European Chemicals Agency

Opinion on the administrative change of the Union authorisation of the biocidal product family: BPF_Iodine_VET

Opinion N° UAD-C-1527976-17-00/F

13 August 2021

Opinion of the European Chemicals Agency

on administrative changes of the Union authorisation of BPF_Iodine_VET

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: BPF_Iodine_VET

Authorisation holder: Applied Biocide GmbH

Target asset number: EU-0020540-0000

Active substance common name: Iodine

Product type: 03

1. Process for the adoption of the opinion

The notification for the administrative change was submitted to ECHA on 16 July 2021 and recorded in R4BP under case number BC-CU068666-08.

Following its acceptance by ECHA, the evaluation of the notification was initiated on 13 August 2021.

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 evaluation 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 the evaluation.

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 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.

Identification	**Description**
1. Title 1, section 1 – Change N° 2 – Name of the biocidal product	FINK - Io Spray 15: Addition of the following names: IO liquid 15 Udder Spray Iodine Des Spray 15 Io Spray 1500 Desintec MH Raidip 1500 Desintec MH Iodine 1500 Concerned meta-SPC: meta-SPC 1
2. Title 1, section 1 – Change N° 2 – Name of the biocidal product	FINK – Io Spray 30: Addition of the following names: IO liquid 30 Udder Spray 30 Iodine Des Spray 30 IO Spray Barriere IO Spray Film FINK - Io Spray Barriere FINK - Io Spray Film Dip Agro Gold Spray ADF iDip+ Io Spray 3000 Desintec MH Raidip 3000 Desintec MH Iodine 3000 Concerned meta-SPC: meta-SPC 2
3. Title 1, section 1 – Change N° 2 – Name of the biocidal product	FINK - Io Spray 50: Addition of the following names: IO liquid 50 Iodine Max Spray Iodine Des Spray 50 ASJ Gato Spray 5000 Io Spray 5000 Desintec MH Iodine 5000 Concerned meta-SPC: meta-SPC 2
4. Title 1, section 1 – Change N° 2 – Name of the biocidal product	FINK – Io Dip 10: Addition of the following names: IO-Film 10 Iodine Des Dip 10 Io Dip 1000 Desintec MH Raidip Desintec MH Iodine Plus Concerned meta-SPC: meta-SPC 4

5. Title 1, section 1 – Change N° 2 – Name of the biocidal product	FINK – Io Dip Protect: Addition of the following names: IO-Special Film IO-Special Barriere Iodine Des Barriere IO-Extra Protect UDDER -Protect IO-Super Iodo Protect IO Film Iodo Film Jodo Film Dip Agro Gold Protect Iodo Film Io Protect Desintec MH Raidip Barrier Concerned meta-SPC: meta-SPC 4
6. Title 1, section 1 – Change N° 2 – Name of the biocidal product	FINK – Io Dip 50: Addition of the following names: IO-Film 50 Iodine Max Dip Iodine Des Dip 50 ASJ Gato Dip 5000 Io Dip 5000 Desintec MH Raidip Forte Desintec MH Iodine Forte Concerned meta-SPC: meta-SPC 5
7. Title 1, section 1 – Change N° 2 – Name of the biocidal product	FINK – Io Dip 30: Addition of the following names: IO-Film 30 Iodine Des Dip 30 Dip Agro Gold Film TvP - Dip Jod 3000 Io Dip 3000 Desintec MH Raidip Film Concerned meta-SPC: meta-SPC 5
8. Title 1, section 1 – Change N° 2 – Name of the biocidal product	IODOSAN 30: Addition of the following names: JodoPhos Iophodes Iodes 15 Iodes 24 Iodes 2400 Des-IO JodoPhos 15 Des-IO 15 Des-IO 24 I-Des I-Des 24 I-Des 15 Iophodes 2.4% JodoPhos 15 Desintec Jodes Concerned meta-SPC: meta-SPC 6
9. Title 1, section 1 – Change N° 2 – Name of the biocidal product	IODOSAN 18: Addition of the following names: Desintec FL-Jodes Plus Desintec Jodes Plus Concerned meta-SPC: meta-SPC 6

10. Title 1, section 1 – Change N° 2 – Name of the biocidal product	IODOSAN 30 plus: Addition of the following names: Iophodes Iodes 30 Des-IO 30 I-Des 30 Iophodes 3.0% Desintec FL-Jodes Forte Desintec Jodes Forte Concerned meta-SPC: meta-SPC 7
11. Title 1, section 1 – Change N° 2 – Name of the biocidal product	IODOSAN 15: Addition of the following names: Desintec FL-Jodes Basic Desintec Jodes Basic Concerned meta-SPC: meta-SPC 8

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° 2 – Name of the biocidal product	The requested change matches the description in the Regulation	Acceptable	Change requiring prior notification
2.	Title 1, section 1 – Change N° 2 – Name of the biocidal product	The requested change matches the description in the Regulation	Acceptable	Change requiring prior notification
3.	Title 1, section 1 – Change N° 2 – Name of the biocidal product	The requested change matches the description in the Regulation	Acceptable	Change requiring prior notification
4.	Title 1, section 1 – Change N° 2 – Name of the biocidal product	The requested change matches the description in the Regulation	Acceptable	Change requiring prior notification
5.	Title 1, section 1 – Change N° 2 – Name of the biocidal product	The requested change matches the description in the Regulation	Acceptable	Change requiring prior notification
6.	Title 1, section 1 – Change N° 2 – Name of the biocidal product	The requested change matches the description in the Regulation	Acceptable	Change requiring prior notification
7.	Title 1, section 1 – Change N° 2 – Name of the biocidal product	The requested change matches the description in the Regulation	Acceptable	Change requiring prior notification
8.	Title 1, section 1 – Change N° 2 – Name of the biocidal product	The requested change matches the description in the Regulation	Acceptable	Change requiring prior notification
9.	Title 1, section 1 – Change N° 2 – Name of the biocidal	The requested change matches the description	Acceptable	Change requiring prior

	product	in the Regulation		notification
10.	Title 1, section 1 – Change N° 2 – Name of the biocidal product	The requested change matches the description in the Regulation	Acceptable	Change requiring prior notification
11.	Title 1, section 1 – Change N° 2 – Name of the biocidal product	The requested change matches the description in the Regulation	Acceptable	Change requiring prior notification

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Annex

Draft Summary of Product Characteristics