Commission Implementing Regulation (EU) 2020/202 of 4 October 2019 granting a Union authorisation for the biocidal product family 'Iodine Teat Dip Products' (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/202

of 4 October 2019

granting a Union authorisation for the biocidal product family 'Iodine Teat Dip 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 20 August 2015, GEA Farm Technologies GmbH, submitted an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for authorisation of a biocidal product family named 'Iodine Teat Dip Products' ('the biocidal 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-AL019223-55 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 6 June 2018, 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 18 January 2019, the Agency submitted to the Commission an opinion[(3)], including the draft summary of the biocidal product characteristics ('SPC') of the biocidal product family and the final assessment report on the biocidal product family in accordance

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/202. (See end of Document for details)*

with Article 44(3) of Regulation (EU) No 528/2012. The opinion concludes that the biocidal 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 biocidal product family meets the conditions laid down in Article 19(1) and (6) of that Regulation.

(5) On 20 May 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 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 GEA Farm Technologies GmbH for the making available on the market and use of the biocidal product family 'Iodine Teat Dip Products' with authorisation number EU-0020125-0000 in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 19 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, 4 October 2019.

For the Commission

The President

Jean-Claude JUNCKER

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ANNEX

Summary of product characteristics for a biocidal product family

Iodine Teat dip products

Product type 3 — Veterinary hygiene (Disinfectants)

Authorisation number: EU-0020125-0000

R4BP asset number: EU-0020125-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. **Family name**

Name	Iodine Teat dip 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	GEA Farm Technologies GmbH
	Address	Siemensstraße 25-27, 59199, Bönen, Germany
Authorisation number	EU-0020125-0000	
R4BP asset number	EU-0020125-0000	
Date of the authorisation	19 November 2019	
Expiry date of the authorisation	31 October 2029	

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

Name of manufacturer	GEA Farm Technologies
Address of manufacturer	Wylye Works, BA12 9HT Warminster United Kingdom
Location of manufacturing sites	Wylye Works, Watery Lane, BA12 9HT Warminster United Kingdom Gewerbestraße 5, 5325 Plainfeld Austria

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	ul. Olowiana 10, 85-461 Bydgoszcz Poland

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

Active substance	Iodine
Name of manufacturer	SQM Europe N.V.
Address of manufacturer	St Pietersvliet 7,, bus 8 2000 Antwerp Belgium
Location of manufacturing sites	Sociedad Quimica y Minera SA, Los Militares, Las Condes, 4290 Piso 4 Santiago Chile

Active substance	Iodine
Name of manufacturer	Nihon Tennen Gas Co., Ltd (Via Mitsui & Co Europe PLC)
Address of manufacturer	Chiba Plant, 2508 Minami-Hinata, Shirako-Machi, Chosei-Gun,, 299-4205 Chosei-Gun Japan
Location of manufacturing sites	Chiba Plant, 2508 Minami-Hinata, Shirako-Machi, Chosei-Gun,, 299-4205 Chosei-Gun Japan

Active substance	Iodine
Name of manufacturer	Norkem Ltd
Address of manufacturer	Norkem House, Bexton Lane,, WA16 9FB Knutsford United Kingdom
Location of manufacturing sites	OFICINA CALA CALA S/N, Unknown 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	0,16	2,47
C9-11 Alcohol Ethoxylate	C 9-11 alcohol with 6 moles of ethoxylate. Various brand	Non-active substance	68439-46-3	614-482-0	0,0	2,35

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	names available including Imbentin C-91-060					

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 — Concentrates — Professional concentrates with 1:3, 1:4 and 1:7 dilution rates

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	1,58	2,47
C9-11 Alcohol Ethoxylate	C 9-11 alcohol with 6 moles of ethoxylate. Various brand	Non-active substance	68439-46-3	614-482-0	1,51	2,35