Commission Implementing Regulation (EU) 2020/1995 of 4 December 2020 amending Implementing Regulation (EU) No 2018/1261 as regards administrative changes of the information related to the Union authorisation of the biocidal product family 'Hypred's iodine based products' (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1995

of 4 December 2020

amending Implementing Regulation (EU) No 2018/1261 as regards administrative changes of the information related to the Union authorisation of the biocidal product family 'Hypred's iodine based products'

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products[(1)], and in particular Article 50(2) thereof,

Whereas:

(1) On 20 September 2018, a Union authorisation with authorisation number EU-0018397-0000 was granted by Commission Implementing Regulation (EU) 2018/1261[(2)] to HYPRED SAS for the making available on the market and use of the biocidal product family 'Hypred's iodine based products'.

(2) On 04 April 2019, HYPRED SAS submitted a notification to the European Chemicals Agency ('the Agency'), in accordance with Article 11(1) of Commission Implementing Regulation (EU) No 354/2013[(3)], in respect of administrative changes to the Union authorisation of the biocidal product family 'Hypred's iodine based products' as described in Title 1, Sections 1 and 2 of the Annex to that Regulation.

(3) HYPRED SAS proposed the following changes to the summary of the product characteristics for the biocidal product family 'Hypred's iodine based products', as set out in the Annex to Implementing Regulation (EU) 2018/1261: (a) the addition of names for the biocidal product family in Section 7.1 of the third information level: individual products in the meta SPCs 1, 2, 3 and 5; (b) the change of the name of the authorisation holder in Section 1.3; (c) the addition of two manufacturers for the active substance and their respective manufacturing sites in Section 1.5; (d) the change of administrative details of the manufacturer in Section 1.4; (e) changes of administrative details of the location of existing manufacturing sites, and addition of location of new manufacturing sites in Section 1.4. The notification was recorded under case number BC-KC049719-36 in the Register for Biocidal Products.

(4) On 19 June 2019, the Agency submitted to the Commission an opinion on the proposed changes, in accordance with Article 11(3) of Implementing Regulation (EU) No 354/2013. The opinion concludes that the amendments to the existing authorisation sought by the authorisation holder falls under the category of change set out in Article 50(3)(a) of Regulation (EU) No 528/2012, and that after the implementation of the changes the conditions of Article 19 to that Regulation are still met.

(5) On 28 June 2019, the Agency transmitted to the Commission the revised summary of the biocidal product characteristics in all the official languages of the Union in accordance with Article 11(6) of Implementing Regulation (EU) No 354/2013.

(6) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to amend the Union authorisation of the biocidal product family 'Hypred's iodine based products'.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

Implementing Regulation (EU) 2018/1261 is amended as follows:

(1) in Article 1, 'HYPRED SAS' is replaced by 'HYPRED SAS – KERSIA Group';

(2) the Annex is replaced by the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 4 December 2020.

For the Commission

The President

Ursula VON DER LEYEN

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1995. (See end of Document for details)*

ANNEX

Summary of product characteristics for a biocidal product family

HYPRED's iodine based products

Product type 3 - Veterinary hygiene (Disinfectants)

Authorisation number: EU-0018397-0000

R4BP asset number: EU-0018397-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. **Family name**

Name	HYPRED's iodine based products

1.2. **Product type(s)**

Product type(s)	PT03 - Veterinary hygiene (Disinfectants)

1.3. **Authorisation holder**

Name and address of the authorisation holder	Name	HYPRED SAS – KERSIA Group
	Address	55, Boulevard Jules Verger - BP10180 35803 DINARD Cedex France
Authorisation number	EU-0018397-0000	
R4BP asset number	EU-0018397-0000	
Date of the authorisation	11 October 2018	
Expiry date of the authorisation	30 September 2028	

1.4. **Manufacturer(s) of the biocidal products**

Name of manufacturer	HYPRED SAS – KERSIA Group

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1995. (See end of Document for details)*

Address of manufacturer	55, Boulevard Jules Verger - BP10180 35803 DINARD France
Location of manufacturing sites	HYPRED SAS – KERSIA Group - 55, Boulevard Jules Verger - BP10180 35803 DINARD France KERSIA POLSKA Sp.z.o.o. - NIEPRUSZEWO, KASZTANOWA 4 64320 Buk Poland KERSIA IBERICA SL - Pol. Miguel Eguía C/Zarapuz s/n 31200 ESTELLA (NAVARRA) Spain KERSIA DEUTSCHLAND GmbH Marie-Curie-Straße 23 53332 Bornheim – Sechtem Germany HYPRED Italia s.r.l. – KERSIA Group Strada Montodine-Gombito Loc. Cà Nova 26010 Ripalta Arpina CR Italy AG France S.A.S – KERSIA Group - Zone Industrielle Le Roineau, 72500 VAAS, FRANCE KERSIA DEUTSCHLAND GmbH - OBERBRÜHLSTRAßE 16-18, 87700 MEMMINGEN, GERMANY KERSIA AUSTRIA GmbH - PFONGAUERSTRAßE 17, 5202 NEUMARKT AM WALLERSEE, AUSTRIA 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, CO ANTRIM BT36 4TY, IRELAND Medentech Ltd – KERSIA Group - Clonard Road, WEXFORD, Y35Y7WY, IRELAND

1.5. **Manufacturer(s) of the active substance(s)**

Active substance	Iodine
Name of manufacturer	COSAYACH : SCM Cía. Cosayach Minera Negreiros, Rut. N°96.625.710-5
Address of manufacturer	Terrenos de Elena S/N Terrenos de Elena S/N Huara, Región de Tarapacá Chile
Location of manufacturing sites	Mined at: S.C.M. Cía. Minera Negreiros, S.C.M. Cosayach Soledad. Refined at: S.C.M. Cía. Minera Negreiros. Pozo Almonte Chile

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1995. (See end of Document for details)*

Active substance	Iodine
Name of manufacturer	ACF MINERA SA
Address of manufacturer	San Martín 499 Iquique Chile
Location of manufacturing sites	Faena Lagunas KM. 1.722 Ruta A-5, Pozo Almonte Chile

Active substance	Iodine
Name of manufacturer	SOCIEDAD QUIMICA y MINERA SA
Address of manufacturer	Los Militares 4290 SANTIAGO DE CHILE Chile
Location of manufacturing sites	Pedro de Valdivia (PV) Route B 180 Antofagasta Chile Nueva Victoria (NV) Route 5 North, Km 1925 Pozo Almonte Chile

Active substance	Iodine
Name of manufacturer	ISE Chemicals Corporation
Address of manufacturer	3-1, Kyobashi 1-Chome, Chuo-ku, Tokyo Japan
Location of manufacturing sites	Shirasato Plant (3695 Kitaimaizumi, Oamishirasato City, Chiba, Japan)

Active substance	Iodine
Name of manufacturer	Nihon Tennen Gas Development Co., Ltd
Address of manufacturer	661 Mobara 297-8550 Mobara City, Chiba Japan
Location of manufacturing sites	Chiba Plant, 2508 Minami Hinata, 299-4205 Shirako-Machi, Chosei-Gun, Chiba Japan

2. PRODUCT FAMILY COMPOSITION AND FORMULATION

2.1. **Qualitative and quantitative information on the composition of the family**

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**	
					Min	**Max**
Iodine		Active substance	7553-56-2	231-442-4	0,25	2,5
Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), -C12-14-(even numbered)-	Non active substance	68439-50-9		2,697	24,199