European Chemicals Agency

Opinion on the administrative change of the Union authorisation of the biocidal product family: IPA Family 1

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Opinion of the European Chemicals Agency

on an administrative change of the Union authorisation of IPA Family 1

In accordance with Article 11(3) of Implementing Regulation (EU) No 354/2013 of the European Commission 18 May 2013 on changes of biocidal products authorised in accordance with Biocidal Product Regulation (EU) No 528/2012 (BPR), the European Chemicals Agency (ECHA) has prepared this opinion on the administrative change to the Union authorisation of:

Name of the biocidal product family: IPA Family 1

Authorisation holder: Ecolab Deutschland GmbH

Target asset number: EU-0028425-0000

Active substance common name: Propan-2-ol

Product types: 2, 4

1. Process for the adoption of the opinion

The notification for the administrative change was submitted to ECHA on 30 November 2023, and recorded in R4BP 3 under case number BC-KE090454-43.

As the notification included an incorrect version of the supporting document, the applicant was requested to provide a new supporting document on 1 December 2023. The applicant provided the requested supporting document on the same day. On 8 December 2023, the applicant was requested to provide a new SPC since the one submitted with the notification did not include any proposed changes to the Union authorisation. The applicant completed the request on 21 December 2023.

Following its acceptance by ECHA, the evaluation of the notification was initiated on 19 January 2024.

The evaluation included a check that the proposed change of an existing authorisation is of a purely administrative nature involving no change to the properties or efficacy of the biocidal product family in accordance with Article 3(1)(aa) of the BPR.

The scope of the assessment itself was based on and limited to the information provided by the authorisation holder in the supporting document for the notification for an administrative change of a Union or simplified authorisation under Regulation (EU) No 354/2013 supplied via R4BP 3.

ECHA prepared this opinion containing the conclusions of its assessment.

2. Detailed opinion and background

2.1. ECHA opinion

During the evaluation, ECHA has assessed whether the change made in the SPC document provided by the applicant is administrative in accordance with Implementing Regulation (EU) No 354/2013.

It is ECHA's opinion that the following change to the biocidal product family sought by the

authorisation holder is a change falling under Article 3(1)(aa) of the BPR, and, after the implementation of the change, the conditions of Article 19 of the BPR will still be met:

- Title 1, section **2** of the Annex to the Regulation (EU) No 354/2013 - *Conditions of use*

Accordingly, it is proposed that the Commission amends the existing authorisation with the below listed administrative change to the biocidal product family sought by the authorisation holder.

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2.2. ECHA assessment

2.2.1. Description of the change as proposed by the authorisation holder

Change as described by the authorisation holder in their supporting document supplied via R4BP 3.

Identification	**Description**
1.	**More precise instructions for use for all products in the family** Application rate is set as 18 mL/m2 in this family for spray application or 10 ml/m2 for wipe application. This is the minimum amount of product to be used to ensure whole complete surface coverage & maximum amount of product used for risk assessment calculations. The proposed instructions of use refer to (max. 18 mL/m2 or max. 10 ml/m2) which seems to be misleading, as customer can believe lower amount can be used. Proposal text is to remove "max" from the wording, just state 18 mL/m2 or 10 mL/m2. Therefore, we propose to update the PAR sections below: - Meta-SPC 1.1, use 1.1, section 2.1.4.2. - Meta-SPC 1.2, use 2.1, section 2.1.4.7. - Meta-SPC 1.3, use 3.1, section 2.1.4.12. - Meta-SPC 1.4, use 4.1, section 2.1.4.17. - Meta-SPC 1.5, use 5.1, section 2.1.4.22. Same proposal for use instructions available in the SPC document. Removing "max" from use instructions wording.

2.2.2. Assessment of the change as proposed by the authorisation holder

The assessment of the change sought by the authorisation holder is presented in the following table:

Identification	Corresponding reference in the Annex to Regulation (EU) No 354/2013	Evaluation	Result of the evaluation	Comments
1.	No specific entry available.	The proposed change is not listed in the Annex of the Regulation (EU) No 354/2013. But due to the nature of the change, the change can be considered to fulfill the definition of administrative change in accordance with Article 3(1)(aa) of the BPR.	Acceptable by considering all available information in the SPC.	ECHA does not agree with the authorisation holder that the proposed change is covered by the change No 7 of Section 2 of Title 1 of the Annex to Regulation (EU) No 354/2013), i.e, "*More precise instructions for use* (..)". Although the proposed change is not considered to make the instructions of use more precise, ECHA agrees that the change is fulfilling the definition of an administrative change in accordance with Article 3(1)(aa) of the BPR. Thus, by considering all available information in the SPC, ECHA concludes that in this particular application the proposed change is acceptable. It needs to be noted that this case should not be considered as a precedent case and every application is evaluated separately by reviewing all available information.

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Annex

Draft Summary of Product Characteristics