

VCI SHORT POSITION ON CURRENT ETHANOL REGULATORY DOSSIERS

Ethanol classification: Serious consequences ahead

Ethanol is currently being evaluated as a biocidal active substance under the Biocidal Products Regulation (EU) No. 528/2012. The evaluating Greek authority forwarded the dossier to the ECHA in March 2024, including a classification proposal as toxic for reproduction category 2. A formal check was successfully completed in the process, which could be concluded with a final classification as early as the **beginning of 2025**.

- **Biocidal Products Regulation:** 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 industry.
- **CLP Regulation:** The same applies to the use as an omnipresent and safe industrial chemical, if a more severe harmonised classification and labelling under regulation (EC) No 1272/2008 (CLP) were introduced as a subsequent consequence.
- The CLH process must no longer be treated as an "automatic mechanism". The European Commission is required to check whether the proposal is "appropriate" and whether a specific risk to human health, occupational health and safety or the environment is reduced. The harmonised hazard classification of substances should not be an end in itself, as there is a risk of **serious impacts on many industrial sectors** and uses.

Overview of the impacts



Solvents and process additives
in chemical industry
Pharmaceutical industry
Skin, hand, and surface
disinfectants
Printing inks and coatings
Food industry

Washing, care and cleaning agents
Cosmetic products
Occupational safety regulations
Craft, trade and professional
applications
Medical products
Fuels and fuel additives

Consideration of the route of exposure

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.
- ◆ **The contrary effect is likely:** Ethanol-based disinfectants have clear advantages over alternatives in ensuring a high level of health protection and were irreplaceable, particularly during the coronavirus pandemic.



VCI policy asks

The use of ethanol as an industrial chemical is essential, safe and must be preserved!

- 1) Available human data are not suitable for classification, the inhalation and dermal routes of exposure should be included.
- 2) Conclude current biocidal process with no classification.
- 3) Socio-economic effects including consideration of alternatives must be taken into account in ongoing procedures.
- 4) Assess whether a new harmonised classification is appropriate.
- 5) Legislative proposals must be postponed to avoid premature major negative effects on industry.

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