

Annex to a news alert

Biocidal Products Committee concludes on a Union authorisation for disinfectants

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Helsinki, 18 December 2018

More information about the opinions

The adopted opinion on Union authorisation concerns an application for a biocidal product family containing **iodine** used in veterinary hygiene for the disinfection of the teats of milk-producing animals (product-type 3).

The opinions on active substances concern the approval of the following active substances in the specified product-types:

Silver zinc zeolite in product-types 2, 7 and 9

Silver zeolite is an existing active substance. Biocidal products containing silver zeolite are used to treat polymers to achieve an antimicrobial effect in product-types 2, 7 and 9.

Silver zeolite in product-type 9

Silver zeolite is an existing active substance. Biocidal products containing silver zeolite are used to treat polymers to achieve an antimicrobial effect in product-type 9.

Silver copper zeolite in product-type 9

Silver zeolite is an existing active substance. Biocidal products containing silver copper zeolite are used to treat polymers to achieve an antimicrobial effect in product-type 9.

Silver sodium hydrogen zirconium phosphate in product-type 9

Silver sodium hydrogen zirconium phosphate is an existing active substance. Biocidal products containing silver sodium hydrogen zirconium phosphate are used to treat polymers to achieve an antimicrobial effect in product-type 9.

The evaluating competent authority of the silver-containing active substance applications is Sweden.

ADBAC/BKC (alkyl (C12-16) dimethylbenzyl ammonium chloride) in product-types 3 and 4

ADBAC/BKC is an existing active substance. Products based on ADBAC/BKC can be used as general disinfectants in areas in which animals are housed, kept or transported in product-type 3 and can be applied as general disinfectants in food and feed areas (such as abattoir, poultry, fruit and vegetable processing lines, bakeries, breweries and food retail) in product-type 4. The evaluating competent authority of the active substance application is Italy.

DDAC (didecyldimethylammonium chloride) in product-types 3 and 4

DDAC is an existing active substance. Products based on DDAC are disinfectants of producttype 3 for use in areas in which animals are housed, kept or transported, and can be applied as general disinfectants in food and feed areas (such as abattoir, poultry, fruit and vegetable processing lines, bakeries, breweries and food retail) in product-type 4. The evaluating competent authority of the active substance application is Italy.

Icaridin in product-type 19

Icaridin is an existing active substance. Icaridin is an insect repellent intended for use by the general public in product-type 19. The evaluating competent authority of the active substance application is Denmark.

The adopted opinions will be available on the Biocidal Products Committee web page.

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.