

Summary of product characteristics for a biocidal product family

Family name: Ecolab Iodien PT3 Family

Product type(s): PT03 - Veterinary hygiene (Disinfectants)

Authorisation number: EU-0018398-0000

R4BP 3 asset reference number: IS-0019667-0000

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Part I.- First information level

1. Administrative information

1.1. Family name

Ecolab Iodien PT3 Family

1.2. 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 am Rhein Germany

Authorisation number

EU-0018398-0000

R4BP 3 asset reference number

IS-0019667-0000

Date of the authorisation

07/11/2018

Expiry date of the authorisation

30/09/2028

1.4. Manufacturer(s) of the biocidal products

Name of the manufacturer	Ecolab Europe GmbH
Address of the manufacturer	Richtstrasse 7, 8304 Wallisellen Switzerland
Location of manufacturing sites	Ecolab Baglan, ECOLAB CONTAMINATION CONTROL BRUNEL WAY, BAGLAN ENERGY PARK, NEATH, SA11 2GA South Wales European Union
	Ecolab Leeds, LOTHERTON WAY, GARFORTH, LEEDS LS25 2JY Leeds United Kingdom
	Ecolab Rovigo, Viale del Lavoro 10 , 45100 Rovigo Italy
	Ecolab Biebesheim Nalco Deutschland Manufacturing GmbH und Co.KG, Justus-von-Liebig-Str. 11 D-64584 Biebesheim Germany
	Ecolab NETHERLANDS BV, NL01ECOLAB, BRUGWAL 11 3432NZ NIEUWEGEIN Netherlands
	Ecolab Weavergate, ECOLAB WEAVERGATE PLANT WINNINGTON AVENUE, NORTHWICH CHESHIRE CW8 3AA NORTHWICH United Kingdom
	Ecolab Mullingar, Forest Park, Mullingar Ind. Estate, Mullingar, Co. Zone C Westmeath Ireland
	Ecolab Maribor, Ecolab d.o.o., Vajngerlova 4 2000 Maribor Slovenia
	Ecolab Rozzano, VIA GRANDI 9/11 20089 ROZZANO Italy
	Ecolab B.V.B.A, Havenlaan: 4 3980 Tessenderlo Belgium
	Ecolab CELRA, Nalco Española Manufacturing, SLU C/Tramuntana s/n, Polígono Industrial de Celrà 17460 CELRÀ Spain
Ecolab Chalons Ecolab production France SAS, BP509 Avenue de Général Patton 51006 Châlons-en-Champagne France	
Ecolab Mandra, 25km Old National Road Athens Mandra, oo Attica Greece	
NALCO FINLAND MANUFACTURING OY, Kivikumuntie 1 FIN-07955 Tesjoki Finland	

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

Active substance	1349 - Polyvinylpyrrolidone iodine
Name of the manufacturer	ISP Chemicals LLC, Affiliate of Ashland Inc.
Address of the 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	1319 - Iodine
Name of the manufacturer	ACF Minera S.A.
Address of the manufacturer	San Martín No 499 00 Iquique Chile
Location of manufacturing sites	Lagunas mine 00 Pozo Almonte Chile

Active substance	1319 - Iodine
Name of the manufacturer	SQM S.A.
Address of the manufacturer	Los Militares 4290 Piso 4 Santiago Chile
Location of manufacturing sites	Nueva Victoria plant 00 Pedro de Valdivia Chile

Active substance	1319 - Iodine
Name of the manufacturer	Cosayach Nitratos S.A.
Address of the manufacturer	Amunategui 178 00 Santiago Chile
Location of manufacturing sites	S.C.M. Cosayach Cala Cala 00 Pozo Almonte Chile

Active substance	1319 - Iodine
Name of the manufacturer	Nihon Tennen Gas Development Co., Ltd/ Kanto Natural Gas Development Co., Ltd
Address of the 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 (%)
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

AL - Any other liquid

Part II.- Second information level - meta SPC(s)

1. Meta SPC administrative information

1.1. Meta SPC identifier

meta SPC 1

1.2. Suffix to the authorisation number

1-1

1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

2. Meta SPC composition

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
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

Formulation(s)

AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

Hazard statements

Precautionary statements

4. Authorised use(s) of the meta SPC

4.1 Use description

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)

Scientific name: Bacteria
Common name: Bacteria
Development stage:

Scientific name: Yeasts
Common name: Yeasts
Development stage:

Scientific name: Enveloped viruses
Common name: Enveloped viruses
Development stage:

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 frequencies	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 , 0.5-1000l

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 of the meta SPC

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.

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

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

Trade name(s)

Ioklar Super Dip D

Market area: EU

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

IS-0019667-0001 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

Trade name(s)

IoKlar Superdip

Market area: EU

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

IS-0019667-0002 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

1. Meta SPC administrative information

1.1. Meta SPC identifier

meta SPC 2

1.2. Suffix to the authorisation number

1-2

1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

2. Meta SPC composition

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
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

Formulation(s)

AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

Hazard statements

Precautionary statements



4. Authorised use(s) of the meta SPC

4.1 Use description

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)	Scientific name: Bacteria Common name: Bacteria Development stage: Scientific name: Yeasts Common name: Yeasts Development stage: Scientific name: Enveloped viruses Common name: Enveloped viruses Development stage:
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 frequencies	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 – 1000 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 of the meta SPC

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.

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

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

Trade name(s)

Io-Shield D	Market area: EU
IoShield	Market area: EU
MEPA Barrier D	Market area: EU
BARIOPROTECT	Market area: EU
MS Cow Udder BLOCK	Market area: EU
Iodocop EXTRA	Market area: EU
Authorisation number <small>(R4BP 3 asset reference number - National Authorisation)</small> IS-0019667-0003 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

Trade name(s)

IoDark	Market area: EU

Iodocop EXTRA GREEN	Market area: EU
Mammizan Protect	Market area: EU
MS Cow Udder BLACK	Market area: EU
Authorisation number (R4BP 3 asset reference number - National Authorisation) IS-0019667-0004 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

1. Meta SPC administrative information

1.1. Meta SPC identifier

meta SPC 3

1.2. Suffix to the authorisation number

1-3

1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

2. Meta SPC composition

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
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

Formulation(s)

AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

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

4.1 Use description

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)

Scientific name: Bacteria
Common name: Bacteria
Development stage:

Scientific name: Yeasts
Common name: Yeasts
Development stage:

Scientific name: enveloped viruses
Common name: Enveloped viruses
Development stage:

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 frequencies

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 – 1000 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

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)	Scientific name: Bacteria Common name: Bacteria Development stage: Scientific name: Yeasts Common name: Yeasts Development stage:
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 frequencies

Pre-milking application 1x – 3x per day - 0 -
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 – 1000 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 of the meta SPC

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.

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

On the Icelandic label the hazard and precautionary statements shall be in Icelandic.

The hazard statement in Icelandic:

H412 Skaðlegt lífi í vatni, hefur langvinn áhrif.

The precautionary statement in Icelandic:

P273 Forðist losun út í umhverfi.

7. Third information level: individual products in the meta SPC

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

Trade name(s)

IoKlar Multi	Market area: EU
MEPA Iospray Plus D	Market area: EU
ASTRI-IO	Market area: EU
DESINTEC MH-Iodine S	Market area: EU

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

IS-0019667-0005 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

1. Meta SPC administrative information**1.1. Meta SPC identifier**

meta SPC 4

1.2. Suffix to the authorisation number

1-4

1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

2. Meta SPC composition

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
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

Formulation(s)

AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

Hazard statements

Precautionary statements

4. Authorised use(s) of the meta SPC

4.1 Use description

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)	<p>Scientific name: Bacteria Common name: Bacteria Development stage:</p> <p>Scientific name: Yeasts Common name: Yeasts Development stage:</p> <p>Scientific name: Enveloped viruses Common name: Enveloped viruses Development stage:</p>
Field(s) of use	<p>Indoor</p> <p>Post-milking disinfection of teats of milk producing animals (cows, buffaloes, goats, sheep)</p>
Application method(s)	<p>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.</p>
Application rate(s) and frequencies	<p>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).</p>
Category(ies) of users	Professional
Pack sizes and packaging material	0.5 L – 1000 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 of the meta SPC

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.

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

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7. Third information level: individual products in the meta SPC

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

Trade name(s)		
	Veloucid Spray D	Market area: EU
	VelouCid Spray	Market area: EU
	MEPA Soft Spray D	Market area: EU
	ASTRI-UC	Market area: EU
	SAC WINTERSPRAY	Market area: EU
Authorisation number <small>(R4BP 3 asset reference number - National Authorisation)</small>	IS-0019667-0006 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

1. Meta SPC administrative information

1.1. Meta SPC identifier

meta SPC 5

1.2. Suffix to the authorisation number

1-5

1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

2. Meta SPC composition

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
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

Formulation(s)

AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

Hazard statements

Precautionary statements

4. Authorised use(s) of the meta SPC

4.1 Use description

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)

Scientific name: Bacteria
Common name: Bacteria
Development stage:

Scientific name: Yeasts
Common name: Yeasts
Development stage:

Scientific name: Enveloped viruses
Common name: Enveloped viruses
Development stage:

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 frequencies

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

Pack sizes and packaging material

Professional
0.5 L – 1000 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 of the meta SPC

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.

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

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

Trade name(s)

Veloucid D	Market area: EU
VelouCid	Market area: EU
MEPA Care D	Market area: EU
Cremadip	Market area: EU
MS Cow Udder SEPIA	Market area: EU

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

IS-0019667-0007 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

1. Meta SPC administrative information

1.1. Meta SPC identifier

meta SPC 6

1.2. Suffix to the authorisation number

1-6

1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

2. Meta SPC composition

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
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

Formulation(s)

AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

Hazard statements

Precautionary statements

4. Authorised use(s) of the meta SPC

4.1 Use description

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)

Scientific name: Bacteria
Common name: Bacteria
Development stage:

Scientific name: Yeasts
Common name: Yeasts
Development stage:

Scientific name: Enveloped viruses
Common name: Enveloped viruses
Development stage:

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 frequencies	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 – 1000 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 of the meta SPC

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.

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

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

Trade name(s)

MEPA Barrier Spray D	Market area: EU
IoShield Spray	Market area: EU
QUARESS-Barrier	Market area: EU
Authorisation number (R4BP 3 asset reference number - National Authorisation) IS-0019667-0008 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
