Commission Implementing Regulation (EU) 2019/423 of 13 March 2019 granting a Union authorisation for the biocidal product family 'Teat disinfectants biocidal product family of Novadan'

COMMISSION IMPLEMENTING REGULATION (EU) 2019/423

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

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 27 August 2015, SCC GmbH, on behalf of Novadan ApS, 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 Novadan' ('the biocidal product family') of product-type 3, as described in Annex V to that Regulation. The competent authority of Denmark 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-YV019394-00 in the Register for Biocidal Products.

(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 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 11 April 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 31 October 2018, 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

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 17 January 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 Novadan ApS for the biocidal product family 'Teat disinfectants biocidal product family of Novadan' with authorisation number EU-0019757-0000.

The Union authorisation is valid from 7 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) 2019/423. (See end of Document for details)*

ANNEX

Summary of product characteristics for a biocidal product family

Teat disinfectants biocidal product family of Novadan

Product type 3 — Veterinary hygiene (Disinfectants)

Authorisation number: EU-0019757-0000

R4BP asset number: EU-0019757-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. **Family name**

Name	Teat disinfectants biocidal product family of Novadan

1.2. **Product type(s)**

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

1.3. **Authorisation holder**

Name and address of the authorisation holder	Name	Novadan ApS
	Address	Platinvej 21, 6000 Kolding, Denmark
Authorisation number	EU-0019757-0000	
R4BP asset number	EU-0019757-0000	
Date of the authorisation	7 April 2019	
Expiry date of the authorisation	31 March 2029	

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

Name of manufacturer	Novadan ApS
Address of manufacturer	Platinvej 21, 6000 Kolding Denmark
Location of manufacturing sites	Platinvej 21, 6000 Kolding Denmark

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) 2019/423. (See end of Document for details)*

Active substance	Polyvinylpyrrolidone iodine
Name of manufacturer	Marcus Research Laboratory, Inc.
Address of manufacturer	Delmar Blvd., 63103-1789 Saint Louis, Missouri United States
Location of manufacturing sites	Delmar Blvd., 63103-1789 Saint Louis, Missouri United States

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, 1180000 Pozo Almonte Chile

Active substance	Iodine
Name of manufacturer	ACF Minera S.A.
Address of manufacturer	San Martin No 499, 11 00000 Iquique Chile
Location of manufacturing sites	Lagunas mine, 1180000 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

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**
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0,714	3,57
Iodine		Active Substance	7553-56-2	231-442-4	0,15	0,75

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

Formulation(s)	SL — Soluble concentrate AL — Any other liquid

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2019/423. (See end of Document for details)*

	EW — Emulsion, oil in water

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
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		3,57	3,57
Iodine		Active Substance	7553-56-2	231-442-4	0,75	0,75

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

Formulation(s)	SL — Soluble concentrate

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

Hazard statements	May be corrosive to metals. Harmful to aquatic life with long lasting effects. Safety data sheet available on request.
Precautionary statements	Keep out of reach of children. Keep only in original packaging. Avoid release to the environment.