

Annex to a news release

Biocidal Products Committee concludes on two active substances in disinfectants – ECHA/NR/18/13

Helsinki, 9 March 2018

More information about the opinions

The adopted opinions concern the approval of the following active substances in the specified product-types:

Salicylic acid for product-types 2, 3 and 4

Salicylic acid is an existing active substance. The biocidal products containing salicylic acid are intended to be used in:

- private and public health areas as ready-to-use hand dishwash products to be used as a
 disinfectant of sponges (and therefore to prevent the spread of micro-organisms onto
 other kitchen utensils and surfaces) by non-professionals (in product-type 2);
- ready-to-use products to disinfect teats of dairy cows by pre- and/or post-milking application as a dip or spray by farmers (in product-type 3); and
- food and feed areas as a disinfectant for surfaces in the (soft) drinks industry, including breweries, where drinks are prepared, processed and stored by professionals (in product-type 4).

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

2-phenoxyethanol for product-types 1, 2 and 4

2-phenoxyethanol is an existing active substance to be used in biocidal products for:

- hand disinfection by professionals and non-professionals (in product-type 1);
- small-scale surface disinfection in public and private places by professionals (e.g. hospitals) (in product-type 2); and
- small-scale surface disinfection in food and feed preparation areas by professionals (in product-type 4).

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

The opinions will be available at the following link in the near future: 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.