Annex to a news alert

Conclusions on of three active substances and four applications for Union authorisation

Helsinki, 9 March 2020

More information about the opinions

The opinions adopted concern applications for the following active substances in the specified product-types:

Chlorophene for product-type 2

Chlorophene is an existing active substance.

It is used as a heavy-duty disinfectant for both professional and private use. Professional use includes several uses in hospitals while private use of chlorophene is limited to disinfection of objects, such as washbasins and toilet facilities.

The evaluating competent authority of the active substance application is Norway.

Glyoxal for product-types 2, 3 and 4

Glyoxal is an existing active substance.

Products containing glyoxal in product types 2, 3 and 4 are used for disinfection performed by professional users. Glyoxal, being a di-aldehyde, acts by crosslinking proteins and nucleic acids essential to microbial life processes such as membrane integrity, metabolism and replication. When the rate of cross-linking overwhelms the repair mechanisms, cell death occurs.

The evaluating competent authority of the active substance application is France.

Reaction mass of peracetic acid and peroxyoctanoic acid for product-types 2, 3 and 4

Reaction mass of peracetic acid and peroxyoctanoic acid (PAA and POOA) is an existing active substance.

Products containing the reaction mass of PAA and POOA are used for disinfection in product-types 2, 3 and 4 by industrial and professional users. The reaction mass of PAA and POOA is used with bactericidal (including spores), yeasticidal, virucidal and fungicidal activities. The mode of action of PAA and POOA is based on an oxidising effect through the hydroxyl radical on organic materials. Three mechanisms have been identified that lead to killing or to permanent inactivation of microbes and viruses.

The evaluating competent authority of the active substance application is France.

On Union authorisation, the adopted opinions concern an application for a biocidal product family containing propan-2-ol (product-types 2 and 4), CMIT/MIT (product-type 6), peracetic acid (product-type 2) and hydrogen peroxide (product-type 2).

The adopted opinions will be available at: Biocidal Products Committee

Background information

The role of the Biocidal Products Committee in EU regulatory processes

The Biocidal Products Committee prepares the opinions of the Agency related to several processes under the Biocidal Products Regulation. Each EU Member State is entitled to appoint one member to the BPC for a renewable term of three years.

In relation to applications for the approval of new active substances, companies have to apply for approval of an active substance by submitting a dossier. After a validation check, the evaluating competent authority carries out an evaluation within one year.

The result of the evaluation is forwarded to the BPC, which prepares an opinion within 270 days. The opinion serves as a basis for decision-making by the European Commission and the Member States. The approval of an active substance is granted for a defined number of years, not exceeding 10 years.

Substances, which were on the market before 14 May 2000 and are evaluated under the biocides review programme in an analogous manner to new active substances, are referred to as existing active substances.

During the approval process of an active substance, the evaluating competent authority may conclude that the active substance meets the criteria for substitution of Article 10(1) of the BPR and is therefore a potential candidate for substitution. The objective of this provision is to identify substances of particular concern to public health or the environment and to make sure that these substances are phased-out and replaced by more suitable alternatives over time. The criteria for substitution are based on the intrinsic hazardous properties in combination with the use and include, for example, if the substance meets at least one of the exclusion criteria listed in the BPR or if the substance is a respiratory sensitiser.

For substances that are identified by the evaluating competent authority as a potential candidate for substitution, ECHA will initiate a public consultation to allow interested third parties to submit relevant information, including information on available substitutes. Subsequently, in the preparation of its opinion, the BPC reviews the proposed identification of the active substance as a candidate for substitution.

Active substances which are candidates for substitution will not be approved for more than seven years, even in the case of renewal. If the active substance meets one or more exclusion criteria, it will only be approved for five years. When an active substance is identified as a candidate for substitution, products containing that active substance will have to be subject to a comparative assessment at the time of authorisation and will only be authorised if there are no better alternatives.