Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the biocidal product family:

Evonik's Hydrogen Peroxide Product Family

ECHA/BPC/343/2022

Adopted

14 June 2022

Opinion of the Biocidal Products Committee

on the Union authorisation of Evonik's Hydrogen Peroxide Product Family

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: Evonik's Hydrogen Peroxide Product Family

Authorisation holder:	**Evonik Operations GmbH**
Active substance common name:	**Hydrogen peroxide (CAS nr 7722-84-1)**
Product types:	**2 and 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 20 January 2017, recorded in R4BP3 under case number BC-UE029056, 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 7 January 2022. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-43) and its Working Groups (WG-I-2022). 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 14 June 2022.

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(1)(s).

The biocidal product family meets 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 Evonik's Hydrogen Peroxide Product Family 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

General

This biocidal product family dossier of Evonik Operations GmbH is intended for the application of a Union authorization of a hydrogen peroxide-based biocidal product family (BPF) which is designated as "Evonik's Hydrogen Peroxide Product Family".

The biocidal products within the biocidal product family comprises 6 water-based biocidal products containing the biocidal active substance hydrogen peroxide which are used by professionals as disinfectants not intended for direct application to humans or animals (PT 2) and for disinfection in food and feed area (PT 4) (for details please refer to sections 2.1.4 and 2.1.5 of the PAR, respectively).

The biocidal product family contains 6 biocidal products which are attributed to the following 3 meta SPCs:

Meta SPC	Biocidal products
Meta SPC 1 - OXTERIL® Group 1	OXTERIL® 350 SPRAY OXTERIL® 350 SPRAY S
Meta SPC 2 - OXTERIL® Group 2	OXTERIL® 350 BATH OXTERIL® 350 COMBI
Meta SPC 3 - CLARMARIN® Group 1	CLARMARIN® 350 CLARMARIN® 500

The biocidal product family contains 2 product types which are attributed to the following claimed uses and concerned meta SPCs:

PTs	Claimed uses	Concerned META SPC
2	Use # 1.1- Surface disinfection by vaporized hydrogen peroxide (VHP) process	Meta SPC 1 - OXTERIL® Group 1
	Use # 3.2 - Laundry disinfection in closed washing machines	Meta SPC 3 - CLARMARIN® Group 1

PTs	Claimed uses	Concerned META SPC
4	Use # 1.3 - Surface disinfection by VHP process	Meta SPC 1 - OXTERIL® Group 1
	Use # 1.4; 2.4 - Aseptic packaging in food and feed industries	Meta SPC 1 - OXTERIL® Group 1 Meta SPC 2 - OXTERIL® Group 2
	Use # 1.5; 2.5; 3.5 - Disinfection of distribution systems for drinking water	Meta SPC 1 - OXTERIL® Group 1 Meta SPC 2 - OXTERIL® Group 2 Meta SPC 3 - CLARMARIN® Group 1
	Use # 1.6; 2.6; 3.6- Disinfection of non-porous hard surfaces & equipment	Meta SPC 1 - OXTERIL® Group 1 Meta SPC 2 - OXTERIL® Group 2 Meta SPC 3 - CLARMARIN® Group 1
	Use # 1.7; 2.7; 3.7- Disinfection of surfaces by CIP	Meta SPC 1 - OXTERIL® Group 1 Meta SPC 2 - OXTERIL® Group 2 Meta SPC 3 - CLARMARIN® Group 1

Physico-chemical properties

Sufficient data is provided to satisfy the requirements of the BPR. Products contain between between 35 and 49.9 % w/w hydrogen peroxide (TK). The products within this family do not contain substances of concern.

Storage conditions should be limited to 40 °C and products should be protected from frost. Products stored in HDPE have a shelf-life of 2 years.

With regard to physical and chemical hazards the products included in the BPF are classified as oxidizing liquids category 2, hence, H272: “May intensify fire: oxidizer” is assigned to the BPF.

An adequate titration method was provided for analysis of the active substance content in all representative products.

Efficacy

The biocidal products of Evonik’s Hydrogen Peroxide Product Family have demonstrated sufficient efficacy against a variety of bacteria, yeasts and fungi, viruses and bacterial spores when the use instructions as provided for on the label are observed. For efficacy testing, hydrogen peroxide-based biocidal products of the biocidal products family were tested accordingly in the different intended uses for PTs 2 and 4, respectively. For use as laundry disinfectant, the efficacy was tested in the presence of the alkaline buffering agent BEIPUR ANP as prescribed[1]. The following uses are authorized: room disinfection, laundry disinfection, aseptic packaging, CIP (in general and for distribution systems for drinking water) and disinfection of non-porous hard surfaces & equipment. The claimed concentrations reflect the efficacious concentrations tested with these products of the hydrogen peroxide-based biocidal products family which due to the similar compositions and in-use concentrations of the active substance show a similar level of efficacy in all claimed uses. Therefore, condition (i) is fulfilled with regard to efficacy. In addition, resistance is not observed in any product type due to the low specificity of reactions of hydrogen peroxide.

[1] This agent is used together with products from the Evonik’s Hydrogen Peroxide Product Family for this use and is required for its efficacy. Subsequently, the agent is considered to be part of the biocidal product.

Human health

The biocidal products of Evonik's Hydrogen Peroxide Product Family have been classified for human toxicology in the following categories: Acute Tox. 4, Skin irrit. 2, Eye Dam. 1, STOT SE 3. The classification is triggered by the content of active substance (hydrogen peroxide). Therefore, the products of Evonik's Hydrogen Peroxide Product Family have been labelled with the following H-statements: H302 Harmful if swallowed, H315 Causes skin irritation, H318 Causes serious eye damage, H335 May cause respiratory irritation.

With a view to the assessment of human exposure towards the active substance hydrogen peroxide in the intended uses of the biocidal product family of Evonik the estimation of systemic doses in the intended applications has not been required due to the absence of a systemic availability and systemic effects of the active substance. Thus, only a risk characterization for local effects via the dermal and inhalative routes of exposure was performed.

The following strategy for the local effects exposure and risk assessment has been chosen:

- Quantitative exposure and risk assessment via the inhalation route of exposure considering the inhalative AEC as derived for hydrogen peroxide in the Assessment Report (AR);
- Qualitative risk characterization for potential local effects via the dermal route of exposure considering both the SCLs set for hydrogen peroxide in the CLP regulations as well as appropriate risk mitigation measures (i.e. gloves, coveralls, etc.) and label instructions (i.e. P-statements associated with the H-statements).

As decided upon during the evaluation of the EU dossier on the approval of active substance hydrogen peroxide, the quantitative exposure and risk assessment consisted of the assessment of inhalation exposure towards both the aerosol and the vapour phases. Both types of inhalation exposures are addressed using the Advanced Reach Tool (ART).

Professional uses:

For all the intended uses of the hydrogen peroxide-based biocidal products of Evonik's Hydrogen Peroxide Product Family, respiratory protection equipment (RPE) is needed to reduce inhalation exposure below the AEC and to protect against potential local effects via the inhalation route of exposure.

The exposure and accompanying risk assessments performed for professional uses of hydrogen peroxide as a disinfectant in PTs 2 and 4 demonstrated that due to their classification and skin irritating/corrosive effects, eye protection and protective clothing to protect against potential dermal exposure and local dermal effects are needed when handling concentrated and diluted products.

General public and consumers via residues in food:

Secondary oral and dermal exposure of consumers to residual hydrogen peroxide in food and drinking water is not likely under PT 4 (aseptic packaging, disinfection of distribution systems for drinking water). Pipes and containers disinfected with hydrogen peroxide are flushed before refilled with drinking water and potential residues of hydrogen peroxide are regarded to be negligible following disinfection of distribution systems for drinking water. Hydrogen peroxide used for aseptic packaging evaporates while the wrapping material is heated before

filled with food, therefore, no residues in food are expected. Furthermore, hydrogen peroxide, if present, would rapidly decompose in contact with any type of food.

Exposure of by-standers to unacceptable concentrations of hydrogen peroxide in air following disinfection is not foreseen as no residual hydrogen peroxide appears.

In case of the use #3.2 for laundry disinfection, products from the Evonik's Hydrogen Peroxide Product Family are to be used together with an alkaline buffering agent (i.e. BEIPUR ANP). The addition of the alkaline buffering agent occurs first, then the biocidal product. Mixing and loading occurs in a closed system. Therefore, also the local risk assessment of the alkaline buffering agent BEIPUR ANP was performed. Exposure of the general public to unacceptable concentrations of hydrogen peroxide and the alkaline buffering agent in disinfected clothes/fabric following disinfection used in laundry disinfection in closed washing machines (PT2) is not foreseen. Laundry processes have two rinsing steps after disinfection. Therefore, no residual hydrogen peroxide and the alkaline buffering agent are expected.

Animal health:

Food, drinking water or livestock exposure of hydrogen peroxide can be excluded when applied according to the recommended uses. Contact of animals with the diluted formulations in PT 2 and 4 applications is not expected.

The outcome of the human exposure and risk assessments demonstrate no unacceptable health risks in all intended uses of the hydrogen peroxide-based biocidal products of Evonik's Hydrogen Peroxide Product Family if appropriate risk mitigation measures and/or protective equipment is observed. Therefore, condition (iii) is fulfilled with regards to risks to human and animal health.

Environment

The biocidal products of Evonik's Hydrogen Peroxide Product Family have been classified for the environment in the category Aquatic Chronic 3, therefore it has been labelled with H412 Harmful to aquatic life with long-lasting effects.

Products from the BPF containing the active substance hydrogen peroxide are used for the disinfection of surfaces and non-porous hard surfaces in PTs 2 and 4. The input parameters to calculate the local emissions are taken from the respective ESDs and the Guidance on Biocidal Products Regulations Volume IV Environment Part B (Guidance on BPR IV/B, 2015). For the estimation of environmental exposure, the degradation of the active substance in the sewer is also considered which is in accordance to the CAR (2015).

For the environmental risk assessment, a worst-case scenario has been calculated for each intended use taking into consideration the different biocidal products of Evonik's Hydrogen Peroxide Product Family. Emissions to the environment occur directly to soil or indirectly via sewage treatment plant to the compartments soil and groundwater and surface water and sediment, respectively. The results of the environmental risk assessment for the hydrogen peroxide-based biocidal products family including the alkaline buffering agent demonstrate no unacceptable risk for the environment when a realistic worst-case parameter setting is applied. The level of risk is considered to be similar and for this reason, condition (iv) is fulfilled with regards to risks to the environment.

Based on the results of the efficacy assessments as well as human, animal and environmental risk assessments performed in the context of the evaluation of Evonik's Hydrogen Peroxide Product Family it is concluded that the application of the active substance hydrogen peroxide in the intended uses of the biocidal product family of Evonik is not associated with an unacceptable risk to humans, animal health and the environment, respectively.

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 Hydrogen peroxide 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 was not needed.

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(s) 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;

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

As the conditions of Article 19(1) are met it is proposed that the biocidal product family shall be authorised, for the uses described under section 2.1 of this opinion.

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