Commission Implementing Regulation (EU) 2018/1258 of 18 September 2018 granting a Union authorisation for the biocidal product family Ecolab Iodine PT3 Family (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1258

of 18 September 2018

granting a Union authorisation for the biocidal product family Ecolab Iodine PT3 Family

(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 23 July 2015, Ecolab Deutschland GmbH submitted an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for authorisation of a biocidal product family named Ecolab Iodine PT3 Family ('the product family') of product-type 3, as described 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-VG018734-32 in the Register for Biocidal Products ('the Register').

(2) The biocidal product family contains iodine, including polyvinylpyrrolidone 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 ('SPC') and the final

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 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 Ecolab Deutschland GmbH for the biocidal product family Ecolab Iodine PT3 Family with authorisation number EU-0018398-0000.

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.

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, 18 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) 2018/1258. (See end of Document for details)*

ANNEX

Summary of product characteristics for a biocidal product family

Ecolab Iodine PT3 Family

Product type 3 — Veterinary hygiene (Disinfectants)

Authorisation number: EU-0018398-0000

R4BP asset number: EU-0018398-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. Family name

Name	Ecolab Iodine PT3 Family

1.2. Product type(s)

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

1.3. Authorisation holder

Name and address of the authorisation holder	Name	Ecolab Deutschland GmbH
	Address	Ecolab-Allee 1, 40789 Monheim, Germany
Authorisation number	EU-0018398-0000	
R4BP asset number	EU-0018398-0000	
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	Ecolab Europe GmbH
Address of manufacturer	Richtistrasse 7, 8304 Walliselen Switzerland
Location of manufacturing sites	Ecolab Baglan, ECOLAB CONTAMINATION CONTROL BRUNEL

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1258. (See end of Document for details)*

	WAY, BAGLAN ENERGY PARK, NEATH, SA11 2GA South Wales United Kingdom Ecolab Leeds, LOTHERTON WAY, GARFORTH, LEEDS LS25 2JY Leeds United Kingdom Ecolab Rovigo, Viale del Lavoro 10, 45100 Rovigo Italy Ecolab Biebesheim Nalco Deutschland Manufacturing GmbH und Co.KG, Justus-von-Liebig-Str. 11 D-64584 Biebesheim Germany Ecolab NETHERLANDS BV, NL01ECOLAB, BRUGWAL 11 3432NZ NIEUWEGEIN Netherlands Ecolab Weavergate, ECOLAB WEAVERGATE PLANT WINNINGTON AVENUE, NORTHWICH CHESHIRE CW8 3AA NORTHWICH United Kingdom Ecolab Mullingar, Forest Park, Mullingar Ind. Estate, Mullingar, Co. Zone C Westmeath Ireland Ecolab Maribor, Ecolab d.o.o.,Vajngerlova 4 2000 Maribor Slovenia Ecolab Rozzano, VIA GRANDI 9/11 20089 ROZZANO Italy Ecolab B.V.B.A, Havenlaan: 4 3980 Tessenderlo Belgium Ecolab CELRA, Nalco Española Manufacturing, SLU C/Tramuntana s/n, Polígono Industrial de Celrà 17460 CELRÀ Spain Ecolab Chalons Ecolab production France SAS, BP509 Avenue de Général Patton 51006 Châlons-en-Champagne France Ecolab Mandra, 25km Old National Road Athens Mandra, oo Attica Greece NALCO FINLAND MANUFACTURING OY, Kivikummuntie 1 FIN-07955 Tesjoki Finland

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

Active substance	Polyvinylpyrrolidone iodine
Name of manufacturer	ISP Chemicals LLC, Affiliate of Ashland Inc.
Address of manufacturer	455 N. MAIN ST. (HWY 95) KY 42029 CALVERT CITY United States
Location of manufacturing sites	455 N. MAIN ST. (HWY 95) KY 42029 CALVERT CITY United States

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1258. (See end of Document for details)*

Active substance	Iodine
Name of manufacturer	ACF Minera S.A.
Address of manufacturer	San Martín No 499 00 Iquique Chile
Location of manufacturing sites	Lagunas mine 00 Pozo Almonte Chile

Active substance	Iodine
Name of manufacturer	SQM S.A.
Address of manufacturer	Los Militares 4290 Piso 4 Santiago Chile
Location of manufacturing sites	Nueva Victoria plant 00 Pedro de Valdivia Chile

Active substance	Iodine
Name of manufacturer	Cosayach Nitratos S.A.
Address of manufacturer	Amunategui 178 00 Santiago Chile
Location of manufacturing sites	S.C.M. Cosayach Cala Cala 00 Pozo Almonte Chile

Active substance	Iodine
Name of manufacturer	Nihon Tennen Gas Development Co., Ltd/ Kanto Natural Gas Development Co., Ltd
Address of manufacturer	661 Mobara Chiba 297-8550 Mobara City Japan
Location of manufacturing sites	Chiba Plant, 2508 Minami-Hinata, Shirako-Machi, Chosei-Gun 299-4205 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
Polyvinylpyrrolidone iodine		Active substance	25655-41-8		1	3
Iodine		Active substance	7553-56-2	231-442-4	0,11	0,33

2.2. Type(s) of formulation

Formulation(s)	AL — Any other liquid