

POSITION PAPER

of Pharma Deutschland e.V.

on Ethanol

date: 14 October 2025

Introduction

In 2000, the ECHA established a programme to regularly assess and evaluate all active substances in biocidal products on the European Union (EU) market for their risks to humans, animals, and the environment. The workload for evaluating the substances in the programme was distributed among the EU countries, with Greece being tasked with evaluating ethanol [1].

The European Chemicals Agency (ECHA) is currently conducting two procedures on ethanol. One for the assessment of ethanol under the EU Biocidal Products Regulation (BPR procedure) and the other following for harmonised classification and labelling (CLH procedure) under the CLP Regulation. Efficacy and safety are assessed in the European Union's BPR procedure.

The approval of ethanol as a biocidal active substance for product types 1 (human hygiene), 2 (healthcare), and 4 (food and feed) in accordance with the Biocidal Products Regulation (EU) No. 528/2012 (Regulation (EU) No. 528/2012 of the European Parliament and of the Council of May 22, 2012, concerning the making available on the market and use of biocidal products; OJ L 167, June 27, 2012, p. 1) has been pending for several years. Under the current BPR procedure, ethanol is being considered for classification as carcinogenic and reprotoxic in hazard category 1 (A or B). Mutagenic endpoints are still under discussion.

Authorisation restrictions apply to class 1 substances. Such a classification would complicate or even prohibit the use of ethanol as disinfectant. It is important to highlight that the (hazard) assessment is largely based on the abusive oral consumption of alcoholic mixtures. In contrast, in the professional use of ethanol in the healthcare sector and in production processes, exposure occurs primarily through dermal or via inhalation exposure. Oral consumption of ethanol-based disinfectants is prevented by denaturated products. There is currently no evidence that dermal or inhaled ethanol uptake in the context of the use of disinfectants has a CMR effect. The current MAK value 200 ml/m³ (ppm) was derived based on the endogenous ethanol level. In addition, according to the MAK commission *Harmful blood ethanol concentrations are difficult to achieve with inhalative exposure* (Ethanol MAK Value Documentation, 2018) [2]. According to the GESTIS Substance Database, under occupational conditions, the primary route of absorption for ethanol is through the respiratory

tract and skin absorption is considered to be of minor importance (GESTIS Substance Database by the IFA (Institute for Occupational Safety and Health of the German Social Accident Insurance), 07/2025) [3].

Under the CLH procedure for the harmonised classification, labelling and packaging of substances and mixtures in accordance with CLP Regulation (EU) No 1272/2008, Greece proposed the following classification: Flam. Liq. 2, H225, Eye Irrit. 2, H319, Repr. 2, H361d, Lact., H362, STOT SE 3, H336, STOT RE 2, H373 which was published in the [Registry of CLH intentions until outcome - ECHA](#). The deadline for submitting the dossier is 31 December 2026. The submission of the CLH dossier has been delayed due to the expectation of new data on dermal studies.

Therefore, the classification of ethanol as CMR under the BPR procedure will also have an impact on the subsequent classification under the CLP Regulation and thus on its general use and handling. Classifying a substance as Category 1 CMR in the CLH process can significantly impact on the production of medicines and medical devices, given related health and safety issues such as workplace regulations, which would then be tightened considerably. This applies to ethanol under the BPR and CLP Regulation.

Use of ethanol (according to BPR and CLP Regulation)

In connection with the BPR

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 and food supplements, dietetics, cosmetics, biocides and in hygiene and social areas for employees.

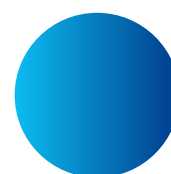
Also, it is known for its safe use in various products with direct exposure to the human skin (e.g., medicinal products like hand disinfectants in occupational settings, cosmetics like hairsprays or mouthwashes, pharmaceutical preparations, and many household products).

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. Therefore, Ethanol is widely used in disinfectants and is important in the production of medicinal products and medical devices, food supplements, dietetics, cosmetics, biocides. In this context, we would like to refer 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, its Table 1 of this publication 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 [4], [5].

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 [6]. 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 there is very limited systemic exposure to ethanol via the inhalation and dermal routes [6, 7]. As also foreseen by Regulation (EC) No 1272/2008 (CLP) 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. Therefore, it is crucial that the route of exposure is considered when determining the classification.

Also, there are several hundred ethanol manufacturers within the European Union, whereas the number of isopropanol manufacturers remains very limited. It is important to note that ethanol can be produced using relatively simple manufacturing processes, which is crucial during situations such as pandemic crises. Ethanol can be produced synthetically via direct or indirect ethylene hydration (e.g., petroleum-derived ethanol). Thus, ethanol is a renewable active material and almost unlimitedly available in very high quantities (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 to produce EBHR during Covid -19 pandemia. 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. 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 pandemia, 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.

Should ethanol receive a CMR classification, it would no longer be accessible to the general public as a disinfectant. The proposed classification effectively constitutes a comprehensive prohibition. 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. Also, switching to inadequate 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).



In connection with CLP-Regulation

Furthermore, Ethanol is 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.

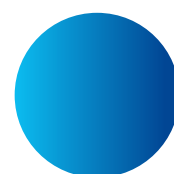
In addition to its use as a disinfectant under BPR, it serves as an extractant, solvent, preservative, process and cleaning agent, in production processes and in laboratory analysis. It is widely used in the pharmaceutical industry as a technical solvent based on the Ph. Eur. monograph, which guarantees its purity, and the ICH Q3C guideline, which classifies it as a Class 3 solvent ("safe"). It is extensively utilized in various processes such as the synthesis/crystallization of active pharmaceutical ingredients (APIs), extraction of herbal medicinal plants and in the manufacturing of finished products (e.g., granulations, film coatings, etc.). Particularly for APIs that degrade in aqueous environments, ethanol is an irreplaceable technical solvent. Also in API synthesis, crystallization from ethanol ensures negligible microbial contamination. In addition to this, ethanol may also be used as an excipient, playing the role of a solvent or co-formulant for flavours, among other functions. When used during the manufacturing processes of medicinal products, ethanol is completely evaporated, and residues shall be within ICH Q3C safety limits.

In case ethanol is used as an excipient, its safe use and levels are supported in the registration dossier based on relevant ICH / EMA guidance (which sets particularly tight standards especially in case of paediatric formulations).

For the time being, no specific safety issues are associated to the use of ethanol in the pharmaceutical field. Most of the production processes involving ethanol are closed-loop (e.g., the loading of alcohol into liquid preparation tanks has a specific utility above the hatch of the said tank); whereas for other uses such as washing solutions, film-forming solution preparation, the tapping occurs in an open system.

Ethanol has outstanding properties as extractant for active pharmaceutical ingredients, as a standard chemical in laboratory and cleansing agent of production equipment. Maximum workplace concentration limits and a risk-based handling of ethanol exist already for many years. There is no evidence of health impairment over a long-term use. Also in this particular field availability, biodegradability and an already existing risk-based handling make ethanol an indispensable substance. The classification of ethanol as CMR under the BPR procedure will also have an impact on the subsequent classification under the CLP Regulation and thus on its general use and handling.

Therefore, the reclassification of ethanol as a CMR (Carcinogenic, Mutagenic, or Reproductive toxicant) substance would also lead to a reassessment of the use of ethanol as an excipient in the pharmaceutical field, which it would have significant technical and economic repercussions on pharmaceutical operations. From an occupational safety perspective, substantial investments (e.g.



closed loop environments, use of isolators etc) and the use of personal protective equipment (PPE) would be required.

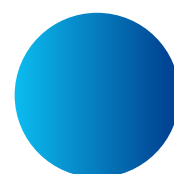
Higher environmental impact would be triggered in case of use of disposable PPE for routine manufacturing activities.

Consequences of a classification as CMR substance category 1A or B according to BPR

- High bureaucratic hurdles for the use of ethanol as a biocide
 - Widespread use as a healthcare disinfectant is no longer permitted.
- Prohibition of use for
 - Private end users
 - Vulnerable groups of people

Consequences of a classification as CMR substance category 1A or B according to CLP

- Fire and explosion protection measures are necessary
- Organisational measures
 - Delimitation of hazardous areas, access restriction, shift plan, storage under lock.
- Ensuring occupational health and safety
 - Protection of employees from CMR substances
 - Personal protective equipment, compliance with occupational exposure limits
- Principles of the Hazardous Substances Ordinance must be observed.
 - Is compliance with the occupational exposure limit value sufficient for vulnerable groups?
- Maternity Protection Act § 11 - Employment ban for pregnant (and breastfeeding) women - irresponsible risk, Youth Protection Act
 - Pregnant and breastfeeding women and young people could no longer be employed in the manufacture of e.g. medicinal products, medical devices, food and food supplements, dietetics, and cosmetics, which contain ethanol or where ethanol is used in context of the manufacture.



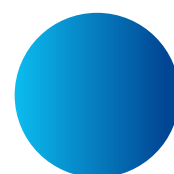
- Loss of well-established medicinal products containing ethanol due to economic and organisational reasons, for which a substitution is not possible.
- Loss of multiple jobs in the healthcare industry

Conclusion

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.

If ethanol is classified as a CMR substance, this will negatively affect its CLH-evaluation under the CLP Regulation and restrict its use in producing medicines, medical devices, food, supplements, dietetics, and cosmetics. Category 1 classification would have major consequences for these industries due to health and safety concerns, such as:

- 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 would have to be observed or applied, e.g. substitution as well as technical, organisational, and personal measures.
- A harmonized classification could affect approved manufacturing processes, which could result in complex, sometimes license-requiring changes to production processes or even product modifications.
- Availability of medicinal products and medical devices would be restricted; some even would not be available anymore. Also, food including food supplements and cosmetics in the European Union would be affected.
- Furthermore, the classification of ethanol as a Category 1 CMR substance in the medical device sector could in some cases result in a new conformity assessment, which would place an additional burden on the industry. Furthermore, the reusability of medical devices would be jeopardized, which could lead to the more frequent use of less resource-efficient single-use products.



Key Asks

Given these factors, we urge maintaining the current harmonised classification of ethanol as a highly flammable liquid (H225), which already provides adequate public health protection based on current usage.

- 1. Clock - Stop until reliable scientific evidence supporting CMR properties of ethanol in the case of inhaled or dermal exposure is available!**
- 2. The assessment should be conducted on a risk basis and linked to exposure routes (oral, dermal), rather than being hazard-based solely on oral alcohol consumption data.**
- 3. An impact assessment for patients regarding the loss of their (critical) therapeutic options!**

References:

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- [5] Persistence of coronaviruses on inanimate surfaces and their inactivation with biocidal agents
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