ECHA
EUROPEAN CHEMICALS AGENCY

Annex

Biocidal Products Committee adopts opinions on three active substances

Helsinki, 17 February 2016

Annex to the news alert ECHA/NA/16/04

More information about the adopted opinions

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

Bacillus thuringiensis subsp. Kurstaki, Serotype 3a3b, Strain ABTS-351 for product-type 18

Bacillus thuringiensis subsp. Kurstaki, Serotype 3a3b, Strain ABTS-351 (*Btk* ABTS-351) is a new active substance which originates from a natural wild strain of the organism and has not been genetically modified.

Btk ABTS-351 is intended to be used by professionals as an insecticide against the larvae *Lepidoptera* insect species for the control of pine and oak processionary caterpillars, *Thaumetopoea pityocampa* and *Thaumetopoea processionea*. The purpose is to protect human and animal populations from the irritant effects of the hairs from late instar caterpillars: when hairs are shed they may remain in aerosols and if inhaled they can have a systemic action and can cause tissue necrosis.

Btk ABTS-351 is applied in non-agricultural and non-silviculture zones including parks and gardens.

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

Citric acid for product-type 2

Citric acid is an existing active substance. Citric acid occurs naturally in plant and animal tissues and fluids and also in many food-stuffs and is often used as a food additive (E330).

The intended use is in facial tissues: three-ply tissues of which the middle layer is impregnated with citric acid. Citric acid is intended to inactivate the viral load in the tissue after it has been used, i.e. when moisture after sneezing, coughing or blowing of the nose into the tissue enters the middle layer, to prevent transfer back to the hands, transmittance of the virus from hand-to-hand contact and transmittance to surfaces with which the tissue comes into contact.

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

Cyfluthrin for product-type 18

Cyfluthrin is an existing active substance. The intended uses of cyfluthrin-based products are to control flying and crawling insects, such as house flies, litter beetles as well as fleas and red mites in animal housings (spray application for use by professionals) and crawling insects, specifically cockroaches (adults, nymphs), ants and termites indoors (ready to use spray foam for use by non-professionals in households).

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

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.