

# 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:** EU-0018398-0000

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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

EU-0018398-0000

##### Date of the authorisation

11/10/2018

##### Expiry date of the authorisation

30/09/2028

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

<b>Name of the manufacturer</b>	Ecolab Europe GmbH
<b>Address of the manufacturer</b>	Richtstrasse 7, 8304 Wallisellen Switzerland
<b>Location of manufacturing sites</b>	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)

<b>Active substance</b>	1349 - Polyvinylpyrrolidone iodine
<b>Name of the manufacturer</b>	ISP Chemicals LLC, Affiliate of Ashland Inc.
<b>Address of the manufacturer</b>	455 N. MAIN ST. (HWY 95) KY 42029 CALVERT CITY United States
<b>Location of manufacturing sites</b>	455 N. MAIN ST. (HWY 95) KY 42029 CALVERT CITY United States

<b>Active substance</b>	1319 - Iodine
<b>Name of the manufacturer</b>	ACF Minera S.A.
<b>Address of the manufacturer</b>	San Martín No 499 00 Iquique Chile
<b>Location of manufacturing sites</b>	Lagunas mine 00 Pozo Almonte Chile

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

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

<b>Active substance</b>	1319 - Iodine
<b>Name of the manufacturer</b>	Nihon Tennen Gas Development Co., Ltd/ Kanto Natural Gas Development Co., Ltd
<b>Address of the manufacturer</b>	661 Mobara Chiba 297-8550 Mobara City Japan
<b>Location of manufacturing sites</b>	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:



<b>Field(s) of use</b>	Indoor  Post-milking disinfection of teats of milk producing animals (cows, buffaloes, goats, sheep)
<b>Application method(s)</b>	Manual dipping using a dip cup -  3-10 ml (dipping)  1-3 post-milking disinfections per day
<b>Application rate(s) and frequencies</b>	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).
<b>Category(ies) of users</b>	Professional
<b>Pack sizes and packaging material</b>	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)

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

**Trade name(s)**

IoKlar Superdip

Market area: EU

**Authorisation number**

(R4BP 3 asset reference number - National Authorisation)

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

## 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

<b>Product type</b>	PT03 - Veterinary hygiene (Disinfectants)
<b>Where relevant, an exact description of the authorised use</b>	-
<b>Target organism(s) (including development stage)</b>	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:
<b>Field(s) of use</b>	Indoor  Post-milking disinfection of teats of milk producing animals (cows, buffaloes, goats, sheep)
<b>Application method(s)</b>	Dipping - Manual dipping using a dip cup
<b>Application rate(s) and frequencies</b>	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).
<b>Category(ies) of users</b>	Professional
<b>Pack sizes and packaging material</b>	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
<b>Authorisation number</b> <small>(R4BP 3 asset reference number - National Authorisation)</small> 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

### 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
<b>Authorisation number</b> (R4BP 3 asset reference number - National Authorisation) 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

## 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

<b>Product type</b>	PT03 - Veterinary hygiene (Disinfectants)
<b>Where relevant, an exact description of the authorised use</b>	-
<b>Target organism(s) (including development stage)</b>	Scientific name: Bacteria Common name: Bacteria Development stage:  Scientific name: Yeasts Common name: Yeasts Development stage:
<b>Field(s) of use</b>	Indoor  Pre-milking disinfection of teats of milk producing animals (cows, buffaloes, goats, sheep)
<b>Application method(s)</b>	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

-

#### 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)

EU-0018398-0005 1-3

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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

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**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)

<b>Where relevant, an exact description of the authorised use</b>	-
<b>Target organism(s) (including development stage)</b>	<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>
<b>Field(s) of use</b>	<p>Indoor</p> <p>Post-milking disinfection of teats of milk producing animals (cows, buffaloes, goats, sheep)</p>
<b>Application method(s)</b>	<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>
<b>Application rate(s) and frequencies</b>	<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>
<b>Category(ies) of users</b>	Professional
<b>Pack sizes and packaging material</b>	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
<b>Authorisation number</b> <small>(R4BP 3 asset reference number - National Authorisation)</small>	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

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## 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)

EU-0018398-0007 1-5

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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

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## 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:

<b>Field(s) of use</b>	Indoor  Post-milking disinfection of teats of milk producing animals (cows, buffaloes, goats, sheep)
<b>Application method(s)</b>	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.
<b>Application rate(s) and frequencies</b>	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).
<b>Category(ies) of users</b>	Professional
<b>Pack sizes and packaging material</b>	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
<b>Authorisation number</b>  (R4BP 3 asset reference number - National Authorisation)  EU-0018398-0008 1-6	

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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

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