Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the biocidal product family:

HYPRED's octanoic acid based products

ECHA/BPC/226/2019

Adopted

26 June 2019

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In accordance with Article 44(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products, the Biocidal Products Committee (BPC) has adopted this opinion on the Union authorisation of:

Name of the biocidal product family: HYPRED's octanoic acid based products

Authorisation holder: HYPRED SAS

Active substance(s) common name: octanoic acid

Product type: 4

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority (eCA).

Process for the adoption of BPC opinions

Following the submission of an application on 25 August 2015, recorded in R4BP3 under case number BC-LR019297-17, the evaluating Competent Authority submitted a draft product assessment report (PAR) containing the conclusions of its evaluation and the draft Summary of Product Characteristics (SPC) to ECHA on 19 December 2017. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-31) and its Working Groups (WG II 2019). Revisions agreed upon were presented and the draft PAR and the draft SPC were finalised accordingly.

Adoption of the BPC opinion

Rapporteur: The Netherlands

The BPC opinion on the Union authorisation of the biocidal product family was reached on 26 June 2019.

The BPC opinion was adopted by consensus. The opinion is published on the ECHA website.

Detailed BPC opinion and background

1. Overall conclusion

The biocidal product family is eligible for Union authorisation in accordance with Article 42(1) of Regulation (EU) No 528/2012 and falls within the scope of the Regulation (EU) No 528/2012 as defined in Article 3(s).

The biocidal product family may be expected to fulfil the conditions laid down in Article 19(6) of Regulation (EU) No 528/2012 and therefore may be authorised. The detailed grounds for the overall conclusion are described in the PAR.

The BPC agreed on the draft SPC of HYPRED‘s octanoic acid based products referred to in Article 22(2) of Regulation (EU) No 528/2012.

2. BPC Opinion

2.1 BPC Conclusions of the evaluation

a) Summary of the evaluation and conclusions of the risk assessment

The sections below are a concise summary of the evaluation and conclusions of the assessment of the biocidal product/biocidal product family.

General

The biocidal product family ‘HYPRED’s octanoic acid based products’ consists of products containing 3% to 10% of the active substance octanoic acid. The following non-active substances are identified as substances of concern due to classification for human health: methanesulfonic acid; L-(+)-lactic acid; N,N-dimethyl-1-Decanamine, N-oxide; ethoxylated alcohol. N,N-dimethyl-1-decamine, N-oxide and lactic acid, were also identified as substances of concern from the environmental point of view.

Products in the family can be used for:

- *meta* SPC 1:
  - Cleaning and disinfecting circuits in dairy industry;
  - Cleaning and disinfecting milking equipment and milking robots in farms;
- *meta* SPC 2: Disinfecting circuits in breweries, dairy and beverage industries;
- *meta* SPC 3: Disinfecting circuits in breweries, dairy and beverage industries;
- *meta* SPC 4: Disinfecting or combined cleaning and disinfecting for membranes used in reverse osmosis and nanofiltration in dairy and beverage industries.

Physico-chemical properties

Products included in HYPRED’s octanoic acid based product family are colourless to slightly yellow, clear to slightly opalescent liquid with characteristic odour of octanoic acid. The products in the family are acidic.

Products included in HYPRED’s octanoic acid based product family are stable according to accelerated storage test (at 40°C for 8 weeks), low temperature stability test and long term storage test at ambient temperature at 20°C for 2 years.

With regard to physical and chemical hazards, all products are classified as corrosive to metals (H290), but they are not flammable, auto-flammable, explosive or oxidising.

Efficacy

All products of the family are PT 4 concentrated biocidal products. The representative products of each meta SPC were effective against bacteria according to EN 1276, and against yeast according to EN 1650 under the claimed use conditions. These tests sufficiently demonstrate efficacy of products in meta SPCs 1-4 against bacteria and yeasts under the claimed use conditions at use concentrations ranging from 0.4% to 1.5%.

Human health

In accordance with the approach described in the assessment report on octanoic acid, a qualitative risk characterisation has been performed based on local effects, following the procedure outlined in the “Guidance on the BPR: Volume III, Part B, Risk Assessment (Version 1.1 of April 2015)”.

Six exposure scenarios have been assessed for the professional user. No unacceptable risks were identified for the protected professional user during loading by connecting / by pouring undiluted HYPRED's octanoic acid based products in an installation, rinsing product containers or maintenance of installations. Gloves, protective clothing and eye protection have been identified as adequate PPE for these tasks. For pumping product through circuits and for pumping water through the installations after use, no exposure is foreseen because of the completely closed systems.

Secondary exposure is considered negligible and therefore no adverse effects are expected for the bystanders due to the use of HYPRED's octanoic acid based products.

Due to the nature of the active substance no quantitative dietary risk assessment was carried out. Furthermore, presence of relevant amounts of residues of the application solution in food or feed is not expected with proper operation of CIP systems. Minimal residues of the application solution in food or feed are unlikely to cause local effects due to the expected high dilution rate in food.

Octanoic acid is an approved active substance for plant protection products. No MRLs are set for octanoic acid under EU 396/2005. No specific needs to set a MRL was identified for HYPRED’s octanoic acid based product family.

The assessment for the active substance covers also the risk for the substances of concern.

Environment

The following scenarios were assessed based on the uses of HYPRED's octanoic acid based products:

- Disinfection, or combined cleaning and disinfection of circuits in agro-food industries (including dairy, beverage and breweries industries) (scenario 1);
- Cleaning and disinfection of milking equipment and milking robots in farms (scenario 2);
- Disinfection or combined cleaning and disinfection of separative membranes in dairy and beverage industries (scenario 3).

All three uses are considered as CIP treatments. Consequently, the cleaning processes are assumed to always take place under closed system conditions. Risk assessment was made for the active substance and two substances of concern (N,N-dimethyl-1-decamine, N-oxide and lactic acid). The main route of exposure to the environment is via the sewer system, ending up in a sewage treatment plant.

The PEC/PNEC (all emission routes and substances) for the STP and sediment compartments are below 1 for all scenarios. Although PEC/PNEC ratio above one has been calculated for application in the brewery industry, monitoring data demonstrated that residual fatty acid levels including octanoic acid are low. Therefore it is concluded that unacceptable risks are not expected for the concerning products.

The PEC/PNEC-ratios for the soil compartment that receives sewage sludge are above 1 for octanoic acid and N,N-dimethyl-1-decamine, N-oxide. It was however demonstrated that octanoic acid disappears quickly from soils even under sterile conditions, which is most likely not related to biodegradation but to irreversible sorption. Octanoic acid also occurs naturally in the environment, but information on background concentrations are not available. Moreover, all PNEC were estimated based on data for aquatic organisms due the absence of terrestrial data, which may likely overestimates terrestrial toxicity. The risk is therefore considered acceptable.

The risks for groundwater and secondary poisoning were quantitatively assessed and found acceptable for the individual substances and their combination.

Overall conclusion

It is concluded that sufficient data have been provided to verify the outcome and conclusions, and permit authorisation of the biocidal product family. Using the products belonging to this biocidal product family according to the conditions as stated in the SPC, the products will be efficacious and will not present an unacceptable risk to human and animal health nor the environment.

b) Presentation of the biocidal product family including classification and labelling

The description of the biocidal product and of the structure of the family is available in the SPC.

The hazard and precautionary statements of the biocidal product family according to the Regulation (EC) 1272/2008 is available in the SPC.

c) Description of uses proposed to be authorised

The uses claimed in the application and their assessment are described in the PAR. The description of the uses proposed to be authorised are available in the SPC.

d) Comparative assessment

The active substance octanoic acid contained in the biocidal product family does not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and is not considered a candidate for substitution. Therefore, a comparative assessment of the biocidal product family is not required.

e) Overall conclusion of the evaluation of the uses proposed to be authorised

The physico-chemical properties, the safety for human and animal health and for the environment and the efficacy of the intended uses of the biocidal product family have been evaluated.

The chemical identity, quantity and technical equivalence requirements for the active substance in the biocidal product family are met.

The physico-chemical properties of the biocidal product family are deemed acceptable for the appropriate use, storage and transportation of the biocidal product.

For the proposed authorised uses, according to Article 19(1)(b) of the BPR, it has been concluded that:

1. the biocidal product family is sufficiently effective;
2. the biocidal product family has no unacceptable effects on the target organisms, in particular unacceptable resistance or cross-resistance;
3. the biocidal product family has no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans, including that of vulnerable groups, or animals, directly or through drinking water, food, feed, air, or through other indirect effects;
4. the biocidal product family has no unacceptable effects itself, or as a result of its residues, on the environment, having particular regard to the following considerations:
    - the fate and distribution of the biocidal product in the environment,
    - contamination of surface waters (including estuarial and seawater), groundwater and drinking water, air and soil, taking into account locations distant from its use following long-range environmental transportation,
    - the impact of the biocidal product on non-target organisms,
    - the impact of the biocidal product on biodiversity and the ecosystem.

The outcome of the evaluation, as reflected in the PAR, is that the uses described in the SPC, may be authorised.

2.2 BPC opinion on the Union authorisation of the biocidal product family

It is proposed that the biocidal product family HYPRED‘s octanoic acid based products shall be authorised for the uses described under section 2.1 of this opinion, subject to compliance with the proposed SPC.

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Annex: Draft Summary of Product Characteristics