

# Summary of product characteristics for a biocidal product family

**Family name:** DeLaval iodine-based teat disinfectant family

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

**Authorisation number:** 2019-07-31-B03

**R4BP 3 asset reference number:** MT-0013584-0000

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## Part I.- First information level

### 1. Administrative information

#### 1.1. Family name

DeLaval iodine-based teat disinfectant family

#### 1.2. Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

#### 1.3. Authorisation holder

**Name and address of the authorisation holder**

Name	DeLaval NV
Address	Industriepark-Drongen 10 9031 Gent Belgium

**Authorisation number**

2019-07-31-B03

**R4BP 3 asset reference number**

MT-0013584-0000

**Date of the authorisation**

02/08/2019

**Expiry date of the authorisation**

01/08/2029

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

**Name of the manufacturer**

DeLaval NV

**Address of the manufacturer**

Industriepark-Drongen 10 9031 Gent Belgium

**Location of manufacturing sites**

Industriepark-Drongen 10 9031 Gent Belgium

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

<b>Active substance</b>	1319 - Iodine
<b>Name of the manufacturer</b>	Sociedad Quimica y Minera (SQM) S.A.
<b>Address of the manufacturer</b>	Supplier EU: SQM Europe NV - Sint-Pietersvliet 7 bus 8 2000 Antwerpen Belgium
<b>Location of manufacturing sites</b>	Los Militares 4290 Piso 4 8320000 Las Condes (Santiago) Chile

## 2. Product family composition and formulation

### 2.1. Qualitative and quantitative information on the composition of the family

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,15 - 0,75
Alcohol ethoxylate		Non-active substance	68439-46-3		0 - 6,34
Sodium iodide		Non-active substance	7681-82-5	231-679-3	0,06 - 0,33

### 2.2. Type(s) of formulation

AL - Any other liquid
SL - Soluble concentrate

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

### 1. Meta SPC administrative information

#### 1.1. Meta SPC identifier

meta SPC 1: Metafamily 1
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## 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 (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,21 - 0,25
Sodium iodide		Non-active substance	7681-82-5	231-679-3	0,092 - 0,12

### 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

Keep out of reach of children.  
Avoid release to the environment.

## 4. Authorised use(s) of the meta SPC

## 4.1 Use description

### Use 1 - Teat disinfection, Ready-to-use dip products applied manually

<b>Product type</b>	PT03 - Veterinary hygiene (Disinfectants)
<b>Where relevant, an exact description of the authorised use</b>	Teat disinfectant
<b>Target organism(s) (including development stage)</b>	Scientific name: Common name: Bacteria Development stage:  Scientific name: Common name: Yeasts Development stage:  Scientific name: Common name: Viruses Development stage:
<b>Field(s) of use</b>	Indoor  The product is intended for post-milking teat disinfection. The product is applied directly after milking on the teats of lactating animals
<b>Application method(s)</b>	Method: Post-milking teat disinfection of udder teats with ready-to-use products. Detailed description: The product is applied manually after milking on the teats by manual dipping using a dip cup.
<b>Application rate(s) and frequencies</b>	Application Rate: ca. 5 ml per cow; ca. 2.5 ml per sheep or goat Dilution (%): 0% Number and timing of application: To be applied after milking, 2 times per day. The products can be used all year during the lactation period.
<b>Category(ies) of users</b>	Professional
<b>Pack sizes and packaging material</b>	Can, Plastic: HDPE , 5L Can, Plastic: HDPE , 10L Can, Plastic: HDPE , 20L Can, Plastic: HDPE , 60L Drum, Plastic: HDPE , 200L IBC, Plastic: HDPE , 1000L

#### 4.1.1 Use-specific instructions for use

#### 4.1.1 Use-specific instructions for use

The product is a ready-to-use product and is used undiluted.  
The product must be brought to a temperature above 20°C before use.

Directions for use:

It is recommended to wear gloves during milking and application to protect the skin and ensure hygienic milking condition. For manual application: use a clean dip cup.

Ensure that teats are clean before use. Apply the ready-to-use solution of the product on each teat immediately after milking:

DIP: dip every teat in the product. Ensure that the teat is covered to at least three quarters length and replenish the dip cup as necessary;

Allow teats to dry after application during at least 5 min and keep the animals standing during this period.

#### 4.1.2 Use-specific risk mitigation measures

There are no use specific risk mitigation measures. See 5.2 for general instructions.

#### 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

There are no use specific instructions. See 5.3 for general instructions.

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

There are no use specific instructions. See 5.4 for general instructions.

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

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#### 4.2 Use description



## Use 2 - Teat disinfection, Ready-to-use spray products applied manually

<b>Product type</b>	PT03 - Veterinary hygiene (Disinfectants)
<b>Where relevant, an exact description of the authorised use</b>	Teat disinfectant
<b>Target organism(s) (including development stage)</b>	Scientific name: Common name: Bacteria Development stage:  Scientific name: Common name: Yeast Development stage:  Scientific name: Common name: Viruses Development stage:
<b>Field(s) of use</b>	Indoor  The product is intended for post-milking teat disinfection. The product is applied directly after milking on the teats of lactating animals
<b>Application method(s)</b>	Method: post-milking teat disinfection of udder teats with ready-to-use products Detailed description: The product is applied manually after milking on the teats by spraying using a spray container.
<b>Application rate(s) and frequencies</b>	Application Rate: ca. 5 ml per cow; ca. 2.5 ml per sheep or goat Dilution (%): 0% Number and timing of application: To be applied after milking, 2 times per day. The products can be used all year during the lactation period.
<b>Category(ies) of users</b>	Professional
<b>Pack sizes and packaging material</b>	Can, Plastic: HDPE , 5L Can, Plastic: HDPE , 10L Can, Plastic: HDPE , 20L Can, Plastic: HDPE , 60L Drum, Plastic: HDPE , 200L IBC, Plastic: HDPE , 1000L

### 4.2.1 Use-specific instructions for use

The product is a ready-to-use product and is used undiluted.  
 The product must be brought to a temperature above 20°C before use.  
 Directions for use:  
 For manual application: use a clean applicator.  
 Ensure that teats are clean before use. Apply the ready-to-use solution of the product on each teat immediately after milking:  
 1) MANUAL TRIGGER SPRAY: spray every teat 1 sec. with the product. Ensure that the teat is covered to at least three quarters length and replenish the spray container as necessary;  
 2) AUTOMATIC SPRAYER: spray every teat 1 sec. with the product.  
 Allow teats to dry after application during at least 5 min and keep the animals standing during this period.

#### 4.2.2 Use-specific risk mitigation measures

Use chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) during post-milking teat disinfection by manual spraying. See 5.2 for general instructions.

#### 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

There are no use specific instructions. See 5.3 for general instructions.

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

There are no use specific instructions. See 5.4 for general instructions.

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

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### 4.3 Use description

#### Use 3 - Teat disinfection, Ready-to-use dip or spray products applied automatically

**Product type**

PT03 - Veterinary hygiene (Disinfectants)

**Where relevant, an exact description of the authorised use**

Teat disinfectant

**Target organism(s) (including development stage)**

Scientific name:  
 Common name: Bacteria  
 Development stage:

Scientific name:  
 Common name: Yeasts  
 Development stage:

Scientific name:

	<p>Common name: Viruses Development stage:</p>
<b>Field(s) of use</b>	<p>Indoor</p> <p>The product is intended for post-milking teat disinfection. The product is applied directly after milking on the teats of lactating animals</p>
<b>Application method(s)</b>	<p>Method: Post-milking teat disinfection of udder teats with ready-to-use products. Detailed description: The product is applied automatically by milking machines after milking on the teats by integrated dipping or spraying device.</p>
<b>Application rate(s) and frequencies</b>	<p>Application Rate: ca. 5 ml per cow; ca. 2.5 ml per sheep or goat Dilution (%): 0% Number and timing of application: To be applied after milking, 3 times per day. The products can be used all year during the lactation period.</p>
<b>Category(ies) of users</b>	<p>Professional</p>
<b>Pack sizes and packaging material</b>	<p>Can, Plastic: HDPE , 5L Can, Plastic: HDPE , 10L Can, Plastic: HDPE , 20L Can, Plastic: HDPE , 60L Drum, Plastic: HDPE , 200L IBC, Plastic: HDPE , 1000L</p>

#### 4.3.1 Use-specific instructions for use

The product is a ready-to-use product and is used undiluted.  
The product must be brought to a temperature above 20°C before use.

#### 4.3.2 Use-specific risk mitigation measures

There are no use specific risk mitigation measures. See 5.2 for general instructions.

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

There are no use specific instructions. See 5.3 for general instructions.

### 4.3.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

There are no use specific instructions. See 5.4 for general instructions.

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

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## 5. General directions for use of the meta SPC

### 5.1. Instructions for use

There are no general instructions for use. See the use specific instructions for use.

### 5.2. Risk mitigation measures

In case a combination of pre- and post-milking disinfection is necessary, using another 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

#### DIRECT/INDIRECT EFFECTS:

According to our experience and to the information provided to us, the product does not have any adverse effects if it is used and handled as specified.

#### FIRST AID MEASURES:

Eye contact: Rinse thoroughly with plenty of water for at least 15 minutes. If eye irritation persists: Get medical advice/attention.

Skin contact: Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes.

Ingestion: Wash out mouth with water. Seek medical advice immediately if symptoms occur and/or large quantities have been ingested.

Inhalation: Move to fresh air.

#### EMERGENCY MEASURES TO PROTECT THE ENVIRONMENT:

Prevent further leakage or spillage if safe to do so. Methods and materials for containment and clean-up: Dam up. Soak up with inert absorbent material. Prevent product from entering drains. Keep in suitable and closed containers for disposal.

### 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.

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

Storage: Store upright in the tightly closed original container. Protect from direct light, temperatures above 30°C and frost.  
Shelf-life: 1 year.

### 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)

Tri-Fender	Market area: EU
Tri-Fender	Market area: CH
Tri-Fender	Market area: IS
Tri-Fender	Market area: NO

##### Authorisation number

(R4BP 3 asset reference number - National Authorisation)

MT-0013584-0001 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,25
Sodium iodide		Non-active substance	7681-82-5	231-679-3	0,12

### Trade name(s)

TriActive

Market area: DK

### Authorisation number

(R4BP 3 asset reference number - National Authorisation)

MT-0013584-0002 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,214
Sodium iodide		Non-active substance	7681-82-5	231-679-3	0,092

## 1. Meta SPC administrative information

### 1.1. Meta SPC identifier

meta SPC 2: Metafamily 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 (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,23 - 0,25
Sodium iodide		Non-active substance	7681-82-5	231-679-3	0,097 - 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

Contains sodium iodate. May produce an allergic reaction.  
Harmful to aquatic life with long lasting effects.

Precautionary statements

Keep out of reach of children.  
Avoid release to the environment.

## 4. Authorised use(s) of the meta SPC

### 4.1 Use description

Use 1 - Teat disinfection, Ready-to-use dip products applied manually

<b>Product type</b>	PT03 - Veterinary hygiene (Disinfectants)
<b>Where relevant, an exact description of the authorised use</b>	Teat disinfectant
<b>Target organism(s) (including development stage)</b>	<p>Scientific name: Common name: Bacteria Development stage:</p> <p>Scientific name: Common name: Yeasts Development stage:</p> <p>Scientific name: Common name: Viruses Development stage:</p>
<b>Field(s) of use</b>	<p>Indoor</p> <p>The product is intended for post-milking teat disinfection. The product is applied directly after milking on the teats of lactating animals.</p>
<b>Application method(s)</b>	<p>Method: Post-milking teat disinfection of udder teats with ready-to-use products. Detailed description: The product is applied manually after milking on the teats by manual dipping using a dip cup.</p>
<b>Application rate(s) and frequencies</b>	<p>Application Rate: ca. 5 ml per cow; ca. 2.5 ml per sheep or goat Dilution (%): 0% Number and timing of application: To be applied after milking, 2 times per day. The products can be used all year during the lactation period.</p>
<b>Category(ies) of users</b>	Professional
<b>Pack sizes and packaging material</b>	<p>Can, Plastic: HDPE , 5L Can, Plastic: HDPE , 10L Can, Plastic: HDPE , 20L Can, Plastic: HDPE , 60L Drum, Plastic: HDPE , 200L IBC, Plastic: HDPE , 1000L</p>

#### 4.1.1 Use-specific instructions for use

The product is a ready-to-use product and is used undiluted.  
The product must be brought to a temperature above 20°C before use.  
Directions for use:



It is recommended to wear gloves during milking and application to protect the skin and ensure hygienic milking condition. For manual application: use a clean dip cup.  
Ensure that teats are clean before use. Apply the ready-to-use solution of the product on each teat immediately after milking: DIP: dip every teat in the product. Ensure that the teat is covered to at least three quarters length and replenish the dip cup as necessary;  
Allow teats to dry after application during at least 5 min and keep the animals standing during this period.

#### 4.1.2 Use-specific risk mitigation measures

There are no use specific risk mitigation measures. See 5.2 for general instructions.

#### 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

There are no use specific instructions. See 5.3 for general instructions.

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

There are no use specific instructions. See 5.4 for general instructions.

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

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### 4.2 Use description

#### Use 2 - Teat disinfection, Ready-to-use spray products applied manually

**Product type**

PT03 - Veterinary hygiene (Disinfectants)

**Where relevant, an exact description of the authorised use**

Teat disinfectant

**Target organism(s) (including development stage)**

Scientific name:  
Common name: Bacteria  
Development stage:

Scientific name:  
Common name: Yeasts  
Development stage:

	<p>Scientific name: Common name: Viruses Development stage:</p>
<b>Field(s) of use</b>	<p>Indoor</p> <p>The product is intended for post-milking teat disinfection. The product is applied directly after milking on the teats of lactating animals.</p>
<b>Application method(s)</b>	<p>Method: Post-milking teat disinfection of udder teats with ready-to-use products. Detailed description: The product is applied manually after milking on the teats by spraying using a spray container.</p>
<b>Application rate(s) and frequencies</b>	<p>Application Rate: ca 5 ml per cow; ca 2.5 ml per sheep or goat Dilution (%): 0% Number and timing of application: To be applied after milking, 2 times per day. The products can be used all year during the lactation period</p>
<b>Category(ies) of users</b>	<p>Professional</p>
<b>Pack sizes and packaging material</b>	<p>Can, Plastic: HDPE , 5L Can, Plastic: HDPE , 10L Can, Plastic: HDPE , 20L Can, Plastic: HDPE , 60L Drum, Plastic: HDPE , 200L IBC, Plastic: HDPE , 1000L</p>

#### 4.2.1 Use-specific instructions for use

The product is a ready-to-use product and is used undiluted.

The product must be brought to a temperature above 20°C before use.

Directions for use:

For manual application: use a clean applicator.

Ensure that teats are clean before use. Apply the ready-to-use solution of the product on each teat immediately after milking:

1) MANUAL TRIGGER SPRAY: spray every teat 1 sec. with the product. Ensure that the teat is covered to at least three quarters length and replenish the spray container as necessary;

2) AUTOMATIC SPRAYER: spray every teat 1 sec. with the product.

Allow teats to dry after application during at least 5 min and keep the animals standing during this period.

#### 4.2.2 Use-specific risk mitigation measures

Use chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) during post-milking teat disinfection by manual spraying. See 5.2 for general instructions.

#### 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

There are no use specific instructions. See 5.3 for general instructions.

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

There are no use specific instructions. See 5.4 for general instructions.

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

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### 4.3 Use description

#### Use 3 - Teat disinfection, Ready-to-use dip or spray products applied automatically

<b>Product type</b>	PT03 - Veterinary hygiene (Disinfectants)
<b>Where relevant, an exact description of the authorised use</b>	Teat disinfectant
<b>Target organism(s) (including development stage)</b>	Scientific name: Common name: Bacteria Development stage:  Scientific name: Common name: Yeasts Development stage:  Scientific name: Common name: Viruses Development stage:
<b>Field(s) of use</b>	Indoor  The product is intended for post-milking teat disinfection. The product is applied directly after milking on the teats of lactating animals.
<b>Application method(s)</b>	Method: Post-milking teat disinfection of udder teats with ready-to-use products. Detailed description: The product is applied automatically by milking machines after milking on the teats by integrated dipping or spraying device.

**Application rate(s) and frequencies**

Application Rate: ca. 5 ml per cow; ca. 2.5 ml per sheep or goat  
Dilution (%): 0%  
Number and timing of application:  
To be applied after milking, 3 times per day. The products can be used all year during the lactation period.

**Category(ies) of users**

Professional

**Pack sizes and packaging material**

Can, Plastic: HDPE , 5L  
Can, Plastic: HDPE , 10L  
Can, Plastic: HDPE , 20L  
Can, Plastic: HDPE , 60L  
Drum, Plastic: HDPE , 200L  
IBC, Plastic: HDPE , 1000L

**4.3.1 Use-specific instructions for use**

The product is a ready-to-use product and is used undiluted.  
The product must be brought to a temperature above 20°C before use.

**4.3.2 Use-specific risk mitigation measures**

There are no use specific risk mitigation measures. See 5.2 for general instructions.

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

There are no use specific instructions. See 5.3 for general instructions.

#### 4.3.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

There are no use specific instructions. See 5.4 for general instructions.

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

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### 5. General directions for use of the meta SPC

#### 5.1. Instructions for use

There are no general instructions for use. See the use specific instructions for use.

#### 5.2. Risk mitigation measures

In case a combination of pre- and post-milking disinfection is necessary, using another 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

##### DIRECT/INDIRECT EFFECTS:

According to our experience and to the information provided to us, the product does not have any adverse effects if it is used and handled as specified.

##### FIRST AID MEASURES:

Eye contact: Rinse thoroughly with plenty of water for at least 15 minutes. If eye irritation persists: Get medical advice/attention.

Skin contact: Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes.

Ingestion: Wash out mouth with water. Seek medical advice immediately if symptoms occur and/or large quantities have been ingested.

Inhalation: Move to fresh air.

##### EMERGENCY MEASURES TO PROTECT THE ENVIRONMENT:

Prevent further leakage or spillage if safe to do so. Methods and materials for containment and clean-up: Dam up. Soak up with inert absorbent material. Prevent product from entering drains. Keep in suitable and closed containers for disposal.

#### 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.

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

Storage: Store upright in the tightly closed original container. Protect from direct light, temperatures above 30°C and frost. Shelf-life: 1 year
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### 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

<b>Trade name(s)</b>	Blockade	Market area: HR
	Blockade	Market area: DK
	Blockade	Market area: FR
	Blockade	Market area: IT
	Blockade	Market area: ES
<b>Authorisation number</b> <small>(R4BP 3 asset reference number - National Authorisation)</small>	MT-0013584-0003 1-2	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,25
Sodium iodide		Non-active substance	7681-82-5	231-679-3	0,1

**Trade name(s)**

IodoFence	Market area: AT
IodoFence	Market area: BE
IodoFence	Market area: BG
IodoFence	Market area: HR
IodoFence	Market area: CY
IodoFence	Market area: CZ
IodoFence	Market area: DK
IodoFence	Market area: EE
IodoFence	Market area: FI
IodoFence	Market area: FR
IodoFence	Market area: DE
IodoFence	Market area: HU

IodoFence	Market area: IE
IodoFence	Market area: IT
IodoFence	Market area: LV
IodoFence	Market area: LT
IodoFence	Market area: LU
IodoFence	Market area: MT
IodoFence	Market area: NL
IodoFence	Market area: PL
IodoFence	Market area: PT
IodoFence	Market area: RO
IodoFence	Market area: SK
IodoFence	Market area: SI
IodoFence	Market area: ES
IodoFence	Market area: SE
IodoFence	Market area: GB
IodoFence	Market area: CH



**Authorisation number**

(R4BP 3 asset reference number - National Authorisation)

IodoFence	Market area: NO
MT-0013584-0004 1-2	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,25
Sodium iodide		Non-active substance	7681-82-5	231-679-3	0,11

**Trade name(s)**

Fortex	Market area: AT
Fortex	Market area: HR
Fortex	Market area: CZ
Fortex	Market area: DK
Fortex	Market area: EE
Fortex	Market area: FI
Fortex	Market area: FR
Fortex	Market area: DE

Fortex	Market area: HU
Fortex	Market area: IT
Fortex	Market area: LV
Fortex	Market area: LT
Fortex	Market area: LU
Fortex	Market area: NL
Fortex	Market area: PL
Fortex	Market area: PT
Fortex	Market area: ES
Fortex	Market area: SE
Fortex	Market area: CH
Fortex	Market area: NO
Fortex	Market area: IS
<b>Authorisation number</b> (R4BP 3 asset reference number - National Authorisation) MT-0013584-0005 1-2	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,23
Sodium iodide		Non-active substance	7681-82-5	231-679-3	0,097

## 1. Meta SPC administrative information

### 1.1. Meta SPC identifier

meta SPC 3: Metafamily 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 (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,15 - 0,15
Alcohol ethoxylate		Non-active substance	68439-46-3		1,25 - 1,25
Sodium iodide		Non-active substance	7681-82-5	231-679-3	0,065 - 0,065

## 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

Keep out of reach of children.

## 4. Authorised use(s) of the meta SPC

### 4.1 Use description

#### Use 1 - Teat disinfection, Ready-to-use dip products applied manually

Product type

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

Teat disinfectant

Target organism(s) (including development stage)

Scientific name:  
Common name: Bacteria  
Development stage:

Scientific name:  
Common name: Yeasts  
Development stage:

Scientific name:  
Common name: Viruses  
Development stage:

Field(s) of use

Indoor

The product is intended for post-milking teat disinfection.  
The product is applied directly after milking on the teats of lactating animals

Application method(s)

Method: Post-milking teat disinfection of udder teats with ready-to-use products  
Detailed description:  
The product is applied manually after milking on the teats by manual dipping using a dip cup.

Application rate(s) and frequencies

Application Rate: ca. 5 ml per cow; ca. 2.5 ml per sheep or goat  
Dilution (%): 0%  
Number and timing of application:  
To be applied after milking, 2 times per day. The products can be used all year during the lactation period.

**Category(ies) of users**

Professional

**Pack sizes and packaging material**

Can, Plastic: HDPE , 5L  
Can, Plastic: HDPE , 10L  
Can, Plastic: HDPE , 20L  
Can, Plastic: HDPE , 60L  
Drum, Plastic: HDPE , 200L  
IBC, Plastic: HDPE , 1000L

**4.1.1 Use-specific instructions for use**

The product is a ready-to-use product and is used undiluted.  
The product must be brought to a temperature above 20°C before use.

**Directions for use:**

It is recommended to wear gloves during milking and application to protect the skin and ensure hygienic milking condition. For manual application: use a clean dip cup.

Ensure that teats are clean before use. Apply the ready-to-use solution of the product on each teat immediately after milking: DIP: dip every teat in the product. Ensure that the teat is covered to at least three quarters length and replenish the dip cup as necessary;

Allow teats to dry after application during at least 5 min and keep the animals standing during this period.

**4.1.2 Use-specific risk mitigation measures**

There are no use specific risk mitigation measures. See 5.2 for general instructions.

**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**

There are no use specific instructions. See 5.3 for general instructions.

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

There are no use specific instructions. See 5.4 for general instructions.

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

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#### 4.2 Use description

##### Use 2 - Teat disinfection, Ready-to-use spray products applied manually

<b>Product type</b>	PT03 - Veterinary hygiene (Disinfectants)
<b>Where relevant, an exact description of the authorised use</b>	Teat disinfectant
<b>Target organism(s) (including development stage)</b>	<p>Scientific name: Common name: Bacteria Development stage:</p> <p>Scientific name: Common name: Yeast Development stage:</p> <p>Scientific name: Common name: Viruses Development stage:</p>
<b>Field(s) of use</b>	<p>Indoor</p> <p>The product is intended for post-milking teat disinfection. The product is applied directly after milking on the teats of lactating animals</p>
<b>Application method(s)</b>	<p>Method: post-milking teat disinfection of udder teats with ready-to-use products Detailed description: The product is applied manually after milking on the teats by spraying using a spray container.</p>
<b>Application rate(s) and frequencies</b>	<p>Application Rate: ca. 5 ml per cow; ca. 2.5 ml per sheep or goat Dilution (%): 0% Number and timing of application: To be applied after milking, 2 times per day. The products can be used all year during the lactation period.</p>
<b>Category(ies) of users</b>	Professional
<b>Pack sizes and packaging material</b>	<p>Can, Plastic: HDPE , 5L Can, Plastic: HDPE , 10L Can, Plastic: HDPE , 20L Can, Plastic: HDPE , 60L Drum, Plastic: HDPE , 200L</p>

IBC, Plastic: HDPE , 1000L

#### 4.2.1 Use-specific instructions for use

The product is a ready-to-use products and is used undiluted.

The product must be brought to a temperature above 20°C before use.

Directions for use:

For manual application: use a clean applicator.

Ensure that teats are clean before use. Apply the ready-to-use solution of the product on each teat immediately after milking:

1) MANUAL TRIGGER SPRAY: spray every teat 1 sec. with the product. Ensure that the teat is covered to at least three quarters length and replenish the spray container as necessary;

2) AUTOMATIC SPRAYER: spray every teat 1 sec. with the product.

Allow teats to dry after application during at least 5 min and keep the animals standing during this period.

#### 4.2.2 Use-specific risk mitigation measures

Use chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) during post-milking teat disinfection by manual spraying. See 5.2 for general instructions.

#### 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

There are no use specific instructions. See 5.3 for general instructions.

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

There are no use specific instructions. See 5.4 for general instructions.

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

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#### 4.3 Use description

Use 3 - Teat disinfection, Ready-to-use dip or spray products applied automatically

<b>Product type</b>	PT03 - Veterinary hygiene (Disinfectants)
<b>Where relevant, an exact description of the authorised use</b>	Teat disinfectant
<b>Target organism(s) (including development stage)</b>	<p>Scientific name: Common name: Bacteria Development stage:</p> <p>Scientific name: Common name: Yeasts Development stage:</p> <p>Scientific name: Common name: Viruses Development stage:</p>
<b>Field(s) of use</b>	<p>Indoor</p> <p>The product is intended for post-milking teat disinfection. The product is applied directly after milking on the teats of lactating animals</p>
<b>Application method(s)</b>	<p>Method: Post-milking teat disinfection of udder teats with ready-to-use products Detailed description: The product is applied automatically by milking machines after milking on the teats by integrated dipping or spraying device.</p>
<b>Application rate(s) and frequencies</b>	<p>Application Rate: ca. 5 ml per cow; ca. 2.5 ml per sheep or goat Dilution (%): 0% Number and timing of application: To be applied after milking, 3 times per day. The products can be used all year during the lactation period.</p>
<b>Category(ies) of users</b>	Professional
<b>Pack sizes and packaging material</b>	<p>Can, Plastic: HDPE , 5L Can, Plastic: HDPE , 10L Can, Plastic: HDPE , 20L Can, Plastic: HDPE , 60L Drum, Plastic: HDPE , 200L IBC, Plastic: HDPE , 1000L</p>

#### 4.3.1 Use-specific instructions for use

The product is a ready-to-use product and is used undiluted.  
The product must be brought to a temperature above 20°C before use.



#### 4.3.2 Use-specific risk mitigation measures

There are no use specific risk mitigation measures. See 5.2 for general instructions.

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

There are no use specific instructions. See 5.3 for general instructions.

#### 4.3.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

There are no use specific instructions. See 5.4 for general instructions.

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

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### 5. General directions for use of the meta SPC

#### 5.1. Instructions for use

There are no general instructions for use. See the use specific instructions for use.

#### 5.2. Risk mitigation measures

In case a combination of pre- and post-milking disinfection is necessary, using another 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

DIRECT/INDIRECT EFFECTS:  
According to our experience and to the information provided to us, the product does not have any adverse effects if it is used and handled as specified.  
FIRST AID MEASURES:

Eye contact: Rinse thoroughly with plenty of water for at least 15 minutes. If eye irritation persists: Get medical advice/attention.  
 Skin contact: Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes.  
 Ingestion: Wash out mouth with water. Seek medical advice immediately if symptoms occur and/or large quantities have been ingested.  
 Inhalation: Move to fresh air.  
**EMERGENCY MEASURES TO PROTECT THE ENVIRONMENT:**  
 Prevent further leakage or spillage if safe to do so. Methods and materials for containment and clean-up: Dam up. Soak up with inert absorbent material. Prevent product from entering drains. Keep in suitable and closed containers for disposal.

#### 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.

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

Storage: Store upright in the tightly closed original container. Protect from direct light, temperatures above 30°C and frost.  
 Shelf-life: 1 year.

#### 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)	Dipal RTU	Market area: AT
	Dipal RTU	Market area: HR
	Dipal RTU	Market area: CY

Dipal RTU	Market area: DK
Dipal RTU	Market area: EE
Dipal RTU	Market area: FI
Dipal RTU	Market area: FR
Dipal RTU	Market area: DE
Dipal RTU	Market area: GR
Dipal RTU	Market area: LT
Dipal RTU	Market area: MT
Dipal RTU	Market area: NL
Dipal RTU	Market area: BE
Dipal RTU	Market area: PT
Dipal RTU	Market area: SI
Dipal RTU	Market area: ES
Dipal RTU	Market area: SE
Dipal RTU	Market area: NO

**Authorisation number**

(R4BP 3 asset reference number - National  
Authorisation)

MT-0013584-0006 1-3

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,15
Alcohol ethoxylate		Non-active substance	68439-46-3		1,25
Sodium iodide		Non-active substance	7681-82-5	231-679-3	0,065

## 1. Meta SPC administrative information

### 1.1. Meta SPC identifier

meta SPC 4: Metafamily 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 (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,15 - 0,15
Alcohol ethoxylate		Non-active substance	68439-46-3		1,5 - 1,5
Sodium iodide		Non-active substance	7681-82-5	231-679-3	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

Causes serious eye irritation.

Precautionary statements

Keep out of reach of children.

Wear eye protection.

Wear face protection.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Wash hands thoroughly after handling.

If eye irritation persists: Get medical advice.

If eye irritation persists: Get medical attention.

## 4. Authorised use(s) of the meta SPC

### 4.1 Use description

Use 1 - Teat disinfection, Ready-to-use dip products applied manually

Product type

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised

Teat disinfectant

## use

### Target organism(s) (including development stage)

Scientific name:  
Common name: Bacteria  
Development stage:

Scientific name:  
Common name: Yeasts  
Development stage:

Scientific name:  
Common name: Viruses  
Development stage:

### Field(s) of use

Indoor

The product is intended for post-milking teat disinfection.  
The product is applied directly after milking on the teats of lactating animals

### Application method(s)

Method: Post-milking teat disinfection of udder teats with ready-to-use products.  
Detailed description:  
The product is applied manually after milking on the teats by manual dipping using a dip cup.

### Application rate(s) and frequencies

Application Rate: ca. 5 ml per cow; ca. 2.5 ml per sheep or goat  
Dilution (%): 0%  
Number and timing of application:  
To be applied after milking, 2 times per day. The products can be used all year during the lactation period.

### Category(ies) of users

Professional

### Pack sizes and packaging material

Can, Plastic: HDPE , 5L  
Can, Plastic: HDPE , 10L  
Can, Plastic: HDPE , 20L  
Can, Plastic: HDPE , 60L  
Drum, Plastic: HDPE , 200L  
IBC, Plastic: HDPE , 1000L

## 4.1.1 Use-specific instructions for use

The product is a ready-to-use product and is used undiluted.  
The product must be brought to a temperature above 20°C before use.

#### Directions for use:

It is recommended to wear gloves during milking and application to protect the skin and ensure hygienic milking condition. For manual application: use a clean dip cup.

Ensure that teats are clean before use. Apply the ready-to-use solution of the product on each teat immediately after milking:  
DIP: dip every teat in the product. Ensure that the teat is covered to at least three quarters length and replenish the dip cup as

necessary;  
Allow teats to dry after application during at least 5 min and keep the animals standing during this period.

#### 4.1.2 Use-specific risk mitigation measures

Use eye/face protection during post-milking teat disinfection by manual dipping.  
See 5.2 for general instructions.

#### 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

There are no use specific instructions. See 5.3 for general instructions.

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

There are no use specific instructions. See 5.4 for general instructions.

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

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### 4.2 Use description

#### Use 2 - Teat disinfection, Ready-to-use spray products applied manually

##### Product type

PT03 - Veterinary hygiene (Disinfectants)

##### Where relevant, an exact description of the authorised use

Teat disinfectant

##### Target organism(s) (including development stage)

Scientific name:  
Common name: Bacteria  
Development stage:

Scientific name:  
Common name: Yeast  
Development stage:

Scientific name:  
Common name: Viruses  
Development stage:

<b>Field(s) of use</b>	Indoor  The product is intended for post-milking teat disinfection. The product is applied directly after milking on the teats of lactating animals
<b>Application method(s)</b>	Method: post-milking teat disinfection of udder teats with ready-to-use products Detailed description: The product is applied manually after milking on the teats by spraying using a spray container.
<b>Application rate(s) and frequencies</b>	Application Rate: ca. 5 ml per cow; ca. 2.5 ml per sheep or goat Dilution (%): 0% Number and timing of application: To be applied after milking, 2 times per day. The products can be used all year during the lactation period.
<b>Category(ies) of users</b>	Professional
<b>Pack sizes and packaging material</b>	Can, Plastic: HDPE , 5L Can, Plastic: HDPE , 10L Can, Plastic: HDPE , 20L Can, Plastic: HDPE , 60L Drum, Plastic: HDPE , 200L IBC, Plastic: HDPE , 1000L

#### 4.2.1 Use-specific instructions for use

The product is a ready-to-use product and is used undiluted.  
The product must be brought to a temperature above 20°C before use.

Directions for use:

For manual application: use a clean applicator.

Ensure that teats are clean before use. Apply the ready-to-use solution of the product on each teat immediately after milking:

1) MANUAL TRIGGER SPRAY: spray every teat 1 sec. with the product. Ensure that the teat is covered to at least three quarters length and replenish the spray container as necessary;

2) AUTOMATIC SPRAYER: spray every teat 1 sec. with the product.

Allow teats to dry after application during at least 5 min and keep the animals standing during this period.

#### 4.2.2 Use-specific risk mitigation measures

Use chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) and eye/face protection during post-milking teat disinfection by manual spraying. See 5.2 for general instructions.

#### 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



There are no use specific instructions. See 5.3 for general instructions.

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

There are no use specific instructions. See 5.4 for general instructions.

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

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### 4.3 Use description

#### Use 3 - Teat disinfection, Ready-to-use dip or spray products applied automatically

##### Product type

PT03 - Veterinary hygiene (Disinfectants)

##### Where relevant, an exact description of the authorised use

Teat disinfectant

##### Target organism(s) (including development stage)

Scientific name:  
Common name: Bacteria  
Development stage:

Scientific name:  
Common name: Yeasts  
Development stage:

Scientific name:  
Common name: Viruses  
Development stage:

##### Field(s) of use

Indoor

The product is intended for post-milking teat disinfection.  
The product is applied directly after milking on the teats of lactating animals

##### Application method(s)

Method: Post-milking teat disinfection of udder teats with ready-to-use products.  
Detailed description:  
The product is applied automatically by milking machines after milking on the teats by integrated dipping or spraying device.

##### Application rate(s) and frequencies

Application Rate: ca. 5 ml per cow; ca. 2.5 ml per sheep or goat  
Dilution (%): 0%  
Number and timing of application:  
To be applied after milking, 3 times per day. The products can be used all year during the lactation period.

<b>Category(ies) of users</b>	Professional
<b>Pack sizes and packaging material</b>	Can, Plastic: HDPE , 5L Can, Plastic: HDPE , 10L Can, Plastic: HDPE , 20L Can, Plastic: HDPE , 60L Drum, Plastic: HDPE , 200L IBC, Plastic: HDPE , 1000L

#### 4.3.1 Use-specific instructions for use

The product is a ready-to-use product and is used undiluted.  
The product must be brought to a temperature above 20°C before use.

#### 4.3.2 Use-specific risk mitigation measures

Use eye/face protection during post-milking teat disinfection by automated dipping or spraying. See 5.2 for general instructions.

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

There are no use specific instructions. See 5.3 for general instructions.

#### 4.3.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

There are no use specific instructions. See 5.4 for general instructions.

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

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## 5. General directions for use of the meta SPC

### 5.1. Instructions for use

There are no general instructions for use. See the use specific instructions for use.

### 5.2. Risk mitigation measures

In case a combination of pre- and post-milking disinfection is necessary, using another 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

#### DIRECT/INDIRECT EFFECTS:

According to our experience and to the information provided to us, the product does not have any adverse effects if it is used and handled as specified.

#### FIRST AID MEASURES:

Eye contact: Rinse thoroughly with plenty of water for at least 15 minutes. If eye irritation persists: Get medical advice/attention.

Skin contact: Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes.

Ingestion: Wash out mouth with water. Seek medical advice immediately if symptoms occur and/or large quantities have been ingested.

Inhalation: Move to fresh air.

#### EMERGENCY MEASURES TO PROTECT THE ENVIRONMENT:

Prevent further leakage or spillage if safe to do so. Methods and materials for containment and clean-up: Dam up. Soak up with inert absorbent material. Prevent product from entering drains. Keep in suitable and closed containers for disposal.

### 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.

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

Storage: Store upright in the tightly closed original container. Protect from direct light, temperatures above 30°C and frost.

Shelf-life: 1 year.

## 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

<b>Trade name(s)</b>	Dipal Plus	Market area: NL
	Dipal Plus	Market area: MT
<b>Authorisation number</b> <small>(R4BP 3 asset reference number - National Authorisation)</small>	MT-0013584-0007 1-4	

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Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,15
Alcohol ethoxylate		Non-active substance	68439-46-3		1,5
Sodium iodide		Non-active substance	7681-82-5	231-679-3	0,11

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## 1. Meta SPC administrative information

### 1.1. Meta SPC identifier

meta SPC 5: Metafamily 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 (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,75 - 0,75
Alcohol ethoxylate		Non-active substance	68439-46-3		6,34 - 6,34
Sodium iodide		Non-active substance	7681-82-5	231-679-3	0,33 - 0,33

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

Formulation(s)

SL - Soluble concentrate

## 3. Hazard and precautionary statements of the meta SPC

Hazard statements

Causes serious eye irritation.  
Harmful to aquatic life with long lasting effects.  
May cause damage to organs thyroid through prolonged or repeated exposure oral route.

Precautionary statements

Keep out of reach of children.  
Avoid release to the environment.  
Wear eye protection.  
Wear face protection.  
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
Wash hands thoroughly after handling.  
If eye irritation persists: Get medical advice.

If eye irritation persists: Get medical attention.

## 4. Authorised use(s) of the meta SPC

### 4.1 Use description

#### Use 1 - Teat disinfection; concentrated dip products applied manually

<b>Product type</b>	PT03 - Veterinary hygiene (Disinfectants)
<b>Where relevant, an exact description of the authorised use</b>	Teat disinfectant
<b>Target organism(s) (including development stage)</b>	Scientific name: Common name: Bacteria Development stage:  Scientific name: Common name: Yeasts Development stage:  Scientific name: Common name: Viruses Development stage:
<b>Field(s) of use</b>	Indoor  The product is intended for post-milking teat disinfection. The product is applied directly after milking on the teats of lactating animals.
<b>Application method(s)</b>	Method: Post-milking disinfection of udder teats with diluted concentrate Detailed description: The product is applied manually after milking on the teats by manual dipping using a dip cup
<b>Application rate(s) and frequencies</b>	Application Rate: ca. 5 ml per cow; ca. 2.5 ml per sheep or goat Dilution (%): 20%: Use concentration: 0.15% w/w iodine Number and timing of application: To be applied after milking, 2 times per day. The products can be used all year during the lactation period.
<b>Category(ies) of users</b>	Professional
<b>Pack sizes and packaging material</b>	Can, Plastic: HDPE , 5L Can, Plastic: HDPE , 10L Can, Plastic: HDPE , 20L Can, Plastic: HDPE , 60L Drum, Plastic: HDPE , 200L IBC, Plastic: HDPE , 1000L Bottle, Plastic, HDPE, 1L



#### 4.1.1 Use-specific instructions for use

**Directions for use:**

It is recommended to wear gloves during milking and application to protect the skin and ensure hygienic milking condition. A 20% dilution should be made with clean water. Take 200 ml of the concentrated product and make up to 1L with water to obtain an end concentration of 0.15% iodine. The use solution must be brought to a temperature above 20°C before use. It is possible that foaming occurs while preparing the ready-to-use solution. In that case it is strongly recommended to only start the treatment after the foam level has sufficiently decreased. For manual application: use a clean dip cup. Ensure that teats are clean before use. Apply the diluted product on each teat immediately after milking: DIP: dip every teat in the product. Ensure that the teat is covered to at least three quarters length and replenish the dip cup as necessary; Allow teats to dry after application during at least 5 min and keep the animals standing during this period.

#### 4.1.2 Use-specific risk mitigation measures

Use eye/face protection during post-milking teat disinfection by manual dipping. See 5.2 for general instructions.

#### 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

There are no use specific instructions. See 5.3 for general instructions.

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

There are no use specific instructions. See 5.4 for general instructions.

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

-

#### 4.2 Use description

## Use 2 - Teat disinfection; concentrated spray products applied manually

<b>Product type</b>	PT03 - Veterinary hygiene (Disinfectants)
<b>Where relevant, an exact description of the authorised use</b>	Teat disinfectant
<b>Target organism(s) (including development stage)</b>	Scientific name: Common name: Bacteria Development stage:  Scientific name: Common name: Yeasts Development stage:  Scientific name: Common name: Viruses Development stage:
<b>Field(s) of use</b>	Indoor  The product is intended for post-milking teat disinfection. The product is applied directly after milking on the teats of lactating animals.
<b>Application method(s)</b>	Method: Post-milking disinfection of udder teats with diluted concentrate Detailed description: The product is applied after manually milking on the teats by spraying using a spray container.
<b>Application rate(s) and frequencies</b>	Application Rate: ca 5 ml per cow; ca. 2.5 ml per sheep or goat Dilution (%): 20% Use concentration: 0.15% w/w iodine Number and timing of application: To be applied after milking 2 times per day. The product can be used all year during the lactation period.
<b>Category(ies) of users</b>	Professional
<b>Pack sizes and packaging material</b>	Can, Plastic: HDPE, 5L Can, Plastic: HDPE, 10L Can, Plastic: HDPE, 20L Can, Plastic: HDPE, 60L Drum, Plastic: HDPE, 200L IBC, Plastic: HDPE, 1000L Bottle, Plastic: HDPE, 1L

### 4.2.1 Use-specific instructions for use



**Directions for use:**

A 20% dilution should be made with clean water. Take 200 ml of the concentrated product and make up to 1L with water to obtain an end concentration of 0.15% iodine.

The use solution must be brought to a temperature above 20°C before use.

It is possible that foaming occurs while preparing the ready-to-use solution. In that case it is strongly recommended to only start the treatment after the foam level has sufficiently decreased.

For manual application: use a clean applicator.

Ensure that teats are clean before use. Apply the diluted product on each teat immediately after milking:

1) MANUAL TRIGGER SPRAY: spray every teat 1 sec. with the product. Ensure that the teat is covered to at least three quarters length and replenish the spray container as necessary;

2) AUTOMATIC SPRAYER: spray every teat 1 sec. with the product.

Allow teats to dry after application during at least 5 min and keep the animals standing during this period.

#### 4.2.2 Use-specific risk mitigation measures

Use chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) and eye/face protection during post-milking teat disinfection by manual spraying. See 5.2 for general instructions.

#### 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

There are no use specific instructions. See 5.3 for general instructions.

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

There are no use specific instructions. See 5.4 for general instructions.

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

-

### 4.3 Use description

#### Use 3 - Teat disinfection, concentrated dip or spray products applied automatically

**Product type**

PT03 - Veterinary hygiene (Disinfectants)

**Where relevant, an exact description of the authorised use**

Teat disinfectant

**Target organism(s) (including development stage)**

Scientific name:  
Common name: Bacteria  
Development stage:

Scientific name:  
Common name: Yeasts

	<p>Development stage:</p> <p>Scientific name: Common name: Viruses Development stage:</p>
<b>Field(s) of use</b>	<p>Indoor</p> <p>The product is intended for post-milking teat disinfection. The product is applied directly after milking on the teats of lactating animals.</p>
<b>Application method(s)</b>	<p>Method: Post-milking disinfection of udder teats with diluted concentrate Detailed description: The product is applied automatically by milking machines after milking on the teats by integrated dipping or spraying device.</p>
<b>Application rate(s) and frequencies</b>	<p>Application Rate: ca. 5 ml per cow; ca. 2.5 ml per sheep or goat Dilution (%): 20%: Use concentration: 0.15% w/w iodine Number and timing of application: To be applied after milking, 3 times per day. The products can be used all year during the lactation period.</p>
<b>Category(ies) of users</b>	<p>Professional</p>
<b>Pack sizes and packaging material</b>	<p>Can, Plastic: HDPE , 5L Can, Plastic: HDPE , 10L Can, Plastic: HDPE , 20L Can, Plastic: HDPE , 60L Drum, Plastic: HDPE , 200L IBC, Plastic: HDPE , 1000L Bottle, Plastic, HDPE, 1L</p>

#### 4.3.1 Use-specific instructions for use

<p>Directions for use: A 20% dilution should be made with clean water. Take 200 ml of the concentrated product and make up to 1L with water to obtain an end concentration of 0.15% iodine. The use solution must be brought to a temperature above 20°C before use. It is possible that foaming occurs while preparing the ready-to-use solution. In that case it is strongly recommended to only start the treatment after the foam level has sufficiently decreased.</p>
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#### 4.3.2 Use-specific risk mitigation measures

Use eye/face protection during post-milking teat disinfection by automated dipping or spraying.  
See 5.2 for general instructions.

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

There are no use specific instructions. See 5.3 for general instructions.

#### 4.3.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

There are no use specific instructions. See 5.4 for general instructions.

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

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### 5. General directions for use of the meta SPC

#### 5.1. Instructions for use

There are no general instructions for use. See section 4 for the use specific instructions for use.

#### 5.2. Risk mitigation measures

In case a combination of pre- and post-milking disinfection is necessary, using another 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

##### DIRECT/INDIRECT EFFECTS

According to our experience and to the information provided to us, the product does not have any adverse effects if it is used and handled as specified.

##### FIRST AID MEASURES

Eye contact: Rinse thoroughly with plenty of water for at least 15 minutes. If eye irritation persists: Get medical advice/attention.

Skin contact: Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes.

Ingestion: Wash out mouth with water. Seek medical advice immediately if symptoms occur and/or large quantities have been

ingested.  
 Inhalation: Move to fresh air.  
**EMERGENCY MEASURES TO PROTECT THE ENVIRONMENT**  
 Prevent further leakage or spillage if safe to do so.  
 Methods and materials for containment and cleanup: Dam up. Soak up with inert absorbent material. Prevent product from entering drains. Keep in suitable and closed containers for disposal.

#### 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.

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

Storage: Store upright in the tightly closed original container. Protect from direct light, temperatures above 30°C and frost.  
 Shelf-life: 2 years

#### 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

<b>Trade name(s)</b>	Iobac Conc	Market area: BE
	Dipal Conc	Market area: BG
	Dipal Conc	Market area: HR
	Dipal Conc	Market area: CY

Dipal Conc	Market area: CZ
Dipal Conc	Market area: DK
Dipal Conc	Market area: EE
Dipal Conc	Market area: FI
Dipal Conc	Market area: FR
Dipal Conc	Market area: HU
Dipal Conc	Market area: LV
Dipal Conc	Market area: LT
Dipal Conc	Market area: LU
Dipal Conc	Market area: PL
Dipal Conc	Market area: RO
Dipal Conc	Market area: SE
Dipal Conc	Market area: NO
Dipal Conc	Market area: IS
<b>Authorisation number</b>  (R4BP 3 asset reference number - National Authorisation)	MT-0013584-0008 1-5

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,75
Alcohol ethoxylate		Non-active substance	68439-46-3		6,34
Sodium iodide		Non-active substance	7681-82-5	231-679-3	0,33

## 1. Meta SPC administrative information

### 1.1. Meta SPC identifier

meta SPC 6: Metafamily 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 (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,15 - 0,15
Sodium iodide		Non-active substance	7681-82-5	231-679-3	0,07 - 0,07

## 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.

May be corrosive to metals.

Precautionary statements

Keep out of reach of children.

Avoid release to the environment.

## 4. Authorised use(s) of the meta SPC

### 4.1 Use description

#### Use 1 - Teat disinfection, Ready-to-use dip products applied manually

Product type

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

Teat disinfectant

Target organism(s) (including development stage)

Scientific name:  
Common name: Bacteria  
Development stage:

Scientific name:  
Common name: Yeasts  
Development stage:

Scientific name:  
Common name: Viruses  
Development stage:

Field(s) of use

Indoor

The product is intended for post-milking teat disinfection.  
The product is applied directly after milking on the teats of lactating animals

Application method(s)

Method: Post-milking teat disinfection of udder teats with ready-to-use products.  
Detailed description:  
The product is applied manually after milking on the teats by manual dipping using a dip cup.

**Application rate(s) and frequencies**

Application Rate: ca. 5 ml per cow; ca. 2.5 ml per sheep or goat  
Dilution (%): 0%  
Number and timing of application:  
To be applied after milking, 2 times per day. The products can be used all year during the lactation period.

**Category(ies) of users**

Professional

**Pack sizes and packaging material**

Can, Plastic: HDPE , 5L  
Can, Plastic: HDPE , 10L  
Can, Plastic: HDPE , 20L  
Can, Plastic: HDPE , 60L  
Drum, Plastic: HDPE , 200L  
IBC, Plastic: HDPE , 1000L

**4.1.1 Use-specific instructions for use**

The product is a ready-to-use product and is used undiluted.  
The product must be brought to a temperature above 20°C before use.

Directions for use:

It is recommended to wear gloves during milking and application to protect the skin and ensure hygienic milking condition. For manual application: use a clean dip cup.

Ensure that teats are clean before use. Apply the ready-to-use solution of the product on each teat immediately after milking:

DIP: dip every teat in the product. Ensure that the teat is covered to at least three quarters length and replenish the dip cup as necessary;

Allow teats to dry after application during at least 5 min and keep the animals standing during this period.

**4.1.2 Use-specific risk mitigation measures**

There are no use specific risk mitigation measures. See 5.2 for general instructions.

**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**



There are no use specific instructions. See 5.3 for general instructions.

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

There are no use specific instructions. See 5.4 for general instructions.

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

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## 4.2 Use description

### Use 2 - Teat disinfection, Ready-to-use spray products applied manually

#### Product type

PT03 - Veterinary hygiene (Disinfectants)

#### Where relevant, an exact description of the authorised use

Teat disinfectant

#### Target organism(s) (including development stage)

Scientific name:  
Common name: Bacteria  
Development stage:

Scientific name:  
Common name: Yeast  
Development stage:

Scientific name:  
Common name: Viruses  
Development stage:

#### Field(s) of use

Indoor

The product is intended for post-milking teat disinfection.  
The product is applied directly after milking on the teats of lactating animals

#### Application method(s)

Method: post-milking teat disinfection of udder teats with ready-to-use products  
Detailed description:  
The product is applied manually after milking on the teats by spraying using a spray container.

#### Application rate(s) and frequencies

Application Rate: ca. 5 ml per cow; ca. 2.5 ml per sheep or goat  
Dilution (%): 0%  
Number and timing of application:  
To be applied after milking, 2 times per day. The products can be used all year during the lactation period.

**Category(ies) of users**

Professional

**Pack sizes and packaging material**

Can, Plastic: HDPE , 5L  
Can, Plastic: HDPE , 10L  
Can, Plastic: HDPE , 20L  
Can, Plastic: HDPE , 60L  
Drum, Plastic: HDPE , 200L  
IBC, Plastic: HDPE , 1000L

**4.2.1 Use-specific instructions for use**

The product is a ready-to-use product and is used undiluted.  
The product must be brought to a temperature above 20°C before use.  
Directions for use:  
For manual application: use a clean applicator.  
Ensure that teats are clean before use. Apply the ready-to-use solution of the product on each teat immediately after milking:  
1) MANUAL TRIGGER SPRAY: spray every teat 1 sec. with the product. Ensure that the teat is covered to at least three quarters length and replenish the spray container as necessary;  
2) AUTOMATIC SPRAYER: spray every teat 1 sec. with the product.  
Allow teats to dry after application during at least 5 min and keep the animals standing during this period.

**4.2.2 Use-specific risk mitigation measures**

Use chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) during post-milking teat disinfection by manual spraying. See 5.2 for general instructions.

**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**

There are no use specific instructions. See 5.3 for general instructions.

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

There are no use specific instructions. See 5.4 for general instructions.

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

-

### 4.3 Use description

#### Use 3 - Teat disinfection, Ready-to-use dip or spray products applied automatically

<b>Product type</b>	PT03 - Veterinary hygiene (Disinfectants)
<b>Where relevant, an exact description of the authorised use</b>	Teat disinfectant
<b>Target organism(s) (including development stage)</b>	Scientific name: Common name: Bacteria Development stage:  Scientific name: Common name: Yeasts Development stage:  Scientific name: Common name: Viruses Development stage:
<b>Field(s) of use</b>	Indoor  The product is intended for post-milking teat disinfection. The product is applied directly after milking on the teats of lactating animals
<b>Application method(s)</b>	Method: Post-milking teat disinfection of udder teats with ready-to-use products. Detailed description: The product is applied automatically by milking machines after milking on the teats by integrated dipping or spraying device.
<b>Application rate(s) and frequencies</b>	Application Rate: ca. 5 ml per cow; ca. 2.5 ml per sheep or goat Dilution (%): 0% Number and timing of application: To be applied after milking, 3 times per day. The products can be used all year during the lactation period.
<b>Category(ies) of users</b>	Professional
<b>Pack sizes and packaging material</b>	Can, Plastic: HDPE , 5L Can, Plastic: HDPE , 10L Can, Plastic: HDPE , 20L Can, Plastic: HDPE , 60L Drum, Plastic: HDPE , 200L IBC, Plastic: HDPE , 1000L

#### 4.3.1 Use-specific instructions for use

#### **4.3.1 Use-specific instructions for use**

The product is a ready-to-use product and is used undiluted.  
The product must be brought to a temperature above 20°C before use.

#### **4.3.2 Use-specific risk mitigation measures**

There are no use specific risk mitigation measures. See 5.2 for general instructions.

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

There are no use specific instructions. See 5.3 for general instructions.

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

There are no use specific instructions. See 5.4 for general instructions.

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

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### **5. General directions for use of the meta SPC**

#### **5.1. Instructions for use**

There are no general instructions for use. See the use specific instructions for use.

#### **5.2. Risk mitigation measures**

In case a combination of pre- and post-milking disinfection is necessary, using another 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**

#### **DIRECT/INDIRECT EFFECTS:**

According to our experience and to the information provided to us, the product does not have any adverse effects if it is used and handled as specified.

#### **FIRST AID MEASURES:**

Eye contact: Rinse thoroughly with plenty of water for at least 15 minutes. If eye irritation persists: Get medical advice/attention.

Skin contact: Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes.

Ingestion: Wash out mouth with water. Seek medical advice immediately if symptoms occur and/or large quantities have been ingested.

Inhalation: Move to fresh air.

#### **EMERGENCY MEASURES TO PROTECT THE ENVIRONMENT:**

Prevent further leakage or spillage if safe to do so. Methods and materials for containment and clean-up: Dam up. Soak up with inert absorbent material. Prevent product from entering drains. Keep in suitable and closed containers for disposal.

### **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.

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

Storage: Store upright in the tightly closed original container. Protect from direct light, temperatures above 30°C and frost.

Shelf-life: 1 year.

## **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)**

Proactive Plus	Market area: DK
Proactive Plus	Market area: FI
Proactive Plus	Market area: SE
Proactive Plus	Market area: NO

**Authorisation number**

(R4BP 3 asset reference number - National Authorisation)

MT-0013584-0009 1-6

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Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,15
Sodium iodide		Non-active substance	7681-82-5	231-679-3	0,07

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

meta SPC 7: Metafamily 7

**1.2. Suffix to the authorisation number**

1-7

### 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 (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,15 - 0,15
Sodium iodide		Non-active substance	7681-82-5	231-679-3	0,06 - 0,06

### 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

Contains sodium iodate. May produce an allergic reaction.  
Harmful to aquatic life with long lasting effects.  
May be corrosive to metals.

Precautionary statements

Keep out of reach of children.  
Avoid release to the environment.

## 4. Authorised use(s) of the meta SPC

## 4.1 Use description

### Use 1 - Teat disinfection, Ready-to-use dip products applied manually

<b>Product type</b>	PT03 - Veterinary hygiene (Disinfectants)
<b>Where relevant, an exact description of the authorised use</b>	Teat disinfectant
<b>Target organism(s) (including development stage)</b>	Scientific name: Common name: Bacteria Development stage:  Scientific name: Common name: Yeasts Development stage:  Scientific name: Common name: Viruses Development stage:
<b>Field(s) of use</b>	Indoor  The product is intended for post-milking teat disinfection. The product is applied directly after milking on the teats of lactating animals.
<b>Application method(s)</b>	Method: Post-milking teat disinfection of udder teats with ready-to-use products. Detailed description: The product is applied manually after milking on the teats by manual dipping using a dip cup.
<b>Application rate(s) and frequencies</b>	Application Rate: ca. 5 ml per cow; ca. 2.5 ml per sheep or goat Dilution (%): 0% Number and timing of application: To be applied after milking, 2 times per day. The products can be used all year during the lactation period.
<b>Category(ies) of users</b>	Professional
<b>Pack sizes and packaging material</b>	Can, Plastic: HDPE , 5L Can, Plastic: HDPE , 10L Can, Plastic: HDPE , 20L Can, Plastic: HDPE , 60L Drum, Plastic: HDPE , 200L IBC, Plastic: HDPE , 1000L



#### 4.1.1 Use-specific instructions for use

The product is a ready-to-use product and is used undiluted.  
The product must be brought to a temperature above 20°C before use.  
Directions for use:  
It is recommended to wear gloves during milking and application to protect the skin and ensure hygienic milking condition. For manual application: use a clean dip cup.  
Ensure that teats are clean before use. Apply the ready-to-use solution of the product on each teat immediately after milking:  
DIP: dip every teat in the product. Ensure that the teat is covered to at least three quarters length and replenish the dip cup as necessary;  
Allow teats to dry after application during at least 5 min and keep the animals standing during this period.

#### 4.1.2 Use-specific risk mitigation measures

There are no use specific risk mitigation measures. See 5.2 for general instructions.

#### 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

There are no use specific instructions. See 5.3 for general instructions.

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

There are no use specific instructions. See 5.4 for general instructions.

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

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#### 4.2 Use description

##### Use 2 - Teat disinfection, Ready-to-use spray products applied manually

Product type

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

Teat disinfectant

**Target organism(s) (including development stage)**

Scientific name:  
Common name: Bacteria  
Development stage:

Scientific name:  
Common name: Yeasts  
Development stage:

Scientific name:  
Common name: Viruses  
Development stage:

**Field(s) of use**

Indoor

The product is intended for post-milking teat disinfection. The product is applied directly after milking on the teats of lactating animals.

**Application method(s)**

Method: Post-milking teat disinfection of udder teats with ready-to-use products.  
Detailed description:  
The product is applied manually after milking on the teats by spraying using a spray container.

**Application rate(s) and frequencies**

Application Rate: ca 5 ml per cow; ca 2.5 ml per sheep or goat  
Dilution (%): 0%  
Number and timing of application:  
To be applied after milking, 2 times per day. The products can be used all year during the lactation period

**Category(ies) of users**

Professional

**Pack sizes and packaging material**

Can, Plastic: HDPE , 5L  
Can, Plastic: HDPE , 10L  
Can, Plastic: HDPE , 20L  
Can, Plastic: HDPE , 60L  
Drum, Plastic: HDPE , 200L  
IBC, Plastic: HDPE , 1000L

**4.2.1 Use-specific instructions for use**

The product is a ready-to-use product and is used undiluted.

The product must be brought to a temperature above 20°C before use.

Directions for use:

For manual application: use a clean applicator.

Ensure that teats are clean before use. Apply the ready-to-use solution of the product on each teat immediately after milking:

1) MANUAL TRIGGER SPRAY: spray every teat 1 sec. with the product. Ensure that the teat is covered to at least three quarters length and replenish the spray container as necessary;

2) AUTOMATIC SPRAYER: spray every teat 1 sec. with the product.

Allow teats to dry after application during at least 5 min and keep the animals standing during this period.

#### 4.2.2 Use-specific risk mitigation measures

Use chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) during post-milking teat disinfection by manual spraying. See 5.2 for general instructions.

#### 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

There are no use specific instructions. See 5.3 for general instructions.

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

There are no use specific instructions. See 5.4 for general instructions.

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

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### 4.3 Use description

#### Use 3 - Teat disinfection, Ready-to-use dip or spray products applied automatically

<b>Product type</b>	PT03 - Veterinary hygiene (Disinfectants)
<b>Where relevant, an exact description of the authorised use</b>	Teat disinfectant
<b>Target organism(s) (including development stage)</b>	Scientific name: Common name: Bacteria Development stage:  Scientific name: Common name: Yeasts Development stage:  Scientific name: Common name: Viruses Development stage:

**Field(s) of use**

<b>Application method(s)</b>	Indoor  The product is intended for post-milking teat disinfection. The product is applied directly after milking on the teats of lactating animals.
	Method: Post-milking teat disinfection of udder teats with ready-to-use products. Detailed description: The product is applied automatically by milking machines after milking on the teats by integrated dipping or spraying device.
<b>Application rate(s) and frequencies</b>	Application Rate: ca. 5 ml per cow; ca. 2.5 ml per sheep or goat Dilution (%): 0% Number and timing of application: To be applied after milking, 3 times per day. The products can be used all year during the lactation period.
<b>Category(ies) of users</b>	Professional
<b>Pack sizes and packaging material</b>	Can, Plastic: HDPE , 5L Can, Plastic: HDPE , 10L Can, Plastic: HDPE , 20L Can, Plastic: HDPE , 60L Drum, Plastic: HDPE , 200L IBC, Plastic: HDPE , 1000L

#### 4.3.1 Use-specific instructions for use

The product is a ready-to-use product and is used undiluted.  
The product must be brought to a temperature above 20°C before use.

#### 4.3.2 Use-specific risk mitigation measures

There are no use specific risk mitigation measures. See 5.2 for general instructions.

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

There are no use specific instructions. See 5.3 for general instructions.

### 4.3.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

There are no use specific instructions. See 5.4 for general instructions.

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

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## 5. General directions for use of the meta SPC

### 5.1. Instructions for use

There are no general instructions for use. See the use specific instructions for use.

### 5.2. Risk mitigation measures

In case a combination of pre- and post-milking disinfection is necessary, using another 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

#### DIRECT/INDIRECT EFFECTS:

According to our experience and to the information provided to us, the product does not have any adverse effects if it is used and handled as specified.

#### FIRST AID MEASURES:

Eye contact: Rinse thoroughly with plenty of water for at least 15 minutes. If eye irritation persists: Get medical advice/attention.

Skin contact: Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes.

Ingestion: Wash out mouth with water. Seek medical advice immediately if symptoms occur and/or large quantities have been ingested.

Inhalation: Move to fresh air.

#### EMERGENCY MEASURES TO PROTECT THE ENVIRONMENT:

Prevent further leakage or spillage if safe to do so. Methods and materials for containment and clean-up: Dam up. Soak up with inert absorbent material. Prevent product from entering drains. Keep in suitable and closed containers for disposal.

#### 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.

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

Storage: Store upright in the tightly closed original container. Protect from direct light, temperatures above 30°C and frost.

Shelf-life: 1 year

#### 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

<b>Trade name(s)</b>	Iobac RTU	Market area: BE
	Proactive	Market area: IT
<b>Authorisation number</b> <small>(R4BP 3 asset reference number - National Authorisation)</small>	MT-0013584-0010 1-7	

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<b>Common name</b>	<b>IUPAC name</b>	<b>Function</b>	<b>CAS number</b>	<b>EC number</b>	<b>Content (%)</b>
Iodine		Active Substance	7553-56-2	231-442-4	0,15
Sodium iodide		Non-active substance	7681-82-5	231-679-3	0,06

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