European Chemicals Agency

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

Opinion N° (UAD-C-1456022-41-00/F)

9 June 2020

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 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: PT03

1. Process for the adoption of the opinion

The notification for the administrative change was submitted to ECHA on 10 April 2020, and recorded in R4BP under case number BC-VD058524-35.

Following its acceptance by ECHA, the evaluation of the notification was initiated on 22 April 2020.

The evaluation included a check that the proposed changes of the 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 – Name of the biocidal product – change N°1: Changes of the name of the biocidal product where

there is no risk of confusion with the names of other biocidal products.

- 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.

- 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.

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° 1 – Name of the biocidal product	Change of the name of the biocidal product: **Meta SPC 2** Old name: Fink Io Spray –30 New name: FINK – Io Spray 30
2. Title 1, section 1 – Change N° 1 – Name of the biocidal product	Change of the name of the biocidal product: **Meta SPC 6** Old name: IODAT New name: JODAT
3. Title 1, section 1 – Change N° 2 – Name of the biocidal product	Addition of names for the biocidal products: **Meta-SPC 2** Io Spray 30 Iodine Spray 30
4. Title 1, section 1 – Change N° 2 – Name of the biocidal product	Addition of names for the biocidal products: -**Meta-SPC 5 - section 7.1** IOFILMO SUPER SUPERIO 4.5 PROTEGO 4500 TIGER 50 ASSOLUTO 5 REDFOX S SUPER MANGUST AUGUSTO P5 IO-DIN 45

5. Title 1, section 1 – Change N° 2 – Name of the biocidal product	Addition of names for the biocidal products: **Meta-SPC 5 – section 7.2** JODOFILM 75/3 IOFILMO SUPERIO 3.0 PROTEGO 3000 TIGER 30 ASSOLUTO 3 REDFOX E MANGUST AUGUSTO P3 IO-DIN 30
6. Title 1, section 2 - change N°2- Formulator(s) of the biocidal product	Change of the name of the formulator of the biocidal products: - Old name: IRCASERVICE New name: I.R.C.A. SERVICE S.p.A.
7. Title 1, section 2 - change N°2 - Formulator(s) of the biocidal product	Change of the name of the formulator of the biocidal products: - Old name: Laboratorios Maymo SA New name: Laboratorios Maymó S.A.
8. Title 1, section 2 - change N°2 - Formulator(s) of the biocidal product	Change of the name of the formulator of the biocidal products: -Old name: Ewabo Chemikalien GmbH & Co KG New name: THESEO Deutschland GmbH

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, section 1 – Change N° 1 – 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° 1 – 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 2 - change N°2- Formulator(s) of the biocidal product	The requested change matches the description in the Regulation	Acceptable	-
7.	Title 1, section 2 - change N°2- Formulator(s) of the biocidal product	The requested change matches the description in the Regulation	Acceptable	-
8.	Title 1, section 2 - change N°2- Formulator(s) of the biocidal product	The requested change matches the description in the Regulation	Acceptable	-

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Annex

Draft Summary of Product Characteristics