13 October 2016

Annex to a news alert

Biocidal Products Committee adopts opinions on four active substances (ECHA/NA/16/32)

Helsinki, 13 October 2016

More information about the opinions

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

Dichlofluanid for product-type 21 (*antifouling products*)

Dichlofluanid is an existing active substance. The intended use for dichlofluanid is in antifouling products to be applied by brush or roller by non-professionals to pleasure crafts to protect surfaces from algae, diatoms and other fouling organisms.

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

Silcium dioxide Kieselguhr for product-type 18 *(insecticides, acaricides and products to control other arthropods)*

Silicium dioxide Kieselguhr is an existing active substance. The intended use is in insecticide products. The products are to be used indoor by professional operators for the control of poultry red mites in poultry pens, by non-professionals for the control of arthropods in private households and by professionals in food and feed processing industry facilities.

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

Pyrogenic, synthetic amorphous silicon dioxide, nano, surface treated for product-type 18

Pyrogenic, synthetic amorphous silicon dioxide, nano, surface treated, is an existing active substance. The intended use is in insecticide products used indoor by professional operators by spraying for the control of poultry red mite (*Dermanyssus gallinae*) to protect domestic animals (fowl) in places such as chicken-breeding farms or egg-producing farms.

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

Non-approval of PHMB (1600; 1.8) for product-type 5 (*disinfection of drinking water for both humans and animals*)

PHMB (1600; 1.8) was notified as an existing active substance in product-types 1, 2, 3, 4, 5, 6, 9 and 11. The BPC opinions for all product-types except for product-type 5 were adopted during BPC-11 in June 2015. In product-type 5 PHMB (1600; 1.8) is intended to be used, as a bactericide, for the disinfection of animal drinking water stored in a tank. It is intended to be used by professional users only.

PHMB (1600; 1.8) is considered a candidate for substitution in accordance with Article 10(1)(d) of the BPR.

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

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.