

# Summary of product characteristics for a biocidal product family

**Family name:** Teat disinfection biocidal product family

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

**Authorisation number:** LV/2019/MR/016

**R4BP 3 asset reference number:** LV-0013292-0000

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6. Other information

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

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## Part I.- First information level

### 1. Administrative information

#### 1.1. Family name

Teat disinfection biocidal product family

#### 1.2. Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

#### 1.3. Authorisation holder

##### Name and address of the authorisation holder

Name	Evans Vanodine Europe
Address	6-9 Trinity Street D02 EY47 Dublin 2 Ireland

##### Authorisation number

LV/2019/MR/016

##### R4BP 3 asset reference number

LV-0013292-0000

##### Date of the authorisation

12/12/2019

##### Expiry date of the authorisation

19/03/2029

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

##### Name of the manufacturer

Evans Vanodine International

##### Address of the manufacturer

Brierley Road, Walton Summit PR5 8AH Preston, Lancashire United Kingdom

##### Location of manufacturing sites

Brierley Road, Walton Summit PR58AH Preston, Lancashire United Kingdom

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

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

<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>	Los Militares 4290, Piso 4 Las Condes Santiago Chile
<b>Location of manufacturing sites</b>	Nueva Victoria Plant Pedro de Valdivia Plant Northern Chile Chile

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

<b>Active substance</b>	1319 - Iodine
<b>Name of the manufacturer</b>	ISE Chemical Corporation
<b>Address of the manufacturer</b>	Kitaimaizumi 3695 - Oamishirasato City Chiba Japan
<b>Location of manufacturing sites</b>	Shirasato Plant - - 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 (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,112 - 2,346
Alcohol Ethoxylate	C13-15 Alcohol Ethoxylate (11EO)	Non-active substance	157627-86-6	500-337-8	0,38 - 19,993

## 2.2. Type(s) of formulation

SL - Soluble concentrate

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 (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,112 - 0,12

Alcohol Ethoxylate	C13-15 Alcohol Ethoxylate (11EO)	Non-active substance	157627-86-6	500-337-8	0,71 - 1,19
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## 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 - Pre-Milking

**Product type**

PT03 - Veterinary hygiene (Disinfectants)

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

DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection products for milkable animals (cows, buffaloes, sheep, goats) for use before milking.

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

Scientific name: bacteria  
Common name: bacteria  
Development stage: N/A

Scientific name: Yeasts  
Common name: Yeasts  
Development stage: N/A

**Field(s) of use**

Indoor

Indoor use – Teats of lactating animals.

**Application method(s)**

Method: Manual dipping/foaming  
Detailed description:  
Pre-milking application  
Apply before each milking every day (1-3 times a day). For manual application ensure full teat is covered for minimum contact time of 60 seconds.  
1. Manual dipping/foaming:  
a. Dipping



	<p>cows and buffaloes: 10 ml/animal per treatment  sheep: 5 ml/animal per treatment  goats: 6 ml/animal per treatment</p> <p>b. Foaming  cows and buffaloes: 5 ml/animal per treatment  sheep: 2.5 ml/animal per treatment  goats: 3 ml/animal per treatment</p> <p>Method: Manual spraying using and electronic sprayer  Detailed description:  Pre-milking application  Apply before each milking every day (1-3 times a day). For manual application ensure full teat is covered for minimum contact time of 60 seconds.</p> <p>2. Manual Spraying using an Electronic Sprayer:  cows and buffaloes: 10-15 ml/animal per treatment  sheep: 5-7.5 ml/animal per treatment  goats: 7-10 ml/animal per treatment</p>
<p><b>Application rate(s) and frequencies</b></p>	<p>Application Rate: see above  Dilution (%):  Number and timing of application:  see above</p> <p>Application Rate: see above  Dilution (%):  Number and timing of application:  see above</p>
<p><b>Category(ies) of users</b></p>	<p>Trained professional  Professional</p>
<p><b>Pack sizes and packaging material</b></p>	<p>Bottle/Pack (HDPE) 5 – 25L  Drum (HDPE) 200L  IBC (HDPE) 1000L</p>

**4.1.1 Use-specific instructions for use**

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#### 4.1.2 Use-specific risk mitigation measures

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#### 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

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

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

#### 5.1. Instructions for use

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

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

Use undiluted.  
Ensure udder and teats are clean and dry before using this product.

1. Manual dipping/foaming  
Fill teat cup  $\frac{2}{3}$  full with product. Dip the teats of each cow, making sure that the full length of the teat is immersed. Allow at least 60 seconds contact time, then using a single service paper towel, wipe and dry the teats thoroughly.  
Top up with fresh solution as required.  
Empty and wash out cups with water after use.

2. Manual spraying using an electronic sprayer  
Before milking, spray the teats of each cow with product. Ensure the spray covers the entire surface of all teats. Leave the product on the teats for at least 60 seconds. Then wipe and dry the teats thoroughly using a single service paper towel.

#### 5.2. Risk mitigation measures

Keep out of reach of children.

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

For manual spraying using an electronic sprayer:

Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).

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

#### **Likely direct or indirect effects may include:**

- Irritation of the eyes.
- General discomfort if swallowed.

#### **First aid measures**

- **Inhalation:** Unlikely route of exposure as the product does not contain volatile substances. If spray/mist has been inhaled, move affected person to fresh air and keep warm and at rest in a position comfortable for breathing.
- **Ingestion:** Do not induce vomiting. Give plenty of water to drink. Get medical attention if any discomfort continues.
- **Skin contact:** Wash with plenty of water.
- **Eye contact:** Rinse immediately with plenty of water. Get medical attention promptly if symptoms occur after washing.

**NEVER LEAVE AN AFFECTED INDIVIDUAL UNATTENDED**

#### **Advice for medical and healthcare personnel:**

- Provide symptomatic and supportive treatment.

**WHEN ASKING FOR MEDICAL ADVICE KEEP PACKAGING OR LABEL AT HAND AND CALL YOUR LOCAL POISON CONTROL CENTER ( [INSERT LOCAL NUMBER HERE].**

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

At the end of the treatment, dispose unused product, the packaging and any contaminated materials 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.  
Avoid release to the environment.

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

Shelf-life 24 months.

Store in original sealed container and protect from extremes of temperature.

Protect from direct sunlight.

Protect from frost, if contents freeze, they must be thawed and thoroughly mixed before use.

Store in a cool, well-ventilated place.

Store below 25°C

### 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>	Pre-Dip	Market area: LV
<b>Authorisation number</b> <small>(R4BP 3 asset reference number - National Authorisation)</small>	LV-0013292-0001 1-1	

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Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,112
Alcohol Ethoxylate	C13-15 Alcohol Ethoxylate (11EO)	Non-active substance	157627-86-6	500-337-8	0,953

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## 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 (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,25 - 0,33
Alcohol Ethoxylate	C13-15 Alcohol Ethoxylate (11EO)	Non-active substance	157627-86-6	500-337-8	0,38 - 0,63

### 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.

Dispose of contents to in accordance with local/regional/national regulations.

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

### 4.1 Use description

Use 1 - Post-Milking

Product type

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection products for milkable animals (cows, buffaloes, sheep, goats) for use after milking.

Target organism(s) (including development stage)

Scientific name: bacteria  
Common name: bacteria  
Development stage: N/A

Scientific name: yeasts  
Common name: yeasts

Development stage: N/A

**Field(s) of use**

Indoor

Indoor use – Teats of lactating animals.

**Application method(s)**

Method: manual dipping

Detailed description:

Post-milking application

Apply after each milking every day (1-3 times a day). For manual application ensure full teat is covered and the animal stands for 5 minutes.

1. Manual dipping

cows and buffaloes: 10 ml/animal per treatment

sheep: 5 ml/animal per treatment

goats: 6 ml/animal per treatment

Method: Manual spraying using an electronic sprayer

Detailed description:

Post-milking application

Apply after each milking every day (1-3 times a day). For manual application ensure full teat is covered and the animal stands for 5 minutes.

2. Manual Spraying using an electronic spray:

cows and buffaloes: 10-15 ml/animal per treatment

sheep: 5-7.5 ml/animal per treatment

goats: 7-10 ml/animal per treatment

Method: automated dipping

Detailed description:

Post-milking application

Apply after each milking every day (1-3 times a day).

Automated dipping:

cows and buffaloes: 10 ml/animal per treatment

sheep: 5 ml/animal per treatment

goats: 6 ml/animal per treatment

Method: Automated spraying using a robot

Detailed description:

Post-milking application

Apply after each milking every day (1-3 times a day).

Automated spraying using a robot:

cows and buffaloes: 10-15 ml/animal per treatment

sheep: 5-7.5 ml/animal per treatment

goats: 7-10 ml/animal per treatment

**Application rate(s) and frequencies**

Application Rate: see above

Dilution (%):

Number and timing of application:

see above

Application Rate: see above

Dilution (%):

Number and timing of application:

	<p>see above</p> <p>Application Rate: As above Dilution (%): Number and timing of application: As above</p> <p>Application Rate: As above Dilution (%): Number and timing of application: As Above</p>
<b>Category(ies) of users</b>	<p>Trained professional</p> <p>Professional</p>
<b>Pack sizes and packaging material</b>	<p>Bottle/Pack (HDPE) 5 – 25L Drum (HDPE) 200L IBC (HDPE) 1000L</p>

**4.1.1 Use-specific instructions for use**

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**4.1.2 Use-specific risk mitigation measures**

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**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**

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

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

#### 5.1. Instructions for use

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

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

To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).

Use undiluted.

Ensure udder and teats are clean and dry before using this product.

1. Manual dipping/

Fill teat cup  $\frac{2}{3}$  full with product. Dip the teats of each cow immediately after each has been milked, making sure that the full length of the teat is immersed.

Top up with fresh solution as required.

Empty and wash out cups with water after milking.

2. Manual spraying using an electronic sprayer

Immediately after milking, spray the teats of each cow with product.

Ensure the spray covers the entire surface of all teats.

3. Automated dipping

The teats are coated with product when the teat cup is withdrawn by the Automatic Cluster Removal (ACR). The whole process is automated.

4. Automated spraying by robot

The teats are cleaned by robot with automatic brushes. After robotic milking, of the product is sprayed automatically onto teats from a cluster arm. Rinsing of the sprayer is automatic.

#### 5.2. Risk mitigation measures

Keep out of reach of children.

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.

For manual spraying using an electronic sprayer:

Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).

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



**Likely direct or indirect effects may include:**

- Irritation of the eyes.
- General discomfort if swallowed.

**First aid measures**

- **Inhalation:** Unlikely route of exposure as the product does not contain volatile substances. If spray/mist has been inhaled, move affected person to fresh air and keep warm and at rest in a position comfortable for breathing.
- **Ingestion:** Do not induce vomiting. Give plenty of water to drink. Get medical attention if any discomfort continues.
- **Skin contact:** Wash with plenty of water.
- **Eye contact:** Rinse immediately with plenty of water. Get medical attention promptly if symptoms occur after washing.

**NEVER LEAVE AN AFFECTED INDIVIDUAL UNATTENDED**

**Advice for medical and healthcare personnel:**

- Provide symptomatic and supportive treatment.

**WHEN ASKING FOR MEDICAL ADVICE KEEP PACKAGING OR LABEL AT HAND AND CALL YOUR LOCAL POISON CONTROL CENTER ( [INSERT LOCAL NUMBER HERE].**

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

At the end of the treatment, dispose unused product, the packaging and any contaminated materials 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

Shelf-life 18 months.  
Store in original sealed container and protect from extremes of temperature.  
Protect from direct sunlight.  
Protect from frost, if contents freeze, they must be thawed and thoroughly mixed before use.  
Store in a cool, well-ventilated place.  
Store below 25°C

## 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)**

PV-Pro

Market area: LV

**Authorisation number**

(R4BP 3 asset reference number - National Authorisation)

LV-0013292-0002 1-2

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Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,291
Alcohol Ethoxylate	C13-15 Alcohol Ethoxylate (11EO)	Non-active substance	157627-86-6	500-337-8	0,5

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**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 (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,269 - 0,5245
Alcohol Ethoxylate	C13-15 Alcohol Ethoxylate (11EO)	Non-active substance	157627-86-6	500-337-8	2,304 - 4,4702

## 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.

Dispose of contents to in accordance with local/regional/national regulations.

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

### 4.1 Use description

#### Use 1 - Post-milking - manual dipping

Product type

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection products for milkable animals (cows, buffaloes, sheep, goats) for use after milking.

Target organism(s) (including development stage)

Scientific name: bacteria  
Common name: bacteria  
Development stage: N/A

Scientific name: yeasts  
Common name: yeasts  
Development stage: N/A

<b>Field(s) of use</b>	Indoor  Indoor use – Teats of lactating animals.
<b>Application method(s)</b>	Method: Manual dipping Detailed description: Post-milking application Apply after each milking every day (1-3 times a day).For manual application ensure full teat is covered and the animal stands for 5 minutes. Manual dipping •cows and buffaloes: 10 ml/animal per treatment •sheep: 5 ml/animal per treatment •goats: 6 ml/animal per treatment
<b>Application rate(s) and frequencies</b>	Application Rate: see above Dilution (%): Number and timing of application: see above
<b>Category(ies) of users</b>	Trained professional  Professional
<b>Pack sizes and packaging material</b>	Bottle/Pack (HDPE) 5 – 25L Drum (HDPE) 200L IBC (HDPE) 1000L

#### 4.1.1 Use-specific instructions for use

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#### 4.1.2 Use-specific risk mitigation measures

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#### 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

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

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

#### 5.1. Instructions for use

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

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

To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).

Use undiluted.

Ensure udder and teats are clean and dry before using this product.

##### 1. Manual dipping

Fill teat cup  $\frac{2}{3}$  full with product. Dip the teats of each cow immediately after each has been milked, making sure that the full length of the teat is immersed.

Top up with fresh solution as required.

Empty and wash out cups with water after milking.

#### 5.2. Risk mitigation measures

Keep out of reach of children.

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

**Likely direct or indirect effects may include:**

- Irritation of the eyes.
- General discomfort if swallowed.

**First aid measures**

- **Inhalation:** Unlikely route of exposure as the product does not contain volatile substances. If spray/mist has been inhaled, move affected person to fresh air and keep warm and at rest in a position comfortable for breathing.
- **Ingestion:** Do not induce vomiting. Give plenty of water to drink. Get medical attention if any discomfort continues.
- **Skin contact :** Wash with plenty of water.
- **Eye contact:** Rinse immediately with plenty of water. Get medical attention promptly if symptoms occur after washing.

**NEVER LEAVE AN AFFECTED INDIVIDUAL UNATTENDED**

**Advice for medical and healthcare personnel:**

- Provide symptomatic and supportive treatment .

**WHEN ASKING FOR MEDICAL ADVICE KEEP PACKAGING OR LABEL AT HAND AND CALL YOUR LOCAL POISON CONTROL CENTER ( [INSERT LOCAL NUMBER HERE].**

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

At the end of the treatment, dispose unused product, the packaging and any contaminated materials 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

Shelf-life 24 months.  
Store in original sealed container and protect from extremes of temperature.  
Protect from direct sunlight.  
Protect from frost, if contents freeze, they must be thawed and thoroughly mixed before use.  
Store in a cool, well-ventilated place.  
Store below 25°C.

## 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)

Masofilm

Market area: LV

### Authorisation number

(R4BP 3 asset reference number - National Authorisation)

LV-0013292-0003 1-3

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Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,269
Alcohol Ethoxylate	C13-15 Alcohol Ethoxylate (11EO)	Non-active substance	157627-86-6	500-337-8	2,304

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### Trade name(s)

Visqodip

Market area: LV

### Authorisation number

(R4BP 3 asset reference number - National Authorisation)

LV-0013292-0004 1-3

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Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,5245
Alcohol Ethoxylate	C13-15 Alcohol Ethoxylate (11EO)	Non-active substance	157627-86-6	500-337-8	4,4702

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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 (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,272 - 0,273
Alcohol Ethoxylate	C13-15 Alcohol Ethoxylate (11EO)	Non-active substance	157627-86-6	500-337-8	2,31 - 2,31

### 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

<b>Hazard statements</b>	Harmful to aquatic life with long lasting effects.
<b>Precautionary statements</b>	Avoid release to the environment. Dispose of contents to in accordance with local/regional/national regulations.

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

#### 4.1 Use description

##### Use 1 - Pre-milking

<b>Product type</b>	PT03 - Veterinary hygiene (Disinfectants)
<b>Where relevant, an exact description of the authorised use</b>	DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection products for milkable animals (cows, buffaloes, sheep, goats) for use before milking.
<b>Target organism(s) (including development stage)</b>	Scientific name: bacteria Common name: bacteria Development stage: N/A  Scientific name: yeasts Common name: yeasts Development stage: N/A
<b>Field(s) of use</b>	Indoor  Indoor use – Teats of lactating animals.
<b>Application method(s)</b>	Method: Manual dipping/foaming Detailed description: Pre-milking application Apply before each milking every day (1-3 times a day). For manual application ensure full teat is covered for minimum contact time of 60 seconds. 1. Manual dipping/foaming: a. Dipping cows and buffaloes: 10 ml/animal per treatment sheep: 5 ml/animal per treatment goats: 6 ml/animal per treatment b. Foaming cows and buffaloes: 5 ml/animal per treatment sheep: 2.5 ml/animal per treatment goats: 3 ml/animal per treatment  Method: Manual spraying using an electronic sprayer

	<p>Detailed description: Pre-milking application Apply before each milking every day (1-3 times a day). For manual application ensure full teat is covered for minimum contact time of 60 seconds.</p> <p>2. Manual Spraying using an Electronic Sprayer: cows and buffaloes: 10-15 ml/animal per treatment sheep: 5-7.5 ml/animal per treatment goats: 7-10 ml/animal per treatment</p>
<p><b>Application rate(s) and frequencies</b></p>	<p>Application Rate: see above Dilution (%): Number and timing of application: see above</p> <p>Application Rate: see above Dilution (%): Number and timing of application: see above</p>
<p><b>Category(ies) of users</b></p>	<p>Trained professional  Professional</p>
<p><b>Pack sizes and packaging material</b></p>	<p>Bottle/Pack (HDPE) 5 – 25L Drum (HDPE) 200L IBC (HDPE) 1000L</p>

#### 4.1.1 Use-specific instructions for use

<p>The product must be brought to a temperature above 20°C before use. The use of a dosing pump for filling the product into the application equipment is recommended.</p> <p>Use undiluted. Ensure udder and teats are clean and dry before using this product.</p> <p>1. <u>Manual dipping/foaming</u> Fill teat cup ¾ full with product. Dip the teats of each cow before milking, making sure that the full length of the teat is immersed. Allow at least 60 seconds contact time, then using a single service paper towel, wipe and dry the teats thoroughly. Top up with fresh solution as required. Empty and wash out cups with water after use.</p> <p>2. <u>Manual spraying using an electronic sprayer</u></p>
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Before milking, spray the teats of each cow with product. Ensure the spray covers the entire surface of all teats. Leave the product on the teats for at least 60 seconds. Then wipe and dry the teats thoroughly using a single service paper towel.

#### 4.1.2 Use-specific risk mitigation measures

Keep out of reach of children.

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

For manual spraying using an electronic sprayer:

Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).

#### 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

-

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

-

#### 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 - Post-Milking

##### Product type

PT03 - Veterinary hygiene (Disinfectants)

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

DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection products for milkable animals (cows, buffaloes, sheep, goats) for use after milking.

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

Scientific name: bacteria  
Common name: bacteria  
Development stage: N/A

Scientific name: yeasts  
Common name: yeasts  
Development stage: N/A

**Field(s) of use**

Indoor  
Indoor use – Teats of lactating animals.

**Application method(s)**

Method: Manual dipping/foaming  
Detailed description:  
Post-milking application  
Apply after each milking every day (1-3 times a day). For manual application ensure full teat is covered and the animal stands for 5 minutes.

1. Manual dipping/foaming:  
a. Dipping

- cows and buffaloes: 10 ml/animal per treatment
- sheep: 5 ml/animal per treatment
- goats: 6 ml/animal per treatment

b. Foaming

- cows and buffaloes: 5 ml/animal per treatment
- sheep: 2.5 ml/animal per treatment
- goats: 3 ml/animal per treatment

Method: Manual spraying using an electronic sprayer  
Detailed description:  
Post-milking application  
Apply after each milking every day (1-3 times a day). For manual application ensure full teat is covered and the animal stands for 5 minutes.

2. Manual Spraying using an electronic spray:  
cows and buffaloes: 10-15 ml/animal per treatment  
sheep: 5-7.5 ml/animal per treatment  
goats: 7-10 ml/animal per treatment

Method: automated dipping  
Detailed description:  
Post-milking application  
Apply after each milking every day (1-3 times a day).  
Automated dipping:  
cows and buffaloes: 10 ml/animal per treatment  
sheep: 5 ml/animal per treatment  
goats: 6 ml/animal per treatment

Method: Automated spraying using a robot  
Detailed description:  
Post-milking application  
Apply after each milking every day (1-3 times a day).  
Automated spraying using a robot:  
cows and buffaloes: 10-15 ml/animal per treatment  
sheep: 5-7.5 ml/animal per treatment  
goats: 7-10 ml/animal per treatment

**Application rate(s) and frequencies**

Application Rate: see above Dilution (%): Number and timing of application: see above
Application Rate: see above Dilution (%): Number and timing of application: see above
Application Rate: As above Dilution (%): Number and timing of application: As above
Application Rate: As above Dilution (%): Number and timing of application: As Above

**Category(ies) of users**

Trained professional
Professional

**Pack sizes and packaging material**

Bottle/Pack (HDPE) 5 – 25L Drum (HDPE) 200L IBC (HDPE) 1000L
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**4.2.1 Use-specific instructions for use**

<p>The product must be brought to a temperature above 20°C before use.</p> <p>The use of a dosing pump for filling the product into the application equipment is recommended.</p> <p>To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).</p> <p>Use undiluted. Ensure udder and teats are clean and dry before using this product.</p> <p><u>1. Manual dipping/foaming</u></p> <p>Fill teat cup 2/3 full with product. Dip the teats of each cow immediately after each has been milked, making sure that the full length of the teat is immersed. Top up with fresh solution as required. Empty and wash out cups with water after milking.</p>
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2. Manual spraying using an electronic sprayer  
Immediately after milking, spray the teats of each cow with product. Ensure the spray covers the entire surface of all teats.
3. Automated dipping  
The teats are coated with product when the teat cup is withdrawn by the Automatic Cluster Removal (ACR). The whole process is automated.
4. Automated spraying by robot  
The teats are cleaned by robot with automatic brushes. After robotic milking the product is sprayed automatically onto teats from a cluster arm. Rinsing of the sprayer is automatic.

#### 4.2.2 Use-specific risk mitigation measures

Keep out of reach of children.

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.

For manual spraying using an electronic sprayer: Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).

#### 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

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

-

#### 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 - Pre- and Post-milking

##### Product type

PT03 - Veterinary hygiene (Disinfectants)

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

DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection products for milkable animals (cows, buffaloes, sheep, goats) for use before and after milking.

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

Scientific name: bacteria  
Common name: bacteria  
Development stage: N/A

Scientific name: yeasts  
Common name: yeasts  
Development stage: N/A

**Field(s) of use**

Indoor

Indoor use – Teats of lactating animals.

**Application method(s)**

Method: Manual dipping/foaming  
Detailed description:

Pre- and Post-milking application

Apply before and after each milking every day (2-6 times a day). For manual application, ensure the full teat is covered with a contact time of 60 seconds for pre-milking and ensure that the full teat is covered and the animals are left standing for 5 minutes post-milking.

1. Manual dipping/foaming:

a. Dipping

- cows and buffaloes: 10 ml/animal per treatment

- sheep: 5 ml/animal per treatment
- goats: 6 ml/animal per treatment

b. Foaming

- cows and buffaloes: 5 ml/animal per treatment
- sheep: 2.5 ml/animal per treatment
- goats: 3 ml/animal per treatment

Method: Manual spraying using an electronic sprayer

Detailed description:

Pre- and Post-milking application

Apply before and after each milking every day (2-6 times a day). For manual application, ensure the full teat is covered with a contact time of 60 seconds for pre-milking and ensure that the full teat is covered and the animals are left standing for 5 minutes post-milking.

2. Manual Spraying using an electronic spray:

- cows and buffaloes: 10-15 ml/animal per treatment
- sheep: 5-7.5 ml/animal per treatment
- goats: 7- 10ml/animal per treatment

**Application rate(s) and frequencies**

Application Rate: see above

Dilution (%):

Number and timing of application:  
see above

	<p>Application Rate: see above  Dilution (%):  Number and timing of application:  see above</p>
<b>Category(ies) of users</b>	<p>Trained professional  Professional</p>
<b>Pack sizes and packaging material</b>	<p>Bottle/Pack (HDPE) 5 – 25L  Drum (HDPE) 200L  IBC (HDPE) 1000L</p>

#### 4.3.1 Use-specific instructions for use

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

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

Post-milking: To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).

Use undiluted.

Ensure udder and teats are clean and dry before using this product.

1. Manual dipping/foaming

Fill teat cup  $\frac{2}{3}$  full with product. Dip the teats of each cow before milking, making sure that the full length of the teat is immersed.

Allow at least 60 seconds contact time, then using a single service paper towel, wipe and dry the teats thoroughly.

Dip the teats of each cow immediately after each has been milked, making sure that the full length of the teat is immersed.

Top up with fresh solution as required.

Empty and wash out cups with water after use.

2. Manual spraying using an electronic sprayer

Before milking, spray the teats of each cow with product. Ensure the spray covers the entire surface of all teats. Leave the product on the teats for at least 60 seconds. Then wipe and dry the teats thoroughly using a single service paper towel.

Immediately after milking, spray the teats of each cow with product. Ensure the spray covers the entire surface of all teats.

#### 4.3.2 Use-specific risk mitigation measures

Keep out of reach of children.



For manual dipping/foaming:  
Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).

For manual spraying using an electronic sprayer:  
Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).  
Wear Suitable protective footwear (EN 13832) when applying this product.  
A protective coverall (at least type 6, EN 13034) shall be worn.

#### **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**

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

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#### **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**

See use specific instructions for use

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

See use specific RMM

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

**Likely direct or indirect effects may include:**

- Irritation of the eyes.
- General discomfort if swallowed.

**First aid measures**

- **Inhalation:** Unlikely route of exposure as the product does not contain volatile substances. If spray/mist has been inhaled, move affected person to fresh air and keep warm and at rest in a position comfortable for breathing.
- **Ingestion:** Do not induce vomiting. Give plenty of water to drink. Get medical attention if any discomfort continues.
- **Skin contact:** Wash with plenty of water.
- **Eye contact:** Rinse immediately with plenty of water. Get medical attention promptly if symptoms occur after washing.

**NEVER LEAVE AN AFFECTED INDIVIDUAL UNATTENDED**

**Advice for medical and healthcare personnel:**

- Provide symptomatic and supportive treatment.

**WHEN ASKING FOR MEDICAL ADVICE KEEP PACKAGING OR LABEL AT HAND AND CALL YOUR LOCAL POISON CONTROL CENTER ( [INSERT LOCAL NUMBER HERE].**

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

At the end of the treatment, dispose unused product, the packaging and any contaminated materials 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

Shelf-life 24 months.  
Store in original sealed container and protect from extremes of temperature.  
Protect from direct sunlight.  
Protect from frost, if contents freeze, they must be thawed and thoroughly mixed before use.  
Store in a cool, well-ventilated place.  
Store below 25°C.

## 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)**

Allantocare	Market area: LV
Pre-Post Gold	Market area: LV

**Authorisation number**

(R4BP 3 asset reference number - National Authorisation)

LV-0013292-0005 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	0,272
Alcohol Ethoxylate	C13-15 Alcohol Ethoxylate (11EO)	Non-active substance	157627-86-6	500-337-8	2,31

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**Trade name(s)**

Contact	Market area: LV
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**Authorisation number**

(R4BP 3 asset reference number - National Authorisation)

LV-0013292-0006 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	0,273
Alcohol Ethoxylate	C13-15 Alcohol Ethoxylate (11EO)	Non-active substance	157627-86-6	500-337-8	2,31

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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 (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,526 - 0,527
Alcohol Ethoxylate	C13-15 Alcohol Ethoxylate (11EO)	Non-active substance	157627-86-6	500-337-8	4,479 - 4,492

### 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.

Dispose of contents to in accordance with local/regional/national regulations.

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

#### 4.1 Use description

##### Use 1 - Post-Milking

#### Product type

PT03 - Veterinary hygiene (Disinfectants)

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

DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection products for milkable animals (cows, buffaloes, sheep, goats) for use after milking.

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

Scientific name: bacteria  
Common name: bacteria  
Development stage: N/A

Scientific name: yeasts  
Common name: yeasts  
Development stage: N/A

#### Field(s) of use

Indoor

Indoor use – Teats of lactating animals.

#### Application method(s)

Method: Manual dipping/foaming

Detailed description:

Post-milking application

Apply after each milking every day (1-3 times a day). For manual application ensure full teat is covered and the animal stands for 5 minutes.

1. Manual dipping/foaming

a. Dipping

cows and buffaloes: 10 ml/animal per treatment

sheep: 5 ml/animal per treatment

goats: 6 ml/animal per treatment

b. Foaming

- cows and buffaloes: 5 ml/animal per treatment

- sheep: 2.5 ml/animal per treatment

- goats: 3 ml/animal per treatment

Method: Manual spraying using an electronic sprayer

Detailed description:

**Application rate(s) and frequencies**

Post-milking application  
 Apply after each milking every day (1-3 times a day). For manual application ensure full teat is covered and the animal stands for 5 minutes.

2. Manual Spraying using an electronic spray:  
 cows and buffaloes: 10-15 ml/animal per treatment  
 sheep: 5-7.5 ml/animal per treatment  
 goats: 7-10 ml/animal per treatment

Method: automated dipping  
 Detailed description:  
 Post-milking application  
 Apply after each milking every day (1-3 times a day).

3 Automated dipping:  
 cows and buffaloes: 10 ml/animal per treatment  
 sheep: 5 ml/animal per treatment  
 goats: 6 ml/animal per treatment

Method: Automated spraying using a robot  
 Detailed description:  
 Post-milking application  
 Apply after each milking every day (1-3 times a day).  
 Automated spraying using a robot:  
 cows and buffaloes: 10-15 ml/animal per treatment  
 sheep: 5-7.5 ml/animal per treatment  
 goats: 7-10 ml/animal per treatment

Application Rate: see above  
 Dilution (%):  
 Number and timing of application:  
 see above

Application Rate: see above  
 Dilution (%):  
 Number and timing of application:  
 see above

Application Rate: As above  
 Dilution (%):  
 Number and timing of application:  
 As above

Application Rate: As above  
 Dilution (%):  
 Number and timing of application:  
 As Above

**Category(ies) of users**

Trained professional  
 Professional

**Pack sizes and packaging material**

Bottle/Pack (HDPE) 5 – 25L  
 Drum (HDPE) 200L

IBC (HDPE) 1000L

#### 4.1.1 Use-specific instructions for use

-

#### 4.1.2 Use-specific risk mitigation measures

-

#### 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

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

-

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

#### 5.1. Instructions for use

The product must be brought to a temperature above 20°C before use.  
The use of a dosing pump for filling the product into the application equipment is recommended.

To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).  
Use undiluted.

Ensure udder and teats are clean and dry before using this product.

1. Manual dipping/foaming

Fill teat cup 2/3 full with product. Dip the teats of each cow immediately after each has been milked, making sure that the full length of the teat is immersed.

Top up with fresh solution as required.

Empty and wash out cups with water after milking.

2. Manual spraying using an electronic sprayer

Immediately after milking, spray the teats of each cow with product. Ensure the spray covers the entire surface of all teats.

3. Automated dipping

The teats are coated with product when the teat cup is withdrawn by the Automatic Cluster Removal (ACR). The whole process is automated.

4. Automated spraying by robot

The teats are cleaned by robot with automatic brushes. After robotic milking, of the product is sprayed automatically onto teats from a cluster arm. Rinsing of the sprayer is automatic.

## 5.2. Risk mitigation measures

Keep out of reach of children.

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.

For manual spraying using an electronic sprayer:

Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).

Wear Suitable protective footwear (EN 13832) when applying this product.

A protective coverall (at least type 6, EN 13034) shall be worn.

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

**Likely direct or indirect effects may include:**

- Irritation of the eyes.
- General discomfort if swallowed.

**First aid measures**

- **Inhalation:** Unlikely route of exposure as the product does not contain volatile substances. If spray/mist has been inhaled, move affected person to fresh air and keep warm and at rest in a position comfortable for breathing.
- **Ingestion:** Do not induce vomiting. Give plenty of water to drink. Get medical attention if any discomfort continues.
- **Skin contact:** Wash with plenty of water.
- **Eye contact:** Rinse immediately with plenty of water. Get medical attention promptly if symptoms occur after washing.

**NEVER LEAVE AN AFFECTED INDIVIDUAL UNATTENDED**

**Advice for medical and healthcare personnel:**

- Provide symptomatic and supportive treatment.

**WHEN ASKING FOR MEDICAL ADVICE KEEP PACKAGING OR LABEL AT HAND AND CALL YOUR LOCAL POISON CONTROL CENTER ( [INSERT LOCAL NUMBER HERE].**



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

At the end of the treatment, dispose unused product, the packaging and any contaminated materials 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**

Shelf-life 24 months.  
Store in original sealed container and protect from extremes of temperature.  
Protect from direct sunlight.  
Protect from frost, if contents freeze, they must be thawed and thoroughly mixed before use.  
Store in a cool, well-ventilated place.  
Store below 25°C.

**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>	Masocare Extra	Market area: LV
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**Authorisation number**

(R4BP 3 asset reference number - National  
Authorisation)

LV-0013292-0007 1-5

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Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,526
Alcohol Ethoxylate	C13-15 Alcohol Ethoxylate (11EO)	Non-active substance	157627-86-6	500-337-8	4,479

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**Trade name(s)**

Masocare RTU

Market area: LV

**Authorisation number**

(R4BP 3 asset reference number - National  
Authorisation)

LV-0013292-0008 1-5

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Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,526
Alcohol Ethoxylate	C13-15 Alcohol Ethoxylate (11EO)	Non-active substance	157627-86-6	500-337-8	4,479

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**Trade name(s)**

Masodine RTU

Market area: LV

**Authorisation number**

(R4BP 3 asset reference number - National Authorisation)

LV-0013292-0009 1-5

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Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,527
Alcohol Ethoxylate	C13-15 Alcohol Ethoxylate (11EO)	Non-active substance	157627-86-6	500-337-8	4,492

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

Meta SPC 6a

**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	0,881 - 1,191
Alcohol Ethoxylate	C13-15 Alcohol Ethoxylate (11EO)	Non-active substance	157627-86-6	500-337-8	7,448 - 10,076

## 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

Harmful to aquatic life with long lasting effects.

Precautionary statements

Avoid release to the environment.

Dispose of contents to in accordance with local/regional/national regulations.

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

### 4.1 Use description

#### Use 1 - Pre-milking

Product type

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection products for milkable animals (cows, buffaloes, sheep, goats) for use before milking.

Target organism(s) (including development stage)

Scientific name: bacteria  
Common name: bacteria  
Development stage: N/A

Scientific name: yeasts  
Common name: yeasts  
Development stage: N/A

Field(s) of use

Indoor

Indoor use – Teats of lactating animals.

**Application method(s)**

Method: Manual dipping/foaming  
Detailed description:  
Pre-milking application  
Apply before each milking every day (1-3 times a day). For manual application ensure full teat is covered for minimum contact time of 60 seconds.

1. Manual dipping/foaming:
  - a. Dipping  
cows and buffaloes: 10 ml/animal per treatment  
sheep: 5 ml/animal per treatment  
goats: 6 ml/animal per treatment
  - b. Foaming  
cows and buffaloes: 5 ml/animal per treatment  
sheep: 2.5 ml/animal per treatment  
goats: 3 ml/animal per treatment

Method: Manual spraying using an electronic sprayer  
Detailed description:  
Pre-milking application  
Before milking, spray the teats of each cow with product. Ensure the spray covers the entire surface of all teats. Leave the product on the teats for at least 60 seconds. Then wipe and dry the teats thoroughly using a single service paper towel.

2. Manual Spraying using an electronic spray:  
cows and buffaloes: 10-15 ml/animal per treatment  
sheep: 5-7.5 ml/animal per treatment  
goats: 7-10 ml/animal per treatment

**Application rate(s) and frequencies**

Application Rate: see above  
Dilution (%):  
Number and timing of application:  
see above

Application Rate: see above  
Dilution (%):  
Number and timing of application:  
see above

**Category(ies) of users**

Trained professional  
Professional

**Pack sizes and packaging material**

Bottle/Pack (HDPE) 5 – 25L  
Drum (HDPE) 200L  
IBC (HDPE) 1000L

#### 4.1.1 Use-specific instructions for use

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

This product requires dilution before use.

Ensure udder and teats are clean and dry before using this product.

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

Prepare a fresh solution daily.

Containers for dilution should be clean and suitable for use.

Mix 1 part product with 3 parts of clean water and mix well.

1. Manual dipping/foaming

Fill teat cup  $\frac{2}{3}$  full with diluted product.

Dip the teats of each cow before milking, making sure that the full length of the teat is immersed. Leave the product on the teats for at least 60 seconds. Then wipe and dry the teats thoroughly using a single service paper towel.

Top up with fresh solution as required.

Empty and wash out cups with water after use.

2. Manual spraying using an electronic sprayer

Before milking, spray the teats of each cow with diluted product. Ensure the spray covers the entire surface of all teats. Leave the product on the teats for at least 60 seconds. Then wipe and dry the teats thoroughly using a single service paper towel.

#### 4.1.2 Use-specific risk mitigation measures

Keep out of reach of children.

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

For manual spraying using an electronic sprayer:

Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).

#### 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

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

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#### 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 - Post-Milking

#### Product type

PT03 - Veterinary hygiene (Disinfectants)

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

DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection products for milkable animals (cows, buffaloes, sheep, goats) for use after milking.

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

Scientific name: bacteria  
Common name: bacteria  
Development stage: N/A

Scientific name: yeasts  
Common name: yeasts  
Development stage: N/A

#### Field(s) of use

Indoor

Indoor use – Teats of lactating animals.

#### Application method(s)

Method: Manual dipping/foaming  
Detailed description:

##### Post-milking application

Apply after each milking every day (1-3 times a day). For manual application ensure full teat is covered and the animal stands for 5 minutes.

1. Manual dipping/foaming:
  - a. Dipping
    - cows and buffaloes: 10 ml/animal per treatment
    - sheep: 5 ml/animal per treatment
    - goats: 6 ml/animal per treatment
  - b. Foaming
    - cows and buffaloes: 5 ml/animal per treatment
    - sheep: 2.5 ml/animal per treatment
    - goats: 3 ml/animal per treatment

Method: Manual spraying using an electronic sprayer

Detailed description:

##### Post-milking application

Apply after each milking every day (1-3 times a day). For manual application ensure full teat is covered and the animal stands for 5 minutes.

2. Manual Spraying using an electronic spray:
  - cows and buffaloes: 10-15 ml/animal per treatment

	<p>sheep: 5-7.5 ml/animal per treatment goats: 7-10 ml/animal per treatment</p> <p>Method: automated dipping Detailed description: Post-milking application Apply after each milking every day (1-3 times a day). Automated dipping: cows and buffaloes: 10 ml/animal per treatment sheep: 5 ml/animal per treatment goats: 6 ml/animal per treatment</p> <p>Method: Automated spraying using a robot Detailed description: Post-milking application Apply after each milking every day (1-3 times a day). Automated spraying using a robot: cows and buffaloes: 10-15 ml/animal per treatment sheep: 5-7.5 ml/animal per treatment goats: 7-10 ml/animal per treatment</p>
<p><b>Application rate(s) and frequencies</b></p>	<p>Application Rate: see above Dilution (%): Number and timing of application: see above</p> <p>Application Rate: see above Dilution (%): Number and timing of application: see above</p> <p>Application Rate: As above Dilution (%): Number and timing of application: As above</p> <p>Application Rate: As above Dilution (%): Number and timing of application: As Above</p>
<p><b>Category(ies) of users</b></p>	<p>Trained professional</p> <p>Professional</p>
<p><b>Pack sizes and packaging material</b></p>	<p>Bottle/Pack (HDPE) 5 – 25L Drum (HDPE) 200L IBC (HDPE) 1000L</p>



#### 4.2.1 Use-specific instructions for use

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

This product requires dilution before use.

Add 1 part product to 3 parts clean water and mix well.

Prepare a fresh solution daily.

Containers for dilution should be clean and suitable for use.

Ensure udder and teats are clean and dry before using this product.

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

To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).

1. Manual dipping/foaming

Fill teat cup  $\frac{2}{3}$  full with diluted product. Dip the teats of each cow immediately after each has been milked, making sure that the full length of the teat is immersed.

Top up with fresh solution as required.

Empty and wash out cups with water after milking.

2. Manual spraying using an electronic sprayer

Immediately after milking, spray the teats of each cow with diluted product.

Ensure the spray covers the entire surface of all teats.

3. Automated dipping

The teats are covered with diluted product when the teat cup is withdrawn by the Automatic Cluster Removal (ACR). The whole process is automated.

4. Automated spraying by robot

After robotic milking, the diluted product is sprayed automatically onto teats from a cluster arm. Rinsing of the sprayer is automatic.

#### 4.2.2 Use-specific risk mitigation measures

Keep out of reach of children.

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.

For manual spraying using an electronic sprayer: Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).

Wear Suitable protective footwear (EN 13832) when applying this product.

A protective coverall (at least type 6, EN 13034) shall be worn.

#### 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

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

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#### 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 - Pre- and Post-milking

##### Product type

PT03 - Veterinary hygiene (Disinfectants)

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

DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection products for milkable animals (cows, buffaloes, sheep, goats) for use before and after milking.

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

Scientific name: bacteria  
Common name: bacteria  
Development stage: N/A

Scientific name: yeasts  
Common name: yeasts  
Development stage: N/A

##### Field(s) of use

Indoor

Indoor use – Teats of lactating animals.

##### Application method(s)

Method: Manual dipping/foaming  
Detailed description:

##### Pre- and Post-milking application

Apply before and after each milking every day (up to 5 applications per day in total). For manual application, ensure the full teat is covered with a contact time of 60 seconds for pre-milking and ensure that the full teat is covered and the animals are left standing for 5 minutes post-milking.

##### 1. Manual dipping/foaming: a. Dipping

- cows and buffaloes: 10 ml/animal per treatment
- sheep: 5 ml/animal per treatment

- goats: 6 ml/animal per treatment
- b. Foaming
- cows and buffaloes: 5 ml/animal per treatment
- sheep: 2.5 ml/animal per treatment
- goats: 3 ml/animal per treatment

Method: Manual spraying using an electronic sprayer  
Detailed description:

Pre- and Post-milking application

Apply before and after each milking every day (up to 5 applications per day in total). For manual application, ensure the full teat is covered with a contact time of 60 seconds for pre-milking and ensure that the full teat is covered and the animals are left standing for 5 minutes post-milking.

2. Manual Spraying using an electronic spray:

- cows and buffaloes: 10-15 ml/animal per treatment
- sheep: 5-7.5 ml/animal per treatment
- goats: 7- 10ml/animal per treatment

**Application rate(s) and frequencies**

Application Rate: see above  
Dilution (%):  
Number and timing of application:  
see above

Application Rate: see above  
Dilution (%):  
Number and timing of application:  
see above

**Category(ies) of users**

Trained professional  
Professional

**Pack sizes and packaging material**

Bottle/Pack (HDPE) 5 – 25L  
Drum (HDPE) 200L  
IBC (HDPE) 1000L

### 4.3.1 Use-specific instructions for use

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

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

Post-milking: To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).

This product requires dilution before use.  
Prepare a fresh solution daily.

Containers for dilution should be clean and suitable for use.

Ensure udder and teats are clean and dry before using this product.

Mix 1 part product with 3 parts of clean water & mix well.

#### 1. Manual dipping/foaming

Fill teat cup 2/3 full with product. Dip the teats of each cow before milking, making sure that the full length of the teat is immersed. Leave the product on the teats for at least 60 seconds. Then wipe and dry the teats thoroughly using a single service paper towel. Dip the teats of each cow immediately after each has been milked, making sure that the full length of the teat is immersed. Top up with fresh solution as required.  
Empty and wash out cups with water after use.

#### 2. Manual spraying using an electronic sprayer

Before milking, spray the teats of each cow with diluted product. Ensure the spray covers the entire surface of all teats. Leave the product on the teats for at least 60 seconds. Then wipe and dry the teats thoroughly using a single service paper towel. Immediately after milking, spray the teats of each cow with diluted product. Ensure the spray covers the entire surface of all teats.

### 4.3.2 Use-specific risk mitigation measures

Keep out of reach of children.

For manual spraying using an electronic sprayer:

Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).

Wear Suitable protective footwear (EN 13832) when applying this product.

A protective coverall (at least type 6, EN 13034) shall be worn.

### 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

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

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#### 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

See use specific instructions for use

#### 5.2. Risk mitigation measures

See use specific RMM

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

**Likely direct or indirect effects may include:**

- Irritation of the eyes.
- General discomfort if swallowed.

**First aid measures**

- **Inhalation:** Unlikely route of exposure as the product does not contain volatile substances. If spray/mist has been inhaled, move affected person to fresh air and keep warm and at rest in a position comfortable for breathing.
- **Ingestion:** Do not induce vomiting. Give plenty of water to drink. Get medical attention if any discomfort continues.
- **Skin contact:** Wash with plenty of water.
- **Eye contact:** Rinse immediately with plenty of water. Get medical attention promptly if symptoms occur after washing.

**NEVER LEAVE AN AFFECTED INDIVIDUAL UNATTENDED**

**Advice for medical and healthcare personnel:**

- Provide symptomatic and supportive treatment.

**WHEN ASKING FOR MEDICAL ADVICE KEEP PACKAGING OR LABEL AT HAND AND CALL YOUR LOCAL POISON CONTROL CENTER ( [INSERT LOCAL NUMBER HERE].**

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

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

At the end of the treatment, dispose unused product, the packaging and any contaminated materials in accordance with local requirements.  
Do not empty into drains.

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

Shelf-life 24 months.  
Store in original sealed container and protect from extremes of temperature.  
Protect from direct sunlight.  
Protect from frost, if contents freeze, they must be thawed and thoroughly mixed before use.  
Store in a cool, well-ventilated place.  
Store below 25°C.

## 6. Other information

Note that if any additions are made to this family Meta-SPC, the in-use concentrations must be within the range covered within the environmental risk assessments.

## 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>	Pro-Tec 1:3	Market area: LV
<b>Authorisation number</b> <small>(R4BP 3 asset reference number - National Authorisation)</small>	LV-0013292-0010 1-6	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	1,036
Alcohol Ethoxylate	C13-15 Alcohol Ethoxylate (11EO)	Non-active substance	157627-86-6	500-337-8	8,762

## 1. Meta SPC administrative information

### 1.1. Meta SPC identifier

Meta SPC 6b

### 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	1,646 - 2,228
Alcohol Ethoxylate	C13-15 Alcohol Ethoxylate (11EO)	Non-active substance	157627-86-6	500-337-8	14 - 16,51

## 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

Harmful to aquatic life with long lasting effects.

Precautionary statements

Avoid release to the environment.

Dispose of contents to in accordance with local/regional/national regulations.

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

### 4.1 Use description

#### Use 1 - Pre-milking

Product type

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection products for milkable animals (cows, buffaloes, sheep, goats) for use before milking.

Target organism(s) (including development stage)

Scientific name: bacteria  
Common name: bacteria  
Development stage: N/A

Scientific name: yeasts  
Common name: yeasts  
Development stage: N/A

Field(s) of use

Indoor

Indoor use – Teats of lactating animals.

Application method(s)

Method: Manual dipping/foaming

Detailed description:

Pre-milking application

Apply before each milking every day (1-3 times a day). For manual application ensure full teat is covered for minimum contact time of 60 seconds.

1. Manual dipping/foaming:

a. Dipping

cows and buffaloes: 10 ml/animal per treatment

sheep: 5 ml/animal per treatment

goats: 6 ml/animal per treatment

b. Foaming

cows and buffaloes: 5 ml/animal per treatment

sheep: 2.5 ml/animal per treatment



	<p>goats: 3 ml/animal per treatment</p> <p>Method: Manual spraying using an electronic sprayer Detailed description: Pre-milking application</p> <p>Before milking, spray the teats of each cow with product. Ensure the spray covers the entire surface of all teats. Leave the product on the teats for at least 60 seconds. Then wipe and dry the teats thoroughly using a single service paper towel.</p> <p>2. Manual Spraying using an electronic spray: cows and buffaloes: 10-15 ml/animal per treatment sheep: 5-7.5 ml/animal per treatment goats: 7-10 ml/animal per treatment</p>
<p><b>Application rate(s) and frequencies</b></p>	<p>Application Rate: see above Dilution (%): Number and timing of application: see above</p> <p>Application Rate: see above Dilution (%): Number and timing of application: see above</p>
<p><b>Category(ies) of users</b></p>	<p>Trained professional</p> <p>Professional</p>
<p><b>Pack sizes and packaging material</b></p>	<p>Bottle/Pack (HDPE) 5 – 25L Drum (HDPE) 200L IBC (HDPE) 1000L</p>

#### 4.1.1 Use-specific instructions for use

<p>The product must be brought to a temperature above 20°C before use.</p> <p>This product requires dilution before use.</p> <p>Ensure udder and teats are clean and dry before using this product.</p> <p>The use of a dosing pump for filling the product into the application equipment is recommended. Prepare a fresh solution daily. Containers for dilution should be clean and suitable for use.</p>
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Mix 1 part product with 7 parts of clean water and mix well.

1. Manual dipping/foaming

Fill teat cup 2/3 full with diluted product.

Dip the teats of each cow before milking, making sure that the full length of the teat is immersed. Leave the product on the teats for at least 60 seconds. Then wipe and dry the teats thoroughly using a single service paper towel.

Top up with fresh solution as required.

Empty and wash out cups with water after use.

2. Manual spraying using an electronic sprayer

Before milking, spray the teats of each cow with diluted product. Ensure the spray covers the entire surface of all teats. Leave the product on the teats for at least 60 seconds. Then wipe and dry the teats thoroughly using a single service paper towel.

#### 4.1.2 Use-specific risk mitigation measures

Keep out of reach of children.

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

For manual spraying using an electronic sprayer:

Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).

#### 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

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

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#### 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 - Post-Milking

##### Product type

PT03 - Veterinary hygiene (Disinfectants)

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

DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection products for milkable animals (cows, buffaloes, sheep, goats) for use after milking.

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

Scientific name: bacteria  
Common name: bacteria  
Development stage: N/A

Scientific name: yeasts  
Common name: yeasts  
Development stage: N/A

**Field(s) of use**

Indoor

Indoor use – Teats of lactating animals.

**Application method(s)**

Method: Manual dipping/foaming  
Detailed description:

Post-milking application

Apply after each milking every day (1-3 times a day). For manual application ensure full teat is covered and the animal stands for 5 minutes.

1. Manual dipping/foaming:

a. Dipping

- cows and buffaloes: 10 ml/animal per treatment
- sheep: 5 ml/animal per treatment
- goats: 6 ml/animal per treatment

b. Foaming

- cows and buffaloes: 5 ml/animal per treatment
- sheep: 2.5 ml/animal per treatment
- goats: 3 ml/animal per treatment

Method: Manual spraying using an electronic sprayer

Detailed description:

Post-milking application

Apply after each milking every day (1-3 times a day). For manual application ensure full teat is covered and the animal stands for 5 minutes.

2. Manual Spraying using an electronic spray:

- cows and buffaloes: 10-15 ml/animal per treatment
- sheep: 5-7.5 ml/animal per treatment
- goats: 7-10 ml/animal per treatment

Method: automated dipping

Detailed description:

Post-milking application

Apply after each milking every day (1-3 times a day).

Automated dipping:

- cows and buffaloes: 10 ml/animal per treatment
- sheep: 5 ml/animal per treatment
- goats: 6 ml/animal per treatment

	<p>Method: Automated spraying using a robot  Detailed description:  Post-milking application  Apply after each milking every day (1-3 times a day).  Automated spraying using a robot:  cows and buffaloes: 10-15 ml/animal per treatment  sheep: 5-7.5 ml/animal per treatment  goats: 7-10 ml/animal per treatment</p>
<p><b>Application rate(s) and frequencies</b></p>	<p>Application Rate: see above  Dilution (%):  Number and timing of application:  see above</p> <p>Application Rate: see above  Dilution (%):  Number and timing of application:  see above</p> <p>Application Rate: As above  Dilution (%):  Number and timing of application:  As above</p> <p>Application Rate: As above  Dilution (%):  Number and timing of application:  As Above</p>
<p><b>Category(ies) of users</b></p>	<p>Trained professional  Professional</p>
<p><b>Pack sizes and packaging material</b></p>	<p>Bottle/Pack (HDPE) 5 – 25L  Drum (HDPE) 200L  IBC (HDPE) 1000L</p>

#### 4.2.1 Use-specific instructions for use

The product must be brought to a temperature above 20°C before use.  
This product requires dilution before use.  
Add 1 part product to 3 parts clean water and mix well.  
Prepare a fresh solution daily.  
Containers for dilution should be clean and suitable for use.

Ensure udder and teats are clean and dry before using this product.

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

To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).

1. Manual dipping/foaming

Fill teat cup 2/3 full with diluted product. Dip the teats of each cow immediately after each has been milked, making sure that the full length of the teat is immersed.

Top up with fresh solution as required.

Empty and wash out cups with water after milking.

2. Manual spraying using an electronic sprayer

Immediately after milking, spray the teats of each cow with diluted product.

Ensure the spray covers the entire surface of all teats.

3. Automated dipping

The teats are covered with diluted product when the teat cup is withdrawn by the Automatic Cluster Removal (ACR). The whole process is automated.

4. Automated spraying by robot

After robotic milking, the diluted product is sprayed automatically onto teats from a cluster arm. Rinsing of the sprayer is automatic.

#### 4.2.2 Use-specific risk mitigation measures

Keep out of reach of children.

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.

For manual spraying using an electronic sprayer: Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).

Wear Suitable protective footwear (EN 13832) when applying this product.

A protective overall (at least type 6, EN 13034) shall be worn.

#### 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

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

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#### 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 - Pre- and Post-milking

##### Product type

PT03 - Veterinary hygiene (Disinfectants)

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

DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection products for milkable animals (cows, buffaloes, sheep, goats) for use before and after milking.

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

Scientific name: bacteria  
Common name: bacteria  
Development stage: N/A

Scientific name: yeasts  
Common name: yeasts  
Development stage: N/A

##### Field(s) of use

Indoor

Indoor use – Teats of lactating animals.

##### Application method(s)

Method: Manual dipping/foaming  
Detailed description:

##### Pre- and Post-milking application

Apply before and after each milking every day (up to 5 applications per day in total). For manual application, ensure the full teat is covered with a contact time of 60 seconds for pre-milking and ensure that the full teat is covered and the animals are left standing for 5 minutes post-milking.

##### 1. Manual dipping/foaming: a. Dipping

- cows and buffaloes: 10 ml/animal per treatment
- sheep: 5 ml/animal per treatment
- goats: 6 ml/animal per treatment
- b. Foaming
- cows and buffaloes: 5 ml/animal per treatment
- sheep: 2.5 ml/animal per treatment
- goats: 3 ml/animal per treatment

	<p>Method: Manual spraying using an electronic sprayer Detailed description:</p> <p><u>Pre- and Post-milking application</u> Apply before and after each milking every day (up to 5 applications per day in total). For manual application, ensure the full teat is covered with a contact time of 60 seconds for pre-milking and ensure that the full teat is covered and the animals are left standing for 5 minutes post-milking.</p> <p>2. Manual Spraying using an electronic spray:</p> <ul style="list-style-type: none"> <li>• cows and buffaloes: 10-15 ml/animal per treatment</li> <li>• sheep: 5-7.5 ml/animal per treatment</li> <li>• goats: 7- 10ml/animal per treatment</li> </ul>
<p><b>Application rate(s) and frequencies</b></p>	<p>Application Rate: see above Dilution (%): Number and timing of application: see above</p> <p>Application Rate: see above Dilution (%): Number and timing of application: see above</p>
<p><b>Category(ies) of users</b></p>	<p>Trained professional</p> <p>Professional</p>
<p><b>Pack sizes and packaging material</b></p>	<p>Bottle/Pack (HDPE) 5 – 25L Drum (HDPE) 200L IBC (HDPE) 1000L</p>

#### 4.3.1 Use-specific instructions for use

<p>The product must be brought to a temperature above 20°C before use.</p> <p>The use of a dosing pump for filling the product into the application equipment is recommended.</p> <p>Post-milking: To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the</p>
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cows standing at least 5 minutes).

This product requires dilution before use.  
Prepare a fresh solution daily.

Containers for dilution should be clean and suitable for use.

Ensure udder and teats are clean and dry before using this product.

Dilutions are different for pre and post milking, therefore separate teat cups are required. See specific instructions.

Pre-milking - Mix 1 part product with 7 parts of clean water and mix well

Post-milking - Mix 1 part product with 3 parts of clean water and mix well

1. Manual dipping/foaming

Fill teat cup  $\frac{2}{3}$  full with product. Dip the teats of each cow before milking, making sure that the full length of the teat is immersed.

Leave the product on the teats for at least 60 seconds. Then wipe and dry the teats thoroughly using a single service paper towel.

Dip the teats of each cow immediately after each has been milked, making sure that the full length of the teat is immersed.

Top up with fresh solution as required.

Empty and wash out cups with water after use.

2. Manual spraying using an electronic sprayer

Before milking, spray the teats of each cow with diluted product. Ensure the spray covers the entire surface of all teats. Leave the

product on the teats for at least 60 seconds. Then wipe and dry the teats thoroughly using a single service paper towel.

Immediately after milking, spray the teats of each cow with diluted product. Ensure the spray covers the entire surface of all teats.

#### 4.3.2 Use-specific risk mitigation measures

Keep out of reach of children.

For manual spraying using an electronic sprayer:

Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).

Wear Suitable protective footwear (EN 13832) when applying this product.

A protective coverall (at least type 6, EN 13034) shall be worn.

#### 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

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

-



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

-

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

#### 5.1. Instructions for use

See use specific instructions for use

#### 5.2. Risk mitigation measures

See use specific RMM

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

**Likely direct or indirect effects may include:**

- Irritation of the eyes.
- General discomfort if swallowed.

**First aid measures**

- **Inhalation:** Unlikely route of exposure as the product does not contain volatile substances. If spray/mist has been inhaled, move affected person to fresh air and keep warm and at rest in a position comfortable for breathing.
- **Ingestion:** Do not induce vomiting. Give plenty of water to drink. Get medical attention if any discomfort continues.
- **Skin contact:** Wash with plenty of water.
- **Eye contact:** Rinse immediately with plenty of water. Get medical attention promptly if symptoms occur after washing.

**NEVER LEAVE AN AFFECTED INDIVIDUAL UNATTENDED**

**Advice for medical and healthcare personnel:**

- Provide symptomatic and supportive treatment.

**WHEN ASKING FOR MEDICAL ADVICE KEEP PACKAGING OR LABEL AT HAND AND CALL YOUR LOCAL POISON CONTROL CENTER ( [INSERT LOCAL NUMBER HERE].**

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

At the end of the treatment, dispose unused product, the packaging and any contaminated materials in accordance with local requirements.  
Do not empty into drains.

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

Shelf-life 24 months.  
Store in original sealed container and protect from extremes of temperature.  
Protect from direct sunlight.  
Protect from frost, if contents freeze, they must be thawed and thoroughly mixed before use.  
Store in a cool, well-ventilated place.  
Store below 25°C.

### 6. Other information

Note that if any additions are made to this family Meta-SPC, the in-use concentrations must be within the range covered within the environmental risk assessments.

### 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>	Masodine 1:3	Market area: LV
<b>Authorisation number</b> <small>(R4BP 3 asset reference number - National Authorisation)</small>	LV-0013292-0011 1-7	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	1,937

Alcohol Ethoxylate	C13-15 Alcohol Ethoxylate (11EO)	Non-active substance	157627-86-6	500-337-8	16,51
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## 1. Meta SPC administrative information

### 1.1. Meta SPC identifier

Meta SPC 7

### 1.2. Suffix to the authorisation number

1-8

### 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	2 - 2,346
Alcohol Ethoxylate	C13-15 Alcohol Ethoxylate (11EO)	Non-active substance	157627-86-6	500-337-8	18 - 19,993

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

Formulation(s)

SL - Soluble concentrate

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

<b>Hazard statements</b>	Causes serious eye damage. Harmful to aquatic life with long lasting effects.
<b>Precautionary statements</b>	Wear eye protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/physician. Avoid release to the environment. Dispose of contents to in accordance with local/regional/national regulations.

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

#### 4.1 Use description

##### Use 1 - Pre-milking

<b>Product type</b>	PT03 - Veterinary hygiene (Disinfectants)
<b>Where relevant, an exact description of the authorised use</b>	DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection products for milkable animals (cows, buffaloes, sheep, goats) for use before milking.
<b>Target organism(s) (including development stage)</b>	Scientific name: bacteria Common name: bacteria Development stage: N/A  Scientific name: yeasts Common name: yeasts Development stage: N/A
<b>Field(s) of use</b>	Indoor  Indoor use – Teats of lactating animals.
<b>Application method(s)</b>	Method: Manual dipping/foaming Detailed description: Pre-milking application Apply before each milking every day (1-3 times a day). For manual application ensure full teat is covered for minimum contact time of 60 seconds. 1. Manual dipping/foaming: a. Dipping cows and buffaloes: 10 ml/animal per treatment sheep: 5 ml/animal per treatment goats: 6 ml/animal per treatment

	<p>b. Foaming cows and buffaloes: 5 ml/animal per treatment sheep: 2.5 ml/animal per treatment goats: 3 ml/animal per treatment</p> <p>Method: Manual spraying using an electronic sprayer Detailed description: Pre-milking application</p> <p>Before milking, spray the teats of each cow with product. Ensure the spray covers the entire surface of all teats. Leave the product on the teats for at least 60 seconds. Then wipe and dry the teats thoroughly using a single service paper towel.</p> <p>2. Manual Spraying using an electronic spray: cows and buffaloes: 10-15 ml/animal per treatment sheep: 5-7.5 ml/animal per treatment goats: 7-10 ml/animal per treatment</p>
<p><b>Application rate(s) and frequencies</b></p>	<p>Application Rate: see above Dilution (%): Number and timing of application: see above</p> <p>Application Rate: see above Dilution (%): Number and timing of application: see above</p>
<p><b>Category(ies) of users</b></p>	<p>Trained professional</p> <p>Professional</p>
<p><b>Pack sizes and packaging material</b></p>	<p>Bottle/Pack (HDPE) 5 – 25L Drum (HDPE) 200L IBC (HDPE) 1000L</p>

#### 4.1.1 Use-specific instructions for use

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

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

This product requires dilution before use.

Add 1 part product to 9 parts clean water and mix well.  
Prepare a fresh solution daily.  
Containers for dilution should be clean and suitable for use.

Ensure udder and teats are clean and dry before using this product.

**1. Manual dipping/foaming**

Fill teat cup  $\frac{2}{3}$  full with diluted product. Dip the teats of each cow before milking, making sure that the full length of the teat is immersed. Leave the product on the teats for at least 60 seconds. Then wipe and dry the teats thoroughly using a single service paper towel.

Top up with fresh solution as required.

Empty and wash out cups with water after use.

**2. Manual spraying using an electronic sprayer**

Before milking, spray the teats of each cow with diluted product. Ensure the spray covers the entire surface of all teats. Leave the product on the teats for at least 60 seconds. Then wipe and dry the teats thoroughly using a single service paper towel.

#### 4.1.2 Use-specific risk mitigation measures

Keep out of reach of children.

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

For manual dipping/foaming:

The use of eye protection during handling of the product is mandatory.

For manual spraying using an electronic sprayer:

Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).

The use of eye protection during handling of the product is mandatory.

#### 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

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

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#### 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 - Post-Milking

<b>Product type</b>	PT03 - Veterinary hygiene (Disinfectants)
<b>Where relevant, an exact description of the authorised use</b>	DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection products for milkable animals (cows, buffaloes, sheep, goats) for use after milking.
<b>Target organism(s) (including development stage)</b>	Scientific name: bacteria Common name: bacteria Development stage: N/A  Scientific name: yeasts Common name: yeasts Development stage: N/A
<b>Field(s) of use</b>	Indoor  Indoor use – Teats of lactating animals.
<b>Application method(s)</b>	Method: Manual dipping/foaming Detailed description: <u>Post-milking application</u> Apply after each milking every day (1-3 times a day). For manual application ensure full teat is covered and the animal stands for 5 minutes.  1. Manual dipping/foaming: a. Dipping <ul style="list-style-type: none"><li>• cows and buffaloes: 10 ml/animal per treatment</li><li>• sheep: 5 ml/animal per treatment</li><li>• goats: 6 ml/animal per treatment</li></ul> b. Foaming <ul style="list-style-type: none"><li>• cows and buffaloes: 5 ml/animal per treatment</li><li>• sheep: 2.5 ml/animal per treatment</li><li>• goats: 3 ml/animal per treatment</li></ul> Method: Manual spraying using an electronic sprayer Detailed description: Post-milking application Apply after each milking every day (1-3 times a day). For manual application ensure full teat is covered and the animal stands for 5 minutes.  2. Manual Spraying using an electronic spray: cows and buffaloes: 10-15 ml/animal per treatment sheep: 5-7.5 ml/animal per treatment goats: 7-10 ml/animal per treatment  Method: automated dipping

**Application rate(s) and frequencies**

Detailed description:  
Post-milking application  
Apply after each milking every day (1-3 times a day).  
Automated dipping:  
cows and buffaloes: 10 ml/animal per treatment  
sheep: 5 ml/animal per treatment  
goats: 6 ml/animal per treatment

Method: Automated spraying using a robot  
Detailed description:  
Post-milking application  
Apply after each milking every day (1-3 times a day).  
Automated spraying using a robot:  
cows and buffaloes: 10-15 ml/animal per treatment  
sheep: 5-7.5 ml/animal per treatment  
goats: 7-10 ml/animal per treatment

Application Rate: see above  
Dilution (%):  
Number and timing of application:  
see above

Application Rate: see above  
Dilution (%):  
Number and timing of application:  
see above

Application Rate: As above  
Dilution (%):  
Number and timing of application:  
As above

Application Rate: As above  
Dilution (%):  
Number and timing of application:  
As Above

**Category(ies) of users**

Trained professional  
Professional

**Pack sizes and packaging material**

Bottle/Pack (HDPE) 5 – 25L  
Drum (HDPE) 200L  
IBC (HDPE) 1000L

**4.2.1 Use-specific instructions for use**



#### 4.2.1 Use-specific instructions for use

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

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

To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).

This product requires dilution before use.

Add 1 part product to 4 parts clean water and mix well.

Prepare a fresh solution daily.

Containers for dilution should be clean and suitable for use.

Ensure udder and teats are clean and dry before using this product.

1. Manual dipping/foaming

Fill teat cup  $\frac{2}{3}$  full with diluted product. Dip the teats of each cow immediately after each has been milked, making sure that the full length of the teat is immersed.

Top up with fresh solution as required.

Empty and wash out cups with water after milking.

2. Manual spraying using an electronic sprayer

Immediately after milking, spray the teats of each cow with diluted product.

Ensure the spray covers the entire surface of all teats.

3. Automated dipping

The teats are covered with diluted product when the teat cup is withdrawn by the Automatic Cluster Removal (ACR). The whole process is automated.

4. Automated spraying by robot

After robotic milking, the diluted product is sprayed automatically onto teats from a cluster arm. Rinsing of the sprayer is automatic.

#### 4.2.2 Use-specific risk mitigation measures

Keep out of reach of children.

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.

For manual dipping/foaming, automated dipping and automated spraying using a robot:

The use of eye protection during handling of the product is mandatory.

For manual spraying using an electronic sprayer:

Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).

Wear Suitable protective footwear (EN 13832) when applying this product.

A protective overall (at least type 6, EN 13034) shall be worn.

The use of eye protection during handling of the product is mandatory.

**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**

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

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**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 - Pre- and Post-milking**

<b>Product type</b>	PT03 - Veterinary hygiene (Disinfectants)
<b>Where relevant, an exact description of the authorised use</b>	DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection products for milkable animals (cows, buffaloes, sheep, goats) for use before and after milking.
<b>Target organism(s) (including development stage)</b>	Scientific name: bacteria Common name: bacteria Development stage: N/A  Scientific name: yeasts Common name: yeasts Development stage: N/A
<b>Field(s) of use</b>	Indoor  Indoor use – Teats of lactating animals.
<b>Application method(s)</b>	Method: Manual dipping/foaming Detailed description:  <u>Pre- and Post-milking application</u> Apply before and after each milking every day (up to 5 applications per day in total). For manual application, ensure the full teat is covered with a contact time of 60 seconds for pre-milking and ensure that the full teat is covered and the animals are left standing for

5 minutes post-milking.

1. Manual dipping/foaming
  - a. Dipping
    - cows and buffaloes: 10 ml/animal per treatment
    - sheep: 5 ml/animal per treatment
    - goats: 6 ml/animal per treatment
    -
  - b. Foaming
    - cows and buffaloes: 5 ml/animal per treatment
    - sheep: 2.5 ml/animal per treatment
    - goats: 3 ml/animal per treatment

Method: Manual spraying using an electronic sprayer  
 Detailed description:

Pre- and Post-milking application  
 Apply before and after each milking every day (up to 5 applications per day in total). For manual application, ensure the full teat is covered with a contact time of 60 seconds for pre-milking and ensure that the full teat is covered and the animals are left standing for 5 minutes post-milking.

2. Manual Spraying using an electronic spray:
  - cows and buffaloes: 10-15 ml/animal per treatment
  - sheep: 5-7.5 ml/animal per treatment
  - goats: 7- 10ml/animal per treatment

**Application rate(s) and frequencies**

Application Rate: see above  
 Dilution (%):  
 Number and timing of application:  
 see above

Application Rate: see above  
 Dilution (%):  
 Number and timing of application:  
 see above

**Category(ies) of users**

Trained professional  
 Professional

## Pack sizes and packaging material

Bottle/Pack (HDPE) 5 – 25L  
Drum (HDPE) 200L  
IBC (HDPE) 1000L

### 4.3.1 Use-specific instructions for use

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

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

Post-milking: To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).

This product requires dilution before use.

Dilutions are different for pre and post milking, therefore separate teat cups are required. See specific instructions.

Prepare a fresh solution daily.

Containers for dilution should be clean and suitable for use.

Ensure udder and teats are clean and dry before using this product.

Pre-milking - Mix 1 part product with 9 parts of clean water and mix well.

Post-Milking - Mix 1 part product with 4 parts of clean water and mix well.

#### 1. Manual dipping/foaming

Fill teat cup  $\frac{2}{3}$  full with product. Dip the teats of each cow before milking, making sure that the full length of the teat is immersed.

Leave the product on the teats for at least 60 seconds. Then wipe and dry the teats thoroughly using a single service paper towel.

Dip the teats of each cow immediately after each has been milked, making sure that the full length of the teat is immersed.

Top up with fresh solution as required.

Empty and wash out cups with water after use.

#### 2. Manual spraying using an electronic sprayer

Before milking, spray the teats of each cow with diluted product. Ensure the spray covers the entire surface of all teats. Leave the product on the teats for at least 60 seconds. Then wipe and dry the teats thoroughly using a single service paper towel.

Immediately after milking, spray the teats of each cow with diluted product. Ensure the spray covers the entire surface of all teats.

### 4.3.2 Use-specific risk mitigation measures

Keep out of reach of children.

For manual dipping/foaming:

The use of eye protection during handling of the product is mandatory.

For and manual spraying using an electronic sprayer:

Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).

Wear Suitable protective footwear (EN 13832) when applying this product

A protective coverall (at least type 6, EN 13034) shall be worn

The use of eye protection during handling of the product is mandatory.

#### **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**

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

-

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

-

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

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

See use specific instructions for use

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

See use specific RMM

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

**Likely direct or indirect effects may include:**

- Severe irritation of the eyes or eye damage.
- General discomfort if swallowed.

**First aid measures**

- **Inhalation:** Unlikely route of exposure as the product does not contain volatile substances. If spray/mist has been inhaled, move affected person to fresh air and keep warm and at rest in a position comfortable for breathing.
- **Ingestion:** Do not induce vomiting. Give plenty of water to drink. Get medical attention if any discomfort continues.
- **Skin contact:** Wash with plenty of water.
- **Eye contact:** Rinse immediately with plenty of water. Get medical attention promptly if symptoms occur after washing.

**NEVER LEAVE AN AFFECTED INDIVIDUAL UNATTENDED**

**Advice for medical and healthcare personnel:**

- Provide symptomatic and supportive treatment.

**WHEN ASKING FOR MEDICAL ADVICE KEEP PACKAGING OR LABEL AT HAND AND CALL YOUR LOCAL POISON CONTROL CENTER ( [INSERT LOCAL NUMBER HERE].**

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

At the end of the treatment, dispose unused product, the packaging and any contaminated materials in accordance with local requirements.

Do not empty into drains.

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

Shelf-life 24 months.

Store in original sealed container and protect from extremes of temperature.

Protect from direct sunlight.

Protect from frost, if contents freeze, they must be thawed and thoroughly mixed before use.

Store in a cool, well-ventilated place.

Store below 25°C.

#### 6. Other information

Note that if any additions are made to this family Meta-SPC, the in-use concentrations must be within the range covered within the environmental risk assessments.

## 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)**

Masocare 1:4

Market area: LV

**Authorisation number**

(R4BP 3 asset reference number - National Authorisation)

LV-0013292-0012 1-8

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	2,346
Alcohol Ethoxylate	C13-15 Alcohol Ethoxylate (11EO)	Non-active substance	157627-86-6	500-337-8	19,993