European Chemicals Agency

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

Opinion N° UAD-C-1613322-44-00/F

29 September 2022

Opinion of the European Chemicals Agency

on administrative changes of the Union authorisation of HYPRED's octanoic acid 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 changes to the Union authorisation of:

Name of the biocidal product family: HYPRED's octanoic acid based products

Authorisation holder: HYPRED SAS

Target asset number: EU-0021020-0000

Active substance common name: Octanoic acid

Product type: 4

1. Process for the adoption of the opinion

The notification for the administrative change was submitted to ECHA on 5 September 2022, and recorded in R4BP under case number BC-SL079611-22.

Following its acceptance by ECHA, the evaluation of the notification was initiated on 28 September 2022.

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 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.*

- 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.*

  - 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 META-SPC 1 : DEPTACID OCTACIP OCTACID ONE OCTA-ONE META-SPC 3 : DEPTIL CB SOPURSAN CB META-SPC 4 : SOPURCLEAN NF WCM Osmotask AS
2.	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 *Change by* **HYPRED SAS** (KERSIA Group) Zone Industrielle Le Roineau 72500 VAAS - FRANCE **HYPRED POLSKA SP. Z O.O.** NIEPRUSZEWO, KASZTANOWA 4, 64320 buk Poland

	Change by **KERSIA POLSKA Sp.z.o.o** Niepruszewo, ul. Kasztanowa 4 64-320 BUK - POLAND **HYPRED GmbH** Marie-Curie-Straße 23, 53332 Bornheim Sechtem Germany *Change by* **KERSIA DEUTSCHLAND GmbH** Marie-Curie-Straße 23 53332 BORNHEIM – SECHTEM GERMANY **Anti-Germ Deutschland GmbH** Oberbrühlstraße 16-18, 87700 Memmingen Germany *Change by* **KERSIA DEUTSCHLAND GmbH** OBERBRÜHLSTRAßE 16-18 87700 MEMMINGEN GERMANY **Anti-Germ Austria GmbH** Pfongauer Straße 17, 5202 Neumarkt am Wallersee' Austria *Change by* **KERSIA AUSTRIA GmbH** PFONGAUERSTRAßE 17 5202 NEUMARKT AM WALLERSEE AUSTRIA **HYPRED Italia s.r.l.** Strada Montodine-Gombito Loc. Cà Nova, 26010 Ripalta Arpina CR Italy *Change by* **KERSIA ITALIA S.r.l** Strada Montodine – Gombito Loc. Cà Nova 26010 RIPALTA ARPINA (CR) ITALY **HYPRED IBERICA S.L** Pol. Ind. Arazuri-Orcoyen C/C n° 32, 31160 Orcoyen – NAVARRA Spain *Change by* **KERSIA IBERICA SL** Pol. Miguel Eguía C/Zarapuz s/n 31200 ESTELLA (NAVARRA) SPAIN
3.	Addition of the following manufacturing location sites for HYPRED SAS : **Kilco Holdings Ltd (KERSIA Group)** Broomhouses 2 Industrial Estate Old Glasgow Road LOCKERBIE DG11 2SD UNITED KINGDOM **Kilco (International) Ltd (KERSIA Group)** 1A Trench Road Mallusk Newtownabbey BT36 4TY CO ANTRIM IRELAND

	Medentech Ltd (KERSIA Group) Clonard Road WEXFORD Y35Y7WY IRELAND **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 **Bio Armor Développement (KERSIA Group)** Zone industrielle de la Gare, 22940 PLAINTEL FRANCE

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	The requested change matches the description in the Regulation	Acceptable	Change requiring prior notification
2.	Title 1, section 2, change n° 2	The requested change matches the description in the Regulation	Acceptable	
3.	Title 1, section 2, change n° 4	The requested change matches the description in the Regulation	Acceptable	

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Annex

Draft Summary of Product Characteristics