Annex to news: ECHA's biocides committee raises concern over missing data in applications

Helsinki, 5 June 2024

Information about the opinions

See product-types

Active substances:

Opinions on the following active substances were adopted:

Medetomidine for product-type 21

Medetomidine is an active substance in antifouling products, used on hulls of vessels such as commercial and government ships, super-yachts and pleasure crafts, to surfaces such as out-drives, outboard legs, propellers and stern gears of pleasure crafts, and to structures and objects subject to immersion. This is to protect submerged surfaces from fouling by hard fouling (shell-building) marine organisms, such as acorn worms and stalked barnacles and tube-building polychaetes such as marine tubeworms. All surfaces are treated while they are out of the water, by professional users via airless spray, brush or roller in paint and by non-professionals via brush or roller in paint and by spray application via paint in an aerosol can.

The opinion on the non-renewal was adopted by consensus.

Norway is the evaluating competent authority of this application.

Dinotefuran for product-type 18

Dinotefuran is an active substance in products to control insects and other arthropods including cockroaches by professional users.

The opinion on the renewal was adopted by simple majority.

Belgium is the evaluating competent authority of this application.

Polymeric betaine for product-type 8

Polymeric betaine is an existing active substance in wood preservatives with preventive action against wood boring beetle *Hylotrupes bajulus* (house longhorn beetle) and wood rotting fungi. The product is intended for industrial and professional use indoors for preventive treatment of wood in use classes 1 and 2, by vacuum pressure treatment of timber.

The opinion on the approval was adopted by consensus.

Greece is the evaluating competent authority of this application.

5-Chloro-2-methyl-2H-isothiazol-3-one (CIT) for product-type 6

5-Chloro-2-methyl-2H-isothiazol-3-one is a new active substance used for the preservation of manufactured products, other than food stuff or feeding stuff or cosmetics, in containers by the control of microbial deterioration (bacteria, yeasts, moulds) to ensure their shelf life during storage.

The opinion on the non-approval was adopted by consensus.

France is the evaluating competent authority of this application.

Union authorisations:

Opinions on the following products and product families were adopted:

Biocidal product family containing hydrogen peroxide for product-type 4
The products in this biocidal product family are intended to be used by professional users for automated disinfection of dishes in industrial dishwashers via an automatic fluid dosing system.

The opinion on the non-authorisation was adopted by consensus.

Austria is the evaluating competent authority of this application.

Biocidal product containing propan-2-ol for product-type 2
The product is a wipe used as a disinfectant used by professionals on smaller hard surface areas in cleanrooms and in similar controlled areas within manufacturing and industrial settings, for the control of bacteria and yeast.

The opinion on the authorisation was adopted by consensus.

Finland is the evaluating competent authority of this application.

Biocidal product family containing propan-1-ol and propan-2-ol for product-type 1
The biocidal product family consists of hand disinfection products for non-professional and professional users containing the active substances Propan-1-ol and Propan-2-ol. The Biocidal product family includes uses for hygienic and surgical hand rub; the latter only for professional users.

The opinion on the authorisation was adopted by consensus.

Germany is the evaluating competent authority of this application.

Biocidal product family containing Margosa extract from cold-pressed oil of the kernels of Azadirachta Indica extracted with super-critical carbon dioxide for product-type 19
The biocidal product family consists of liquids or aerosols, to be applied by non-professional users on cats and/or dogs' fur and skin to repel biting parasites (fleas, mosquitoes and ticks).

The opinion on the authorisation was adopted by simple majority.

France is the evaluating competent authority of this application.

Biocidal product containing Glutaral (Glutaraldehyde); Reaction mass of 5-chloro-2-methyl-2h-isothiazol-3-one and 2-methyl-2h-isothiazol-3-one (3:1) for product-types 6, 11 and 12
The product is used in product-types 6, 11 and 12 by professional users for the control of bacteria, fungi, yeasts, algae and cyanobacteria depending on the use. The product is used as preservative of water used in the paper industry and of water used in pasteurisers, conveyor belts, air washers, paint spray booths, electrodeposition coating systems, closed recirculating cooling systems and heating systems

The opinion on the authorisation was adopted by consensus.

France is the evaluating competent authority of this application.

Biocidal product family containing Reaction mass of 5-chloro-2-methyl-2h-isothiazol 3-one and 2-methyl-2h-is thiazol-3-one (3:1) for product-types 4, 11 and 12
The products in the family are used by professional users as disinfectants in food and feed area, as preservatives in liquid-cooling and processing systems and as slimicides.

The opinion on the authorisation was adopted by consensus.

The Netherlands is the evaluating competent authority of this application.

Biocidal product family containing peracetic acid for product-types 2, 3 and 4
The family concerns a hard-surface disinfectant for hospitals and other health care institutions, non-food industry and laboratories, areas other than hospitals and care institutions where humans reside and swimming pools (PT 2), a hard-surface disinfectant in accommodations and adjacent rooms for animals (PT 3), a hard-surface disinfectant in the food industry and disinfectant of inner surfaces of installations coming into contact with water (potable water systems for humans and animals and process water) (PT 4). The family contains the active substance peracetic acid (PAA) and the equilibrium partners H_2O_2 and acetic acid.The product is used both by professionals and non-professionals.

The opinion on the authorisation was adopted by consensus.

The Netherlands is the evaluating competent authority of this application.

Evaluation of post-authorisation data submitted for a biocidal product family containing propan-2-ol for product-types 2 and 4
The regulation authorising the product family included a post-authorisation requirement to conduct storage stability testing. The 24-month storage period was confirmed by a new study.

The opinion on the authorisation was adopted by consensus.

The Netherlands is the evaluating competent authority of this application.

Article 75(1)(g):

Draft BPC opinion on examination of efficacy tier 2 data for RP 1:1 and RP 3:2, product-type 6 and 13 (4 opinions)

The efficacy tier 2 data of these active substances (acting as preservatives in PT 6 and 13) was examined. It was concluded that the available data can be considered as tier 2, therefore the data requirements have been fulfilled and efficacy has been proven.

The BPC adopted the opinion by consensus.

Austria is the evaluating competent authority of this case.

Draft BPC opinion on Questions on the risks of exposure of workers to corrosive particles during the use of biocidal products by coarse spraying (Questions 1-3)

General questions related to coarse spraying of corrosive products were answered, allowing further assessment of specific products with these specific use patterns.

The BPC adopted the opinion by consensus.

ECHA is the rapporteur of this case.

Article 15(2):

Draft BPC opinion on the review of approval of the active substance zineb

Data on endocrine disrupting potential of the active substance were examined and it was concluded that zineb has endocrine disrupting properties.

The BPC adopted the opinion by consensus.

Ireland is the evaluating competent authority of this case.

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The opinions will be available on ECHA's website at: Biocidal Products Committee

Note on the assessment of biocidal products concerning misuse

A document was presented on the concept of "misuse". It was clarified that misuse is not a factor in the assessment of a biocidal product authorisation, as it is not in the scope of the Biocidal Products Regulation, BPR. In line with the BPR and existing guidance for the assessment of biocidal products, only realistic worst case should be considered.

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.