ECHA
EUROPEAN CHEMICALS AGENCY

Annex

The Biocidal Products Committee adopts 13 opinions

Helsinki, 11 February 2015

Annex to the news alert ECHA/NA/15/04

More information about the adopted opinions

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

Hydrogen peroxide for PTs 1 to 6

Hydrogen peroxide is an existing active substance evaluated in PTs 1 to 6. Uses evaluated include disinfection of human skin for professionals and non-professionals (PT 1), surface disinfection of private or public rooms (PT 2), disinfection of animal housing by spraying (PT 3), aseptic packaging: disinfection of packaging for milk products (PT 4), surface disinfection in food processing facilities (PT 4), disinfection of distribution systems for drinking water (PT 4), disinfection of drinking water for humans and animals (PT 5), and preservation of paper additives (PT 6).

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

Medetomidine for PT 21

Medetomidine is a new active substance evaluated in PT 21, to be used on hulls of vessels such as commercial and government ships, super-yachts and pleasure craft, to surfaces such as outdrives, outboard legs, propellers and stern gears of pleasure craft, and to structures and objects subject to immersion.

The BPC confirmed that medetomidine is a candidate for substitution by being a substance for which two of the three PBT criteria are met and contains a significant proportion of non-active isomers. The evaluating competent authority of the active substance application is the UK.

C(M)IT /MIT for PTs 6 and 11

The reaction mass of 5-chloro-2-methyl-2h-isothiazol-3-one and 2-methyl-2h-isothiazol-3-one (3:1) (C(M)IT/MIT) is an existing active substance evaluated in PTs 6 and 11. CMIT/MIT is used as an in-can preservative for wide use of applications including among others liquid detergents, paints and coatings, textile treatment solutions, adhesives and sealents (PT 6); and in liquid cooling and processing systems (PT 11).

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

Biphenyl-2-ol for PT 1,2 and 13

Biphenyl-2-ol was notified as an existing active substance in PTs 1, 2 and 13. For PT 1, Biphenyl-2-ol is used a liquid soap formulation for hand disinfection. PT 2 products containing Biphenyl-2-ol are intended to be used as surface disinfectants in health care settings. PT 13 products are added to metal working fluids as preservatives.

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

Triflurmuron for PT 18

For triflumuron in PT 18, the BPC adopted an opinion for non-approval, as no safe use could be demonstrated for the environment.

Triflumuron is an existing active substance where products containing triflumuron are intended to be used by professionals against house flies (Musca domestica) and litter beetles (Alphitobius diaperinus) indoors and in livestock and poultry houses. It is applied to locations where insects breed such as litter, the surface of manure, cesspools and bedding materials.

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

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.