Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the biocidal product family:

STERI-PEROX

ECHA/BPC/393/2023

Adopted

14 September 2023

Opinion of the Biocidal Products Committee

on the Union authorisation of STERI-PEROX biocidal product family

In accordance with Article 44(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council of 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:	**STERI-PEROX**
Authorisation holder:	**Veltek Associates Inc. Europe**
Active substance common name:	**Hydrogen peroxide**
Product type:	**PT02**

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 27/01/2017, recorded in R4BP3 under case number BC-GQ029577-18 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 27 February 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 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 September 2023.

The BPC opinion was adopted by consensus.

The opinion is 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 PAR.

The BPC agreed on the draft SPC of **STERI-PEROX** 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 family.

General

STERI-PEROX is a biocidal product family that is used to disinfect hard non-porous inanimate surfaces, materials and equipment which are not used for direct contact with food or feeding stuffs (PT2). The applicant applied for two Meta SPC's and three uses in total. The product is used by industrial users.

The biocidal product family contains 2 biocidal products which are attributed to the following 2 meta SPCs:

Meta SPC	Biocidal products
Meta SPC 1 - Wipes	STERI-PEROX® 6% WIPE
Meta SPC 2 - Liquid	STERI-PEROX® 6%

The products in the biocidal product family belong to one product type (PT02) with the following claimed uses and corresponding Meta SPCs:

PTs	Claimed uses	Concerned META SPC	Use proposed for authorization (Yes/No)?
2	Use # 1.1 – Professional/industrial use – Wipe - Indoors - Meta SPC 1 *Surface disinfectant use Indoors (Wipes)*	Meta SPC 1 - Wipes	Yes
	Use # 2.1 - Professional/industrial use – Liquid spraying - Indoors - Meta SPC 2 *Surface disinfectant Indoors, Sporicidal use (Liquid spraying)*	Meta SPC 2 - Liquid	Yes
	Use # 2.2 - Professional/industrial use – Liquid Soaking – Indoors – Meta SPC 2 *Surface disinfectant Indoors, Sporicidal use (Liquid soaking)*	Meta SPC 2 - Liquid	Yes

Physico-chemical properties

The STERI-PEROX product family consists of two meta SPCs both containing 6.4% w/w hydrogen peroxide. The products are sold as soaked wipes, bottles with or without a separate sprayer and drums. These packagings are supported by storage stability studies. The following storage conditions are assigned:

- Protect from frost.
- Do not store at temperatures >40°C.

None of the meta SPCs of this product family should be classified under any physical hazard according to Regulation (EC) No 1272/2008. The validation of the methods to determine the active substance content in the products are provided and are acceptable.

Efficacy

The products in the biocidal product family are used to disinfect surfaces and the target organisms are bacteria, yeasts, fungi and bacterial spores. Efficacy is substantiated by the required tests as described in the BPR guidance for the claimed uses for all test organisms. It is therefore concluded that use of the STERI-PEROX product family as a PT 2 disinfectant is acceptable.

Human Health

Acceptable risk was demonstrated for human health following product use under worst-case assumptions. It is therefore concluded that use of the STERI-PEROX product family as a PT 2 disinfectant is acceptable. The use of respiratory protective equipment (RPE) is required dependent on the ventilation rate predominantly influencing the in-air hydrogen peroxide concentrations.

The following risk mitigation measures are therefore proposed for all uses:

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

During application and for re-entry, the airborne hydrogen peroxide levels may not exceed the AEC inhalation limit of 1.25 mg/m3 (or a lower relevant national reference value). A calibrated sensor shall be used to establish that the airborne hydrogen peroxide levels are not exceeded

Environment

Acceptable risk was demonstrated for all relevant environmental compartments following product use under worst-case assumptions. It is therefore concluded that use of the STERI-PEROX product family as a PT 2 disinfectant is acceptable.

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

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

The hazard and precautionary statements of the biocidal product family according to 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.

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/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, in particular unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates;
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.

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