

Annex to the news alert ECHA/NA/15/40

Biocidal Products Committee adopts fourteen opinions

Helsinki, 14 December 2015

More information about the adopted opinions

The adopted opinions concern the approval of the following active substances and their product types (PTs):

Bardap 26 for PT 8

Didecylmethylpoly(oxyethyl)ammonium propionate (Bardap 26) is an existing active substance evaluated in product type 8.

The field of application of Bardap 26 includes wood preservation for preventive treatment against wood-destroying insects and against wood-discolouring moulds and fungi. The representative product is an aqueous solution with preventive efficacy against wood-destroying basidiomycetes, soft rot fungi and insects.

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

DBDCB for PT 6

The active substance 1,2-Dibromo-2,4-dicyanobutane (DBDCB) is an existing active substance evaluated in product type 6.

DBDCB is used as an antimicrobial preservative in product type 6 for water-based decorative paints applied by brushes or rollers indoors. Paints containing DBDCB may be used by professionals and non-professionals.

The evaluating competent authority of the active substance application is the Czech Republic.

Ampholyt for PTs 2 and 4

Ampholyt is an existing active substance evaluated in product types 2, 3 and 4. An opinion on product type 3 was already adopted by the BPC.

Products containing ampholyt are used as a hard surface disinfectant in hospitals, institutional and industrial areas, including public health areas (PT 2) and in treatments to surfaces, walls, and floors in industrial food and feed preparation areas (PT 4) by professionals to prevent the spread of various microorganisms.

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

Biphenyl-2-ol for PT 3

Biphenyl-2-ol was notified as an existing active substance in product types 1, 2, 3, 4, 6 and 13. The BPC opinions for product types 1, 2 and 13 have been adopted during BPC-9 in February 2015; the opinions for product types 4 and 6 have been adopted during BPC-11 in June 2015. PT 3 products containing Biphenyl-2-ol are used to control pathogenic microorganisms in intensive farming installation.

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

Copper thiocyanate for PT 21 Copper, coated flake for PT 21 Dicopper oxide (cuprous oxide) for PT 21

Copper thiocyanate, copper coated flake and cuprous oxide are existing active substances evaluated in product type 21. Products containing these active substances are intended to be used for protection against fouling of both mobile (including but not limited to marine and freshwater vessels) and stationary (including but not limited to buoys, aquaculture nets, immersed structures) objects.

The evaluating competent authority of these active substance applications is France.

Granulated copper for PT 8

Granulated copper is a new active substance evaluated in product type 8. It is a recycled copper in granular form intended to be used as a preventive wood preservative. The active substance is restricted to industrial use only, in timber treatment plants operated by professionals. The function of granulated copper is as a fungicide and insecticide to control fungi (wood rotting basidiomycetes and soft rot fungi) and insects (wood boring beetles and termites).

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

Tolyfluanid for PT 7

Tolyfluanid is an existing active substance evaluated in product types 7, 8 and 21 and is already approved for product types 8 and 21.

Tolyfluanid in product type 7 is intended to be used mainly against moulds to protect paint film coating for wooden window and door frames and doors outdoors (corresponding to wood preservative use classes 2 and 3).

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

L(+) lactic acid for PT 1

(S)-2-Hydroxypropanoic acid (L(+)
lactic acid) is an existing active substance evaluated in product types 1, 2, 3, 4 and 6.

L(+)
Lactic acid is intended to be used as a ready to use product directly on the hands as a disinfecting hand soap for professionals and non-professionals.

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

***Bacillus amiloliquefaciens* for PT 3**

Bacillus amyloliquefaciens strain ISB06 is an existing active substance evaluated in product type 3. During the early stage of identification in 2000, the microorganism has been allocated

to the species *Bacillus subtilis* based on initial gene sequence analysis. Subsequent gene sequence analyses in 2007 indicated that the strain actually belonged to the species *Bacillus amyloliquefaciens*. A notice to take over the role of the participant for *Bacillus subtilis* was already published by ECHA earlier this year.

The biocidal product is designed to control potentially harmful bacteria in livestock buildings and equipment of animal-rearing facilities, e.g. for poultry and pigs. Target organisms of *B. amyloliquefaciens* ISB06 are bacteria including potential pathogens, e.g. *Enterococcus*, *Listeria*, *Staphylococcus*, *Escherichia*, *Pasteurella*, *Salmonella* and *Yersinia*. The product is intended to complement but not to substitute chemical disinfection measures as a prophylactic treatment.

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

Formaldehyde for PT 3

Formaldehyde is an existing active substance evaluated in product types 2, 3 and 22. In product type 3 it is applied as a disinfectant for veterinary hygiene in areas in which animals are housed, kept or transported to prevent animal diseases. This includes the disinfection of animal housing, the disinfection of eggs as well as the disinfection of animals' feet. Formaldehyde is used by professionals as an aqueous solution by spraying, wiping and fogging/fumigation.

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

Cyromazine for PT 18

Cyromazine is an existing active substance in product type 18. Cyromazine is an insect growth regulator developed for the control of fly larvae in manure and other breeding sites in animal housing (e.g. cattle, swine, poultry facilities).

Biocidal products containing cyromazine can be used by professionals and non-professionals after formulation into water soluble granules or a water soluble powder. The biocidal product is applied to manure or any decaying organic matter either by: i) direct dispersal of the dry granules; ii) directional spraying after dissolution in water with any spray equipment; or iii) pouring using a watering can after dissolution in water.

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

The total number of opinions adopted in 2015 is 50 of which:

- 46 opinions were adopted for active substance approval for the Review Programme;
- 3 opinions were adopted for new active substances for which an application was submitted under article 11 of the Biocidal Products Directive;
- 1 opinion was adopted under Article 75(1)(g) on request of the Commission.

Further information

The opinions will be available at the following link in the near future:

[Biocidal Products Committee](#)

Background Information

The role of BPC 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.