# Commission Implementing Regulation (EU) 2018/1261 of 20 September 2018 granting a Union authorisation for the biocidal product family Hypred's iodine based products (Text with EEA relevance)

## COMMISSION IMPLEMENTING REGULATION (EU) 2018/1261

of 20 September 2018

granting a Union authorisation for 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 44(5) thereof,

Whereas:

(1) On 16 July 2015, Hypred SAS submitted an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for authorisation of a biocidal product family named Hypred's iodine based products (‘the product family’) of product-type 3, as defined in Annex V to that Regulation. The Netherlands agreed that their competent authority referred to in Article 43(1) of Regulation (EU) No 528/2012 evaluate this application. The application was recorded under the case number BC-LC018584-49 in the Register for Biocidal Products (‘the Register’).

(2) The biocidal product family contains iodine as active substance, which is included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012. Taking into account the intrinsic properties of the active substance, once the scientific criteria for the determination of endocrine-disrupting properties set out in Commission Delegated Regulation (EU) 2017/2100[(2)] will become applicable, the Commission will consider the need to review the approval of iodine, including polyvinylpyrrolidone iodine, in accordance with Article 15 of Regulation (EU) No 528/2012. Depending on the outcome of that review, the Commission will then consider whether the Union authorisations for products containing the active substance have to be reviewed in accordance with Article 48 of Regulation (EU) No 528/2012.

(3) On 6 June 2017 the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, the assessment report and the conclusions of its evaluation to the European Chemicals Agency (‘the Agency’).

(4) On 12 January 2018, the Agency submitted to the Commission an opinion[(3)], including the draft summary of the biocidal product characteristics (hereinafter ‘SPC’) and the final product assessment report on the product family in accordance with Article 44(3)

of Regulation (EU) No 528/2012. The opinion concluded that the product family falls within the definition of 'biocidal product family' laid down in Article 3(1)(s) of Regulation (EU) No 528/2012, that it was found eligible for Union authorisation in accordance with Article 42(1) of that Regulation and that, subject to compliance with the draft SPC, the product family meets the conditions laid down in Article 19(1) and (6) of that Regulation.

(5) On 26 February 2018, the Agency transmitted to the Commission the draft SPC in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.

(6) The Commission concurs with the opinion of the Agency and considers therefore appropriate to grant a Union authorisation for the biocidal product family, and to record the SPC and the product assessment report on the product family in the Register in accordance with Article 71(6) of Regulation (EU) No 528/2012.

(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*

A Union authorisation is granted to **[**[F1]HYPRED SAS – KERSIA Group**]** for the biocidal product family Hypred's iodine based products with authorisation number EU-0018397-0000.

The Union authorisation is valid from 11 October 2018 until 30 September 2028.

The Union authorisation is subject to compliance with the SPC set out in the Annex.

**Textual Amendments**

**F1** Substituted by 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).

*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.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1261. (See end of Document for details)*

[F1ANNEX

**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 |
| Address of manufacturer | 55, Boulevard Jules Verger - BP10180 35803 DINARD France |

**Changes to legislation:** *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1261. (See end of Document for details)*

| | |
|---|---|
| Location of manufacturing sites | HYPRED SAS – KERSIA Group - 55, Boulevard Jules Verger - BP10180 35803 DINARD France<br>KERSIA POLSKA Sp.z.o.o. - NIEPRUSZEWO, KASZTANOWA 4 64320 Buk Poland<br>KERSIA IBERICA SL - Pol. Miguel Eguía C/Zarapuz s/n<br>31200 ESTELLA (NAVARRA) Spain<br>KERSIA DEUTSCHLAND GmbH Marie-Curie-Straße 23 53332 Bornheim – Sechtem Germany<br>HYPRED Italia s.r.l. – KERSIA Group Strada Montodine-Gombito Loc. Cà Nova 26010 Ripalta Arpina CR Italy<br>AG France S.A.S – KERSIA Group - Zone Industrielle Le Roineau, 72500 VAAS, FRANCE<br>KERSIA DEUTSCHLAND GmbH - OBERBRÜHLSTRAßE 16-18, 87700 MEMMINGEN, GERMANY<br>KERSIA AUSTRIA GmbH - PFONGAUERSTRAßE 17, 5202 NEUMARKT AM WALLERSEE, AUSTRIA<br>Kilco Holdings Ltd – KERSIA Group - Broomhouses 2 Industrial Estate, Old Glasgow Road, LOCKERBIE - DG11 2SD, UNITED KINGDOM<br>Kilco (International) Ltd – KERSIA Group - 1A Trench Road Mallusk, Newtownabbey, CO ANTRIM BT36 4TY, IRELAND<br>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.<br>Refined at: S.C.M. Cía. Minera Negreiros. Pozo Almonte Chile |

| | |
|---|---|
| Active substance | Iodine |

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1261. (See end of Document for details)*

| | |
|---|---|
| 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<br>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)-alkyl--hydroxy | Non active substance | 68439-50-9 | | 2,697 | 24,199 |