

Ethanol in disinfectants essential for an effective infection control

Alliance pro Ethanol for Infection Prevention (ApEI) position paper – May, 2021

It is widely accepted that one of the most effective protective measures against bacterial and viral infections is hand disinfection as well as the disinfection of surfaces. Disinfection measures can quickly and safely break chains of infection to prevent the transmission of pathogens.

Relevance for infection control

Alcohol-based disinfectants play a particularly important role in disinfection measures. They work quickly and comprehensively against most pathogens, are safe and well tolerated. Ethanol in particular shows superior efficacy against viruses compared to other alcohols. The quantities of ethanol absorbed through hand disinfection are below toxicologically relevant concentrations. To ensure that ethanol-based disinfectants are not taken orally, a denaturing agent is added.

Ethanol is the most frequently used active substance in disinfectants due to its high efficacy, safe use, and wide availability, making it an essential component of infection prevention. Moreover, the WHO lists ethanol as an essential substance, making it part of the basic care supply. In terms of infection prevention, a loss of ethanol in disinfectants would have serious consequences for the current health crisis and future pandemics. *Further information can be found in the statement by the German Association for Applied Hygiene (VAH).*

Problem of future availability

The basis for the future use of ethanol as an active substance in disinfectants is a positive evaluation for its use in hand and surface disinfectants under the European Biocidal Product Regulation (Regulation (EU) No 528/2012). Although ethanol is already classified as an active substance in a harmonized way, the new evaluation could also include a classification according to CLP Regulation (EC) No 1272/2008. It requires a CMR classification and labelling for carcinogenic, mutagenic, and reproductive toxicants. The reclassification of ethanol will start with the submission of a CLH classification proposal. Currently, the responsible EU Member State Greece is developing a proposal for the classification and labelling of ethanol. In July 2020, a classification as toxic for reproduction category 2 was suggested. The formal submission of the proposal should have been made by the Greek authorities by December 2020. No submission has been made so far.

Occupational health and safety implications

A CMR classification of ethanol will have far-reaching consequences. If a substance is classified as a CMR substance of category 1A, 1B or category 2, it may no longer be used in the national healthcare systems. In Germany, for instance, this is due to the different occupational health and safety regulations. In particular, the Maternity Protection Act (Mutterschutzgesetz, MuSchG) has an enormous impact on the use of ethanol in everyday practice. For hospitals and other healthcare facilities, a category 2 classification would mean that pregnant women would no longer be allowed to use disinfectants containing ethanol.

Current evidence base

It is undisputed that ethanol is harmful to humans when consumed in large quantities as a beverage and stimulant. Numerous studies prove the negative consequences of alcohol consumption. However, there is no scientific evidence that ethanol leads to relevant health damage when used on the skin or on surfaces (dermal and inhalation). Instead, toxicological risk assessments show that dermal and inhalation exposure to ethanol-containing chemicals in the professional, industrial and consumer sectors can be considered safe. Alcohol as a beverage and stimulant does not fall within the scope of biocides. Consequently, with a CMR classification and labelling, only disinfectants could no longer be used.

The available data on the hazard potential of alcohol as a beverage cannot be automatically transferred to the assessment of ethanol as an active substance in disinfectants. A separate consideration of ethanol is necessary, because of the different routes of exposure. *Further information can be found in the statement by the German Association for Applied Hygiene (VAH).*

Solution

To ensure that products containing ethanol for hand and surface disinfection can continue to be used for the prevention and control of infections, **ethanol must not be classified as a CMR substance**. Ethanol is already classified in a harmonized way. A new classification and labelling is not justified for ethanol in its use as a disinfectant. It would not only jeopardize effective and rapid infection control but make it impossible.

- ➔ **Classifying ethanol as a CMR substance has serious consequences for infection control. Consequently, experts and associations must use the consultation process to ensure that ethanol will not be classified as a CMR substance. A statement on the consultation procedure is only possible within 6 weeks after the proposal for CLH classification is published.**