

Authorisation of Disinfectants Containing Ethanol

Factsheet Ethanol

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The approval of ethanol as an active substance under the EU Biocidal Products Regulation (BPR – Regulation (EU) No. 528/2012) is imminent. According to a draft submitted to the WTO, the approval is set to take effect on May 1, 2028, and will remain valid for 10 years.
This has direct implications for biocidal products that contain ethanol as an active substance. Currently, such disinfectants may be placed on the market in Germany under national transitional arrangements. However, once the active substance authorisation comes into force, these products must have applied for authorisations under the BPR in order to remain on the market.
Given the significant effort required for data acquisition, conducting studies, performing risk assessments, and preparing dossiers, preparations should begin immediately. The application must be submitted by the deadline and in a format that allows for validation.

Scope

The approval of ethanol as an active substance will apply to the following product types:

- Human hygiene (eg. skin desinfection)
- Disinfectants and algaecides not intended for direct application to humans or animals (e.g. disinfection of surfaces)
- Food and feed area (Products used for the disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food or feed (including drinking water) for humans and animals. Products used to impregnate materials which may enter into contact with food.

Authorisation of Biocidal Products

Biocidal products may be granted authorisation at national or EU level. The authorisation may apply to an individual product or to a family of biocidal products. To obtain authorisation, an application for authorisation must be submitted. The scope of the data required depends on the product type, intended use, target group and claimed efficacy.

Typically, the following data will be required:

- Product data: Composition, specifications & analytical data
- Efficacy data: Test reports on applications & claims
- Safety data: Physico-chemical, toxicological & ecotoxicological information
- Risk assessments: Exposure & risks to humans, animals & the environment
- Product information: Labelling, instructions for use and summary of product characteristics

As some of the data must be determined in the laboratory on a product-specific basis, a period of several months should be allowed for the preparation of an application for authorisation.

Deadlines

If a complete application for authorization is submitted by the approval deadline of May 1, 2028, the product may, in principle, continue to be made available and used under the transitional arrangements while the authorization process is underway.

If no application is submitted by the deadline, the following timeframes generally apply:

- 180 days after the approval of the active substance: The product may still be placed on the market.
- 365 days after the approval of the active substance: Existing stocks may still be used. This does not constitute an additional period for distribution.
- Thereafter: Without a granted authorization, the product may no longer placed on the market nor used.

For further information, please visit:

dekra.com/en/chemical-safety-advisory

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