

Annex to a news alert ECHA/NA/17/04

Helsinki, 7 March 2017

Biocidal Products Committee (BPC) adopted opinions supporting the approval of three active substances as follows:

The adopted opinions concern the approval of the following active substances in the specified product-types (PTs):

MIT for product-type 12

MIT is an existing active substance evaluated in product-types 6, 11, 12 and 13. The BPC has already adopted an opinion on product-type 11 and 13. The products containing MIT in product-type 12 are used as slimicides for preservation against harmful microorganisms in aqueous products such as paper or pulp slurries in paper mills. The prevention of bacterial and fungal growth needs to be achieved for the protection against slime-producing organisms in these systems.

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

Fludioxonil for product-types 7, 9 and 10

Fludioxonil is a new active substance. In product-type 7 it is used in preservative products which are applied to, or incorporated into, various end-applications covering protection of paints, silicon coatings, mineral and silicon sealants and grout products; in product-type 9 it is used as a preservative of paper that is used for the production of wall linings; in product-type 10 it is used as a preservative of building materials such as gypsum boards.

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

Margosa extract for PT 19

Margosa extract, cold-pressed oil of *Azadirachta indica* seeds without shells extracted with super-critical carbon dioxide is an existing active substance. Margosa extract has already been included in the Union list of approved active substances for PT 18 with the name margosa extract from the kernels of *Azadirachta indica* extracted with water and further processed with organic solvents. In product-type 19 it is intended to be used as a repellent to deter ants from entering buildings. It is aimed at non-professional users to be used in private homes.

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

Comparative assessment for anticoagulant rodenticides

As anticoagulant rodenticides meet the substitution criteria a comparative assessment will need to be carried out at product authorisation. This assessment will, following a decision at the meeting of the Competent Authorities, be carried out at Union level. The Commission requested in an Article 75(1)(g) procedure a BPC opinion on the following questions:

- a) Is the chemical diversity of the active substances in authorised rodenticides in the EU adequate to minimise the occurrence of resistance in the target harmful organisms?
- b) For the different uses specified in the applications for renewal, are alternative author-

- ised biocidal products or non-chemical means of control and prevention methods available?
- c) Do these alternatives present a significantly lower overall risk for human health, animal health and the environment?
 - d) Are these alternatives sufficiently effective?
 - e) Do these alternatives present no other significant economic or practical disadvantages?

Alpha chloralose, aluminum phosphide releasing phosphine and carbon dioxide were identified as alternatives eligible for the comparative assessment. The assessment showed significant practical or economical disadvantages for these alternatives compared to anticoagulant rodenticides.

For the seven identified non-chemical methods reviewed, no robust scientific evidence was available to demonstrate that these are sufficiently effective. Consequently, following the tiered approach in the Technical Guidance Note on Comparative Assessment, these methods were considered not to be eligible alternatives for the purpose of the comparative assessment. It is concluded that each of the alternatives, on their own or in combination with other alternatives may provide sufficient efficacy in certain, perhaps limited, circumstances. However, there is insufficient scientific evidence to prove that any of the non-chemical alternatives reviewed are sufficiently effective to negate the need for anticoagulant rodenticides.

The following opinion is expected to be adopted via a written procedure: the opinion will need to address also the relationship with the quality standards set in the Water Framework Directive and amend the assessment of indirect exposure.

Cypermethrin for product-type 18

Cypermethrin is an existing active substance. Products containing cypermethrin are intended to be used in and around domestic and public buildings including farms, animal housing and food processing facilities by professionals as a broad spectrum insecticide against crawling and flying insects.

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

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.

Further information about BPC is available on the ECHA website at the link below:
<https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee>