Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the biocidal product family:

Hydrogen Peroxide Family 1

ECHA/BPC/264/2020

Adopted

18 June 2020

Opinion of the Biocidal Products Committee

on the Union authorisation of biocidal product family Hydrogen Peroxide Family 1

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 Family 1**
Authorisation holder:	**Ecolab Deutschland GmbH**
Active substance(s) common name:	**Hydrogen Peroxide**
Product types:	**1, 2, 3 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 19 January 2017, recorded in R4BP3 under case number BC-DY029028-18, 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 5 October 2018. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-35) and its Working Groups (WG-II-2019; WG-V-2019; WG-I-2020). Revisions agreed upon were presented and the draft PAR and the draft SPC were finalised accordingly.

Adoption of the BPC opinion

Rapporteur: Latvia

The BPC opinion on the Union authorisation of the biocidal product family was reached on 18 June 2020.

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 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 **Hydrogen Peroxide Family 1** 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 Hydrogen Peroxide Family 1 consists of products containing 1% to 36.75% hydrogen peroxide as an active substance. Hydrogen Peroxide Family 1 consists of a number of products belonging to MAIN GROUP 1: Disinfectants, according to the BPR. All formulations included in the family fulfil conditions of similar use and are proposed for use in PTs 1, 2, 3 and 4 (Human hygiene biocidal products, Products for surface disinfection for non-food contact surfaces, Veterinary hygiene biocidal products, Products for surface disinfection for food contact surfaces).

The Hydrogen Peroxide 1 product family has been built into 12 Meta groups. Each Meta group contains a single product or multiple products each with the same (or very similar) formulation. It is important to note that the biocidal products covered by the family have been grouped using the guidance[1] applicable at timepoint of submission where it is indicated that classification of products belonging to one Meta group should always be identical. Ranges of the biocidal product family have been set up using classification criteria. When adding products to a selected Meta level, any additional product will always have the same classification as an existing formulation.

Hydrogen Peroxide Family 1 contains thirteen substances of concern due to their classification for certain human endpoints.

- n-Propanol;
- Citric acid monohydrate;
- 2-Phenoxyethanol;
- Capryleth-9 Carboxylic acid (in: mixture of alkylether carboxylic acids);
- Hexeth-4 Carboxylic Acid (in: mixture of alkylether carboxylic acids);
- Sodium lauryl Sulphate;
- Sodium caprylolglutamate;

[1] CA-Nov14-Doc.5.8 - Final.rev3 - Implementing the new BPF concept.doc.

- Sulfuric acid, mono-C12-14-alkyl esters, ammonium salts;
- Phosphoric acid;
- Nitric acid;
- Alcohol EO phosphate ester;
- Alkylpolyglycoside C8-C10;
- Alcohols, C10-C16 ethoxylated propoxylated.

In total, for Hydrogen Peroxide Family 1, 47 uses are proposed in 8 different areas:

- Life sciences cleanrooms – PT2;
- Industry (non-food contact) – PT2;
- Food and beverage industry (food contact) – PT4;
- Teat disinfection – PT3;
- Health care application – PT2;
- Institutional application (non-food contact) – PT2;
- Institutional application (food contact) – PT4;
- Hand disinfection – PT1.

Meta-SPC 1:

- Application methods: spraying using trigger sprayer and dry wipe; mopping using mop and bucket; wiping using impregnated RTU wipes and mopping using impregnated RTU mop wipes;
- Formulation type: RTU solution and impregnated RTU wipes;
- Users: Professionals;
- PT2 uses: Disinfection of life sciences cleanrooms.

Meta-SPC 2:

- Application methods: spraying using trigger sprayer and dry wipe; mopping using mop and bucket; spraying using trigger sprayer and dry wipe and mopping using flat mop and bucket; fixed installed spraying;
- Formulation type: RTU solution;
- Users: Professionals;
- PT2 uses: Disinfection of surfaces in industry (e.g. dining areas, bathrooms) and industry plants;
- PT4 uses: Disinfection of food contact surfaces in food and beverage industry.

Meta-SPC 3:

- Application methods: automated dipping or spraying in closed system and CIP;
- Formulation type: RTU solution;
- Users: Professionals;
- PT4 uses: Disinfection of food contact surfaces in food and beverage industry.

Meta-SPC 4:

- Application methods: manual dipping using a dip/foam cup;
- Formulation type: RTU solution;
- Users: Professionals;
- PT3 use: Teat dips for pre-milking disinfection.

Meta-SPC 5:

- Application methods: spraying using trigger sprayer and dry wipe; mopping using mop and bucket; wiping using cloth/wipe and bucket; spraying using trigger sprayer and dry wipe and mopping using mop and bucket; wiping using cloth/wipe and bucket and mopping using mop and bucket;
- Formulation type: RTU solution;
- Users: Professionals;
- PT2 uses: Disinfection of life sciences cleanrooms; Disinfection of non-food contact surfaces in health care applications; Disinfection of non-food contact surfaces in institutional applications;
- PT4 use: Disinfection of food contact surfaces in institutional applications.

Meta-SPC 6:

- Application methods: spraying using trigger sprayer;
- Formulation type: RTU solution;
- Users: Professionals;
- PT2 use: Disinfection of small surfaces in industry (e.g. dining areas, bathrooms);
- PT4 use: Disinfection of food contact surfaces in food and beverage industry.

Meta-SPC 7:

- Application methods: spraying using trigger sprayer and dry wipe, mopping using mop and bucket; spraying using trigger sprayer and dry wipe and mopping using mop and bucket; spraying with a wall mounted device;
- Formulation type: water soluble concentrate;
- Users: Professionals;
- PT2 uses: Disinfection of non-food contact surfaces in health care applications; Disinfection of non-food contact surfaces in institutional applications;
- PT4 use: Disinfection of food contact surfaces in institutional applications.

Meta-SPC 8:

- Application methods: wiping using impregnated RTU wipes;
- Formulation type: impregnated RTU wipes;
- Users: Professionals;
- PT2 uses: Disinfection of surfaces in industry (e.g. dining areas, bathrooms); Disinfection of non-food contact surfaces in health care applications;
- PT4 use: Disinfection of food contact surfaces in food and beverage industry.

Meta-SPC 9:

- Application methods: spraying using trigger spray and dry wipe; wiping using cloth/wipe and bucket; mopping using mop and bucket; spraying using trigger sprayer and dry wipe and mopping using mop and bucket; wiping using cloth/wipe and bucket and mopping using mop and bucket, spraying with a wall mounted device;
- Formulation type: water soluble concentrate;
- Users: Professionals;
- PT2 uses: Disinfection of non-food contact surfaces in health care applications; Disinfection of non-food contact surfaces in institutional applications;
- PT4 uses: Disinfection of food contact surfaces in institutional applications.

Meta-SPC 10:

- Application methods: direct application onto skin;
- Formulation type: water soluble gel;
- Users: Professionals;
- PT1 use: antimicrobial hand soap for food and beverage industry.

Meta-SPC 11:

- Application methods: wiping using impregnated RTU wipes; mopping using impregnated RTU mop wipes;
- Formulation type: impregnated RTU wipes;
- Users: Professionals;
- PT2 uses: Disinfection of life sciences cleanrooms; Disinfection of non-food contact surfaces in health care applications; Disinfection of non-food contact surfaces in institutional applications;
- PT4 use: Disinfection of food contact surfaces in institutional applications.

Meta-SPC 12:

- Application methods: wiping using impregnated RTU wipes;
- Formulation type: impregnated RTU wipes;
- Users: Professionals;
- PT2 use: Disinfection of surfaces in industry (e.g. dining areas, bathrooms);
- PT4 use: Disinfection of food contact surfaces in food and beverage industry.

Physico-chemical properties

The physical, chemical and technical properties for hydrogen Peroxide Family 1 are acceptable for the liquid formulation supplied to the user in different packaging volumes and impregnated wipe products. For the majority of properties data on the liquid formulation alone can be extrapolated to the impregnated wipes as the liquid formulations are identical. Therefore, the data provided are sufficient to support the BPF requested. The data provided on accelerated and long-term storage stability studies was sufficient to enable a shelf life to be concluded for all Metas.

The products in Meta-SPC 1, 2, 3, 5, 8 and 11 are to be stored at temperatures not exceeding 35 ^{0}C, the products in Meta-SPC 4, 7, 9 and 10 are to be stored at temperatures not exceeding 25 ^{0}C based on accelerated storage stability tests, and Meta-SPC 6 and Meta-SPC 12 is to be stored at temperatures not exceeding 30 ^{0}C based on flammable liquids testing.

With regards to classification and labelling for physical and chemical hazards, based on the data presented, Meta-SPCs 1, 2, 3, 5, 7, 8 and 11 of Hydrogen peroxide family 1 are not classified with regards to physical and chemical hazards.

Based on the data presented in metal corrosivity testing, Meta-SPCs 4, 9 and 10 are classified as corrosive to metals, category 1 (Met. Corr. 1, H290). Based on the data presented in flammable liquids testing, the flash point for Meta-SPC 6 and 12 has been determined to be 35.5 °C. Therefore, Meta-SPC 6 and 12 are classified as flammable liquid, category 3 (Flam. Liq. 3, H226). Meta-SPC-3 is classified as oxidising liquid, category 2 (Ox. Liq. 2, H272).

The iodometric titration method has been developed and validated for the determination of hydrogen peroxide in the biocidal product family. The validation data are acceptable for all products in the BPF.

Efficacy

The efficacy of the biocidal product family is demonstrated for all 12 Meta-SPCs. In some cases, due to identical formulations between liquid products and wipe products, read across is applied.

Organisms to be controlled: bacteria, yeasts, fungi, mycobacteria, *Clostridium* spores, bacterial spores and viruses.

Following efficacy claims against specific target organisms can be claimed for each Meta-SPC:

- Meta-SPC 1: Bacteria; Yeast; Fungi; Bacterial spores; Viruses;
- Meta-SPC 2: Bacteria; Yeast; Fungi; Mycobacteria;
- Meta-SPC 3: Bacteria; Yeast; Fungi; Bacterial spores;
- Meta-SPC 4: Bacteria; Yeast;
- Meta-SPC 5: Bacteria; Yeast; Fungi; Mycobacteria; Viruses; *Clostridium* spores, Bacterial spores;
- Meta-SPC 6: Bacteria; Yeast;
- Meta-SPC 7: Bacteria; Yeast;
- Meta-SPC 8: Bacteria; Yeast; Fungi; Mycobacteria;
- Meta-SPC 9: Bacteria; Yeast; Fungi, Viruses;
- Meta-SPC 10: Bacteria; Yeast;
- Meta-SPC 11: Bacteria; Yeast; Fungi; Mycobacteria; *Clostridium* spores, Bacterial spores; Viruses;
- Meta-SPC 12: Bacteria; Yeast.

Human health

Based on the active substance content and content of co-formulants, each Meta-SPC in the biocidal product family is classified as follows:

Meta-SPC 1:
- Eye Irrit. 2, H319.

Meta-SPC 2:
- Not classified.

Meta-SPC 3:
- Acute Tox. 4, H302;
- Skin Irrit. 2, H315;
- Eye Dam. 1, H318;
- STOT SE 3, H335.

Meta-SPC 4:
- Eye Irrit. 2, H319.

Meta-SPC 5:
- Not classified.

Meta-SPC 6:
- Eye Dam. 1, H318.

Meta-SPC 7:
- Skin Corr. 1, H314;
- Eye Dam. 1, H318 (note that labelling with H318 is not required).

Meta-SPC 8:
- Not classified.

Meta-SPC 9:
- Skin Corr. 1B, H314;
- Eye Dam. 1, H318 (note that labelling with H318 is not required).

Meta-SPC 10:
- Eye Irrit. 2, H319.

Meta-SPC 11:
- Not classified.

Meta-SPC 12:
- Eye Dam. 1, H318.

Professional user risk assessment

The human health exposure and risk assessment (HHRA) is mainly based on field studies and modelling which cover the intended uses and related scenarios relevant for the Hydrogen Peroxide Family 1.

The link between the 12 Meta-SPCs of the biocidal product family and its 47 intended uses, uses and related scenarios, HHRA approach (field study vs. modelling) per scenario and derived risk mitigation measures per use are detailed in the PAR and SPC. Due to the complexity of the Hydrogen Peroxide Family 1, these are not repeated here.

The conclusion from the field studies and modelling was that all 47 intended uses could be derived as safe and there was no unacceptable risk from a human health perspective.

At the timepoint of discussing and amending the PAR according to the comments of MS, it was acknowledged that there was no clear guidance available to applicants as to the way of conducting, reporting and evaluating exposure studies in the context of a BPF dossier. This point has been notified to the Chair of HEAdhoc and included in the list for guidance development. Therefore, the present exposure and risk assessment may need to be updated at the renewal stage to take into account the latest HEAdhoc guidance.

General public risk assessment

The biocidal product family is not intended for use by the general public therefore no primary exposure scenarios have been identified.

In scenarios where the biocidal products are not used in controlled professional environments that exclude the general public from entry, acceptable risks to the general public were determined.

Environment

All biocidal products within Hydrogen Peroxide Family 1 are marketed as aqueous ready-to-use disinfectants, water soluble concentrates or water soluble gels. All products are applied indoors and are applied using application methods listed in general section.

Based on the active substance content and content of co-formulants, one Meta-SPC in the biocidal product family is classified with regards to environment as follows:

Meta-SPC 3:

- Aquatic Chronic 3, H412.

The environmental risk assessment for the biocidal product family has followed the agreements made within the active substance approval assessment of hydrogen peroxide.

Acceptable levels of risk to all environmental compartments have been demonstrated for the proposed uses of the biocidal product family.

Overall conclusion

To summarise, taking all information into consideration and noting that:

- physical, chemical and technical properties of the biocidal product family are considered to be acceptable;
- the biocidal product family is efficacious against bacteria, yeast, fungi, mycobacteria, *Clostridium* spores, bacterial spores and viruses;
- risks to professional users are largely acceptable without any risk mitigation measures; for some of the uses personal risk mitigation measures include PPE (gloves, coveralls and eye protection) or RPE (protection factor 10); technical measures include overnight application, use of automated dosing systems, workplace measurements or technical ventilation;
- no unacceptable risks are identified for professional users, the general public or the environment;

the BPC considers that 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 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 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 use(s) 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 family 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 family on non-target organisms;
    - the impact of the biocidal product family 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 / 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, subject to compliance with the proposed SPC.

Two co-formulants are identified as potentially having endocrine-disrupting properties. There is however no need to trigger a process under REACH by the eCA (Latvia) in line with paragraph 31(b) of the note CA-March18-Doc.7.3.b-final[2], as one of them is an active substance undergoing currently an assessment on endocrine-disrupting properties and for the other a process under REACH has already been triggered.

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[2] The implementation of scientific criteria for the determination of endocrine-disrupting properties in the context of biocidal product authorisation (Note agreed by Member States' Competent Authorities for Biocidal Products).