

To the Biocides Product Committee and European Commission

Ethanol must be approved as an active substance for hand antiseptics without a CMR Classification



Alcohol-based hygienic hand rubs have long been established as the single most important measure to prevent and control infections inside and outside of healthcare institutions.

As frontline health care professionals and as the German Association of Applied Hygiene (VAH) with a unique expertise in disinfectant efficacy, we are writing to you to express our serious concerns regarding the ongoing evaluation of ethanol as an active substance for hand antiseptics (Product Type 1) under the European Biocidal Products Regulation (Regulation (EU) 528/2012, "BPR"). The Greek authorities, acting as the evaluating authority, have now been proposing ethanol to be reclassified as a Reproductive Toxicant Category 2. However, they base their proposal on human consumption data from pregnant women in doses representing alcohol abuse. This approach is flawed because the route of administration is not oral intake but topical dermal application. There is neither scientific evidence nor epidemiological data to justify this reclassification for the use of ethanol-based hygienic hand rubs.

What are the consequences? Category 2 Reprotoxic Classification requires biocides to carry labels such as *Suspected of damaging the unborn child/May cause harm to breast fed children/Avoid contact during pregnancy/while nursing*. Thus, in future potential users might view ethanol-based hand rubs as unsafe. Occupational safety regulations, for example, the Pregnant Workers Directive, could make it impossible to use them in the healthcare setting where many young women are working. Given the current shortage of nursing staff across Europe, it would place a major burden on the healthcare system, if young female employees were to become anxious and worried and possibly leave their important jobs at the patient's bedside.

Why do we need ethanol? One major reason is that ethanol is the only available substance for hand rubs which can inactivate non-enveloped viruses such as enteroviruses. These viruses have the potential to cause high disease burdens and mortality in infants. Data from enterovirus surveillance [1] and Disease Outbreak News from Member States in the European Countries [2] show that enteroviruses pose significant risks to the public as well as to healthcare staff treating hospitalized patients infected with enteroviruses. Propanol-based hand rubs cannot inactivate these viruses within an appropriate contact time [3].

In view of future outbreaks and pandemics with hitherto unknown viruses the widespread availability of hand disinfectants containing ethanol in Europe must be guaranteed without unjustifiably unsettling users and thus jeopardizing their use when indicated and necessary. Independent of whether ethanol-based hand rubs are marketed as biocides, medicinal drugs or formulations produced according to WHO recommendations, the classification should be the same and should not include reproductive toxicity.

We strongly request all regulators to review the reclassification of ethanol and approve ethanol as active substance for product-type1-biocides without classification as a Reproductive Toxicant Category 2.

We remain available for further discussions or clarifications and recommend retaining ethanol's current classification to safeguard its essential role in public health.

Thank you for your attention to this urgent matter.

Verbund für Angewandte Hygiene e.V. (VAH)

European Association of Hospital Pharmacists (EAHP)

European Specialist Nurses Organisation (ESNO)

References

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