European Chemicals Agency

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

Opinion N° UAD-C-1677318-26-00/F

31 August 2023

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 changes 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: 3

1. Process for the adoption of the opinion

The notification for the administrative change was submitted to ECHA on 25 July 2023, and recorded in R4BP 3 under case number BC-TS087940-00.

Following its acceptance by ECHA, the evaluation of the notification was initiated on 5 August 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.

Identification	**Description**
1.	FINK - Io Spray 15: Addition of the following names: Iodine Spray 1500 Iodine Liquid 1500 Raidip 15 Iodine 15 Iodine Plus 15 Iodine Forte 15 Iodine 1500 Iodine Spray 1500 Iodine Spray 15 TVP Spray Jod 1500 Blatticlean Io-Spray 15 Blattides Io-Spray 1500 Annuvet Io-Dip 1500 Livisto Iodine Pro 15 Agro Prax Iodine Spray 1500

2.	FINK - Io Spray 30: Addition of the following names: Iodine Spray 3000 Iodine liquid 3000 KerbaDip Jod KerbaSpray Jod Raidip 30 Iodine 30 Iodine S Raidip Plus Iodine Plus 30 Iodine Forte 30 Iodine 3000 Iodine Spray 30 TVP Spray Jod 3000 Blatticlean Io-Spray 30 Blattides Io-Spray 3000 Annuvet Io-Dip 3000 Livisto Iodine Pro 30
3.	FINK - Io Spray 50: Addition of the following names: Iodine Spray 5000 Iodine Liquid 5000 Raidip 50 Iodine 50 Iodine Plus 50 Iodine Forte 50 Iodine 5000 Iodine Spray 50 TVP Spray Jod 5000 Blatticlean Io-Spray 50 Blattides Io-Spray 5000 Annuvet Io-Dip 5000 Livisto Iodine Pro 50 Agro Prax Iodine Spray 5000
4.	FINK - Io Spray 50 (Jodophor): Addition of the following names: Iodine Extra 5000 Iodine Liquid Extra 5000
5.	FINK - Io Dip 10: Addition of the following names: Iodine Dip 1000 IodineDip Extra 1000 Raidip Iodine Plus Iodine Barrier 10 Iodine Film 10 Iodine Dip 1000 TVP Dip Jod 1000 Blatticlean Io-Dip 10 Blattides Io-Film 1000 Annuvet Io-Barrier 1000 Livisto Iodine Dip 10 Agro Prax Iodine Dip 1000

6.	FINK - Io Dip Protect: Addition of the following names: Iodine Special Barriere Iodine Extra Barriere UdderoDip Protect Raidip Barrier Iodine Barrier Iodine Barrier 15 Iodine Film 15 Iodine Dip 1500 TVP Dip Jod 1500 Blatticlean Io-Dip 15 Blattides Io-Film 1500 Annuvet Io-Barrier 1500 Livisto Iodine Dip 15 Agro Prax Iodine Dip 1500
7.	FINK - Io Dip 15: Addition of the following names: Iodine Dip 1500 Iodine Joddip 1500
8.	Jodfilm 75/5 4500 ppm: Addition of the following names: Iodine Dip 4500 Iodine Joddip 4500
9.	FINK - Io Dip 50: Addition of the following names: Iodine Dip 5000 Iodine Joddip 5000 Raidip Forte Iodine Forte Iodine Barrier 50 Iodine Film 50 TVP Dip Jod 5000 Blatticlean Io-Dip 50 Blattdes Io-Film 5000 Annuvet Io-Barrier 5000 Livisto Iodine Dip 50 Agro Prax Iodine Dip 5000
10.	FINK - Io Dip 30: Addition of the following names: Iodine Dip 3000 Iodine Joddip 3000 UdderoDip Jod Raidip Film Iodine Film Iodine Barrier 30 Iodine Film 30 Blatticlean Io-Dip 30 Blattdes Io-Film 3000 Annuvet Io-Barrier 3000 Livisto Iodine Dip 30 Agro Prax Iodine Dip 3000
11.	IODOSAN 30: Addition of the following names: Iodine Kalt Iodine Des 240 TVP Jod 240 Blatticlean Iod Des 24 Blattides Iod Des 24 Annuvet Iodine D 24 Livisto Des Iodine 24

12.	IODOSAN 18: Addition of the following names: Iodine Des 175 Blatticlean Iod Des Blattides Iod Des Annuvet Iodine D Livisto Des Iodine
13.	IODOSAN 30 plus: Addition of the following names: Iodine Des 300 Blatticlean Iod Des 30 Blattides Iod Des 30 Annuvet Iodine D 30 Livisto Des Iodine 30
14.	IODOSAN 15: Addition of the following names: Jodes Stalldes Stalldes Jod Extra Iodine Des 150 Blatticlean Iod Des 15 Blattides Iod Des 15 Annuvet Iodine D 15 Livisto Des Iodine 15

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 - 14	Title 1, section 1, 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