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-1478333-29-00/F

26 October 2020

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 change(s) 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 substance(s) common name: Polyvinylpyrrolidone iodine - Iodine

Product type(s): PT 3

1. Process for the adoption of the opinion

The notification for the administrative change was submitted to ECHA on 21 September 2020, and recorded in R4BP under case number BC-WA061912-42.

Following its acceptance by ECHA, the evaluation of the notification was initiated on 24 October 2020.

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 change(s), 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 - Name of the biocidal product - change N° 2: Addition of a name for the biocidal product where there is no risk of confusion with the names of other biocidal products.

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.

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.	**Addition of a name for the biocidal product where there is no risk of confusion with the names of other biocidal products.** For the product "calgodip D 1200" (meta-SPC 7), the trade names "Horndip 1200", "Fulldip 1200", "COWISAN 1200" and "COWICUR 1200" should be added. For the product "calgodip D 3000 Film" (meta-SPC 8), the trade names "COWISAN 3000 Film" and "COWICUR 3000 Film" should be added. For the product "calgodip D 5000" (meta-SPC 8), the trade names "Horndip 5000", "Fulldip 5000", "COWISAN 5000 Film", "COWICUR 5000 Film", "BestFarm Filmdip 5000", "BestFarm Dip Premium 5000" and "BestFarm Opti Filmdip 5000" should be added. For the product "calgodip D 3000" (meta-SPC 9), the trade names "Fulldip 3000", "COWISAN 3000" and "COWICUR 3000" should be added.

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	Assessment	Result of the assessment	Comments *
1.	Title 1, section1, change n°2	The requested changes match the description in the Regulation	Acceptable	Changes requiring prior notification

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Annex

Draft Summary of Product Characteristics