Biocidal Products Committee (BPC)

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

Hydrogen Peroxide Family 1

ECHA/BPC/398/2023

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 13 October 2022, recorded in R4BP 3 under case number BC-SX080682-96, 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 change, 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 change 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 change as proposed by the authorisation holder

The following change to the authorised products was proposed by the applicant:

- Extension of shelf-life from 6 months to 18 months for meta SPC 8 (a).

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

In the initial assessment of the Union authorisation, the shelf-life of meta SPC 8 (a) was limited to 6 months since the efficacy of the products after storage had not been sufficiently demonstrated when the active substance degradation exceeded 10 %. Therefore, the evaluation of the change is based on existing storage stability data already provided during the initial assessment of the Union authorisation. Based on the evaluation, an extension of shelf-life to 18 months is supported by the data since the products of meta SPC 8 (a) show sufficient efficacy after 18 months and the degradation products of hydrogen peroxide are of no concern.

ii) Efficacy

The proposed change affects the conclusions reached regarding the efficacy of the biocidal product family due to the degradation of the active substance during storage. Based on the evaluation, the new efficacy data, together with the existing efficacy data, demonstrate sufficient efficacy after 18 months for products in meta SPC 8 (a).

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 proposed change is limited to the shelf-life. The products' formulation, the dose rate, instructions for use and user category 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.

iv) Environment

The proposed change does not affect the risks to the environment associated with the use of the biocidal product family since the change is limited to the shelf-life. 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. 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 change does 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 change 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 change.

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Annex

Draft Revised Summary of Product Characteristics