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Active ingredient ethanol

Effective, safe, indispensable

WIRKSAMKEIT GEPRÜFT NACH EU NORMEN
IHO
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DESINFEKTIONSMITTEL-LISTE

GW GESUNDHEITSWESEN

GK GROßKÜCHENHYGIENE

GR GEBÄUDEREINIGUNG

LEV LEBENSMITTEL-ERZEUGUNG & -VERARBEITUNG

Ethanol – all-rounder in many industries

Introduction

Ethanol is characterised by a variety of specific properties and has a number of unique features compared to other alcohols. This makes ethanol an indispensable raw material for the healthcare, pharmaceutical, medical device and food industries, among others.

The European Chemicals Agency (ECHA) is currently evaluating ethanol, a process that could significantly restrict its future use. This assessment impacts the Biocidal Products Regulation (BPR) and, subsequently, the Classification, Labelling, and Packaging (CLP) Regulation. In the short term, ethanol faces the risk of being classified as a reproductive toxin and/or a carcinogen under Category 2 – or even the highest hazard Category 1 (Carcinogen, Mutagen, Reprotoxic, abbreviated as CMR).

The experts report on the significance of ethanol for their industry and explain what a **CMR classification** would mean for their sector, as well as for the protection of consumers, patients, and employees.

- Dr Maren Eggers, Virologist and Specialist in Infection Prevention, Laboratory Prof. G. Enders & Partner,
- Dr Meike Criswell, Head of Phytopharmaceuticals/Homeopathics/ Anthroposophics at the Anthroposophics at the German Pharmaceutical Industry Association
- Dr Birgit Christall, Scientific Director of the German Food Association Germany
- Dr rer. nat. Thorsten Reinecke, Head of the Hazardous Substances-Biological Substances Division, BG BAU – Employer's Liability Insurance Association for the Construction Industry

Their conclusion: The hazard-based approach to the classification of ethanol under the CLP regulation is solely based on data from (abusive) oral intake of ethanol mixtures, without further risk assessment, and is therefore unsuitable for evaluating the technical application or the substance ethanol itself. On the contrary, the objective of enhancing consumer health protection would be counteracted by a CMR classification.

Find out in this brochure what specific effects a CMR classification would have for your industry. Our **supplement** also provides you with information on the current status of the of the classification procedure and how you can actively contribute to the continued safe use of ethanol as a raw material in production processes and as an additive and active ingredient.

Important properties of ethanol

Rapid volatility without residue

Due to its low molecular weight, ethanol volatilises very quickly and dries residue-free – an advantage, for example, in the rapid disinfection of surfaces.

Base material for many applications

- For the production of many chemicals
- As a solvent for oils, fats, resins, and many dyes, among others
- For the production, preservation, and stabilisation of pharmaceutical preparations and medicines
- As a cleaning agent or additive

Odourless and colourless

Ethanol is an ideal carrier for fragrances.

Unique virus efficacy among alcohols

A unique feature of ethanol is its effectiveness against non-enveloped viruses, e.g.: poliovirus, coxsackieviruses, echoviruses and the enterovirus A71, which cannot be inactivated by other alcohols such as 1-propanol and 2-propanol.

Flexibility in application

Ethanol is very well suited for combination with other active ingredients such as acids and excipients such as glycerine. This means that appropriate formulations can, for example, increase the efficacy and skin compatibility of hand disinfectants.

High safety and tolerability

The dermal uptake or inhalation, e.g. as part of hand disinfection, is far below toxicologically relevant concentrations. Ethanol does not accumulate in the environment long-term.

International relevance

Ethanol is used worldwide as an active ingredient in hand disinfection. The WHO lists Ethanol as an indispensable active ingredient for antiseptic applications.

Why does the healthcare system need ethanol Dr Eggers?

Dr Eggers, ethanol was first recommended for surgical hand disinfection by Fürbringer in 1888. What role does the active ingredient ethanol play in protecting patients and staff today?

Maren Eggers: When we talk about ethanol in the healthcare sector, we usually do not refer to the pure active substance. Ethanol has an aseptic effect and can be combined with a variety of other active ingredients and excipients. Thanks to these properties, such formulations are now used for hand disinfection and rapid surface disinfection. The alcohol-based hand disinfectants established on the market, for example, contain skin-caring substances. As a result, they achieve better skin compatibility without compromising the effectiveness. It also increases the willingness of staff to disinfect their hands due to better skin compatibility. Compared to other alcohols used for asepsis, ethanol has a decisive unique feature for patient and staff protection: its exceptional antiviral efficacy.

What characterises the viral efficacy of ethanol?

Maren Eggers: Of all three alcohols used for hand disinfection, only ethanol-containing products are effective against hydrophilic non-enveloped viruses within practicable application times. While noroviruses can still be inactivated by formulations containing 2-propanol and 1-propanol, the efficacy of these alcohols is insufficient against adenoviruses, human enteroviruses, echoviruses, coxsackieviruses, and polioviruses. Even against human papillomaviruses, virucidal formulations can be used. This makes ethanol essential for combating infections caused by these viruses.

How clinically relevant are these viruses?

Maren Eggers: Poliovirus, echovirus and coxackievirus belong to the enteroviruses. Coxsackie A viruses, but also enterovirus 71, cause hand-foot-and-mouth disease, which often leads to outbreaks in childcare facilities. Enterovirus infections can lead to aseptic meningoencephalitis or myopericarditis and, in rare cases, to polio-like, flaccid paralyses. While complications during pregnancy are rare, a maternal enterovirus infection around the time of birth can be transmitted to the newborn and, in rare cases, lead to severe neonatal complications. Polio is unfortunately by no means close to eradication. This was evidenced by the cases in the Gaza Strip and Ukraine in 2015 and 2022 – unfortunately, complicated by geopolitical difficulties. In Pakistan and Afghanistan, the wild poliovirus type 1 is still circulating. Recently, poliovirus have been detected in environmental samples in several European countries, including Germany.

Experts are warning of new pandemics. What role does ethanol play in combating the pandemic?

Maren Eggers: An indispensable one: no one can currently say what a pandemic virus will look like. The possibility that only a virucidal disinfectant can interrupt the transmission path is therefore realistic. But it is about more than effectiveness: without ethanol, we would be left as bare as we were during the SARS-CoV-2 pandemic, where no hand disinfectants were available in the beginning. Ethanol is widely available, with numerous ethanol producers compared to far fewer propanol manufacturers. Furthermore, we need well-formulated, tested products to protect the skin health of our healthcare staff.

The SARS-CoV-2 pandemic has also shown how important standardised test protocols according to EN methods are. They ensure that disinfectants and antiseptics are effective and safe in everyday clinical practice and in outbreak scenarios. Ethanol has been established as the reference in the EN17430 testing standard due to its superior efficacy against unenveloped viruses The standard tests the effectiveness of hand disinfectants against viruses on artificially contaminated hands. The European standards for infection prevention and disinfection are not only of significant importance in Europe, but are also recognised in the USA, Canada and the Asia-Pacific region.

Dr Eggers, thank you for the interview.

PD Dr Maren Eggers, Virologist and Specialist for Infection Prevention, Laboratory Prof. G. Enders & Partner, Stuttgart, Germany

Why does the pharmaceutical industry need ethanol Dr Criswell?

Dr Criswell, ethanol is an all-round raw material due to its versatile applications. What role does the chemical play in the pharmaceutical industry?

Meike Criswell: The production processes in the pharmaceutical industry are subject to the highest hygienic requirements. In professional cleaning and disinfection, ethanol is used primarily because of its excellent effectiveness and high volatility. Ethanol is also effective against non-enveloped viruses, which are difficult to inactivate. When applied, ethanol evaporates, meaning it does not leave unwanted residues on the skin or surfaces, unlike other active ingredients. This property is indispensable for the cleaning disinfection of surfaces in the production environment. Ethanol is widely used in pharmaceuticals and production processes as a solvent, activity enhancer, extraction agent, stabilizer, and preservative. The use of this raw material affects not only industrial processes and disinfectants for professional use but also a wide range of products for the public.

There is currently a threat of ethanol being categorised as a CMR substance. What would that mean for your industry?

Meike Criswell: This would have profound consequences. Ethanol is a well-documented and safe raw material that is highly biodegradable. Substitution would only be possible in a few individual cases. With ethanol, we have the only sustainable solvent produced from renewable raw materials that would have to be replaced by petrochemical solvents in the event of a CMR classification. For health protection, such as in the disinfection sector and for end consumers, many everyday products would be lost. The medium- and long-term consequences for professional use and industry are not yet foreseeable. The production processes from delivery to storage would become more complicated and expensive. The ethanol supply chains would be massively affected and purchasing would become more difficult. This would lead to massive competitive disadvantages.

From a toxicological perspective, classifying ethanol as carcinogenic and reproductive-toxic is understandable based on data from abusive oral intake.

Meike Criswell: Data on oral exposure cannot be applied to the technical use of ethanol in production processes or as an ingredient, such as in disinfectants. Here the exposure occurs through inhalation and dermal contact.
In the CLP regulation and subsequent frameworks, this hazard-based approach results in insufficient risk assessment. How the chemical is used and whether a risk actually exists is therefore not taken into account in the assessment.
Furthermore, the existing oral data is predominantly based on the misuse of ethanol mixtures. For a comprehensive scientific assessment of a substance's hazard potential is therefore not sufficient.

What does a risk assessment for ethanol exposure look like, and what does scientific data say about the risks of inhalation and dermal exposure?

Meike Criswell: The OECD concluded in 2004 that there was no compelling evidence of risks in the workplace or from the use of ethanol in consumer products. Critical ethanol concentrations are not reached by either dermal or inhalation exposure. Oral exposure of workers can also be virtually ruled out due to the applicable health and safety regulations. The use of denatured alcohol in disinfectants prevents improper oral intake during application
The hazard-oriented classification approach is based solely on data from food and beverage consumption, including oral ingestion and abuse, without further risk assessment. Therefore, it is not suitable for evaluating the technical applications or the substance ethanol itself. Rather, it should be examined whether a harmonised classification of ethanol is even necessary, especially as this would counteract the increase of consumer health protection.

Dr Criswell, thank you for your time.

Dr Meike Criswell, Business Unit Manager Disinfectants, Business Unit Manager Phytopharmaceuticals/Homeopathics/Anthroposophics at the Federal Association of the Pharmaceutical Industry e.V.

Why does the Food Industry need Ethanol, Dr Christall?

Dr Christall, ethanol is a natural component of many foods. However, it is also an important ingredient and functional substance in the food industry. Which areas of application are particularly relevant to your sector?

Birgit Christall: There are three main areas of application in the food industry. Ethanol is added as an ingredient to baked goods and confectionery and is a key raw material for the production of vinegar. Functional use refers to when ethanol is used as a solvent or extraction agent, for example, for plant extracts or as a carrier for food flavours. Finally, ethanol-containing disinfectants are used for hand disinfection and for rapid surface disinfection in production areas and the foodservice industry.

At present, there is a risk that ethanol could be classified as a CMR substance. What impact would this have on your industry?

Birgit Christall: From a regulatory perspective, an assessment under the Biocidal Products Regulation currently leads automatically to classification under CLP, requiring adjustments to further legal regulations. This would have immense consequences, particularly for occupational health and safety across all affected industries. Classification as a carcinogenic and reproductive toxicant would effectively mean an employment ban for pregnant and breastfeeding women. In production, significant investments would be needed to modify manufacturing facilities. Consider, for example, winemaking-aging wine in barrels would no longer be possible without installing large ventilation systems and closed systems. Additionally, such a classification would lead to a loss of consumer trust in food safety. As an ingredient, ethanol cannot be replaced by other substances, but it is also indispensable as a functional substance and for implementing hygiene concepts in many production processes.

Which processes are those?

Birgit Christall: In the production of baby food and organic foods, ethanol-based disinfectants are one of the few remaining alternatives for disinfecting machines and equipment following the phase-out of other biocidal agents, such as quaternary ammonium compounds (e.g., BAC and DDAC) and chlorine-based substances. Ethanol has unique antimicrobial properties, is water-free, and evaporates quickly without leaving residues. This makes ethanol indispensable, for example, in dairies. If isopropanol were used as an alternative, rinsing would be mandatory due to potential residues, increasing the risk of microbial and fungal contamination.

The classification aims to improve consumer health protection. From your industry's perspective, do you believe this goal is being achieved?

Birgit Christall: Since ethanol-containing finished products intended for end consumers do not fall under the CLP Regulation, the misuse of alcoholic beverages would remain entirely unrestricted. The classification of ethanol would have no impact on the labelling, packaging, or sale of alcoholic beverages to consumers. Therefore, it would not contribute to an increased level of protection. Additionally, since third countries can continue to place alcohol-containing products on the EU market without restrictions, we see a significant economic risk of food production shifting to countries where EU harmonization does not apply. For these reasons, we do not consider the CMR classification of ethanol as a chemical to be an effective measure. Instead, prevention and education on the responsible handling of alcoholic beverages would be more appropriate approaches.

Dr Christall, thank you for the interview.

Dr Birgit Christall, Scientific Director of the Food Association Germany

What does Occupational Safety say about ethanol, Dr Reinecke?

Dr Reinecke, is the classification and labelling of a hazardous substance according to the CLP Regulation sufficient to regulate its handling in the workplace?

Thorsten Reinecke: One of the fundamental obligations of the Hazardous Substances Ordinance is the implementation of a risk assessment. An employer may only allow work involving hazardous substances to begin once a risk assessment has been conducted and the necessary protective measures have been implemented. The risk assessment serves as the basis for determining protective measures that ensure the health and safety of employees working with hazardous substances. It must take into account inhalation, dermal, and physicochemical hazards (e.g., fire and explosion risks) associated with the tasks. When conducting the risk assessment, both substance-related and task-related information must be considered. An important substance-related factor is the classification and labelling of a hazardous substance according to the CLP Regulation. Additional relevant substance-related factors include occupational exposure limits and the skin absorption properties of hazardous substances. Significant task-related aspects include the type, extent, and duration of exposure to hazardous substances through inhalation or skin contact. Therefore, the classification and labelling of a hazardous substance alone cannot determine the associated hazards and necessary protective measures for specific activities.

What other data on ethanol is relevant for occupational safety assessments?

Thorsten Reinecke: Primarily, the workplace exposure limit (AGW). Ethanol has a binding AGW of 380 mg/m³, which should be used to assess inhalation in workplaces as part of the risk assessment and to check the effectiveness of protective measures. Ethanol is listed in TRGS 900 ('Occupational Exposure Limits') with the remark 'Y', indicating that, when the occupational exposure limit is observed, there is no concern regarding fetal harm.
Ethanol is not a skin-absorbable substance. If substances have skin-absorption properties, they can penetrate intact skin due to their physicochemical properties and cause health issues. Skin-absorbable substances are marked with 'H' in TRGS 900, but this does not apply to ethanol. Therefore, in workplace settings, compliance with the AGW is sufficient to protect employees' health when handling ethanol.

The BG BAU has conducted numerous workplace measurements for activities involving ethanol-based cleaning agents, such as glass cleaners, including under worst-case conditions. In all cases, the occupational exposure limit (AGW) for ethanol was met.

How do you assess a CMR classification of ethanol in terms of its practical application in the workplace?

Thorsten Reinecke: Ethanol is not skin-absorbable. Inhalation exposure to ethanol when using ethanol-based cleaning agents is low, and even under worst-case conditions, the AGW for ethanol is consistently met. Compliance with the AGW ensures the protection of employees and, if the activity is carried out by a pregnant woman, also protects the unborn child. According to the Maternity Protection Act, an unacceptable risk to pregnant women is considered ruled out if a substance is classified with the remark 'Y' in TRGS 900 and if the risk assessment confirms compliance with the AGW. A classification of ethanol as a reproductive toxicant would not change this assessment. However, the Maternity Protection Act does not contain a comparable exclusion rule for breastfeeding women, as there are no workplace-specific regulations that definitively rule out effects on lactation. As a result, breastfeeding women would no longer be allowed to handle ethanol-containing products if ethanol were classified as such.

Dr Reinecke, thank you for your time.

Dr rer. nat. Thorsten Reinecke,
Head of the Hazardous Substances and Biological Agents Department,
BG BAU – German Social Accident Insurance Institution for the Construction Industryt

This document was created by members of the Industrial Association for Hygiene and Surface Protection (IHO) for the healthcare, pharmaceutical, medical device, and food industries. It provides information on the effects of a CMR classification of ethanol.

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