European Chemicals Agency

Opinion on the administrative change of the Union authorisation of the biocidal product family: HYPRED's iodine based products

Opinion N° UAD-C-1512147-41-00/F

26 May 2021

Opinion of the European Chemicals Agency

on administrative changes of the Union authorisation of biocidal product family HYPRED's iodine based products

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: HYPRED's iodine based products

Authorisation holder: HYPRED SAS

Target asset number: EU-0018397-0000

Active substance(s) common name: 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 20 April 2021 and recorded in R4BP under case number BC-BP066008-35.

The evaluation of the notification was initiated on 21 April 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 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.
    - Manufacturer of the active substance - change N° 5 : Addition of a manufacturer of the active substance or in their manufacturing location or process.
- 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.
    - Formulator(s) of the biocidal product - change N° 4 : Addition of a formulator of the biocidal product, 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.

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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.	**Addition of the following names for the biocidal product family** Liq-io 2500 : JODIP 2500 L JODOTHEN 2500 Liq DERMI J LIQ Tehotippi Soft 2500 ROBOSPRAY IODE EXTRA Liq-io 5500 : JODIP 5500 L JODOTHEN 5500 DERMI J II LIQ IODO CIDA LIQUIDO D-SAN IOD SPRAY FP IODINE SPRAY IODISSIMO POWER IODE RBT Liq-io concentrate : POLY-IODE C Dip-io 2500 : JODIP 2500 G JODOTHEN 2500 DIP GEL DERMI J GEL IRON-FILM PRODIP FILM Dip-io 5000 : JODIP 5000 G JODOTHEN 5000 DIP GEL DERMI J II F/F IODO CIDA FILM D-SAN IOD FORTE PRODIP BARIER FP IODINE
2.	**Addition of one manufacturer for the active substance and their respective manufacturing sites.** **Atacama Minerals SCM** Coronel Pereira No 72 Of. 701, Las Condes, Santiago, Chile Plant location : Atacama Minerals SCM, Aguas Blancas Facility, Antofagasta, Chile The technical equivalence of this source has been established by the Agency. The asset number is EU-0014306-0000.
3.	**Change of the administrative details for the following manufacturing location site for HYPRED SAS**. **AG France S.A.S** Zone Industrielle Le Roineau 72500 VAAS – FRANCE *The name of the manufacturing site is changed to* **HYPRED SAS – KERSIA Group** Zone Industrielle Le Roineau 72500 VAAS - FRANCE **HYPRED Italia s.r.l. – KERSIA Group** Strada Montodine-Gombito Loc. Cà Nova 26010 Ripalta Arpina CR Italy *The name of the manufacturing site is changed to* **KERSIA Italia s.r.l.** Strada Montodine-Gombito Loc. Cà Nova 26010 Ripalta Arpina CR Italy

4.	**Addition of the following manufacturing location site for HYPRED SAS** • **SOPURA – KERSIA Group** Parc Paysager de Tyberchamps 14 7180 SENEFFE BELGIUM • **SOPURA Quimica – KERSIA Group** Pol. Ind. " La Canaleta " Avinguda Júpiter n° 7 25300 TARREGA (LLEIDA) SPAIN • **Holchem Laboratories Ltd – KERSIA Group** Gateway House, Pilsworth Road, Pilsworth Industrial Estate, Bury BL9 8RD UNITED KINGDOM

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°2	The requested changes match the description in the Regulation.	Acceptable	Change requiring prior notification
2.	Title 1, section 1, change n°5	The new manufacturer of the active substance is an alternative source for which a technical equivalence decision has been provided.	Acceptable	Change requiring prior notification
3.	Title 1, section 2, change n°2	The requested changes match the description in the Regulation.	Acceptable	
4.	Title 1, section 2, change n°4	The requested changes match the description in the Regulation.	Acceptable	

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Annex

Draft Summary of Product Characteristics