argentina, and Kenya, which rely on EU exports for hygiene and infection control. The EU supplies high-quality, cost-effective ethanol products. Disruptions would: • Break global supply chains, forcing reliance on costlier or less effective alternatives. • Increase trade barriers for low-income countries unable to quickly adapt. • Undermine public health, especially during pandemics, where ethanol is vital for disinfection. • Raise prices and reduce availability, hitting vulnerable populations hardest. Sectors such as healthcare, tourism, and public services would face increased costs and reduced hygiene capacity. The combined impact could deepen global health inequalities, underscoring the need for coordinated international responses.
Information above is confidential	
Justification for confidentiality	
Other comments	The ethanol-based disinfectant industry is a well-established and growing sector within the European Economic Area

	(EEA), supporting: • Thousands of jobs, particularly in SMEs. • A resilient regional supply chain spanning production, formulation, packaging, and distribution. • A strong export and intra-EU trade network, particularly in medical and hygiene-related products. Restricting ethanol would result in: • Disruption of production lines, as companies would be forced to seek, validate, and integrate less effective or more expensive alternatives. • Increased operational costs, with knock-on effects for healthcare providers, food safety operators, and industrial facilities. • Barriers for SMEs, which may lack the resources to invest in reformulation or meet new compliance requirements, risking closures or market exit. The economic burden would ultimately be passed on to consumers, with higher retail prices for disinfectants and hygiene products, disproportionately affecting low-income populations. Public Perception and Regulatory Trust Ethanol enjoys high public acceptance due to its widespread use and proven track record, especially during the COVID-19 pandemic. A restriction or ban on ethanol in hygiene contexts, while its use in alcoholic beverages remains permitted, would appear contradictory to the public and risk: • Undermining trust in EU regulatory decisions. • Fostering confusion and skepticism about risk assessment processes. • Jeopardizing compliance with public health recommendations. This perceptual disconnect could have long-term impacts on public confidence in regulatory institutions and health guidance. Impact on the Market: EU Competition, Market Consolidation, and Market Disruption In the event of restrictions or non-approval of ethanol for biocidal use under PT1, PT2, and PT4, the EU market would likely experience significant structural changes. A key consequence would be market consolidation, as small and medium-sized enterprises (SMEs)—which make up a large portion of the ethanol-based product supply chain—may struggle to meet new regulatory requirements or absorb the costs of reformulation.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	A-Letter Pt4.docx
Attachments (confidential information)	

Justification for confidential attachment	

Comment 340	2025/04/30 18:13
Country	Belgium
Name of organization/institution	Eres-Sapoli.nv
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	

Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	The evaluation of ethanol as active substance should be a well-balanced risk based evaluation. The unique combination of advantages ethanol offers versus the challenges the alternatives pose have to be taken into account in this evaluation. Therefore, we plea the evaluation takes into account amongst others the effectiveness, ease in use and the well-established production and supply chain of a sustainable active substance when evaluating ethanol. All data included in the classification study must reflect the proper route and dose of exposure in order to adequately assess the risk of ethanol as active substance and compare it with the alternative substances. An aggravated classification based on data from ingestion and intoxication when no relevant risk has been proven for the route and doses of exposure appropriate for the use biocidal products (PT1. 2 and 4) would render ethanol unavailable as active substance. This would be detrimental to both public and health care sector (and other sectors such as food, feed and livestock, ...). It would leave Europe vulnerable in many different ways. The consequences are not to be overseen, not just for infection control in the occurrence of an epidemic / pandemic, but also in day to day life.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	Kramer A, Arvand M, Christiansen B, Dancer S, Eggers M, Exner M, Müller D, Mutters NT, Schwebke I, Pittet D. Ethanol is indispensable for virucidal hand antisepsis: memorandum from the alcohol-based hand rub (ABHR) Task Force, WHO Collaborating Centre on Patient Safety, and the Commission for Hospital Hygiene and Infection Prevention (KRINKO), Robert Koch Institute, Berlin, Germany. Antimicrob Resist Infect Control. 2022 WHO Guidelines on Hand Hygiene in Health Care: First Global Patient Safety Challenge Clean Care Is Safer Care. Geneva:

	World Health Organization; 2009. 12, WHO-recommended handrub formulations.
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 341	2025/04/30 18:32
Country	France
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	See enclosed contribution.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	

Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	See enclosed contribution.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	SNIAA - Contribution to ECHA Consultation - Ethanol 30042025.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 342	2025/04/30 18:37
Country	Portugal
Name of organization/institution	AIC – Associação dos Industriais de Cosmética, Perfumaria e Higiene Corporal

I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	AIC is the association representing the cosmetics and personal care industry in Portugal. Our membership includes 74 companies (from SMEs to multinationals), for a market value of 1.800 bn euro that contribute for the 96 bn euro in total Europe. AIC wishes to stress the significant implications of classifying ethanol as a carcinogenic, mutagenic or toxic for reproduction (CMR) substance and urges a comprehensive review of the balance between negative and positive consequences of CMR classification of ethanol, particularly concerning its downstream uses in the cosmetics sector. Ethanol used in cosmetic products is denatured, i.e. unfit for consumption. By that alone, a consumer risk of (regular or excessive) oral consumption is negated and any CMR property assigned to ethanol as pure chemical substance, based on oral intake, would not be relevant to cosmetic use. AIC believes that it's crucial to detach the hazard classification of ethanol (harmonized classification under the CLP Regulation) from its ongoing evaluation as a biocidal active substance. Given the unique context of ethanol use in cosmetics, AIC favors a tailored approach that considers exposure routes, specific uses/applications and safety profile.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	

Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Classifying ethanol as a CMR substance offers no tangible benefits to consumers, and, on the contrary, can cause unnecessary uncertainty and concerns with consumers that have used ethanol-based products for decades. The primary health concerns associated with ethanol arise from its consumption in alcoholic beverages, not its use in cosmetics. A CMR Classification with a subsequent ban or severe restriction for ethanol would be disproportionate given its safe use in cosmetics and the lack of suitable alternatives. Ethanol serves multiple functions in cosmetics (ANTIFOAMING, ANTIMICROBIAL, ASTRINGENT, FRAGRANCE, SOLVENT, VISCOSITY CONTROLLING) that cannot be easily replaced by a single ingredient. Its uses include – but are not limited to – fine fragrances, after-shave products, sunscreen, make-up, mouthwashes, hair care products and skincare products. Ethanol's intrinsic volatile and antimicrobial properties make it extremely difficult to replace with a single ingredient. The classification of ethanol as a CMR substance would have cascading effects on the cosmetics sector, potentially disrupting sometimes centuries-old products, and the supply chain economy. For many companies' entire product portfolios depend on the use of ethanol.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	

Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 343	2025/04/30 19:08
Country	Germany
Name of organization/institution	
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Since ethanol is not a CMR risk for external use on the skin, this ban makes no sense for liquid fragrances. There is no study supporting any harm for this type of application. There is no study providing evidence that cancer rate increase for users of ethanol-containing fragrances. Liquid fragrances based on ethanol should be exempted from a ban.
Product Type	1,2,4
Alternative Identity and Properties	Most hygiene products can be developed without ethanol, but liquid perfumes and fragrances are dependent on alcohol. This product class would lose one of its core functions. A ban on ethanol would basically ban this whole product group.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	There is no alternative for ethanol in liquid perfumes.

Information above is confidential	
Justification for confidentiality	
Economic Feasibility	A ban on ethanol would likely damage or destroy the entire fragrance industry. Consumers all over the EU would suffer because classic fragrances would no longer be available. This would be a self inflicted economic Trump-moment. Especially, when the real danger of drinking alcohol is not touched at all!
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	The risk of using an alternative solvent is that liquid fragrances may not be accepted by customers anymore. Other types of alcohols bear a higher risk. Basically there is no alternative for ethanol.
Information above is confidential	
Justification for confidentiality	
Availability	none
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	For the application of fragrances there is no safe alternative for ethanol. Alternatives would be much more expensive and less safe.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	

Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 344	2025/04/30 19:09
Country	Belgium
Name of organization/institution	Belgian Bioethanol Association asbl
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	The Belgian Bioethanol Association (BBA) represents the interests of the Belgian bioethanol producers. These biorefineries are at the heart of the energy transition and represent an essential technology for converting biomass into low-carbon fuels, as well as a range of other valuable low-carbon by-products, including food and feed, fertilizers, lignin, CO2 and biomaterials. The classification of ethanol as carcinogenic or toxic to reproduction could mean that many biocidal products could lose their authorisation in the future. Some critical use cases are described below. We therefore see the need to keep ethanol-based products on the market.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	

Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Summary: Why ethanol should not be classified? • The human drinking data considered by the biocidal competent authorities is not scientifically suitable for classification. Using abusive drinking data is not a sound method that can be reasonably expected for biocidal applications. Without an evaluation of appropriate and accurate data related specifically to the impacts of alcohol via skin contact and inhalation, a hazard assessment is impossible. Because extrapolating epidemiological drink data to worker/consumer exposure is scientifically invalid, the scientific basis to classify a substance under biocidal legislation as a Cat. 1 Carcinogenic and Toxic for Reproduction substance using results from intake data of foodstuffs is unsound and inappropriate. • Ethanol is a unique case, being one of the most widely used basic chemicals in numerous applications worldwide. A BPC recommendation for a CMR classification leading to exclusion or substitution criteria will: - o Prevent the usage of Ethanol by the general public (hand gels) and professional users (hospitals) where no suitable alternatives exist that are effective against non-enveloped viruses, as demonstrated by the Assessment of Alternatives. - o Impact various industries beyond biocidal applications linked to cosmetic products, chemical agents at work, food contact materials, EU Ecolabel, waste, medical devices, and general food law. • Such a classification

	would bring no health benefit at all but would create severe health issues and would have severe socio-economic consequences for many industries that would be left with no alternative. • Considering the complexity of the discussion around classification and its significant consequences, the Risk Assessment Committee (RAC) under the CLP Framework, not the Biocidal Products Committee (BPC), should address the harmonized classification discussion.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	250430 HL – Biocidal Ethanol Use – BBA Reply.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 345	2025/04/30 20:36
Country	Netherlands
Name of organization/institution	Kimberly-Clark B.V.
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Despite the availability of several potential alternatives, none have proven suitable to replace ethanol-based products for PT4 applications (disinfectants in the food and feed area). Ethanol provides rapid microbial efficacy, broad-spectrum activity against bacteria, fungi, and viruses,

	and minimal skin irritation. Its rapid evaporation minimizes prolonged surface contact, making it ideal for disinfecting equipment, small surfaces, and high-frequency touchpoints in food and feed sectors.
Product Type	1,2,4
Alternative Identity and Properties	Three substances were selected as potential alternatives based on their functionality and similarity to ethanol-based products in PT4 applications: L-(+)-lactic acid, Propan-1-ol, Propan-2-ol (IPA). Non-chemical disinfection methods could be also considered, such as UV-C light and steam sterilization, however, have significant limitations.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Propan-1-ol and propan-2-ol do not meet the technical criteria for PT4 applications due to: - Inadequate spectrum of action, especially against non-enveloped viruses. - Limited application methods unsuitable for large-scale disinfection. - Slower efficacy and narrower usage environments. - Cost-effectiveness and scalability concerns. Ethanol remains the optimal choice, offering unmatched efficacy, versatility, and alignment with the stringent disinfection needs of the food and feed industry under PT4.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Propan-1-ol and propan-2-ol, while technically feasible, are economically disadvantageous due to higher costs, reliance on non-renewable resources, supply shortages, limited scalability, and dependence on few suppliers. They also have a narrower spectrum of action and longer required contact times, reducing efficiency and increasing costs in food and feed settings. Considering these limitations, ethanol remains the most practical and economically feasible choice for PT4 disinfection applications. Its well-established production infrastructure within the EU and globally utilizes biomass and agricultural residues.
Information above is confidential	
Justification for confidentiality	

Hazards and Risks of the Alternative	From a human risk perspective, there is no reduction in risk when using Ethanol compared to Propan-2-ol, and L(+)lactic acid. There is a risk reduction from a Human risk perspective using Ethanol compared to Propan-1-ol. Regarding environmental risk, using alternatives to Ethanol does not result in risk reduction, as the overall risk to environmental compartments remains unchanged.
Information above is confidential	
Justification for confidentiality	
Availability	While propan-1-ol, propan-2-ol, and L(+) lactic acid are available, the limited number of approved suppliers raises concerns about meeting EU-wide demand, especially during high-demand situations like pandemics. The Article 95 list includes 9 suppliers for propan-1-ol, 68 for propan-2-ol, and 3 for L-(+)-lactic acid, compared to over 240 suppliers for ethanol. Ethanol's robust supply chain ensures reliable availability even during health crises.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol remains the most suitable and widely available disinfectant for PT4 applications due to its effectiveness, safety, and environmental benefits. Alternatives like propan-1-ol and propan-2-ol are less suitable due to higher costs, limited supply, and narrower spectrum of action. Ethanol's robust supply chain and favorable safety profile make it indispensable for maintaining infection control and supporting sustainability goals in the food and feed industry. Ethanol is a highly effective and environmentally benign disinfectant for PT4 applications, with a favorable safety profile in controlled environments. Proper control measures are essential to prevent environmental contamination, especially when used in large quantities or concentrated forms. Adhering to proper storage, handling, and disposal practices minimizes risks to the environment. Maintaining ethanol is crucial for sustainability and public health, as it balances efficacy, safety, and environmental considerations. Replacing ethanol with less eco-friendly alternatives would compromise infection control and the EU's commitment to a greener future.
Information above is confidential	

Justification for confidentiality	
Other comments	Considering that the proposed classification and human toxicity findings on Ethanol rely mainly on data considering oral exposure when, as far as the biocidal uses are concerned, the routes of exposure for ethanol-based disinfectants are exclusively dermal and inhalation exposures. Due to PT4 biocidal use, the exposure is negligible low.
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 346	2025/04/30 20:55
Country	Italy
Name of organization/institution	Cosmetica Italia - associazione nazionale imprese cosmetiche
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Cosmetica Italia è l'associazione che rappresenta l'industria dei cosmetici e della cura della persona a livello nazionale. Con un valore di mercato pari a 13.4 miliardi di euro, l'industria occupa 36.000 addetti che raggiungono i 400.000 se consideriamo l'intera filiera. Cosmetica Italia vuole qui sottolineare le implicazioni significative della classificazione dell'etanolo come sostanza cancerogena, mutagena e/o tossica per la riproduzione (CMR), sollecitando una completa revisione del bilanciamento tra conseguenze negative e positive di tale classificazione, in particolare per quanto riguarda i suoi usi a valle nel settore cosmetico. Questo

	documento vuole delineare le potenziali interruzioni del mercato, la mancanza di benefici per i consumatori, gli oneri normativi aggiuntivi e le considerazioni strategiche per i responsabili politici dell'UE e dell'Agenzia europea per le sostanze chimiche (ECHA). L'etanolo utilizzato nei prodotti cosmetici è denaturato, cioè inadatto al consumo. Già in questo modo, il rischio per il consumatore di un consumo orale (regolare o eccessivo) è annullato e qualsiasi proprietà CMR assegnata all'etanolo come sostanza chimica pura, basata sull'assunzione orale, non sarebbe rilevante per l'uso cosmetico. Cosmetica Italia ritiene che sia fondamentale svincolare la classificazione di pericolo dell'etanolo (classificazione armonizzata ai sensi del regolamento CLP) dalla sua valutazione in corso come principio attivo biocida.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	

Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Mancanza di alternative adeguate L'etanolo svolge molteplici funzioni nei cosmetici che non possono essere facilmente sostituite da un singolo ingrediente: • Proprietà solubilizzanti: l'etanolo dissolve vari ingredienti cosmetici e migliora le prestazioni del prodotto. • Proprietà volatili: Contribuisce all'esperienza del consumatore fornendo freschezza e riducendo la viscosità. • Attività antimicrobica: le proprietà antimicrobiche intrinseche dell'etanolo consentono un minore utilizzo di conservanti e contribuiscono alla funzionalità disinfettante dei prodotti
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	Classificazione dell'etanolo - posizione di Cosmetica Italia.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 347	2025/04/30 20:56
Country	France
Name of organization/institution	STOCKMEIER FRANCE S.A.S.
I do not wish the name of my organisation/institution to be published on the ECHA website.	

General information	Our company manufactures biocidal products containing ethanol as an active substance, as well as detergent products using ethanol as a co-formulant, and distributes ethanol as a biocidal active substance to companies formulating biocidal products in France. This contribution aims to provide essential information on the use of ethanol, its benefits, and the potential implications of its substitution.
Product Type	1,2,4
Alternative Identity and Properties	Ethanol is a widely used biocidal active ingredient, recognized for its broad-spectrum efficacy, particularly in disinfectants and antiseptics. It is recommended by World Health Organization, which propose a note to formulate it (https://iris.who.int/bitstream/handle/10665/332006/WHO-IER-PSP-2010.5-fre.pdf). Its key advantages include: • Proven virucidal, bactericidal, fungicidal, and tuberculocidal activity; • High efficacy against non-enveloped viruses, essential for infection control; • No residue on surfaces, ensuring safety for food contact applications; • Rapid evaporation, ensuring its use in healthcare and public settings; • Well-documented safety profile with minimal risks when used correctly.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Ethanol is one of the few substances that is completely virucidal and effective against non-enveloped viruses such as norovirus and poliovirus, tahn can be easily applied on skin of human beings, professionnels as consumers. Ethanol is supported by WHO recommendations and studies (such as Kramer et al., 2022) that highlight its superior disinfection properties. Alternatives like 1-propanol and 2-propanol seem to have a limited activity against non-enveloped viruses, based on biocide products authorisations delivered. Ethanol has no toxicologically relevant residues or persistent environmental contamination if applied as a biocide product, no reported cases of skin sensitization during normal use, reduced risk of accidental poisoning due to rapid evaporation, no food contamination and odorless, making it suitable for workers in food applications, as well as in healthcare.
Information above is confidential	
Justification for confidentiality	

Economic Feasibility	Alternatives like 1-propanol and 2-propanol have a higher price (up to at least 20%, based on pure product), have a limited number of manufacturers, limited volumes produced in Europe that import large quantities from other countries. But as seen during recent sanitary crisis, this dependence is a major issue in case of troubles in logistic chain and as well as in high and rapid increase of need on the market.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Alternatives like 1-propanol and 2-propanol have higher toxicity profiles or leave residues, as they evaporate more slowly / completely. In France, AFSSET / ANSES has done an evaluation of the risks of ethanol in the professional population and in the general population, when applied for skin disinfection, and conclusions are "The results of the expert assessment work did not reveal any chronic health risk, specifically linked to professional exposure by inhalation or skin contact", and "no excess risk can be demonstrated in the case of short-term exposure to ethanol in the general population" (https://www.anses.fr/fr/content/evaluation-des-risques-lies-lethanol).
Information above is confidential	
Justification for confidentiality	
Availability	Alternatives like 1-propanol and 2-propanol have a higher price (up to at least 20%, based on pure product), have a limited number of manufacturers, limited volumes produced in Europe that import large quantities from other countries. But as seen during recent sanitary crisis, this dependence is a major issue in case of troubles in logistic chain and as well as in high and rapid increase of need on the market. Ethanol is historically produced in a major part of the European countries.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Recognizing the essential role of ethanol in infection control and public health is essential to maintaining effective and safe disinfection practices. Ethanol classification must

	remain based on its real-world biocidal use, rather than being inaccurately compared to chronic, excessive alcohol consumption. Considering realistic exposure scenarios is crucial to ensure that regulations are based on accurate and relevant data, to avoid inappropriate classifications that are ineffective in reducing a nonexistent risk in this type of application, and to ensure that Europe continues to have a substance that is highly effective in reducing the transmission of infections in both the general population and occupational settings.
Information above is confidential	
Justification for confidentiality	
Other comments	There is no conclusive evidence of carcinogenicity at real-world exposure levels, with ethanol used as a biocide product. Toxicological assessments must differentiate between ingestion, dermal, and inhalation exposure. Any classification must consider a risk-based assessment rather than a classification based solely on hazards. If classified as carcinogenic to humans, ethanol will be banned of the market by consumer, even if there is no chronic health risk for user with application on skin. So this classification won't help to reduce an existing risk (that doesn't exist for most professional uses of ethanol), and won't help to protect in any manner general population as well as professionals. More than that, the difficulties to replace ethanol in many applications and particularly as a biocide active substance could fragilize public health, at the ethanol efficacy is well-known / documented and accepted, to avoid chain of transmission in populations and healthcare domains.
Information above is confidential	
Justification for confidentiality	
References	AVIS et rapport de l'Afsset relatifs à : L'évaluation des risques de l'éthanol en population professionnelle (2007-ET-0001), https://www.anses.fr/fr/system/files/CHIM2007et0001Ra.pdf Avis de l'Anses Saisine n° 2007-SA-0416
Attachments (non-confidential information)	
Attachments (confidential information)	

Justification for confidential attachment	

Comment 348	2025/04/30 21:04
Country	France
Name of organization/institution	PROMER
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Nous utilisons l'éthanol pour la fabrication d'un gel hydroalcoolique et d'un gel main désinfectant en TP1 Mais nous l'utilisons également dans beaucoup d'autres fabrications détergentes.
Product Type	1,2,4
Alternative Identity and Properties	Pas d'alternative fiable à ce jour pour ce genre de produit. Pas d'alternative qui propose une efficacité suffisante sur les virus et obtenir les mêmes normes. Pas d'alternative en terme d'odeur et de temps de séchage. Pas d'alternative d'origine végétale, qui soit biodégradable et non dangereuse pour l'environnement
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	Frais de recherche pour trouver des alternatives et établir les nouvelles concentrations nécessaires pour l'obtention des normes. Problème de temps de séchage sur les mains.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Alternatives plus chères et moins disponibles Coût important de R&D + passage des nouvelles normes
Information above is confidential	

Justification for confidentiality	
Hazards and Risks of the Alternative	Pas d'alternative d'origine végétale, qui soit biodégradable et non dangereuse pour l'environnement avec la même efficacité
Information above is confidential	
Justification for confidentiality	
Availability	Alternatives moins disponibles
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Il n'y a pas d'alternative efficace qui pourrait remplacer l'éthanol à ce jour. Si cette nouvelle classification venait à passer, nous serions probablement contraints d'arrêter la fabrication des produits biocides qui en contiennent. L'impact économique serait catastrophique pour les petites PME comme la notre qui ne pourront pas engager des frais de R&D et de normes biocides pour trouver des formules alternatives équivalentes à celles actuellement sur le marché.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 349	2025/04/30 21:18
Country	Italy
Name of organization/institution	Farindustria
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Farindustria is the Association of Pharmaceutical Companies operating in Italy, national and multinational. It is a member of Confindustria (the Italian National Federation of Industry), the European Pharma Federation (EFPIA) and the World Pharma Federation (IFPMA). It has about 200 member companies – 42% of which are nationally-owned and 58% foreign-owned – with over 130 plants all over the nation, 71,000 highly-qualified employees. Farindustria welcomes the opportunity to provide its contribution on the issue in line with EFPIA position. Ethanol is a critical substance used in varied contexts within the pharmaceutical life cycle. Under the scope of the Biocidal Products Regulation (BPR), it remains essential for human hygiene applications like hand and skin disinfection and hence cannot be subject to substitution. Moreover, the cascading impact of the re-clasification of Ethanol under the Biocidal Products Regulation (BPR) on further EU regulations risks limiting other ethanol uses in the pharmaceutical context. Any regulatory conclusions must ensure no compromise on safety and efficacy. Farindustria endorses the preliminary analysis already embedded in the public consultation attachments. Particularly, section 3.3.1. of PT 2 “The EU disinfectant industry” covers the main use of ethanol for pharmaceutical sectors covered by the Biocidal Products Regulation. In some cases, the pharmaceutical sector also has uses as PT1, for hand disinfection, and protection of workers. - From a chemical and regulatory perspective, ethanol is superior due to: -Faster biodegradation (lower persistence in soil/water) -Lower VOC reactivity (less air pollution impact) -More sustainable production (bioethanol vs. petrochemical IPA) - While there are available substances for substitution, the benefit/risk for workers exposure as well as for sustainability illustrate that these solutions would present regrettable substitutions. For industries aiming for greener solvents, safer disinfectants, and reduced regulatory burden, ethanol is the preferred

	choice over isopropanol or methanol. Overall, the use of ethanol in the context of the pharmaceutical sector specificities is neither hazardous for workers (as non-ingested or used in enough quantity that inhalation can be harmful) nor replaceable. Farindustria urges the authorities to consider our sectoral-specific uses and to find a proportionate solution for the proposed CMR classification of Ethanol to avoid disruption risks in the cascading effect of the classification under BPR. Additionally, and in the context of simplifying the EU complex framework, we encourage reevaluating the interplay of overlapping framework, i.e. BPR and REACH, CLP, for a pragmatic and simplified regulatory approach, to reduce resource constraints and uncertainties. Current regulatory measures are disproportionate, especially in the case of ethanol, increasing bureaucracy without effectively minimizing risk. Such effort would contribute to incentivizing the EU market and support prioritizing resource efficiency, focusing research on necessary alternatives.
Product Type	1,2,4
Alternative Identity and Properties	PT2: Isopropyl alcohol (CAS no 67-63-0) (various conc mix with water) Mixture E (aminoethanol (CAS 141-43-5)/didecyldimethylammonium chloride (CAS 7173-51-5)/potassium carbonate CAS 584-08-7/fatty alcohol polyglycoether CAS 68439-49-6/isopropyl alcohol CAS 67-63-0) Mixture V : (pentapotassium bis(peroxymonosulphate) bis(sulphate) (CAS 70693-62-8)/ Benzenesulfonic acid, C10-13-alkyl derivs., sodium salts CAS 68411-30-3)/malic acid (CAS 6915-15-7)/ sulphamidic acid (CAS 5329-14-6)/ potassium hydrogensulphate (CAS 7646-93-7)/ dipotassium disulphate (CAS 7790-62-7)/sodium toluenesulphonate (CAS 12068-03-0)/ dipotassium peroxodisulphate (CAS 7727-21-1)/dipentene (CAS 138-86-3) To note that, as stated in the attachments in the public consultation, (analysis of alternatives): the use of isopropanol (IPA), Propan-2-ol), even if it might be able to provide similar technical properties, suffers from higher costs, limited supply chains, and limited efficacy against non-enveloped viruses, making them less practical for frequent surface disinfection.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	PT1: GMP manufacturing of medicinal products: No alternatives for cleaning and disinfection when entering GMP

	zones. If the alternative is found, re-validation can take many years. PT2: Disinfection of cell labs: So far, no alternative found that does not kill the cell lines. GMP manufacturing of medicinal products: Validated disinfecting/cleaning processes involve ethanol. If the alternative is found, re-validation can take many years. Currently ethanol cleaning and disinfection is part of licence to operate. Ethanol is part of the validated disinfection and cleaning methods for analytical instruments. Cannot be replaced for existing equipment. Ethanol is used as a disinfectant when working with genetically modified microorganisms. Currently no alternative is identified. The validation standards are based on the context of use of ethanol. The feasibility of substitution depends on conducting new validation testing to ensure that the alternative preserves ethanol's essential chemical properties and functionality, maintaining its effectiveness in the specific applications and uses without introducing unintended consequences. General combined cleaning and disinfection of labs and offices: Products containing isopropanol are available on the market, but reluctant to use as more acute toxic than ethanol. Mixture E and mixture V have been tried but leave residues and can corrode steel surfaces.
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Farindustria endorses the PT economic impact analysis regarding the use of ethanol over other substitutions. Ethanol emerges as the most economically viable option for PT2 applications due to: • Lower production costs and alignment with sustainability objectives. • Widespread availability and robust supply chain networks within the EU. High cost-effectiveness, driven by its broad-spectrum efficacy, rapid action and adaptability, positions it as the leading choice for surface disinfection across diverse settings. The alternatives (propan-1-ol, propan-2-ol, citric acid, and copper sulfate pentahydrate) are economically less favorable: - Propan-1-ol and propan-2-ol suffer from higher costs, limited supply chains, and limited efficacy against non-enveloped viruses, making them less practical for frequent surface disinfection. - L(+)lactic acid is not broadly effective against the full range of pathogens required for PT2 applications, limiting its suitability for these diverse environments. Given these factors, ethanol remains the most practical and cost-effective choice for PT2 surface

	disinfection, ensuring effective infection control. The research, qualification, supply and implementation factors of substituting ethanol would bring economic burden to pharmaceutical resources and bring resource constraints into investing in more critical alternatives R&D. Not only will there be no added benefit to workers, but it would be counterproductive to foster innovation in Europe.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	In terms of hazards and risks, ethanol and isopropanol have similar properties. However, ethanol evaporates faster, and as the main route of occupational exposure when used in PT2 is inhalation, workers will be exposed for a shorter time. By contrast, the mixtures tested as per above, are corrosive and toxic to aquatic life with long lasting effects. Ethanol has lower volatile organic compound (VOC) emissions compared to isopropanol, reducing air pollution and smog formation. Ethanol is often classified as "Generally Recognized as Safe" (GRAS) by the FDA, while isopropanol has more restrictions in food and pharmaceutical applications. "Isopropanol and n-propanol caused significant stratum corneum and keratinocyte perturbation in vitro together with damage to skin condition and function in vivo whereas ethanol did not. [...] Ethanol-based sanitizers are better tolerated by skin, particularly in high-use settings, than other alcohols and should be the active ingredient of choice." Ref: (Cartner T, Brand N, Tian K, Saud A, Carr T, Stapleton P, Lane ME, Rawlings AV. Effect of different alcohols on stratum corneum kallikrein 5 and phospholipase A2 together with epidermal keratinocytes and skin irritation. Int J Cosmet Sci. 2017 Apr;39(2):188-196. doi: 10.1111/ics.12364. Epub 2016 Sep 22. PMID: 27578266.) Both ethyl alcohol and isopropyl alcohol are flammable liquids which share similarities in their physicochemical properties (flash point, water solubility, boiling point) nonetheless one could find differences in evaporation rate, potency, auto-ignition temperature and material compatibility, limiting a 1:1 substitution. Although isopropanol has a narrower concentration range with regard to the formation of explosive alcohol-air mixtures, isopropanol has a decisive safety-related disadvantage. Like other secondary alcohols, 2-propanol can form explosive peroxides with atmospheric oxygen. In ten-year-old original containers of isopropanol, for example, a peroxide content of 1% was found. Peroxide concentrations of up to 4.2%

	have been reported. This has led to some serious accidents when distilling IPA to dryness. (BGChemie.de „Accidents due to peroxide-forming substances“).
Information above is confidential	
Justification for confidentiality	
Availability	Ethanol can be produced from renewable sources (e.g., corn, sugarcane, or cellulosic biomass), making it more environmentally sustainable. Isopropanol, on the other hand, is derived from petrochemicals, which rely on fossil fuel extraction and hence not aligned with Europe sustainable development. Farindustria endorses the Analysis of Alternatives for use of ethanol for PT2 Section 6.1.6: Ethanol benefits from a robust and diversified supply chain with over 240 suppliers in the EU, ensuring reliability even during high demand. Alternative substances like isopropanol have significantly fewer suppliers, raising concerns about their ability to meet EU-wide demand, especially during crises. Ethanol's established supply chain and adaptability to demand surges make it a more reliable option for critical sectors like healthcare.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	Ethanol is essential in pharmaceutical manufacturing, serving as not only an irreplaceable disinfectant but also at the pharmaceutical product level. It ensures product stability, shelf life, and manufacturability, with no viable alternative. A potential ban on ethanol due to its classification as a CMR substance under BPR would impact on the medicinal products, R&D and manufacturing, as well as manufacturing processes, by cascading consequences into overlapping frameworks (i.e. REACH). Currently, the classification proposal is only based on the hazard of ethanol ingestion. When the route of administration needs to be considered for hazard characterization, Ethanol is used as safe and effective application on skin and surfaces. Restricting ethanol use would compromise hygiene, healthcare, and the protection of vulnerable populations, particularly in hospitals and during pandemics. Furthermore, exemptions would likely be ineffective due to regulatory burdens. To ensure a secure supply of disinfectants, cleaners and pharmaceuticals to the population, as well as the production and delivery capacity of corresponding end

	products, we do not recommend substituting ethanol by any regrettable alternatives such as isopropanol. Classifying ethanol as a CMR substance for the inhalation and dermal route would far miss the purpose of the Biocidal Products and CLP Regulations, which is to improve human health. Instead, it would result in a significant deterioration in hygiene and healthcare.
Information above is confidential	
Justification for confidentiality	
Other comments	Acute Toxicity Isopropyl is not intended for human consumption and is toxic to ingest. Drinking even a small amount of rubbing alcohol can lead to severe health issues, including alcohol poisoning and organ damage. Ethanol in alcoholic beverages is intended for adult consumption in moderation. When consumed responsibly, it may provide some social and recreational benefits. However, excessive and irresponsible drinking can lead to health problems, addiction, and other negative consequences. Ingesting Isopropanol affects the central nervous system and can lead to coma, painful throat and airway burns, swelling, seizures, dangerously low blood pressure, and heart attack. Ethanol is a central nervous system depressant and can cause intoxication with symptoms such as slurred speech, sedation, and unsteadiness. Excessive alcohol consumption can lead to impaired judgment, motor skills, and coordination. When isopropyl alcohol is ingested, it is rapidly absorbed by the body, leading to a peak in blood levels between 30 minutes and 3 hours after ingestion. The body metabolizes isopropyl alcohol differently from ethanol, converting it into acetone. Acetone is a gastrointestinal irritant that can cause abdominal pain, nausea, vomiting, bleeding in the stomach and intestines, and even bladder rupture. Additionally, it triggers severe depression of the central nervous system, leading to dizziness, headaches, inebriation, and potentially coma. Rubbing alcohol is much more potent than ethanol found in alcoholic beverages. It is more intoxicating at comparable concentrations and more likely to produce impaired consciousness, dangerously low blood pressure, and even cardiopulmonary collapse if you drink rubbing alcohol. Drinking rubbing alcohol can lead to a range of life-threatening conditions, including internal bleeding, depressed cardiovascular function, shock, organ damage, and death.

Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 350	2025/04/30 21:48
Country	Germany
Name of organization/institution	BPI e.V.
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	BPI-Statement on the public consultation on potential candidates for substitution (substance name: ethanol) regarding an assessment of the potential impact on the pharmaceutical sector (risk classification of ethanol by the European Chemicals Agency ECHA). There is currently a discussion about classifying ethanol as "toxic to reproduction" and/or "carcinogenic," Category 1 or 2, under chemical law and labeling it in accordance with BPR and CLP Regulation (EC). A classification of ethanol in category 1 or 2 would have far-reaching negative consequences for the industrial healthcare sector and thus for healthcare provision. It would make the use of ethanol as a main or auxiliary active ingredient in medicinal products/medical devices and its use in production processes more difficult/complex, and its use would be severely restricted due to current occupational health and safety regulations. Disinfection and hygiene: Ethanol is an essential active ingredient in disinfectants for hands, surfaces and medical devices, because it is particularly effective against bacteria and viruses and is safe and biodegradable. The World

	Health Organization (WHO) has classified ethanol-containing hand sanitizers as essential for pandemic and civil protection. Ethanol has a specific, unaltered effect against non-enveloped viruses such as polioviruses. One of the most effective protective measures against bacterial and viral infections is therefore proven to be hand and surface disinfection with ethanol. During the COVID-19 pandemic, it has been shown that disinfection measures with ethanol can safely and quickly break chains of infection. A CMR classification would significantly impair the widespread use of these disinfectants. Isopropanol and n-propanol are no alternatives due to their toxicity and less comprehensive effect. Ethanol is also used in denatured form. Accordingly, the use of ethanol as a chemical does not pose a reproductive toxicity risk to workers or private users. Therefore, nearly 30 international medical associations and expert committees recently urged that ethanol must be approved without restrictions as an active ingredient in hand hygiene products. The BPI also supports this recommendation. Most ethanol-containing hand and surface disinfectants are currently approved as biocides in the EU, only a few are nationally approved as medicinal products in Germany. Biocides are directly affected by such a risk classification. The sale of ethanol-containing disinfectants to patients/hospitals, etc. would then no longer be permitted. Ethanol would have to be substituted in the products, regardless of whether alternatives with equivalent benefits are available – which is not the case. Consumer uncertainty would also be expected, as it is difficult to explain why a large proportion of ethanol-based disinfectants (biocides) are no longer permitted to be sold due to a corresponding toxicity assessment, while others are still available as medicinal products and drinking alcohol as a food remains permitted despite health risks. Pharmaceuticals and Production: Ethanol is used in pharmaceutical manufacturing as a carrier, preservative, and for extraction of active ingredients, essential oils, and other substances that are not soluble in water. Ethanol has properties that contribute significantly to the efficacy of a pharmaceutical product, yet only minimal amounts are required. Ethanol is particularly indispensable in the field of herbal medicinal products, as alcohol is one of the most important substances in the production of extracts. It also contributes significantly to the stability, shelf life, and manufacturability of medicinal products. There is no alternative to the use of ethanol in production processes. A corresponding CMR (carcinogenic, mutagenic, toxic to reproduction) classification of ethanol could affect the availability of ethanol as a starting chemical, its use in production

	processes, and occupational safety. Manufacturers may have to make extensive modifications to their production facilities, which would result in a locational and economic disadvantage for Europe. Additional argument: The hazard-based approach ("Generic Approach to Risk Management" (GRA) of the current procedure is not useful for scientific risk assessment, chemical diversity, innovation, and competitiveness. The GRA aims to regulate chemicals based on their inherent, hazardous properties, regardless of how the chemicals are used and regardless of whether a risk actually exists. The precautionary principle alone is not sufficient to justify chemical bans. Even highly toxic or carcinogenic substances can be used safely if appropriate measures are taken. Ethanol is well known in terms of its chemical properties and potential toxicity risk and can be used safely. New, less effective alternatives would have to prove their safety in the medium to long term. This means that the objective of the CLP Regulation, to ensure a high level of protection for human health and the environment, is not achieved in this case. Regarding the scientific data used, the respective route of exposure and the efficacy/concentration of ethanol were not considered in the assessment. Regarding the methodology, food/beverages, their use, and the data source (epidemiological data on oral consumption/abuse) should not be used for classification purposes under the CLP Regulation and are not suitable for this purpose. In particular, the risk assessment of a substance should consider the intended use, but not its misuse. Accordingly, in the past, the RAC Committee did not include data on the effects of smoking and alcohol consumption in humans in the assessment of the substance when classifying acetaldehyde, for example. Overall, it therefore does not appear to be a mandatory requirement of the CLP Regulation that human data must be used without restrictions for CLP classification. Accordingly, the inclusion of this data in the scientific assessment for the classification of ethanol could also be dispensed with. BPI-conclusion: To ensure a secure supply of disinfectants, medical products, and medical devices to the population, as well as the production and delivery capacity of corresponding products, the classification of ethanol as a CMR substance in Category 1 or 2 must be urgently avoided and immediately stopped. Classifying ethanol as a CMR substance would miss the purpose of the Biocidal Products and CLP Regulations, which is to improve human health. Instead, it would lead to a deterioration in hygiene and healthcare. The protection of vulnerable patient groups, particularly in hospitals and the outpatient sector, but also during pandemics, could no longer be ensured. The

	pandemic and civil protection would be endangered. With regard to the pharmaceutical industry, such a classification represents a locational and economic disadvantage for Europe. Attachments: Position papers and IHO brochure
Product Type	1,2,4
Alternative Identity and Properties	see point General Information: Isopropanol and n-propanol are no alternatives due to their toxicity and less comprehensive effect. Ethanol is particularly indispensable in the field of medicinal products, as alcohol is one of the most important substances in the production for example of extracts. It also contributes significantly to the stability, shelf life, and manufacturability of medicinal products. There is no alternative to the use of ethanol in production processes. Ethanol is used in pharmaceutical manufacturing as a carrier, preservative, and for extraction of active ingredients, essential oils, and other substances that are not soluble in water. Ethanol has properties that contribute significantly to the efficacy of a pharmaceutical product, yet only minimal amounts are required. In general: Ethanol is well known in terms of its chemical properties and potential toxicity risk and can be used safely. New, less effective alternatives would have to prove their safety in the medium to long term. This means that the objective of the CLP Regulation, to ensure a high level of protection for human health and the environment, is not achieved in this case.
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	see point General Information: A corresponding CMR (carcinogenic, mutagenic, toxic to reproduction) classification of ethanol could affect the availability of ethanol as a starting chemical, its use in production processes, and occupational safety. Manufacturers may have to make extensive modifications to their production facilities, which would result in a locational and economic disadvantage for Europe. A secure supply of disinfectants, medical products, and medical devices to the population, as well as the production and delivery capacity of

	corresponding products can no longer be guaranteed. The pandemic and civil protection would be endangered.
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	see point General Information: In general: New, less effective alternatives would have to prove their safety in the medium to long term. But there are simply no alternatives.
Information above is confidential	
Justification for confidentiality	
Availability	see point General Information: There are simply no alternatives.
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	To ensure a secure supply of disinfectants, medical products, and medical devices to the population, as well as the production and delivery capacity of corresponding products, the classification of ethanol as a CMR substance in Category 1 or 2 must be urgently avoided and immediately stopped. Classifying ethanol as a CMR substance would miss the purpose of the Biocidal Products and CLP Regulations, which is to improve human health. Instead, it would lead to a deterioration in hygiene and healthcare. The protection of vulnerable patient groups, particularly in hospitals and the outpatient sector, but also during pandemics, could no longer be ensured. The pandemic and civil protection would be endangered. Regarding the pharmaceutical industry, such a classification represents a locational and economic disadvantage for Europe.
Information above is confidential	
Justification for confidentiality	
Other comments	see point General Information: The hazard-based approach ("Generic Approach to Risk Management" (GRA) of the current procedure is not useful for scientific risk assessment, chemical diversity, innovation, and competitiveness. The GRA aims to regulate chemicals based

	on their inherent, hazardous properties, regardless of how the chemicals are used and regardless of whether a risk actually exists. The precautionary principle alone is not sufficient to justify chemical bans. Even highly toxic or carcinogenic substances can be used safely if appropriate measures are taken. Ethanol is well known in terms of its chemical properties and potential toxicity risk and can be used safely.
Information above is confidential	
Justification for confidentiality	
References	1. Stellungnahmen des Verbundes für Angewandte Hygiene e.V. et al. (Hrsg.). Ethanol ist als biozider Wirkstoff zur hygienischen Händedesinfektion unverzichtbar: chrome-extension://efaidnbmnnnibpcajpcgclefindmkaj/https://vah-online.de/files/download/news/VAH_Ethanol_Biozidwirkstoff_29Oktober2020.pdf 2. Kramer, A., Pittet, D., Exner, M., Wendt, C. Medical associations and expert committees urge that ethanol be approved as a virucidal active substance for use in hand antiseptics under the European Biocidal Products Regulation, without a CMR classification. GMS Hyg Infect Control. 2024 Aug 21;19: Doc40.
Attachments (non-confidential information)	BPI-Attachments-Public-Consultation-EtOH-2025.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 351	2025/04/30 22:25
Country	Greece
Name of organization/institution	HELLENIC AEROSOL ASSOCIATION
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Hellenic Aerosol Association (HAA) is a non-profit trade association whose members are involved in the

	manufacturing and distribution of Biocidal products, Air Fresheners and Cosmetics in aerosol and liquid packaging. HAA has thirteen members the association is a non -profit trade organization and its objective is to defend and promote the common interests of the aerosol trade. It is a member of the European Aerosol Federation (FEA). The use of ethanol in our industry, whether it has to do with the production of biocides (PT2, PT18 & PT19), air fresheners or cosmetics, is very important. The use of ethanol apart from as a biocidal active in biocides PT2, is also very important for our members. Ethanol is used as a solvent for active ingredients and aromatics (usually oils), as a preservative in the formulas and as a drying agent for better application and spraying performance. Ethanol is a widely used biocidal active substance known for its broad-spectrum efficacy, especially in disinfectants and antiseptics. It offers proven virucidal, bactericidal, fungicidal, and tuberculocidal activity, with high effectiveness against non-enveloped viruses, which is crucial for infection control. Ethanol leaves no residues on surfaces, making it safe for food contact applications, and its rapid evaporation ensures convenient use in healthcare and public settings. Additionally, it has a well-documented safety profile with minimal risks when used appropriately. While the current consultation focuses on ethanol in PT1, PT2, and PT4 biocidal applications, since ethanol is used broadly across a great number of other consumer and professional products, any potential classification as CMR under the BPR will have critical impacts to those products too. Specifically: For insecticides and repellents, ethanol plays an important role as an effective solvent, helping to dissolve other ingredients that might not be soluble in water or oil and ensures an even distribution of active ingredients throughout the products. These products are important in preventing mosquito-borne diseases such as West Nile Virus, chikungunya, Zika, dengue, malaria, especially in areas, safeguarding public health public health. Additionally, ethanol is less likely to irritate the skin or create allergic reactions compared to other solvents like oils or synthetic chemicals used in insect repellents and this is crucial since insect repellents are applied to the skin. Moreover, ethanol evaporates quickly, reducing prolonged skin contact and minimizing sensitivity. For Air-fresheners, ethanol's properties make it a versatile and effective ingredient, offering several advantages when used in air fresheners compared to other solvents. Specifically, ethanol is excellent at dissolving essential oils and fragrance compounds, ensuring an even distribution of scent. Its rapid evaporation helps disperse the fragrance throughout the room. Additionally, unlike some other

	solvents, ethanol is practically odorless, allowing the pure fragrance of the air freshener to come through without interference . Moreover, ethanol has mild antimicrobial properties, which help prevent microbial growth within the product, extending its shelf life.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	The proposed reclassification of ethanol is based on oral intake of high doses (utilising data on the adverse effects of (excessive) drinking of alcoholic beverages) and not based on the typical uses of ethanol in biocidal products. It also does not take into account industry's mitigation measures such as denaturation of ethanol to prevent drinking of

	ethanol-containing products. If ethanol is substituted or restricted, several risks must be considered. There are no equally effective alternatives, as no substitute biocidal active substance matches ethanol's virucidal efficacy against non-enveloped viruses, and other substances may have higher toxicity or leave residues. Supply chain vulnerabilities include higher costs and limited availability of alternatives, along with significant investments needed for new facilities, technologies, and regulatory approvals, which may face resistance from authorities and NGOs. Potential public health risks involve reduced availability of effective disinfectants, leading to increased infection rates in healthcare, food processing, and public hygiene, and the increased use of weaker disinfectants may result in higher microbial resistance. The current consultation on ethanol's classification as a substance under the BPR could have far-reaching consequences beyond its biocidal use. Ethanol is an effective and versatile ingredient broadly used across various industries—including repellents, insecticides, air-fresheners, cosmetics, pharmaceuticals, fuels, food, and personal care—as a key solvent. A potential classification as CMR under BPR will impact or even ban chemical products for general public which contain ethanol with concentrations greater than the relevant specific or generic classification limits under CLP Regulation (EC No 1272/2008).
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 352	2025/04/30 23:02
Country	Denmark
Name of organization/institution	Kosmetik- og hygiejnebranchen
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Please find the attached document regarding PT4 - Food and feed area.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	

Justification for confidentiality	
Conclusion on suitability and availability of the alternative	No suitable alternative substance is available.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	ECHA Høring - PT04.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 353	2025/04/30 23:02
Country	Denmark
Name of organization/institution	Kosmetik- og hygiejnebranchen
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Please find the attached document regarding PT1 - Human hygiene.
Product Type	1,2,4
Alternative Identity and Properties	

Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	No suitable alternative substance is available.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	

Attachments (non-confidential information)	ECHA Høring - PT01.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 354	2025/04/30 23:02
Country	Denmark
Name of organization/institution	Kosmetik- og hygiejnebranchen
I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	Please find the attached document regarding PT2 - Disinfectants and algaecides not intended for direct application to humans or animals.
Product Type	1,2,4
Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	

Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	No suitable alternative substance is available.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	ECHA Høring - PT02.pdf
Attachments (confidential information)	
Justification for confidential attachment	

Comment 355	2025/04/30 23:44
Country	Belgium
Name of organization/institution	EuromContact

I do not wish the name of my organisation/institution to be published on the ECHA website.	
General information	As the European association representing manufacturers of contact lenses and lens care products, we wish to express our serious concern regarding the classification of ethanol as a CMR substance under the Biocidal Products Regulation (BPR) for the production of medical devices in Europe. Ethanol is widely used and indispensable across the medtech and healthcare sectors, including in the manufacture and use of medical devices. It is a cornerstone of effective infection prevention and control. We submit that the derogation conditions outlined in Article 5(2)(a),(b) and (c) of the BPR are met in the case of ethanol used in the healthcare sector to to disinfect equipment and surfaces, for the reasons outlined below. Consideration for derogation under Article 5(2)(b) – Ethanol is essential to prevent or control serious danger to human health Because its antimicrobial properties are highly effective against bacteria and viruses, ethanol plays a critical role in maintaining patient safety and infection control. Ethanol is widely used in the MedTech sector, including in the contact lens industry, to disinfect equipment and surfaces within controlled environments sites without leaving residues on the parts or surfaces which may lead to contamination of devices and to clean dispensers. Ethanol is essential to hygiene protocols in the manufacture of safe medical devices. As mentioned in the ANALYSIS OF ALTERNATIVES For the use of Ethanol in disinfectants and algacides not intended for direct application to humans or animals (Product Type 2), “Ethanol is widely recognized as a highly effective disinfectant, particularly in PT2 applications where frequent surface cleaning is essential to maintain hygiene” (Page 93). Classifying ethanol as a CMR substance would severely disrupt the production and use of these essential disinfectants, undermining infection control measures and putting patients at risk. Its broad-spectrum antimicrobial activity, including against enveloped and non-enveloped viruses, makes it irreplaceable for the production of medical devices and in consequence on patient care. Consideration for derogation under Article 5(2)(c) – Disproportionate negative impact on society A CMR classification for ethanol would have far-reaching consequences for the use of ethanol-containing disinfectants in the healthcare sector. In particular, it could significantly impair the necessary widespread use of these disinfectants and might have a significant impact on the industrial health sector where

	ethanol is used in a variety of production processes in the manufacture of medical devices. The restriction or ban of ethanol would have substantial societal consequences, including reduced availability of critical disinfectants, causing disruption in the manufacturing processes of medical devices and increased risk of infection due to a lack of effective alternatives. Such outcomes would compromise public health and have negative impact on the cost and availability of medical devices. For highly regulated products like medical devices, changing disinfectants would require extensive disinfection efficacy testing for each site, retraining staff, updating documentation, and modifying controlled procedures. These processes are time-consuming and would significantly increase operational costs. The societal consequences would far outweigh the theoretical risks associated with ethanol, particularly given its long-standing, safe use in professional environments. Consideration for derogation under Article 5(2)(a) – the risk from exposure to Ethanol, under realistic worst case conditions of use, is negligible, in particular where the product is used in professional and industrial settings We consider the classification of ethanol as a CMR substance to be disproportionate. Ethanol, when used professionally in healthcare and controlled industrial environments, poses negligible risk. In professional and industrial settings, especially healthcare, ethanol exposure is predominantly dermal or via inhalation, not oral, while the majority of data on human toxicity are based on oral exposure. According to the ANALYSIS OF ALTERNATIVES For the use of Ethanol in disinfectants and algaecides not intended for direct application to humans or animals (Product Type 2), “No evidence supports significant risks linked to inhalation exposure under typical use conditions for ethanol in biocidal applications” (page 15). The same analysis also concludes that “While ethanol is classified as a flammable liquid and its vapor can pose risks to human health if inhaled in large quantities or in poorly ventilated areas, its overall safety profile remains favorable when incorporated into disinfectant formulations designed for surface disinfection across various environments. In PT2 settings, ethanol's rapid action against a broad spectrum of microorganisms—including bacteria, fungi, and viruses—underscores its critical role in ensuring hygiene on frequently touched surfaces, such as tables, door handles, and equipment. Its quick evaporation minimizes residue risks, making it particularly suitable for applications in high-traffic areas where operational efficiency and safety are paramount”.
Product Type	1,2,4

Alternative Identity and Properties	
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	The Analysis of Alternatives for ethanol in Product-Type 2 (PT2: surface disinfectants) has concluded that: • Alternatives such as propan-1-ol, propan-2-ol, citric acid, and copper sulfate pentahydrate, as well as non-chemical methods, do not match the efficacy, safety, and broad-spectrum activity of ethanol; • Particularly in healthcare settings, these alternatives fail to deliver the same level of rapid disinfection and effectiveness against a wide range of pathogens. As noted in the AoA: “Ethanol remains indispensable for PT2 uses, particularly in healthcare environments where its effectiveness, safety profile, and rapid disinfection capabilities are unmatched. Based on the findings of this AoA, there is no viable alternative to Ethanol for surface disinfection in PT2

	applications” (page 84). Different disinfectants have different evaporation rates and contact times. For instance, IPA evaporates faster than ethanol, which could necessitate using more disinfectant to achieve the required contact duration. The additional liquid may cause unforeseen externalities. Ethanol has a long and well-documented history for use as a disinfectant. It is quite likely that any replacements/alternatives would be more toxic than ethanol, as a certain level of cytotoxicity is necessary in disinfectants by definition. In light of the above, we urge to apply the derogation provided under Article 5(2) of the BPR and maintain the availability of ethanol for essential biocidal applications in the healthcare sector. The classification of ethanol as a CMR substance would endanger public health, hinder the production and safe use of medical devices, and compromise infection control.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	ANALYSIS OF ALTERNATIVES For the use of Ethanol in disinfectants and algaecides not intended for direct application to humans or animals (Product Type 2)
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	

Comment 356	2025/05/01 01:01
Country	France
Name of organization/institution	

I do not wish the name of my organisation/institution to be published on the ECHA website.	1
General information	Nous utilisons l'ethanol en tant que fabricant de produits d'entretien pour la maison et le soin du linge. Cet ingrédient nous est indispensable pour d'une part assurer le niveau de désinfection requis par les normes européennes, d'autres part pour participer à la conservation des formules afin d'éviter l'utilisation systématique d'Ammoniums quaternaires, qui ont des effets nocifs reconnus sur la santé
Product Type	1,2,4
Alternative Identity and Properties	Acide lactique mais le produit est plus efficace si combiné avec de l'éthanol pour passer les normes de désinfection. Nous excluons la famille des ammonium quaternaires, notoirement nocifs pour la santé et conduisant à des résistances bactériennes
Information above is confidential	
Justification for confidentiality	
Technical Feasibility	L'éthanol est LA meilleure et SEULE solution pour conserver des formules en pH supérieur à 5,5 sans utiliser de conservateurs nocifs pour la santé (isothiazolinones, phenoxyethanol, ...).
Information above is confidential	
Justification for confidentiality	
Economic Feasibility	Nous joignons dans le courrier attaché les données économiques de l'éthanol pour notre PME française de produits d'entretien
Information above is confidential	
Justification for confidentiality	
Hazards and Risks of the Alternative	Impact fort sur la santé des Ammonium quaternaires (irritations notamment) pour la désinfection. Impact de sensibilisation pour les conservateurs efficaces en pH supérieur à 5,5 : isothiazolinones. Ou impact sur le foie et la perturbation endocrinienne pour le phenoxyethanol. Ce sont

	des ingrédients à éviter impérativement, l'ethanol est le seul à le permettre
Information above is confidential	
Justification for confidentiality	
Availability	
Information above is confidential	
Justification for confidentiality	
Conclusion on suitability and availability of the alternative	L'ethanol est indispensable pour désinfecter les surfaces et également conserver convenablement les produits d'entretien sans qu'il ne présente d'impact sur la santé dans notre catégorie de produit.
Information above is confidential	
Justification for confidentiality	
Other comments	
Information above is confidential	
Justification for confidentiality	
References	
Attachments (non-confidential information)	
Attachments (confidential information)	
Justification for confidential attachment	