Commission Implementing Regulation (EU) 2018/1853 of 27 November 2018 granting a Union authorisation for the biocidal product family Teat disinfectants biocidal product family of CVAS (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1853

of 27 November 2018

granting a Union authorisation for the biocidal product family Teat disinfectants biocidal product family of CVAS

(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 28 August 2015, the Scientific Consulting Company — SCC GmbH acting on behalf of CVAS Development GmbH submitted an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for authorisation of a biocidal product family named Teat disinfectants biocidal product family of CVAS (‘product family’) of product-type 3, as described in Annex V to that Regulation. The competent authority of Netherlands 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-WU019429-99 in the Register for Biocidal Products (‘the Register’).

(2) The biocidal product family contains iodine, including polyvinylpyrrolidone 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 following the entry into application of 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 30 August 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 19 March 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 25 April 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 CVAS Development GmbH for the biocidal product family Teat disinfectants biocidal product family of CVAS with authorisation number EU-0018724-0000.

The Union authorisation is valid from 18 December 2018 until 30 November 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, 27 November 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) 2018/1853. (See end of Document for details)*

ANNEX

Summary of product characteristics for a biocidal product family

TEAT DISINFECTANTS BIOCIDAL PRODUCT FAMILY OF CVAS

Product type 3 — Veterinary hygiene (Disinfectants)

Authorisation number: EU-0018724-0000

R4BP 3 asset number: EU-0018724-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. Family name

Name	**TEAT DISINFECTANTS BIOCIDAL PRODUCT FAMILY OF CVAS**

1.2. Product type(s)

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

1.3. Authorisation holder

Name and address of the authorisation holder	Name	CVAS Development GmbH
	Address	Dr Albert Reimann Str. 16a, 68526 Ladenburg, Germany
Authorisation number	EU-0018724-0000	
R4BP asset number	EU-0018724-0000	
Date of the authorisation	18 December 2018	
Expiry date of the authorisation	30 November 2028	

1.4. Manufacturer(s) of the biocidal products

Name of manufacturer	Calvatis GmbH
Address of manufacturer	Dr Albert Reimann Str. 16a, 68526 Ladenburg, Germany

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1853. (See end of Document for details)*

Location of manufacturing sites	Dr Albert Reimann Str. 16a, 68526 Ladenburg, Germany

Name of manufacturer	Arthur Schopf Hygiene GmbH & Co. KG
Address of manufacturer	Pfaffensteinstr. 1, 83115 Neubeuern, Germany
Location of manufacturing sites	Pfaffensteinstr. 1, 83115 Neubeuern, Germany

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

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

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

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

Active substance	Iodine
Name of manufacturer	Nihon Tennen Gas Co., Ltd/Kanto Natural Gas Development Co., Ltd
Address of manufacturer	661 Mobara 297-8550 Mobara City, Chiba Japan
Location of manufacturing sites	Chiba Plant, 2508 Minami-Hinata 299-4205 Shirako-Machi, Chosei-Gun, Chiba Japan

Active substance	Polyvinylpyrrolidone iodine
Name of manufacturer	Norkem Limited (manufacturer of PVP-iodine)

Address of manufacturer	Norkem House, Bexton Lane WA 16 9FB Knutsford, Cheshire United Kingdom
Location of manufacturing sites	Norkem House, Bexton Lane WA 16 9FB Knutsford, Cheshire United Kingdom

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	0,54
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0	4,16
Acetic acid	Acetic acid	Non active substance	64-19-7	200-580-7	0	0,33

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)