FACTSHEET

Ethanol in the Healthcare Sector

Essential applications of ethanol

A current process by the European Chemicals Agency (ECHA) for the assessment of ethanol could severely restrict its use in the future.

Within the Biocidal Products Regulation (BPR) [1] and subsequently the Regulation on Classification, Labelling and Packaging of Substances and Mixtures (CLP) [2] ethanol is expected to be classified as toxic to reproduction and/or carcinogenic category 2, or even the highest hazard category 1 (carcinogenic mutagen reprotoxic, CMR) in the near future.

This might have a significant impact on the industrial health sector and healthcare supplies. Consequently, the availability and use of ethanol would be severely restricted or even banned as a main or auxiliary active ingredient due to occupational health and safety regulations. This includes, for example, hand sanitisers, surface disinfectants, and the use in production and hygiene processes. The classification would also have a serious impact on the production of important medicinal products, medical devices, and in-vitro diagnostics – and in consequence on patient care.

The risk classification data used for the assessment is essentially based on the (abusive) oral consumption of alcoholic beverages.

Ethanol for disinfection and hygiene

Ethanol is an essential active ingredient in disinfectants as it is particularly effective against bacteria and viruses and is also safe and biodegradable. The World Health Organisation (WHO) has classified hand disinfectants containing ethanol as indispensable. Ethanol acts specifically and without alternative against non-enveloped viruses such as poliovirus [3]. The prevalence of nosocomial infections has also been reduced through the use of alcohol-based hand sanitisers.

Particularly 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. In hygiene and other professional applications, only denatured alcohol is used to prevent oral absorption.

A CMR classification 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.

In addition, 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.

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Ethanol in the Healthcare Sector

Ethanol for medical devices and in-vitro diagnostics (IVD)

Medical devices and IVDs are massively affected by the potential categorisation of ethanol as a CMR substance:

- Ethanol is used in a variety of **production** processes, including the cleaning and disinfection of equipment, preparation for production processes (bonding, coating), as a solvent for inks for labels, etc., but also within occupational safety (cleaning and disinfection).
- Ethanol is used as an **auxiliary material** and **adjuvant** in products and reagents in in-vitro diagnostics (e.g. as a solvent, carrier, preservative, or extraction agent).
- Ethanol is used as the **main active ingredient** in core products. This includes medical devices, but also so-called dual-use products. These disinfectants are intended for use both as disinfectants for medical devices and IVDs and their equipment and as surface/hand disinfectants and are placed on the market as biocidal products and medical devices.

Classification of ethanol as a category 1 CMR substance would possibly result in a "justification" for the use of a CMR substance in medical devices in accordance with Annex I point 10.4.1 of the Medical Device Regulation (MDR) [4]. This could be considered as a substantial modification of products, accompanied by corresponding conformity assessment procedures, which require at least 18-24 months.

Ethanol for pharmaceuticals and production

Since disinfectants are not only placed on the market as biocides or medical devices, but also as medicinal products, there is a risk that a ban on ethanol will soon be extended to this product group.

Ethanol has important functions and advantages in pharmaceutical production. It is primarily used as a carrier, preservative, and extraction agent for active substances, essential oils, and other ingredients that are not soluble in water. Ethanol has properties that contribute significantly to the efficacy of a medicinal product, although only very small quantities are required. Especially in the field of herbal medicines, ethanol is indispensable, 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 medical products.

There is no alternative to the use of ethanol in production processes.

[1] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products
[2] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures
[3] Burke M; Public health put at risk by mooted EU classification of ethanol as reprotoxic, Chemistry World, 09.2024
[4] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

Conclusion

In order to ensure a secure supply of disinfectants, cleaners, pharmaceuticals, medical devices, and IVDs, as well as the production and supply of finished products, a classification of ethanol as a CMR substance as toxic to reproduction and/or carcinogenic (category 1 or 2) must be avoided as a matter of urgency. Classifying ethanol as a CMR substance would seriously undermine the purpose of the Biocidal Products and CLP Regulations, which is to improve and protect human health. Instead, there would be a significant negative impact on hygiene and healthcare.

A CMR classification would be disproportionate and inappropriate, as it is based solely on a hazard-based assessment of (abusive) oral consumption of ethanol mixtures. Furthermore, it should be noted that in hygiene and other applications, denatured alcohol is used, thus preventing oral ingestion. In addition, the dermal application and the application on surfaces is effective and safe. Moreover ethanol is effective, safe, and indispensable for use in production processes and for the manufacture of disinfectants, medicinal products, medical devices, or IVDs. In addition, vulnerable patient groups, especially in hospitals or in the outpatient sector, but also in times of pandemics, would no longer be protected. Possible exemptions appear to be neither effective nor attractive in view of the regulatory and bureaucratic burden.