Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the biocidal product family:

Hydrogen peroxide product family

ECHA/BPC/392/2023

Adopted

13 September 2023

Opinion of the Biocidal Products Committee

on the Union authorisation of 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:	**Hydrogen peroxide product family**
Authorisation holder:	**ARCHE Consortia**
Active substance(s) common name:	**Hydrogen peroxide**
Product type(s):	**PT02, PT04**

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 19 January 2017 recorded in R4BP3 under case number BC-FN029041-50, 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 March 8, 2023. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-48) and its Working Groups (WG-II-2023). Revisions agreed thereupon 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 13 September 2023.

The BPC opinion was adopted by simple majority of the members present having the right to vote. The opinion and the minority positions are published on the ECHA website.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that 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 Product Assssment report (PAR).

The BPC agreed on the draft Summary of the Product Characteristics (SPC) of 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 ARCHE Consortia is intended for the application of a Union authorisation of a hydrogen peroxide-based biocidal product family (BPF) that is designated as "Hydrogen peroxide product family".

The biocidal products within the biocidal product family are ready to use liquids and soluble concentrates biocidal products, containing hydrogen peroxide at concentration (w/w) varying from 6.04% to 49.5%, that are used by professionals as disinfectants not intended for direct application to humans or animals (PT02) and for disinfection in food and feed area (PT04) (for details please refer to sections 2.1.4 and 2.1.5 of the PAR, respectively).

The biocidal product family contains 10 biocidal products which are attributed to the following five meta SPCs:

Meta SPC	Biocidal products
Meta SPC 1	HP-BPF-12 HP-BPF-14 HP-BPF-07 HP-BPF-03 HP-BPF-08
Meta SPC 2	HP-BPF-01 HP-BPF-06
Meta SPC 3	HP-BPF-15
Meta SPC 4	HP-BPF-09
Meta SPC 5	HP-BPF-10

The biocidal product family covers two product types which are attributed to the following claimed uses and respective Meta SPCs:

PTs	Claimed uses	Concerned Meta SPC	Use proposed for authorization (Yes/No)?
2	Use # 1.1; # 2.1; # 3.1 – Surface disinfection healthcare, RTU	Meta SPC 1 Meta SPC 2 Meta SPC 3	Yes
	Use # 1.2; # 2.2; # 3.2 – Surface disinfection non-	Meta SPC 1 Meta SPC 2	Yes

	healthcare and food/feed areas, RTU	Meta SPC 3	
	Use # 4.3 – Laundry disinfectant in non-healthcare areas, concentrate	Meta SPC 4	Yes
	Use # 5.1 – Surface disinfection healthcare, concentrate	Meta SPC 5	Yes
	Use # 5.2 – Surface disinfection non-healthcare and food/feed areas, concentrate	Meta SPC 5	Yes
	Use # 5.5 – Room disinfection by fogging, concentrate	Meta SPC 5	Yes
	Use # 5.6 – Equipment/instruments disinfection, concentrate	Meta SPC 5	Yes
	Use # 5.7 – Surface disinfection healthcare, concentrate	Meta SPC 5	**No**
4	Use # 1.2; # 2.2; # 3.2 – Surface disinfection non-healthcare and food/feed areas, RTU	Meta SPC 1 Meta SPC 2 Meta SPC 3	Yes
	Use # 5.2 – Surface disinfection non-healthcare and food/feed areas, concentrate	Meta SPC 5	Yes
	Use # 5.4 – Disinfection of inner surfaces (incl. CIP and drinking water systems), concentrate	Meta SPC 5	Yes
	Use # 5.6 – Equipment/instruments disinfection, concentrate	Meta SPC 5	Yes

Physico-chemical properties

The Hydrogen Peroxide product family contains ready to use liquids and soluble concentrates biocidal products with an active substance concentration varying between 6.04% (w/w) and 49.5% (w/w) of hydrogen peroxide. The physical, chemical and technical characteristics have been sufficiently addressed for the types of formulations included in the BPF.

The long-term storage tests have been performed up to a period of 2 years for all Meta-SPCs and of 3 years for Meta-SPC 1 and 2. A shelf life of 3 years in High Density Polyethylene (HDPE) is supported for the products included in Meta-SPC 1 and 2, while for Meta-SPC 3, 4 and 5, a shelf life of 2 years is supported.

The products included in Meta-SPC 1 are classified as corrosive to metals cat. 1 (H290). The products in Meta-SPC 2 are classified as oxidizing liquids cat. 3 (H272). The products in Meta-SPC 3 are classified as oxidizing liquids cat. 3 (H272) and corrosive to metals cat. 1 (H290). The products in Meta-SPC 4 are classified as oxidizing liquids cat. 3 (H272). The products in Meta-SPC 5 are classified as oxidizing liquids cat. 2 (H272) and as corrosive to metals cat. 1 (H290). The products included in the BPF are not classified for other physical hazards and characteristics.

The analytical method (potentiometric titration with permanganate solution) used to

determine the content of the active substance in the product was sufficiently validated using three different mixtures (AM1, AM2 and AM3), covering all the different co-formulants in the family. It has been demonstrated that the method is accurate, precise and specific in the presence of the co-formulants.

Efficacy

The products of Hydrogen Peroxide product family are used to disinfect:

- hard surfaces in healthcare (PT2), target organisms: bacteria, yeasts, fungi and viruses;
- hard surfaces in non-healthcare and food/feed areas (PT2 and 4), target organisms: bacteria, yeasts, fungi and viruses;
- laundry in non-healthcare area (PT2), target organisms: bacteria and yeasts;
- inner surfaces in food industry (including CIP) and inner surfaces in veterinary and human drinking water systems (PT 4), target organisms: bacteria, yeasts, fungi, viruses and Legionella pneumophila (in drinking water systems);
- rooms (hard surfaces) in healthcare by fogging (PT2), target organisms: bacteria, yeasts, fungi and tuberculosis bacilli;
- equipment/instruments in healthcare, non-healthcare and food industry (PT2 and 4), target organisms: bacteria, yeasts, fungi and viruses.

Efficacy for the claimed uses has been substantiated by the required tests as described in the BPR guidance for all test organisms. Therefore, it can be concluded that the products in this family are efficacious when used in accordance with the use instructions proposed in the SPC.

Human health

Hydrogen peroxide product family (all Meta SPCs) is classified as H318 (Causes serious eye damage). In addition, Meta SPC 4 and Meta SPC 5 also are classified as H314 (Causes severe skin burns and eye damage), and Meta SPC 5 further as H302 (Harmful if swallowed), and H335 (May cause respiratory irritation). It contains one active substance, hydrogen peroxide, and five substances of concern for human health: sulphuric acid (with OEL value); isotridecanol, ethoxylated; D-Glucopyranose, oligomers, decyl octyl glycosides; alcohols, C12-14, ethoxylated, sulfates, sodium salts; and sodium etasulfate, which contribute to the classification of the products.

Professional users:

Exposure for the professional users is acceptable if the following PPE and RPE are worn, except for the coarse spray application included in use #5.2. Authorisation for coarse spraying has not been supported by the working group at TOX WG-II-2023. The elements to exclude the exposure could not be demonstrated, therefore the use cannot be authorised.

Meta-SPC	Use	Task	RMM/PPE
1	Surface disinfection	Loading manual	Protective gloves and goggles Wash hands after use
		Trigger spraying	RPE (APF 20) Protective gloves and goggles Wash hands after use Always spray away from user
2	Surface disinfection	Trigger spraying	RPE (APF 40) Protective gloves and goggles Wash hands after use Always spray away from user
3	Surface disinfection	Loading manual	Protective gloves and goggles Wash hands after use
		Trigger spraying	RPE (APF 40) Protective gloves and goggles Wash hands after use Always spray away from user
4	Laundry disinfection	Loading automated	Protective gloves and goggles Wash hands after use
5	Surface disinfection	Mixing & loading manual	RPE (APF 4) Protective gloves and goggles Wash hands after use
		Mixing & loading automated	Protective glovesand goggles Wash hands after use
		Trigger spraying – healthcare	RPE (APF 20) Protective gloves and goggles Wash hands after use Always spray away from user
		Trigger spraying – non-healthcare	RPE (APF 4) Protective gloves and goggles Wash hands after use Always spray away from user
		Manual application wiping – healthcare general	RPE (APF 20) Protective gloves and goggles Wash hands after use
		Manual application wiping – healthcare hospital room	RPE (APF 4) Protective gloves and goggles Wash hands after use
		Manual application wiping – non-healthcare	RPE (APF 4) Protective gloves and goggles Wash hands after use
		Manual application mopping – healthcare general	RPE (APF 40) Protective gloves and goggles Wash hands after use Ventilation rate minimum 1.5/h.
		Manual application mopping – healthcare hospital room	RPE (APF 40) Protective gloves and goggles Wash hands after use
		Manual application mopping – non-healthcare	RPE (APF 10) Protective gloves and goggles Wash hands after use
	Disinfection inner surfaces	Mixing & loading manual	Protective gloves and goggles Wash hands after use
		Mixing & loading automated	Protective gloves and goggles Wash hands after use

Meta-SPC	Use	Task	RMM/PPE
	Fogging	Mixing & loading manual	Protective gloves and goggles Wash hands after use
		Mixing & loading automated	Protective gloves and goggles Wash hands after use
	Disinfection instruments/equipment	Mixing & loading manual	Protective gloves and goggles Wash hands after use
		Mixing & loading automated	Protective gloves and goggles Wash hands after use
		Immersion - healthcare	RPE (APF 10) Protective gloves and goggles Wash hands after use
		Immersion – non-healthcare	Protective gloves and goggles Wash hands after use

Non-professional users:

Exposure for non-professional users to Meta SPC 1 RTU trigger spray (one of the applications proposed in use #1.2) has not been considered acceptable. Authorisation of this use has not been supported by the working group at TOX WG-II-2023 giving consideration to the classification of the Meta SPC 1 products as H318 - Severe eye damage and the decision that elements to contain the exposure could not be demonstrated. No more uses were claimed for non-professinal users.

General public:

For the general public, certain conditions have to be fulfilled to quarantee a safe re-entry after product use:

During application, only the user of the product can be present in the room.

Do not touch treated surfaces until they are wiped dry with a cloth or air-dried.

Risk for consumers via residues in food:

Due to the expected high degradation of the substance, negligible exposure to residues of hydrogen peroxide is anticipated. Therefore, the exposure for consumers via residues in food has been considered acceptable.

Environment

The active substance is classified as H412. Consequently, in accordance with the CLP regulation, products in meta-SPC 5 are classified for chronic toxicity for the aquatic environment (category 3, H412). Products in the other meta-SPCs are not classified for the environment. None of the co-formulants is a substance of concern for the environment as the conditions as set in the guidance part B+C are not fulfilled.

Environmental emissions have been estimated based on the worst-case exposure scenarios in combination with the highest in-use concentration of the products. The assessed scenarios all resulted in acceptable risk for the environment. According to the CAR for hydrogen peroxide (2015), aggregated exposure is not deemed necessary due to the reactive nature of hydrogen peroxide.

b) Presentation of the biocidal product/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) No 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 as well as in Section 2 a) of the BPC opinion.

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 is 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 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 use(s) described under section 2.1 of this opinion.

This biocide product family contains non-active substances that in formulation have been identified as having an endocrine disrupting potential based on the CompTox Chemistry Database. However, the screening performed showed that none of them should be considered substance of concern in term of endocrine disrupting properties.

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