Commission Implementing Regulation (EU) 2020/579 of 27 April 2020 granting a Union authorisation for the biocidal product family 'HYPRED's octanoic acid based products' (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/579

of 27 April 2020

granting a Union authorisation for the biocidal product family 'HYPRED's octanoic acid 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 the first subparagraph of Article 44(5) thereof,

Whereas:

(1) On 25 August 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 octanoic acid based products' of product-type 4, as described in Annex V to that Regulation, providing written confirmation that the competent authority of the Netherlands had agreed to evaluate the application. The application was recorded under the case number BC-LR019297-17 in the Register for Biocidal Products.

(2) 'HYPRED's octanoic acid based products' contains octanoic acid, as the 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.

(3) On 19 December 2017, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, an assessment report and the conclusions of its evaluation to the European Chemicals Agency ('the Agency').

(4) On 11 July 2019, the Agency submitted to the Commission an opinion[(2)], including the draft summary of the biocidal product characteristics ('SPC') of 'HYPRED's octanoic acid based products' and the final assessment report on the biocidal product family in accordance with Article 44(3) of Regulation (EU) No 528/2012.

(5) The opinion concludes that 'HYPRED's octanoic acid based products' is a 'biocidal product family' within the meaning of Article 3(1)(s) of Regulation (EU) No 528/2012, that it is eligible for Union authorisation in accordance with Article 42(1) of that Regulation and that subject to compliance with the draft SPC, it meets the conditions laid down in Article 19(1) and (6) of that Regulation.

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/579. (See end of Document for details)*

(6) On 25 July 2019, 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.

(7) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for 'HYPRED's octanoic acid based products'.

(8) 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 with authorisation number EU-0021020-0000 is granted to HYPRED SAS for the making available on the market and use of the biocidal product family 'HYPRED's octanoic acid based products' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 18 May 2020 until 30 April 2030.

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, 27 April 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) 2020/579. (See end of Document for details)*

ANNEX

Summary of product characteristics for a biocidal product family

HYPRED‘s octanoic acid based products

Product type 4 – Food and feed area (Disinfectants)

Authorisation number: EU-0021020-0000

R4BP asset number: EU-0021020-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. Family name

Name	HYPRED‘s octanoic acid based products

1.2. Product type(s)

Product type(s)	PT04 – Food and feed area (Disinfectants)

1.3. Authorisation holder

Name and address of the authorisation holder	Name	HYPRED SAS
	Address	55 boulevard Jules Verger, 35803 DINARD, France
Authorisation number	EU-0021020-0000	
R4BP asset number	EU-0021020-0000	
Date of the authorisation	18 May 2020	
Expiry date of the authorisation	30 April 2030	

1.4. Manufacturer(s) of the biocidal products

Name of manufacturer	HYPRED SAS
Address of manufacturer	55 Boulevard Jules Verger, 35803 DINARD France
Location of manufacturing sites	HYPRED SAS – 55 Boulevard Jules Verger – BP 10180, 35803 DINARD France

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/579. (See end of Document for details)*

	HYPRED POLSKA SP. Z O.O. NIEPRUSZEWO, KASZTANOWA 4, 64320 buk Poland HYPRED IBERICA S.L Pol. Ind. Arazuri-Orcoyen C/C n° 32, 31160 Orcoyen – NAVARRA Spain HYPRED GmbH Marie-Curie-Straße 23, 53332 Bornheim – Sechtem Germany HYPRED Italia s.r.l. Strada Montodine-Gombito Loc. Cà Nova, 26010 Ripalta Arpina CR Italy AG France S.A.S – Zone Industrielle Le Roineau, 72500 Vaas France Anti-Germ Austria GmbH – 'Pfongauer Straße 17, 5202 Neumarkt am Wallersee' Austria Anti-Germ Deutschland GmbH – Oberbrühlstraße 16-18, 87700 Memmingen Germany

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

Active substance	Octanoic acid
Name of manufacturer	Emery Oleochemicals (M)
Address of manufacturer	Sdn Bhd (63112-D), Lot 4, Jalan Perak, Kawasan Perusahaan, 42500 Telok Panglima Garang, Selangor Malaysia
Location of manufacturing sites	Sdn Bhd (63112-D), Lot 4, Jalan Perak, Kawasan Perusahaan, 42500 Telok Panglima Garang, Selangor Malaysia

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
Octanoic acid		Active Substance	124-07-2	204-677-5	3,0	10,0
Methanesulfonic acid		Non-active substance	75-75-2	200-898-6	0,0	21,0
L-(+)-Lactic acid		Non-active substance	79-33-4	201-196-2	0,0	17,6
N,N-dimethyl-1-Decanamine, N-oxid		Non-active substance	2605-79-0	220-020-5	2,25	6,0

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/579. (See end of Document for details)*

Ethoxylated alcohol	Ethoxylated alcohol	Non-active substance	31726-34-8	500-077-5	0,0	15,0

2.2. **Type(s) of formulation**

Formulation(s)	SL – Soluble concentrate

PART II

SECOND INFORMATION LEVEL – META SPC(S)

META SPC 1

1. **META SPC 1 ADMINISTRATIVE INFORMATION**

1.1. **Meta SPC 1 identifier**

Identifier	Meta SPC 1

1.2. **Suffix to the authorisation number**

Number	1-1

1.3. **Product type(s)**

Product type(s)	PT04 – Food and feed area (Disinfectants)

2. **META SPC 1 COMPOSITION**

2.1. **Qualitative and quantitative information on the composition of the meta SPC 1**

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**	
					Min	**Max**
Octanoic acid		Active Substance	124-07-2	204-677-5	3,0	3,0
Methanesulfonic acid		Non-active substance	75-75-2	200-898-6	21,0	21,0
L-(+)-Lactic acid		Non-active substance	79-33-4	201-196-2	0,0	0,0
N,N-dimethyl-1-Decanamine, N-oxid		Non-active substance	2605-79-0	220-020-5	2,25	2,25
Ethoxylated alcohol	Ethoxylated alcohol	Non-active substance	31726-34-8	500-077-5	5,0	5,0