

European Chemicals Agency

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

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27 September 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 substance(s) common name: Polyvinylpyrrolidone iodine, Iodine

Product type: 03

1. Process for the adoption of the opinion

The notification for the administrative changes were submitted to ECHA on 16 August 2023, and recorded in R4BP 3 under case number BC-SJ088220-34.

Following its acceptance by ECHA, the evaluation of the notification was initiated on 23 September 2023

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 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 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 - *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.

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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.

<u>Identification</u>	<u>Description</u>
1.	For the product „Dip es barriere“ (meta-SPC 1), the trade names “Dip Agro Gold Film 1400”, “BaktoStop barier 1400”, “IDF 14”, “Kuhmiline JBD” and “Vir Bak Iod F14” should be added.
2.	For the product “Dip es Io-film” (meta-SPC 2), the trade names “Dip Agro Protect Film”, “BaktoStop film”, “IDF 30 P”, “Kuhmiline JPD” and “Vir Bak Iod P30” should be added.
3.	For the product “Dip es barriere S” (meta-SPC 3), the trade names “Dip Agro Gold Film”, “IDF 30”, “Kuhmiline JBD3” and “Vir Bak Iod F30” should be added.
4.	For the product “Dip es barriere RS” (meta-SPC 3), the trade names “Dip Agro Gold Film 5000”, “IDF 50”, “Kuhmiline JBD5” and “Vir Bak Iod F50” should be added.
5.	For the product “Dip es SF” (meta-SPC 5), the trade names “Dip Agro Gold Spray 1400”, “BaktoStop spray 1400”, “IDS 14”, “Kuhmiline JBS”, “Vir Bak Iod S14”, “Dip Agro Gold Spray”, “BaktoStop spray 3000”, “IDS 30”, “Kuhmiline JBS3” and “Vir Bak Iod S30” should be added.
6.	For the product “Dip es Io-foam” (meta-SPC 6), the trade names “Dip Agro Protect Foam”, “IDS 14 F”, “Kuhmiline JVM” and “Vir Bak Iod” should be added.
7.	For the product “calgodip D 3000 Film” (meta-SPC 8), the trade name “HappyFarm JodDip Film 20” should be added.
8.	For the product “calgodip D 3000” (meta-SPC 9), the trade name “HappyFarm JodDip Spray20” 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:

<u>Identification</u>	<u>Corresponding reference in the Annex to Regulation (EU) No 354/2013</u>	<u>Evaluation</u>	<u>Result of the evaluation</u>	<u>Comments</u>
1 - 8	Title 1, section 1, change n° 2	The requested changes match the description in the Regulation	Acceptable	Change requiring prior notification

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Annex

Draft Summary of Product Characteristics