Commission Implementing Regulation (EU) 2018/1288 of 24 September 2018 granting a Union authorisation for the biocidal product family Prodhynet's iodine based products (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1288

of 24 September 2018

granting a Union authorisation for the biocidal product family Prodhynet'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 3 August 2015, Prodhynet SA submitted to the European Chemicals Agency ('the Agency') an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 and Article 4 of Commission Implementing Regulation (EU) No 414/2013[(2)] for authorisation of a same biocidal product family, as referred to in Article 1 of Regulation (EU) No 414/2013, named Prodhynet's iodine based products ('the same product family') of product-type 3, as described in Annex V to Regulation (EU) No 528/2012. The application for the same product family was recorded under the case number BC-YK019030-42 in the Register for Biocidal Products ('the Register'). The application also indicated the application number of the related reference product family (Hypred's iodine based products), recorded in the Register under the case number BC-LC018584-49.

(2) The same 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[(3)] 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 biocidal products containing the active substance have to be reviewed in accordance with Article 48 of Regulation (EU) No 528/2012.

(3) On 26 January 2018, the Agency submitted to the Commission an opinion[(4)], including the draft summary of the biocidal product characteristics ('SPC'), in accordance with Article 6(2) of Regulation (EU) No 414/2013. The opinion concluded that the same

product family falls within the definition of 'biocidal product family' laid down in Article 3(1)(s) of Regulation (EU) No 528/2012, that the proposed differences between the same product family and the related reference biocidal product family are limited to information which can be the subject of an administrative change in accordance with Commission Implementing Regulation (EU) No 354/2013[(5)], and that based on the assessment of the above-mentioned related reference product family and subject to compliance with the draft SPC, the same product family meets the conditions laid down in Article 19(1) and (6) of Regulation (EU) No 528/2012.

(4) On 6 March 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.

(5) The Commission concurs with the opinion of the Agency and considers therefore appropriate to grant a Union authorisation for the same product family, and to record the SPC in the Register in accordance with Article 71(6) of that Regulation.

(6) 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 Prodhynet SA for the same biocidal product family Prodhynet's iodine based products with authorisation number EU-0018497-0000.

The Union authorisation is valid from 15 October 2018 until 30 September 2028.

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

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, 24 September 2018.

For the Commission

The President

Jean-Claude JUNCKER

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1288. (See end of Document for details)*

ANNEX

Summary of product characteristics for a biocidal product family

PRODHYNET's iodine based products

Product type 3 - Veterinary hygiene (Disinfectants)

Authorisation number: EU-0018497-0000

R4BP asset number: EU-0018497-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. Family name

Name	PRODHYNET'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	PRODHYNET SA
	Address	11 Avenue des châtelets, 22440, PLOUFRAGAN, France
Authorisation number	EU-0018497-0000	
R4BP asset number	EU-0018497-0000	
Date of the authorisation	15 October 2018	
Expiry date of the authorisation	30 September 2028	

1.4. Manufacturer(s) of the biocidal products

Name of manufacturer	PRODHYNET SA
Address of manufacturer	11, Avenue des Châtelets 22440 PLOUFRAGAN France

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1288. (See end of Document for details)

Location of manufacturing sites	PRODHYNET SA - 11, Avenue des Châtelets 22440 PLOUFRAGAN France

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

Active substance	Iodine
Name of manufacturer	COSAYACH: SCM Cía. Cosayach Minera Negreiros, Rut. N^{o} 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

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

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

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1288. (See end of Document for details)*

	alkyl--hydroxy					

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

Formulation(s)	AL - Any other liquid 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: Dipping products - ready to use

1.2. **Suffix to the authorisation number**

Number	1-1

1.3. **Product type(s)**

Product type(s)	PT03 - Veterinary hygiene (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**
Iodine		Active substance	7553-56-2	231-442-4	0,25	0,49
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	4,993