Commission Implementing Regulation (EU) 2019/403 of 13 March 2019 granting a Union authorisation for the biocidal product family 'Deosan Activate BPF based on Iodine'

COMMISSION IMPLEMENTING REGULATION (EU) 2019/403

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granting a Union authorisation for the biocidal product family 'Deosan Activate BPF based on Iodine'

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 7 July 2015, Diversey Europe Operations B.V. submitted an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for authorisation of a biocidal product family named 'Deosan Activate BPF based on Iodine' ('the product family') of product-type 3, as described in Annex V to that Regulation. The competent authority of United Kingdom agreed to evaluate the application as referred to in Article 43(1) of Regulation (EU) No 528/2012. The application was recorded under the case number BC-JN018376-30 in the Register for Biocidal Products.

(2) The biocidal product family contains iodine, 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. Taking into account the intrinsic properties of the active substance, and the scientific criteria for the determination of endocrine-disrupting properties set out in Commission Delegated Regulation (EU) 2017/2100[(2)], 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 20 December 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 6 July 2018, the Agency submitted to the Commission an opinion[(3)], including the draft summary of the biocidal product characteristics ('SPC') of the product family and the final assessment report on the product family in accordance with Article 44(3) of Regulation (EU) No 528/2012. The opinion concludes 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 is 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 17 September 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 it therefore appropriate to grant a Union authorisation for the biocidal product family.

(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 Diversey Europe Operations B.V. for the biocidal product family ‘Deosan Activate BPF based on Iodine’ with authorisation number EU-0019228-0000.

The Union authorisation is valid from 3 April 2019 until 31 March 2029.

The Union authorisation is subject to compliance with the summary of the biocidal product characteristics 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, 13 March 2019.

For the Commission

The President

Jean-Claude JUNCKER

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2019/403. (See end of Document for details)*

ANNEX

Summary of product characteristics for a biocidal product family

Deosan Activate BPF based on Iodine

Product type 3 — Veterinary hygiene (Disinfectants)

Authorisation number: EU-0019228-0000

R4BP asset number: EU-0019228-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. **Family name**

Name	Deosan Activate BPF based on Iodine

1.2. **Product type(s)**

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

1.3. **Authorisation holder**

Name and address of the authorisation holder	Name	Diversey Europe Operations B.V.
	Address	Maarssenbroeksedijk 2, 3542DN Utrecht, Netherlands
Authorisation number	EU-0019228-0000	
R4BP asset number	EU-0019228-0000	
Date of the authorisation	3 April 2019	
Expiry date of the authorisation	31 March 2029	

1.4. **Manufacturer(s) of the biocidal products**

Name of manufacturer	Diversey Europe Operations B.V.
Address of manufacturer	Maarssenbroeksedijk 2, 3542 DN Utrecht Netherlands
Location of manufacturing sites	Strada Statale 235, 26010 Bagnolo Cremasco (CR) Italy

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2019/403. (See end of Document for details)*

	Avenida Conde Duque 5, 7 y 9 Poligono Industrial La Postura, 28343 Valdemoro (Madrid) Spain Rembrandtlaan 414, 7545 ZW Enschede Netherlands Cotes Park Industrial Estate, DE55 4PA Somercotes Alfreton United Kingdom Morschheimer Strasse 12, 67292 Kirchheimbolanden Germany

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

Active substance	Iodine
Name of manufacturer	ACF Minera S.A.
Address of manufacturer	San Martin No 499, 1100000 Iquique Chile
Location of manufacturing sites	Lagunas mine, 118 0000 Pozo Almonte Chile

Active substance	Iodine
Name of manufacturer	Sociedad Quimica y Minera (SQM) S.A.
Address of manufacturer	Los Militares 4290, Piso 4, Las Condes, 8320000 Santiago Chile
Location of manufacturing sites	Nueva Victoria plant, 5090000 Pedro de Valdivia plant Chile

Active substance	Iodine
Name of manufacturer	Cosayach Nitratos S.A.
Address of manufacturer	Hnos Amunátegui 178, 8320000 Santiago Chile
Location of manufacturing sites	S.C.M. Cosayach Cala Cala, 118 0000 Pozo Almonte Chile

Active substance	Iodine
Name of manufacturer	Nihon Tennen Gas Development Co., Ltd
Address of manufacturer	Chiba Plant, 2508 Minami-Hinata, Shirako-Machi, Chosei-Gun, 299-4205 Chiba Japan
Location of manufacturing sites	Chiba Plant, 2508 Minami-Hinata, Shirako-Machi, Chosei-Gun, 299-4205 Chiba Japan

Active substance	Iodine
Name of manufacturer	ISE Chemicals Corporation
Address of manufacturer	3-1, Kyobashi 1-Chome, 104-0031 Tokyo Japan

Location of manufacturing sites	Shirasto Plant (3695 Kitaimaizumi, Oamishirasato City, 299-3201 Chiba Japan

Active substance	Iodine
Name of manufacturer	Atacama Minerals SCM
Address of manufacturer	Coronel Pereira No 72 Of. 701, Las Condes, 8320000 Santiago Chile
Location of manufacturing sites	Atacama Minerals SCM, Aguas Blancas Facility, 3580000 Antofagasta 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	0,3	1,6

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

Formulation(s)	AL — Any other liquid SL — Soluble concentrate GW — Water soluble gel

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 — Deosan Activate BPF — Concentrate

1.2. **Suffix to the authorisation number**

Number	1-1

1.3. **Product type(s)**

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