ECHA
EUROPEAN CHEMICALS AGENCY

Annex

Biocidal Products Committee adopts opinions on six active substances

Helsinki, 18 April 2016

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

More information about the opinions

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

Chlorocresol for product-types 1, 2, 3, 6, 9 and 13

Chlorocresol (CMK) is an existing active substance evaluated in product-types 1, 2, 3, 6, 9 and 13.

Products containing CMK are used as hygienic hand disinfectants in hospitals and medical practices by professional users and for personal hygiene purposes for non-professionals (PT 1); as disinfectants in industrial premises, institutional and private areas (PT 2); for veterinary disinfection by professionals (PT 3); as preservatives for products during storage against potentially harmful and spoilage microorganisms (PT 6); for preservation of fibre, leather, rubber and polymerised material by professional users (PT 9); and for the preservation of aqueous metal working fluids (PT 13).

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

ATMAC/TMAC for product-type 8

The active substance coco alkyltrimethylammonium chloride (ATMAC/TMAC) is an existing active substance evaluated in product-type 8.

The field of application of ATMAC/TMAC includes wood preservatives for the preventive treatment against wood-discolouring moulds and fungi. ATMAC/TMAC is used for preventive protection of wood and constructional timbers.

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

Burnt lime, hydrated lime, burnt dolomitic lime and hydrated dolomitic lime for product-types 2 and 3

Burnt lime is an inorganic salt produced by heating limestone (a natural material consisting predominantly of calcium carbonate). Hydrated lime is an inorganic salt produced by the

reaction of calcium oxide (burnt lime) with water. Burnt dolomitic lime is generated by heating dolomitic limestone (calcium magnesium carbonate). Hydrated dolomitic lime is formed following hydration under pressure of burnt dolomitic lime.

Products containing burnt lime, hydrated lime, burnt dolomitic lime and hydrated dolomitic lime are used to treat sewage sludge to control bacteria, viruses and parasites (professional use only; PT 2) and to treat manure and other digestive tract contents to control bacteria, viruses and parasites (professional use only; PT 3), both before their use as fertilisers in agricuture.

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

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.