Commission Implementing Regulation (EU) 2019/1844 of 22 October 2019 granting a Union authorisation for the biocidal product family 'BPF_Iodine_VET' (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2019/1844

of 22 October 2019

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

(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 7 August 2015, Applied Biocide GmbH submitted an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for authorisation of a biocidal product family named 'BPF_Iodine_VET' of product-type 3, as described in Annex V to that Regulation, providing written confirmation that the competent authority of Austria had agreed to evaluate the application. The application was recorded under case number BC-XJ019074-33 in the Register for Biocidal Products.

(2) 'BPF_Iodine_VET' 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 22 August 2018, 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 4 April 2019, the Agency submitted to the Commission an opinion[(3)], including the draft summary of the biocidal product characteristics ('SPC') of 'BPF_Iodine_VET' and the final assessment report on the biocidal product family in accordance with Article 44(3) of Regulation (EU) No 528/2012. The opinion concludes that 'BPF_Iodine_VET' is a biocidal product family within the meaning of Article 3(1)(s) of Regulation (EU)

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2019/1844. (See end of Document for details)*

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.

(5) On 4 June 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.

(6) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for 'BPF_Iodine_VET'.

(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 with authorisation number EU-0020540-0000 is granted to Applied Biocide GmbH for the making available on the market and use of the biocidal product family 'BPF_Iodine_VET', in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 25 November 2019 until 31 October 2029.

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, 22 October 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) 2019/1844. (See end of Document for details)*

ANNEX

Summary of product characteristics for a biocidal product family

BPF_Iodine_VET

Product type 3 - Veterinary hygiene (Disinfectants)

Authorisation number: EU-0020540-0000

R4BP asset number: EU-0020540-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. Family name

Name	BPF_Iodine_VET

1.2. Product type(s)

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

1.3. Authorisation holder

Name and address of the authorisation holder	Name	Applied Biocide GmbH
	Address	Sprl 31, Rue Jules Melotte, 4350, Remicourt, Belgium
Authorisation number	EU-0020540-0000	
R4BP asset number	EU-0020540-0000	
Date of the authorisation	25 November 2019	
Expiry date of the authorisation	31 October 2029	

1.4. Manufacturer(s) of the biocidal products

Name of manufacturer	Ewabo Chemikalien GmbH & Co KG
Address of manufacturer	Kolpingstrasse 4, 49835 Wietmarschen Germany
Location of manufacturing sites	Kolpingstrasse 4, 49835 Wietmarschen Germany
Name of manufacturer	FINK TEC GmbH

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Address of manufacturer	Oberster Kamp 23, 59069 Hamm Germany
Location of manufacturing sites	Oberster Kamp 23, 59069 Hamm Germany
Name of manufacturer	IRCASERVICE
Address of manufacturer	S.S. Cremasca 591 no. 10, 24040 Fornovo S. Giovanni (BG) Italy
Location of manufacturing sites	S.S. Cremasca 591 no. 10, 24040 Fornovo S. Giovanni (BG) Italy
Name of manufacturer	Laboratorios Maymo SA
Address of manufacturer	Via Augusta, 302, 08017 Barcelona Spain
Location of manufacturing sites	Via Augusta, 302, 08017 Barcelona Spain

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

Active substance	Iodine
Name of manufacturer	Cosayach S.A. Compania de Salitre y Yodo
Address of manufacturer	Amunátegui 178, 7th Floor, 8320000 Santiago Chile
Location of manufacturing sites	S.C.M. Cosayach Cala, 1180000 Pozo Almonte Chile Chile
Active substance	Iodine
Name of manufacturer	ACF Minera S.A.
Address of manufacturer	San Martin 499, 1100000 Iquique Chile
Location of manufacturing sites	Lagunas mine, 1180000 Pozo Almonte Chile
Active substance	Iodine
Name of manufacturer	Sociedad Quimica y Minera SA
Address of manufacturer	Los Militares 4290, 7550000 Las Condes Chile
Location of manufacturing sites	Nueva Victoria, 1180000 Pozo Almonte Chile Pedro de Valdivia, 1240000 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	0,1	3,0

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Phosphoric Acid	Trihydroxidooxidophosphorus	Non-active substance	7664-38-2	231-633-2	0,0	10,0
	phosphoric acid					
Poly(oxy-1,2-ethanediyl).alpha.-tridecyl-.omega.-hydroxy-,branched	Poly(oxy-1,2-ethanediyl).alpha.-tridecyl-.omega.-hydroxy-,branched	Non-active substance	69011-36-5	500-241-6	0,0	31,8
Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Non-active substance	68439-46-3	614-482-0	0,0	31,8

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

Formulation(s)	meta SPC 1-5: AL — any other liquid meta SPC 6-8: 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)	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	0,15	0,15