

3 July 2017

## Annex to a news alert

### Biocidal Products Committee adopts 11 opinions (ECHA/NA/17/19)

Helsinki, 3 July 2017

#### More information about the opinions

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

##### **MBIT for product-type 6**

MBIT is a new active substance evaluated in product-types 6 (Preservatives for products during storage) and 13 (Working or cutting fluid preservatives). The BPC has already adopted an opinion on product-type 13.

Biocidal products containing MBIT in product-type 6 are used to protect against a wide variety of microorganisms (bacteria, fungi) that occur within in-can preservation systems. Examples are paints and detergents. MBIT containing biocidal products are used by industrial users.

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

##### **Imiprothrin for product-type 18**

Imiprothrin is an existing active substance for product-type 18 (Insecticides, acaricides and products to control other arthropods). The products containing imiprothrin are ready-to-use insecticidal aerosols designed to be used by non-professionals indoors.

Products are used as surface sprays for spot, crack and crevice treatments in domestic or restaurant kitchens and other areas in buildings where small infestations and harbourages of crawling insects may occur.

The evaluating competent authority of the active substance application is the United Kingdom.

##### **Reaction products of para-formaldehyde and 2-hydroxy-propylamine (ratio 3:2) for product-types 2, 6, 11, 12 and 13**

Reaction products of paraformaldehyde and 2-hydroxy-propylamine (ratio 3:2) (RP 3:2) is an existing active substance originally notified as 3,3'-methylene-bis(5-methyl-oxazolidine) or MBO.

Biocidal products containing RP 3:2 are used for the disinfection of inner surfaces of vessels and tubes in metal working systems in product-type 2 (Disinfectants and algacides not intended for direct application to humans or animals); for the preservation of fuels prone to bacterial decay in product-type 6 (Preservatives for products during storage); for the preservation of closed liquid cooling systems in product-type 11 (Preservatives for liquid-cooling and processing systems); for the prevention or control of slime growth on materials, equipment and structures in offshore oil industry installations in product-type 12 (Slimeicides) and for the preservation of metal working fluids prone to bacteria decay in product-type 13 (Working or cutting fluid preservatives).

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

**Reaction products of para-formaldehyde and 2-hydroxy-propylamine (ratio 1:1) for product-types 2, 6, 11 and 13**

Reaction products of para-formaldehyde and 2-hydroxy-propylamine (ratio 1:1) (RP 1:1) is an existing active substance originally notified as  $\alpha,\alpha',\alpha''$ -trimethyl-1,3,5-triazine-1,3,5(2H,4H,6H)-triethanol or HPT.

Biocidal products are used for the same applications as RP 3:2 in product-types 2 (Disinfectants and algaecides not intended for direct application to humans or animals), 6 (Preservatives for products during storage), 11 (Preservatives for liquid-cooling and processing systems) and 13 (Working or cutting fluid preservatives).

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

The opinions will be available on ECHA's website in the near future:

<https://echa.europa.eu/about-us/who-we-are/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.