

# Ethanol: Soon to Be Classified as a CMR Substance?

For several years now, the EU has been conducting an evaluation of ethanol as part of the review process for biocidal active substances. As part of this evaluation, an assessment of its hazardous properties is mandatory.

During the process, consideration was given to classifying ethanol as both carcinogenic and toxic to reproduction, which caused great concern among many stakeholders. Now, the Biocidal Product Committee (BPC) of the ECHA has adopted its opinion.



Ethanol (also known as ethyl alcohol) is a basic chemical with a wide range of uses. Its applications include (without claiming to be exhaustive): solvents, process chemicals, pharmaceuticals, cosmetic products, detergents and cleaning products, printing inks, paints and coatings, fuels, and disinfectants.

More than 20 years ago, a comprehensive review of all biocidal active substances began in the EU, known as the EU Review Program. Since the disinfecting properties of ethanol have been known for a long time, it is the subject of this EU-wide project. An important part of the review program addresses the risks to human health.

## Biocidal Report from Greece: Ethanol Potentially Reproductive Toxic

As part of the EU Review Program for Biocides, Greece was assigned responsibility for evaluating ethanol. In accordance with legal requirements, the Greek competent authority conducted an intensive review of the available data and information on toxic effects. The result of the evaluations was a dossier, which the Greek experts submitted to ECHA in March 2024 for further discussion.

Based on the available data, the assessment report from Greece proposed, among other things, that ethanol be classified as “possibly toxic to reproduction” (Repr. 2, H361).

## **ECHA Biocidal Products Committee (BPC): Is ethanol carcinogenic and toxic to reproduction?**

The report from Greece was then discussed within the framework of the so-called working groups of the Biocidal Products Committee (BPC-WG). In September 2024, these expert teams developed a proposal for the classification of ethanol using scientific criteria, which went significantly beyond the original application. The outcome of the deliberations in the expert groups was that ethanol should be classified, among other things, as carcinogenic (Category 1) and toxic to reproduction (Category 1).

In November 2025, the ECHA Biocidal Products Committee (BPC) discussed a draft opinion regarding the authorization of ethanol. However, there was a lack of consensus within the committee, so the adoption of the opinion was postponed.

There were differing views on the potential implications of classifying ethanol as a Category 1 CMR substance<sup>1</sup>. Particularly with regard to effective hygiene in hospitals and medical practices, as well as for private consumers, widespread concern was expressed that such a step would entail significant risks. This is because ethanol-based disinfectants could consequently no longer be made available on the market, or only with considerable regulatory effort. From today's perspective, there are no viable alternatives to ethanol as an effective and readily available active ingredient for controlling risks posed by pathogens such as viruses and bacteria.

Other experts pointed out that the EU Biocidal Products Regulation (Regulation (EU) No. 528/2012, BPR) provides for exceptions, meaning that active substances with CMR properties could also be authorized. While this is true, the relevant passages of the legal text are complex and could be interpreted in different ways.

At the same time, it should be noted that various stakeholders have strongly criticized the BPR's lack of operational feasibility. Although the BPR's objectives are widely recognized, reports indicate that its practical implementation involves disproportionate regulatory burdens, significant inefficiencies, and years-long delays in the authorization processes. Against this backdrop, concerns that a CMR classification would significantly impede the supply of ethanol-containing disinfectants are difficult to dismiss. Experts and renowned institutions in the hygiene sector have, in any case, issued urgent warnings about negative consequences should ethanol be classified as carcinogenic and toxic to reproduction.

### **The next step: Expansion of the harmonized CLP classification?**

Due to the strict legal requirements of EU chemicals legislation, a potential classification of ethanol as a CMR substance would hardly be limited to its use as a disinfectant. Greece has already submitted an intention to ECHA to assign an expanded harmonized CLP classification

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<sup>1</sup> CMR stands for carcinogenic, mutagenic, and/or toxic to reproduction.

to ethanol in general. The findings and conclusions from the review program for biocidal active substances would likely be incorporated into this process, meaning that the general legal classification for ethanol would presumably follow the assessment in the biocidal sector.

### **How reliable are the underlying studies?**

Critics of the proposed classification of ethanol as a CMR substance point out that the underlying data consider only oral ingestion and that carcinogenic or reproductive toxic effects were observed only following excessive consumption of alcoholic beverages. The widespread use of ethanol for hand and surface disinfection, however, results in only very minimal absorption into the human body. The German Society for General and Hospital Hygiene wrote on this subject: “Other routes of exposure (inhalation, dermal) result, under real-world conditions in healthcare settings, in blood levels that are at background levels ...”

### **BPC recommends ethanol as a biocidal active ingredient—currently without CMR classification**

At the BPC’s February 2026 meeting, an expert opinion (BPC Opinion) on ethanol was adopted. According to this opinion, the Biocidal Products Committee recommends approving ethanol as a biocidal active substance in product types 1, 2, and 4. The experts were unable to reach a conclusion regarding the carcinogenic and reproductive toxic properties, and therefore no new harmonized classification was proposed.

However, a stricter harmonized classification of ethanol is not yet entirely off the table. New studies are currently underway, and their results remain to be seen. However, the BPC did not wish to wait any longer for the biocidal use of ethanol and has therefore recommended approval of the active substance. The ball is now in the court of the European Commission, which will make a decision on the approval of ethanol as a biocidal active substance.

### **Notes for Switzerland**

The Swiss Ordinance on Biocidal Products (SR 813.12, OBP) is considered equivalent to the EU BPR. This is a prerequisite for the mutual recognition of authorizations for such products between Switzerland and the EU. In particular, the Mutual Recognition Agreement (MRA) stipulates that Switzerland applies the same evaluation procedure for biocidal active substances as the EU. Consequently, the European Commission’s decision on whether to approve or reject ethanol will also be binding for the biocidal sector in Switzerland. If ethanol is approved as an active substance in the EU, its inclusion in the “positive list” of the Swiss OBP (list per Annex 2 OBP) should be merely a formality.

If the EU Commission follows the BPC's recommendation and approves ethanol for product types 1, 2, and 4, many Swiss holders of disinfectant product authorizations will have a lot of work ahead of them. All biocidal products with transitional authorizations Z<sub>N</sub> or Z<sub>B</sub> that contain only ethanol as a biocidal active substance (or, in addition to ethanol, only other active substances already approved in the EU) will then rapidly approach the end of their validity period. To keep their products marketable, the affected companies must take proactive action.

Any follow-up solutions should be prepared now, because once the last biocidal active substance is included in the lists under Annex 1 or 2 of the Ordinance on Biocidal Products (OBP), the transitional authorizations will remain valid for only 6 months if affected companies do not react in time (Art. 8 para. 1 lit. c OBP).

I+K will provide further updates once the European Commission's decision on the approval or non-approval of ethanol is published.

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Through our [services](#), we advise and support our clients on all matters related to safety data sheets, chemical labeling, as well as product notifications and product approvals.

Our [C<sup>3</sup> ChemComplianceCheck](#) is a preventive assessment of chemical safety in the workplace. Guided by the motto "Act instead of react," vulnerabilities are identified before regulatory orders or even damage occur.

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