Commission Implementing Regulation (EU) 2020/580 of 27 April 2020 granting a Union authorisation for the biocidal product family 'SOPURCLEAN' (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/580

of 27 April 2020

granting a Union authorisation for the biocidal product family 'SOPURCLEAN'

(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 28 August 2015, SOPURA N.V., submitted an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for authorisation of a biocidal product family named 'SOPURCLEAN' of product-type 4, as described in Annex V to that Regulation, providing written confirmation that the competent authority of Belgium had agreed to evaluate the application. The application was recorded under the case number BC-PJ019489-22 in the Register for Biocidal Products.

(2) 'SOPURCLEAN' contains octanoic acid and decanoic acid, as the active substances, which are included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012.

(3) On 15 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 15 July 2019, the Agency submitted to the Commission an opinion[(2)], including the draft summary of the biocidal product characteristics ('SPC') of 'SOPURCLEAN' 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 'SOPURCLEAN' 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.

(6) On 26 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 'SOPURCLEAN'.

(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-0021157-0000 is granted to SOPURA N.V. for the making available on the market and use of the biocidal product family 'SOPURCLEAN' 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) 2020/580. (See end of Document for details)*

ANNEX

Summary of product characteristics for a biocidal product family

SOPURCLEAN

Product type 4 – Food and feed area (Disinfectants)

Authorisation number: EU-0021157-0000

R4BP asset number: EU-0021157-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. Family name

Name	SOPURCLEAN

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	SOPURA N.V.
	Address	Rue de Trazegnies 199, 6180 COURCELLES, Belgium
Authorisation number	EU-0021157-0000	
R4BP asset number	EU-0021157-0000	
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	SOPURA N.V.
Address of manufacturer	Rue de Trazegnies 199, 6180 COURCELLES Belgium
Location of manufacturing sites	PIB de Tyberchamps 14, 7180 SENEFFE Belgium Rue de Trazegnies 199, 6180 COURCELLES Belgium

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/580. (See end of Document for details)*

Name of manufacturer	SOPURA QUIMICA
Address of manufacturer	Poligon 'La Canaleta', Avinguda Júpiter 9, 25300 TARREGA Spain
Location of manufacturing sites	Poligon 'La Canaleta', Avinguda Júpiter 9, 25300 TARREGA Spain

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

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

Active substance	Decanoic acid
Name of manufacturer	Emery Oleochemicals (M) Sdn Bhd (63112-D)
Address of manufacturer	Lot 4, Jalan Perak, Kawasan Perusahaan, Telok Panglima Garang, 42500 Selangor Malaysia
Location of manufacturing sites	Lot 4, Jalan Perak, Kawasan Perusahaan, Telok Panglima Garang, 42500 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	1,1	2,7
Decanoic acid		Active Substance	334-48-5	206-376-4	0,3	1,5
Sulfuric acid		Non-active substance	7664-93-9	231-639-5	0,0	31,2
Propionic acid		Non-active substance	79-09-4	201-176-3	0,0	19,5

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/580. (See end of Document for details)*

Phosphoric acid		Non-active substance	7664-38-2	231-633-2	0,0	30,0
Nitric acid		Non-active substance	7697-37-2	231-714-2	0,0	18,0
Methane sulfonic acid		Non-active substance	75-75-2	200-898-6	0,0	20,3
Glycolic acid		Non-active substance	79-14-1	201-180-5	0,0	4,2
Lactic acid		Non-active substance	79-33-4	201-196-2	0,0	35,2
Citric acid		Non-active substance	77-92-9	201-069-1	0,0	3,0

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**