

# Infection control at risk - The harmonized classification of ethanol as a CMR substance must be stopped

As associations representing the German healthcare industry, we are deeply concerned about the European Chemicals Agency's classification procedure for ethanol as a biocide. This process poses an imminent threat to the use of ethanol in the healthcare sector and could have far-reaching negative consequences for **infection control**, **patient safety**, and the **protection of employees** in Germany. We call for a halt in the inappropriate and disproportionate classification of ethanol as a CMR substance.

## Background

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.

## Problem – The Procedure

Ethanol is currently regulated at the EU level under both the Biocidal Products Regulation (BPR) and the Classification, Labelling and Packaging (CLP) Regulation concerning chemicals. It is anticipated that ethanol will soon be classified as a CMR substance (carcinogenic, mutagenic, toxic for reproduction) in hazard category 2 (including effects on lactation), or potentially even in the highest hazard category 1. The classification of ethanol as a CMR substance would impose extensive restrictions on its use, with significant negative consequences, particularly for the healthcare sector. Such a classification would complicate or even prohibit the production and use of disinfectants, pharmaceuticals, and medical products. It is especially important to highlight that the risk assessment is largely based on the abusive **oral** consumption of alcoholic mixtures. In contrast, in the professional use of ethanol in the healthcare sector, exposure occurs primarily through the skin or, in rare cases, via inhalation. Furthermore, the substance is denatured, eliminating the possibility of recreational consumption. There is currently no evidence that dermal or inhalation ethanol uptake in the context of the use of disinfectants has a CMR effect.

### Further Information

[Press release by BPI, BVMed, IHO und VDGH \(2024\)](#)

[Statement by VAH and other organizations \(2020\)](#)

[Statement by DGKH \(2024\)](#)

[Position paper of the Alliance pro Ethanol on infection prevention \(2022\)](#)

[Publication by DGKH, WHO etc. \(2024\)](#)

[Open letter from the VAH together with FAHP and ESNO to the EU \(2024\)](#)

[Press release by BPI \(2024\)](#)

[Factsheet Ethanol by BPI \(2024\)](#)

## Consequences for Germany

A CMR classification of ethanol would be tantamount to a de facto ban, jeopardising hygiene and healthcare, and particularly compromising the protection of patients and vulnerable groups. Furthermore, the planned classification of ethanol as toxic for reproduction, with effects on lactation, would effectively prohibit women of childbearing age from working under German labour law. We therefore consider the classification of ethanol as a CMR substance to be disproportionate and inappropriate, given that ethanol is safe and irreplaceable when used as intended.

## Calls to Action

The reclassification of ethanol must be prevented by all means. Germany, as an important and economically strong member of the EU, plays a significant role in this decision. As things currently stand, the German government has yet to adopt a firm position on the matter. It is essential that the German government—despite the early parliamentary elections—promptly takes a clear stance and supports the continued use of ethanol in the healthcare sector. **To this end, the inappropriate classification of ethanol as a CMR substance must be stopped.**