Biocidal Products Committee (BPC)

Opinion on the minor change to the Union authorisation of the biocidal product family:

Hydrogen Peroxide Family 1

ECHA/BPC/399/2023

Adopted

10 October 2023

Opinion of the Biocidal Products Committee

on the minor change to a Union authorisation

In accordance with Article 12(4) of Commission Implementing Regulation (EU) No 354/2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 (BPR), the Biocidal Products Committee (BPC) has adopted this opinion on the minor change to the Union authorisation of:

Name of the biocidal product family	**Hydrogen Peroxide Family 1**
Asset number	**EU-0024303-0000**
Authorisation holder	**Ecolab Deutschland GmbH**

This document presents the opinion adopted by the BPC, having regard to the conclusions of the ECHA secretariat.

Procedural history

Following the submission of an application on 5 December 2022, recorded in R4BP 3 under case number BC-SR082474-07, the ECHA secretariat presented its conclusions to the Member State Competent Authorities (MSCA). In order to review the draft revised product assessment report (PAR), the draft revised summary of product characteristics (SPC) and the conclusions of the ECHA secretariat, the Agency organised a consultation of the MSCAs. Revisions agreed upon were presented and the draft revised PAR and the draft revised SPC were updated accordingly.

Adoption of the BPC opinion

The BPC opinion on the minor change to the Union authorisation of the biocidal product family was adopted on **10 October 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 authorisation of Hydrogen Peroxide Family 1 can be amended with the proposed minor change.

After the introduction of the changes, the biocidal product family meets the conditions laid down in Article 19(1) of the BPR and therefore the authorisation of Hydrogen Peroxide Family 1 may be amended with the proposed changes as specified in this opinion. The detailed grounds for the overall conclusion are described in the PAR.

The BPC agreed on the draft revised SPC of Hydrogen Peroxide Family 1 submitted with the minor change application, as referred to in Article 22(2) of the BPR.

2. BPC Opinion

2.1 BPC conclusions of the evaluation

a) Description of the changes as proposed by the authorisation holder

The following changes to the authorised products were proposed by the authorisation holder:

- Addition of several packaging to meta SPC 1, 5 and 11.
- Addition of new wipe material to meta SPC 1.
- Removal of HDPE bucket from meta SPC 1.

b) Summary of the evaluation and conclusions

The effects of the proposed change on the physico-chemical properties, the safety for human and animal health and for the environment and the efficacy of the already authorised biocidal product family have been evaluated.

i) Physico-chemical properties

The addition of new packaging material and pack sizes may affect the conclusions reached in terms of storage and packaging stability of the biocidal products. Based on the evaluation conducted as part of this minor change application, the storage and packaging stability data evaluated during the initial assessment of the Union authorisation by the evaluating Competent Authority (eCA) are representative for the proposed new packaging.

Regarding the new wipe material, the authorisation holder provided new accelerated and long term storage stability data. Based on the evaluation of this data, the addition of the new wipe material does not affect the conclusions underlying the authorisation of the biocidal product family. Since the proposed change is limited to the wipe material and the formulation of the liquid impregnating the wipes remains unchanged, the proposed change does not affect the conclusions on other physico-chemical properties and physical hazards for the products.

In conclusion, the proposed changes do not affect the conclusions underlying the authorisation of the biocidal product family.

ii) Efficacy

An addition in packaging material and pack size does not affect the efficacy of the biocidal product family since the composition of the products, dose rate and instructions for use remain

unchanged compared to the one evaluated in the initial assessment of the Union authorisation by the eCA. It is therefore not necessary to perform a supplementary evaluation.

In the context of the new wipe material, the authorisation holder provided several new efficacy studies. Based on the evaluation of this data, sufficient efficacy is demonstrated for the product with the new wipe material.

iii) Human health

The proposed change does not affect the risks to human health associated with the use of the biocidal product family since the products' formulation, the dose rate and instructions for use remain unchanged compared to the one evaluated in the initial assessment of the Union authorisation. Furthermore, the new wipe material does not have an effect on the conclusions reached for the human health risk assessment since this assessment has been based on a worst-case scenario consisting of direct exposure ot the highest concentrated product. It is therefore not necessary to perform a supplementary evaluation.

iv) Environment

The proposed change does not affect the risks to the environment associated with the use of the biocidal product family since the proposed change is limited to the packaging and wipe material. The composition of the products, the dose rate and instructions for use remain unchanged compared to the one evaluated in the initial assessment of the Union authorisation. Furthermore, the risk management measures do not change. It is therefore not necessary to perform a supplementary evaluation.

v) Overall conclusion of the evaluation

The outcome of the evaluation, as reflected in the PAR, is that the proposed changes do not affect the conclusions with regard to the fulfilment of the conditions of Article 19(1) of the BPR.

2.2 BPC opinion on the changes to the Union authorisation

As the conditions of Article 19(1) of the BPR are met it is proposed that the authorisation of Hydrogen Peroxide Family 1 shall be amended with the proposed changes.

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Annex

Draft Revised Summary of Product Characteristics