

## **Biocidal Products Committee (BPC)**

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

**perform-IPA**

ECHA/BPC/400/2023

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:

<b>Name of the biocidal product family</b>	<b>perform-IPA</b>
<b>Asset number</b>	<b>EU-0023656-0000</b>
<b>Authorisation holder</b>	<b>Schuelke &amp; Mayr GmbH</b>

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 1 February 2023, recorded in R4BP 3 under case number BC-NJ084251-38, 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 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 was proposed by the authorisation holder:

- Addition of a claim for limited spectrum virucidal activity to all product type 2 uses of meta SPC 1 to 6.

##### 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 proposed change does not affect the physico-chemical properties of the biocidal product/family since the proposed change is limited to the new efficacy claim. The products composition and packaging 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.

##### ii) Efficacy

The proposed change affects the conclusions reached regarding the efficacy of the biocidal product family. The new efficacy claim must be assessed.

Based on the assessment, the biocidal product show sufficient efficacy to substantiate the new claim.

##### 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 new efficacy claim. The composition of the products, 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 proposed change is limited to the new efficacy claim. 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**