European Chemicals Agency

Opinion on the administrative change of the Union authorisation of the biocidal product family: SALVECO SALVESAFE PRODUCTS

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Opinion of the European Chemicals Agency

on an administrative change of the Union authorisation of SALVECO SALVESAFE PRODUCTS

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: SALVECO SALVESAFE PRODUCTS

Authorisation holder: SALVECO S.A.S.

Target asset number: EU-0028967-0000

Active substance common name: L-(+)-lactic acid

Product types : 2, 3, 4

1. Process for the adoption of the opinion

The notification for the administrative change was submitted to ECHA on 10 January 2024, and recorded in R4BP 3 under case number BC-HR091384-18.

Following its acceptance by ECHA, the evaluation of the notification was initiated on 06 February 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 changes as proposed by the authorisation holder

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

Identification	Description
1.	Addition of a new pack size within the authorised range into meta 7

2.2.2. Assessment of the changes 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 since it does not have an impact on the properties or efficacy of the product. By considering all available information in the SPC, ECHA	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 (..)". Nonetheless,

		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		ECHA agrees that the change is fulfilling the definition of an administrative change in accordance with Article 3(1)(aa) of the BPR.

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Annex

Draft Summary of Product Characteristics