

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1258

of 18 September 2018

granting a Union authorisation for the biocidal product family Ecolab Iodine PT3 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 Article 44(5) thereof,

Whereas:

- (1) On 23 July 2015, Ecolab Deutschland GmbH submitted an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for authorisation of a biocidal product family named Ecolab Iodine PT3 Family ('the product family') of product-type 3, as described in Annex V to that Regulation. The Netherlands agreed that their competent authority referred to in Article 43(1) of Regulation (EU) No 528/2012 evaluate this application. The application was recorded under the case number BC-VG018734-32 in the Register for Biocidal Products ('the Register').
- (2) The biocidal product family contains iodine, including polyvinylpyrrolidone iodine, as 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, once the scientific criteria for the determination of endocrine-disrupting properties set out in Commission Delegated Regulation (EU) 2017/2100 ⁽²⁾ will become applicable, 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 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 12 January 2018, the Agency submitted to the Commission an opinion ⁽³⁾, including the draft summary of the biocidal product characteristics ('SPC') and the final assessment report on the product family in accordance with Article 44(3) of Regulation (EU) No 528/2012. The opinion concluded 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 was found 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 26 February 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 therefore appropriate to grant a Union authorisation for the biocidal product family, and to record the SPC and the assessment report on the product family in the Register in accordance with Article 71(6) of Regulation (EU) No 528/2012.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ Commission delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council (OJ L 301, 17.11.2017, p. 1).

⁽³⁾ ECHA opinion of 12 December 2017 on the Union authorisation of Ecolab Iodine PT3 Family (ECHA/BPC/177/2017).

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation is granted to Ecolab Deutschland GmbH for the biocidal product family Ecolab Iodine PT3 Family with authorisation number EU-0018398-0000.

The Union authorisation is valid from 11 October 2018 until 30 September 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, 18 September 2018.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Summary of product characteristics for a biocidal product family

Ecolab Iodine PT3 Family

Product type 3 — Veterinary hygiene (Disinfectants)

Authorisation number: EU-0018398-0000

R4BP asset number: EU-0018398-0000

PART I

FIRST INFORMATION LEVEL**1. ADMINISTRATIVE INFORMATION****1.1. Family name**

Name	Ecolab Iodine PT3 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	Ecolab Deutschland GmbH
	Address	Ecolab-Allee 1, 40789 Monheim, Germany
Authorisation number	EU-0018398-0000	
R4BP asset number	EU-0018398-0000	
Date of the authorisation	11 October 2018	
Expiry date of the authorisation	30 September 2028	

1.4. Manufacturer(s) of the biocidal products

Name of manufacturer	Ecolab Europe GmbH
Address of manufacturer	Richtstrasse 7, 8304 Wallisellen Switzerland
Location of manufacturing sites	<p>Ecolab Baglan, ECOLAB CONTAMINATION CONTROL BRUNEL WAY, BAGLAN ENERGY PARK, NEATH, SA11 2GA South Wales United Kingdom</p> <p>Ecolab Leeds, LOTHERTON WAY, GARFORTH, LEEDS LS25 2JY Leeds United Kingdom</p> <p>Ecolab Rovigo, Viale del Lavoro 10, 45100 Rovigo Italy</p> <p>Ecolab Biebesheim Nalco Deutschland Manufacturing GmbH und Co.KG, Justus-von-Liebig-Str. 11 D-64584 Biebesheim Germany</p> <p>Ecolab NETHERLANDS BV, NL01ECOLAB, BRUGWAL 11 3432NZ NIEU-WEGEIN Netherlands</p>

	<p>Ecolab Weavergate, ECOLAB WEAVERGATE PLANT WINNINGTON AVENUE, NORTHWICH CHESHIRE CW8 3AA NORTHWICH United Kingdom</p> <p>Ecolab Mullingar, Forest Park, Mullingar Ind. Estate, Mullingar, Co. Zone C Westmeath Ireland</p> <p>Ecolab Maribor, Ecolab d.o.o., Vajngerlova 4 2000 Maribor Slovenia</p> <p>Ecolab Rozzano, VIA GRANDI 9/11 20089 ROZZANO Italy</p> <p>Ecolab B.V.B.A, Havenlaan: 4 3980 Tessenderlo Belgium</p> <p>Ecolab CELRA, Nalco Española Manufacturing, SLU C/Tramuntana s/n, Polígono Industrial de Celrà 17460 CELRÀ Spain</p> <p>Ecolab Chalons Ecolab production France SAS, BP509 Avenue de Général Patton 51006 Châlons-en-Champagne France</p> <p>Ecolab Mandra, 25km Old National Road Athens Mandra, oo Attica Greece</p> <p>NALCO FINLAND MANUFACTURING OY, Kivikumuntie 1 FIN-07955 Tesjoki Finland</p>
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1.5. Manufacturer(s) of the active substance(s)

Active substance	Polyvinylpyrrolidone iodine
Name of manufacturer	ISP Chemicals LLC, Affiliate of Ashland Inc.
Address of manufacturer	455 N. MAIN ST. (HWY 95) KY 42029 CALVERT CITY United States
Location of manufacturing sites	455 N. MAIN ST. (HWY 95) KY 42029 CALVERT CITY United States

Active substance	Iodine
Name of manufacturer	ACF Minera S.A.
Address of manufacturer	San Martín No 499 00 Iquique Chile
Location of manufacturing sites	Lagunas mine 00 Pozo Almonte Chile

Active substance	Iodine
Name of manufacturer	SQM S.A.
Address of manufacturer	Los Militares 4290 Piso 4 Santiago Chile
Location of manufacturing sites	Nueva Victoria plant 00 Pedro de Valdivia Chile

Active substance	Iodine
Name of manufacturer	Cosayach Nitratos S.A.
Address of manufacturer	Amunategui 178 00 Santiago Chile
Location of manufacturing sites	S.C.M. Cosayach Cala Cala 00 Pozo Almonte Chile

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

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		1	3
Iodine		Active substance	7553-56-2	231-442-4	0,11	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
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1.2. Suffix to the authorisation number

Number	1-1
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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		1	1
Iodine		Active substance	7553-56-2	231-442-4	0,11	0,11

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

Formulation	AL — Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

Hazard statements	
Precautionary statements	

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

4.1. **Use description****Table 1. Use # 1 – Teat dips for post-milking disinfection**

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts Enveloped viruses
Field(s) of use	Indoor Post-milking disinfection of teats of milk-producing animals (cows, buffaloes, goats, sheep)
Application method(s)	Manual dipping using a dip cup - 3-10 ml (dipping) 1-3 post-milking disinfections per day
Application rate(s) and frequency	3-10 ml (dipping) Post-milking application 1x - 3x per day (apply after every milking). Per milking event 3-10 ml of product are needed (animals with four teats).
Category(ies) of users	Professional
Pack sizes and packaging material	container, Plastic: HDPE, 0,5-1 000 l

4.1.1. *Use-specific instructions for use*

See general directions for use of meta SPC 1

4.1.2. *Use-specific risk mitigation measures*

See general directions for use of meta SPC 1

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use of meta SPC 1

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use of meta SPC 1

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use of meta SPC 1

5. GENERAL DIRECTIONS FOR USE ⁽¹⁾ OF THE META SPC 1

5.1. **Instructions for use**

Always read the label or leaflet before use and follow all the instructions provided.

Product to be applied post-milking by use of a dipping cup.

The products must be brought to temperatures above 20 °C before use.

Apply product on the whole teat and do not wipe it. Keep the animals standing for 5 min. Before the next milking, carefully clean the teats.

The use of a dosing pump for filling the product into the application equipment is recommended.

5.2. **Risk mitigation measures**

In case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered for pre-milking disinfection.

5.3. **Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

Potential Health Effects

Eyes: Health injuries are not known or expected under normal use.

Skin: Health injuries are not known or expected under normal use.

Ingestion: Health injuries are not known or expected under normal use.

Inhalation: Health injuries are not known or expected under normal use.

Chronic Exposure: Health injuries are not known or expected under normal use.

First Aid Measures:

Eye contact: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.

Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. In case of inhalation of decomposition products in a fire, symptoms may be delayed. Get medical attention if symptoms occur.

Skin contact: Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.

Ingestion: Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Environmental emergency measures: Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer if legally allowed.

5.4. **Instructions for safe disposal of the product and its packaging**

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29.

⁽¹⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC1.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Store between 5 °C and 25 °C and away from direct sunlight. Keep out of reach of children. Keep container tightly closed. Store in the original containers.

Shelf life: 24 months

6. OTHER INFORMATION**7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1****7.1. Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	Ioklar Super Dip D				
Authorisation number	EU-0018398-0001 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Polyvinylpyrrolidone iodine		Active substance	25655-41-8		1
Iodine		Active substance	7553-56-2	231-442-4	0,11

7.2. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	IoKlar Superdip				
Authorisation number	EU-0018398-0002 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Polyvinylpyrrolidone iodine		Active substance	25655-41-8		1
Iodine		Active substance	7553-56-2	231-442-4	0,11

META SPC 2**1. META SPC 2 ADMINISTRATIVE INFORMATION****1.1. Meta SPC 2 identifier**

Identifier	meta SPC 2
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1.2. Suffix to the authorisation number

Number	1-2
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1.3. Product type(s)

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

2. META SPC 2 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Polyvinylpyrrolidone iodine		Active substance	25655-41-8		1,35	1,35
Iodine		Active substance	7553-56-2	231-442-4	0,15	0,15

2.2. Type(s) of formulation of the meta SPC 2

Formulation	AL — Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

Hazard statements	
Precautionary statements	

4. AUTHORISED USE(S) OF THE META SPC 2

4.1. Use description

Table 2. Use # 1 – Teat dips for post-milking disinfection

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts Enveloped viruses
Field(s) of use	Indoor Post-milking disinfection of teats of milk-producing animals (cows, buffaloes, goats, sheep)
Application method(s)	Manual dipping using a dip cup
Application rate(s) and frequency	Post-milking application 1x - 3x per day (apply after every milking). Per milking event 3-10 ml of product are needed (animals with four teats).
Category(ies) of users	Professional
Pack sizes and packaging material	0,5 l – 1 000 l HDPE container

4.1.1. Use-specific instructions for use

See general directions for use of meta SPC 2

4.1.2. Use-specific risk mitigation measures

See general directions for use of meta SPC 2

- 4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use of meta SPC 2

- 4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use of meta SPC 2

- 4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use of meta SPC 2

5. GENERAL DIRECTIONS FOR USE ⁽¹⁾ OF THE META SPC 2

5.1. **Instructions for use**

Always read the label or leaflet before use and follow all the instructions provided.

The products must be brought to temperatures above 20 °C before use.

Product to be applied post-milking by use of a dipping cup.

Apply product on the whole teat and do not wipe it. Keep the animals standing for 5 min. Before the next milking, carefully clean the teats.

The use of a dosing pump for filling the product into the application equipment is recommended.

5.2. **Risk mitigation measures**

In case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered for pre-milking disinfection.

5.3. **Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

Potential Health Effects

Eyes: Health injuries are not known or expected under normal use.

Skin: Health injuries are not known or expected under normal use.

Ingestion: Health injuries are not known or expected under normal use.

Inhalation: Health injuries are not known or expected under normal use.

Chronic Exposure: Health injuries are not known or expected under normal use.

First Aid Measures:

Eye contact: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.

Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. In case of inhalation of decomposition products in a fire, symptoms may be delayed. Get medical attention if symptoms occur.

Skin contact: Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.

⁽¹⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC2.

Ingestion: Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Environmental emergency measures: Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer if legally allowed.

5.4. Instructions for safe disposal of the product and its packaging

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Store between 5 °C and 25 °C and away from direct sunlight. Keep out of reach of children. Keep container tightly closed. Store in the original containers.

Shelf life: 24 months

6. OTHER INFORMATION

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 2

7.1. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	Io-Shield D IoShield MEPA Barrier D BARIOPROTECT MS Cow Udder BLOCK Iodocop EXTRA				
Authorisation number	EU-0018398-0003 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Polyvinylpyrrolidone iodine		Active substance	25655-41-8		1,35
Iodine		Active substance	7553-56-2	231-442-4	0,15

7.2. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	IoDark Iodocop EXTRA GREEN Mammizan Protect MS Cow Udder BLACK				
Authorisation number	EU-0018398-0004 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Polyvinylpyrrolidone iodine		Active substance	25655-41-8		1,35
Iodine		Active substance	7553-56-2	231-442-4	0,15

META SPC 3

1. META SPC 3 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 3 identifier**

Identifier	meta SPC 3
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1.2. **Suffix to the authorisation number**

Number	1-3
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1.3. **Product type(s)**

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

2. META SPC 3 COMPOSITION

2.1. **Qualitative and quantitative information on the composition of the meta SPC 3**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Polyvinylpyrrolidone iodine		Active substance	25655-41-8		2,45	2,45
Iodine		Active substance	7553-56-2	231-442-4	0,27	0,27

2.2. **Type(s) of formulation of the meta SPC 3**

Formulation	AL — Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 3

Hazard statements	Harmful to aquatic life with long lasting effects.
Precautionary statements	Avoid release to the environment.

4. AUTHORISED USE(S) OF THE META SPC 3

4.1. **Use description****Table 3. Use # 1 – Teat dips or sprays for post-milking disinfection**

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts Enveloped viruses
Field(s) of use	Indoor Post-milking disinfection of teats of milk-producing animals (cows, buffaloes, goats, sheep)

Application method(s)	Dipping or spraying: Manual dipping using a dip cup or Manual spraying using a trigger sprayer or Manual spraying using an electronic sprayer or Automated spraying by robot.
Application rate(s) and frequency	Post-milking application 1x – 3x per day Per milking event 3-10 ml (dipping) to 10-15 ml (spraying) of product are needed (animals with four teats).
Category(ies) of users	Professional
Pack sizes and packaging material	0,5 l – 1 000 l HDPE container

4.1.1. Use-specific instructions for use

Product to be applied by dipping or spraying on teats of milk-producing animals post-milking, using manual or automatic equipment. Post-milking: Apply product on the whole teat and do not wipe it. Keep the animals standing for 5 min. Before the next milking, carefully clean the teats.

See also general instructions for use of meta SPC 3.

4.1.2. Use-specific risk mitigation measures

In case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered for pre-milking disinfection.

See also general risk mitigation measures of meta SPC 3.

4.1.3. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use of meta SPC 3

4.1.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use of meta SPC 3

4.1.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use of meta SPC 3

4.2. Use description

Table 4. Use # 2 – Teat dips or sprays for pre-milking disinfection

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 Pre-milking disinfection of teats of milk-producing animals (cows, buffaloes, goats, sheep)
Application method(s)	Dipping or spraying: Manual dipping using a dip cup or Manual spraying using a trigger sprayer or Manual spraying using an electronic sprayer.

Application rate(s) and frequency	Pre-milking application 1x – 3x per day Per milking event 3-10 ml (dipping) to 10-15 ml (spraying) of product are needed (animals with four teats).
Category(ies) of users	Professional
Pack sizes and packaging material	0,5 l – 1 000 l HDPE container

4.2.1. *Use-specific instructions for use*

Product to be applied by dipping or spraying on teats of milk-producing animals pre-milking, using manual equipment.

Pre-milking: Clean teats by wiping with cloth before disinfection. Apply product on the whole teats and leave it for 1 min. Then wipe with a single use paper or a towel.

See also general instructions for use of meta SPC3.

4.2.2. *Use-specific risk mitigation measures*

In case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered for post-milking disinfection.

See also general risk mitigation measures of meta SPC3.

4.2.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use of meta SPC 3

4.2.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use of meta SPC 3

4.2.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use of meta SPC 3

5. GENERAL DIRECTIONS FOR USE ⁽¹⁾ OF THE META SPC 3

5.1. **Instructions for use**

See use-specific instructions for each use.

Always read the label or leaflet before use and follow all the instructions provided.

The products must be brought to temperatures above 20 °C before use.

The use of a dosing pump for filling the product into the application equipment is recommended

5.2. **Risk mitigation measures**

See use-specific risk mitigation measures for each use.

Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) for spraying application.

5.3. **Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

Potential Health Effects

Eyes: Health injuries are not known or expected under normal use.

Skin: Health injuries are not known or expected under normal use.

⁽¹⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC3.

Ingestion: Health injuries are not known or expected under normal use.

Inhalation: Health injuries are not known or expected under normal use.

Chronic Exposure: Health injuries are not known or expected under normal use.

First Aid Measures:

Eye contact: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.

Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. In case of inhalation of decomposition products in a fire, symptoms may be delayed. Get medical attention if symptoms occur.

Skin contact: Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.

Ingestion: Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Environmental emergency measures: Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer if legally allowed.

5.4. Instructions for safe disposal of the product and its packaging

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Store between 5 °C and 25 °C and away from direct sunlight. Keep out of reach of children. Keep container tightly closed. Store in the original containers.

Shelf life: 24 months

6. OTHER INFORMATION

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 3

7.1. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	IoKlar Multi MEPA Iospray Plus D ASTRI-IO DESINTEC MH-Iodine S				
Authorisation number	EU-0018398-0005 1-3				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Polyvinylpyrrolidone iodine		Active substance	25655-41-8		2,45
Iodine		Active substance	7553-56-2	231-442-4	0,27

META SPC 4

1. META SPC 4 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 4 identifier**

Identifier	meta SPC 4
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1.2. **Suffix to the authorisation number**

Number	1-4
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1.3. **Product type(s)**

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

2. META SPC 4 COMPOSITION

2.1. **Qualitative and quantitative information on the composition of the meta SPC 4**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Polyvinylpyrrolidone iodine		Active substance	25655-41-8		1	1
Iodine		Active substance	7553-56-2	231-442-4	0,11	0,11

2.2. **Type(s) of formulation of the meta SPC 4**

Formulation	AL — Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 4

Hazard statements	
Precautionary statements	

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

4.1. **Use description****Table 5. Use # 1 – Teat dips or sprays for post-milking disinfection**

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts Enveloped viruses
Field(s) of use	Indoor Post-milking disinfection of teats of milk-producing animals (cows, buffaloes, goats, sheep)

Application method(s)	Dipping or spraying: Manual dipping using a dip cup or Manual spraying using a trigger sprayer or Manual spraying using an electronic sprayer or Automated spraying by robot.
Application rate(s) and frequency	Post-milking application 1x - 3x per day. Per milking event 3-10 ml (dipping) to 10-15 ml (spraying) of product are needed (animals with four teats).
Category(ies) of users	Professional
Pack sizes and packaging material	0,5 l – 1 000 l HDPE container

4.1.1. *Use-specific instructions for use*

See general directions for use of meta SPC 4

4.1.2. *Use-specific risk mitigation measures*

See general directions for use of meta SPC 4

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use of meta SPC 4

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use of meta SPC 4

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use of meta SPC 4

5. GENERAL DIRECTIONS FOR USE ⁽¹⁾ OF THE META SPC 4

5.1. **Instructions for use**

Always read the label or leaflet before use and follow all the instructions provided.

The products must be brought to temperatures above 20 °C before use.

Product to be applied by dipping or spraying on teats of milk-producing animals post-milking using manual or automatic equipment.

Apply product on the whole teat and do not wipe it. Keep the animals standing for 5 min. Before the next milking, carefully clean the teats.

The use of a dosing pump for filling the product into the application equipment is recommended.

5.2. **Risk mitigation measures**

Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) for spraying application.

In case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered for pre-milking disinfection.

⁽¹⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC4.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Potential Health Effects

Eyes: Health injuries are not known or expected under normal use.

Skin: Health injuries are not known or expected under normal use.

Ingestion: Health injuries are not known or expected under normal use.

Inhalation: Health injuries are not known or expected under normal use.

Chronic Exposure: Health injuries are not known or expected under normal use.

First Aid Measures:

Eye contact: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.

Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. In case of inhalation of decomposition products in a fire, symptoms may be delayed. Get medical attention if symptoms occur.

Skin contact: Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.

Ingestion: Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Environmental emergency measures: Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer if legally allowed.

5.4. Instructions for safe disposal of the product and its packaging

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Store between 5 °C and 25 °C and away from direct sunlight. Keep out of reach of children. Keep container tightly closed. Store in the original containers.

Shelf life: 24 months

6. OTHER INFORMATION

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 4

7.1. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	Veloucid Spray D VelouCid Spray MEPA Soft Spray D ASTRI-UC SAC WINTERSPRAY
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Authorisation number	EU-0018398-0006 1-4				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Polyvinylpyrrolidone iodine		Active substance	25655-41-8		1
Iodine		Active substance	7553-56-2	231-442-4	0,11

META SPC 5

1. META SPC 5 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 5 identifier**

Identifier	meta SPC 5
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1.2. **Suffix to the authorisation number**

Number	1-5
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1.3. **Product type(s)**

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

2. META SPC 5 COMPOSITION

2.1. **Qualitative and quantitative information on the composition of the meta SPC 5**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Polyvinylpyrrolidone iodine		Active substance	25655-41-8		1	1
Iodine		Active substance	7553-56-2	231-442-4	0,11	0,11

2.2. **Type(s) of formulation of the meta SPC 5**

Formulation	AL — Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 5

Hazard statements	
Precautionary statements	

4. AUTHORISED USE(S) OF THE META SPC 5

4.1. **Use description****Table 6. Use # 1 – Teat dips for post-milking disinfection**

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—

Target organism(s) (including development stage)	Bacteria Yeasts Enveloped viruses
Field(s) of use	Indoor Post-milking disinfection of teats of milk-producing animals (cows, buffaloes, goats, sheep)
Application method(s)	Dipping Manual dipping using a dip cup.
Application rate(s) and frequency	Post-milking application 1x – 3x per day Per milking event 3-10 ml of product are needed (animals with four teats).
Category(ies) of users	Professional
Pack sizes and packaging material	0,5 l – 1 000 l HDPE container

4.1.1. *Use-specific instructions for use*

See general directions for use of meta SPC 5

4.1.2. *Use-specific risk mitigation measures*

See general directions for use of meta SPC 5

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use of meta SPC 5

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use of meta SPC 5

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use of meta SPC 5

5. GENERAL DIRECTIONS FOR USE ⁽¹⁾ OF THE META SPC 5

5.1. **Instructions for use**

Always read the label or leaflet before use and follow all the instructions provided.

The products must be brought to temperatures above 20 °C before use.

Product to be applied post-milking by use of a dipping cup.

Apply product on the whole teat and do not wipe it. Keep the animals standing for 5 min. Before the next milking, carefully clean the teats.

The use of a dosing pump for filling the product into the application equipment is recommended.

5.2. **Risk mitigation measures**

In case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered for pre-milking disinfection.

⁽¹⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC5.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Potential Health Effects

Eyes: Health injuries are not known or expected under normal use.

Skin: Health injuries are not known or expected under normal use.

Ingestion: Health injuries are not known or expected under normal use.

Inhalation: Health injuries are not known or expected under normal use.

Chronic Exposure: Health injuries are not known or expected under normal use.

First Aid Measures:

Eye contact: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.

Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. In case of inhalation of decomposition products in a fire, symptoms may be delayed. Get medical attention if symptoms occur.

Skin contact: Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.

Ingestion: Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Environmental emergency measures: Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer if legally allowed.

5.4. Instructions for safe disposal of the product and its packaging

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Store between 5 °C and 25 °C and away from direct sunlight. Keep out of reach of children. Keep container tightly closed. Store in the original containers.

Shelf life: 18 months

6. OTHER INFORMATION

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 5

7.1. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	Veloucid D VelouCid MEPA Care D Cremadip MS Cow Udder SEPIA
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Authorisation number	EU-0018398-0007 1-5				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Polyvinylpyrrolidone iodine		Active substance	25655-41-8		1
Iodine		Active substance	7553-56-2	231-442-4	0,11

META SPC 6

1. META SPC 6 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 6 identifier**

Identifier	meta SPC 6
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1.2. **Suffix to the authorisation number**

Number	1-6
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1.3. **Product type(s)**

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

2. META SPC 6 COMPOSITION

2.1. **Qualitative and quantitative information on the composition of the meta SPC 6**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Polyvinylpyrrolidone iodine		Active substance	25655-41-8		1,35	1,35
Iodine		Active substance	7553-56-2	231-442-4	0,15	0,15

2.2. **Type(s) of formulation of the meta SPC 6**

Formulation	AL — Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 6

Hazard statements	
Precautionary statements	

4. AUTHORISED USE(S) OF THE META SPC 6

4.1. **Use description****Table 7. Use # 1 – Teat dips or sprays for post-milking disinfection**

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—

Target organism(s) (including development stage)	Bacteria Yeasts Enveloped viruses
Field(s) of use	Indoor Post-milking disinfection of teats of milk-producing animals (cows, buffaloes, goats, sheep)
Application method(s)	Dipping or spraying: Manual dipping using a dip cup or Manual spraying using a trigger sprayer or Manual spraying using an electronic sprayer or Automated spraying by robot.
Application rate(s) and frequency	Post-milking application 1x – 3x per day Per milking event 3-10 ml (dipping) to 10-15 ml (spraying) of product are needed (animals with four teats).
Category(ies) of users	Professional
Pack sizes and packaging material	0,5 l – 1 000 l HDPE container

4.1.1. Use-specific instructions for use

See general directions for use of meta SPC 6

4.1.2. Use-specific risk mitigation measures

See general directions for use of meta SPC 6

4.1.3. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use of meta SPC 6

4.1.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use of meta SPC 6

4.1.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use of meta SPC 6

5. GENERAL DIRECTIONS FOR USE ⁽¹⁾ OF THE META SPC 6

5.1. Instructions for use

Always read the label or leaflet before use and follow all the instructions provided.

The products must be brought to temperatures above 20 °C before use.

Product to be applied by dipping or spraying post-milking using manual or automatic equipment.

Apply product on the whole teat and do not wipe it. Keep the animals standing for 5 min. Before the next milking, carefully clean the teats.

The use of a dosing pump for filling the product into the application equipment is recommended.

⁽¹⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC6.

5.2. Risk mitigation measures

Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) for spraying application

In case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered for pre-milking disinfection.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Potential Health Effects

Eyes: Health injuries are not known or expected under normal use.

Skin: Health injuries are not known or expected under normal use.

Ingestion: Health injuries are not known or expected under normal use.

Inhalation: Health injuries are not known or expected under normal use.

Chronic Exposure: Health injuries are not known or expected under normal use.

First Aid Measures:

Eye contact: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.

Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. In case of inhalation of decomposition products in a fire, symptoms may be delayed. Get medical attention if symptoms occur.

Skin contact: Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.

Ingestion: Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Environmental emergency measures: Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer if legally allowed.

5.4. Instructions for safe disposal of the product and its packaging

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Store between 5 °C and 25 °C and away from direct sunlight. Keep out of reach of children. Keep container tightly closed. Store in the original containers.

Shelf life: 24 months

6. OTHER INFORMATION

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 6

7.1. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	MEPA Barrier Spray D IoShield Spray QUARESS-Barrier				
Authorisation number	EU-0018398-0008 1-6				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Polyvinylpyrrolidone iodine		Active substance	25655-41-8		1,35
Iodine		Active substance	7553-56-2	231-442-4	0,15