Biocidal Products Committee (BPC)

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

perform-IPA

ECHA/BPC/397/2023

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	**perform-IPA**
Asset number	**EU-0023656-0000**
Authorisation holder	**Schuelke & Mayr 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 20 December 2021, recorded in R4BP 3 under case number BC-SN072185-20, the ECHA secretariat evaluated the minor change. Subsequently, the ECHA secretariat transmitted an ECHA opinion on the change to the European Commission on 6 June 2022. The European Commission considered the ECHA opinion invalid on the basis of Article 75 of the BPR. Therefore, 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 from 4 September until 13 September 2023. 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 perform-IPA 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 perform-IPA 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 perform-IPA 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 were proposed by the applicant:

- Change in the pack size range:
    - Extension of pack size range for canisters from 5-10 L to 5-30 L for meta SPC 1 and 3.
    - Addition of 200-220 L HDPE drums to meta SPC 1 and 3.
    - Addition of 900-1000 L containers (IBC) to meta SPC 1 and 3.

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

A change in pack size 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. Therefore, the proposed change does not affect the conclusions underlying the authorisation of the biocidal product family.

ii) Efficacy

The proposed change 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.

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 realistic worst-case scenario in terms of exposure – manual decanting of canisters – has already been evaluated during the initial assessment of the Union authorisation by the eCA. 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 proposed change is limited to the pack size. 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 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 perform-IPA shall be amended with the proposed change.

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Annex

Draft Revised Summary of Product Characteristics