Commission Implementing Regulation (EU) 2019/1794 of 22 October 2019 granting a Union authorisation for the biocidal product family 'Boumatic Iodine product family' (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2019/1794

of 22 October 2019

granting a Union authorisation for the biocidal product family 'Boumatic Iodine product 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 the first subparagraph of Article 44(5) thereof,

Whereas:

(1) On 21 August 2015, Boumatic Gascoigne Melotte submitted an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for authorisation of a biocidal product family named 'Boumatic Iodine product family' of product-type 3, as described in Annex V to that Regulation, providing written confirmation that the competent authority of the Netherlands had agreed to evaluate the application. The application was recorded under case number BC-PG019260-52 in the Register for Biocidal Products.

(2) The 'Boumatic Iodine 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 10 April 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 the 'Boumatic Iodine product family' 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 the 'Boumatic Iodine product family' is a biocidal product family within the meaning of 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, it meets the conditions laid down in Article 19(1) and (6) of that Regulation.

(5) On 20 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 the 'Boumatic Iodine 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 with authorisation number EU-0020541-0000 is granted to Boumatic Gascoigne Melotte for the making available on the market and use of the biocidal product family 'Boumatic Iodine product family', in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 18 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) 2019/1794. (See end of Document for details)*

ANNEX

Summary of product characteristics for a biocidal product family

Boumatic Iodine product family

Product type 3 — Veterinary hygiene (Disinfectants)

Authorisation number: EU-0020541-0000

R4BP asset number: EU-0020541-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. Family name

Name	Boumatic Iodine product 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	Boumatic Gascoigne Melotte
	Address	31, Rue Jules Melotte, 4350, Remicourt, Belgium
Authorisation number	EU-0020541-0000	
R4BP asset number	EU-0020541-0000	
Date of the authorisation	18 November 2019	
Expiry date of the authorisation	31 October 2029	

1.4. Manufacturer(s) of the biocidal products

Name of manufacturer	Christeyns n.v.
Address of manufacturer	Afrikalaan 182, 9000 Ghent Belgium
Location of manufacturing sites	Afrikalaan 182, 9000 Ghent Belgium

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

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2019/1794. (See end of Document for details)*

Active substance	Iodine
Name of manufacturer	Christeyns n.v.
Address of manufacturer	Afrikalaan 182, 9000 Ghent Belgium
Location of manufacturing sites	Cosayach Nitratos S.A, Oficina Cala Cala S/N, Pozo Almonte Iquique 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	0,26	0,5
Fatty alcohol ethoxylate		Non-active substance	69011-36-5	500-241-6	1,0	2,99

2.2. Type(s) of formulation

Formulation(s)	AL — Any other liquid

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

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2019/1794. (See end of Document for details)*

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0,44	0,5
Fatty alcohol ethoxylate		Non-active substance	69011-36-5	500-241-6	1,0	2,99

2.2. Type(s) of formulation of the meta SPC 1

Formulation(s)	AL — Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

Hazard statements	Causes serious eye irritation. Harmful to aquatic life with long lasting effects.
Precautionary statements	Wash hands thoroughly after handling. Wear eye protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice. Avoid release to the environment.

4. AUTHORISED USE(S) OF THE META SPC 1

4.1. Use description

TABLE 1. USE # 1 – MANUAL DIP TREATMENT, PRE- OR POST-MILKING TEAT DISINFECTANTS

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfectants for pre- or post-milking manual dip treatment of cow teats
Application method(s)	Open system: dip treatment For pre-milking: min. 1 minute contact time For post-milking min. 5 minutes contact time