European Chemicals Agency

Opinion on the administrative change of the Union authorisation of the biocidal product family: TEAT DISINFECTANTS BIOCIDAL PRODUCT FAMILY OF CVAS

Opinion N° UAD-C-1635713-35-00/F

3 January 2023

Opinion of the European Chemicals Agency

on administrative changes of the Union authorisation of TEAT DISINFECTANTS BIOCIDAL PRODUCT FAMILY OF CVAS

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 changes to the Union authorisation of:

Name of the biocidal product family: TEAT DISINFECTANTS BIOCIDAL PRODUCT FAMILY OF CVAS

Authorisation holder: CVAS Development GmbH

Target asset number: EU-0018724-0000

Active substances common name: Polyvinylpyrrolidone iodine; Iodine

Product type: 3

1. Process for the adoption of the opinion

The notification for the administrative change was submitted to ECHA on **30 November 2022**, and recorded in R4BP under case number **BC-PM082301-35**.

Following its acceptance by ECHA, the evaluation of the notification was initiated on **29 December 2022**.

The evaluation included a check that the proposed changes of an existing authorisation are 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.

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 changes made in the SPC document provided by the applicant are administrative changes in accordance with Implementing Regulation (EU) No 354/2013.

It is ECHA's opinion that the following changes to the biocidal product family sought by the authorisation holder are changes falling under Article 3(1)(aa) of the BPR, and, after the implementation of the changes, the conditions of Article 19 of the BPR will still be met:

- Title 1, section **1** of the Annex to the Regulation (EU) No 354/2013 – *Authorisation holder* - change N° 4: *Change in the name or address of the authorisation holder, which remains in the EEA.*

- Title 1, section **2** of the Annex to the Regulation (EU) No 354/2013 – *Formulator(s) of the biocidal product* - change N° 2: *Change in the name, the administrative details or the formulating location of the biocidal product formulator, where the biocidal product composition and the formulating process remain unchanged.*

Accordingly, it is proposed that the Commission amends the existing authorisation with the below listed administrative changes 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.

Identification	**Description**
1.	Change in the name or address of the authorisation holder, which remains in the EEA. The address of the authorisation holder CVAS Development GmbH needs to be updated from: CVAS Development GmbH Dr. Albert Reimann Str. 16a, 68526 Ladenburg, Germany to the new address: CVAS Development GmbH Am Hafen 16, 68526 Ladenburg, Germany
2.	Change in the name, the administrative details or the formulating location of the biocidal product formulator, where the biocidal product composition and the formulating process remain unchanged. The address of the manufacturing of the biocidal product,

	Calvatis GmbH needs to be updated from: Calvatis GmbH Dr. Albert Reimann Str. 16a, 68526 Ladenburg, Germany to the new address: Calvatis GmbH Am Hafen 16, 68526 Ladenburg, Germany

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

The assessment of the changes 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.	Title 1, section 1, change n° 4	The requested change matches the description in the Regulation	Acceptable	Change requiring prior notification
2.	Title 1, section 2, change n° 2	The requested change matches the description in the Regulation	Acceptable	

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Annex

Draft Summary of Product Characteristics