## Summary of product characteristics for a biocidal product family

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

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

**Authorisation number:** 

R4BP 3 asset reference number: NL-0013188-0000

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### Part I.- First information level

### 1. Administrative information

### 1.1. Family name

DeLaval iodine-based teat disinfectant family

### 1.2. Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

#### 1.3. Authorisation holder

Name and address of the authorisation holder

| Name    | DeLaval NV                                 |
|---------|--|
| Address | Industriepark-Drongen 10 9031 Gent Belgium |
|         |  |

**Authorisation number** 

R4BP 3 asset reference number

Date of the authorisation

Expiry date of the authorisation

| NL-0013188-0000 |
|-----------------|
| 02/08/2019      |
| 01/08/2029      |

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

Name of the manufacturer

DeLaval NV

Address of the manufacturer

Industriepark-Drongen 10 9031 Gent Belgium

**Location of manufacturing sites** 

Industriepark-Drongen 10 9031 Gent Belgium

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

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

### 2. Product family composition and formulation

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

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

### 2.2. Type(s) of formulation

AL - Any other liquid
SL - Soluble concentrate

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

### 1. Meta SPC administrative information

### 1.1. Meta SPC identifier

meta SPC 1: Metafamily 1

#### 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 (%)  |
|--------------------|------------|------------------|------------|-----------|--------------|
| lodine             |            | Active Substance | 7553-56-2  | 231-442-4 | 0,21 - 0,25  |
| Alcohol ethoxylate |            |                  | 68439-46-3 |           | 0 - 0        |
| Sodium iodide      |            |                  | 7681-82-5  | 231-679-3 | 0,092 - 0,12 |

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

Formulation(s)

AL - Any other liquid

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

**Hazard statements** 

Harmful to aquatic life with long lasting effects.

**Precautionary statements** 

Keep out of reach of children.

Avoid release to the environment.

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

### 4.1 Use description

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

#### **Product type**

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised

Teat disinfectant

Target organism(s) (including development stage)

Scientific name: Common name: Bacteria Development stage:

Scientific name: Common name: Yeasts Development stage:

Scientific name: Common name: Viruses Development stage:

Field(s) of use

Indoor

The product is intended for post-milking teat disinfection.

The product is applied directly after milking on the teats of lactating animals

Application method(s)

Post-milking teat disinfection of udder teats with ready-to-use products. -

The product is applied manually after milking on the teats by manual dipping using a dip

Application rate(s) and frequencies

ca. 5 ml per cow; ca. 2.5 ml per sheep or goat - 0% -

To be applied after milking, 2 times per day. The products can be used all year during

the lactation period.

Category(ies) of users

Professional

Pack sizes and packaging material

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

### 4.1.1 Use-specific instructions for use

| The product is a ready-to-use product ar<br>The product must be brought to a tempe   |  |  |  |  |
|--|--|--|--|--|
| Directions for use:  |  |  |  |  |
| It is recommended to wear gloves during manual application: use a clean dip cup.   | milking and application to protect the skin and ensure hygienic milking condition. For   |  |  |  |
| Ensure that teats are clean before use. A  | Apply the ready-to-use solution of the product on each teat immediately after milking:   |  |  |  |
| DIP: dip every teat in the product. Ensure necessary;  | e that the teat is covered to at least three quarters length and replenish the dip cup as  |  |  |  |
| Allow teats to dry after application during  | at least 5 min and keep the animals standing during this period.   |  |  |  |
| 4.1.2 Use-specific risk mitiga   | ation measures   |  |  |  |
| There are no use specific risk mitigation  | measures. See 5.2 for general instructions.  |  |  |  |
|  |  |  |  |  |
| 4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment      |  |  |  |  |
|  |  |  |  |  |
| There are no use specific instructions. So   | <u> </u>   |  |  |  |
| ·  | <u> </u>   |  |  |  |
| 4.1.4 Where specific to the u  | ee 5.3 for general instructions.  se, the instructions for safe disposal of the product and its  |  |  |  |
| 4.1.4 Where specific to the upackaging  There are no use specific instructions. So   | ee 5.3 for general instructions.  se, the instructions for safe disposal of the product and its  ee 5.4 for general instructions.  se, the conditions of storage and shelf-life of the product         |  |  |  |
| 4.1.4 Where specific to the upackaging  There are no use specific instructions. See 4.1.5 Where specific to the use  | ee 5.3 for general instructions.  se, the instructions for safe disposal of the product and its  ee 5.4 for general instructions.  se, the conditions of storage and shelf-life of the product         |  |  |  |
| 4.1.4 Where specific to the upackaging  There are no use specific instructions. See 4.1.5 Where specific to the use  | ee 5.3 for general instructions.  se, the instructions for safe disposal of the product and its  ee 5.4 for general instructions.  se, the conditions of storage and shelf-life of the product         |  |  |  |
| 4.1.4 Where specific to the upackaging  There are no use specific instructions. See 4.1.5 Where specific to the use  | ee 5.3 for general instructions.  se, the instructions for safe disposal of the product and its  ee 5.4 for general instructions.  se, the conditions of storage and shelf-life of the product         |  |  |  |
| 4.1.4 Where specific to the upackaging  There are no use specific instructions. So  4.1.5 Where specific to the usunder normal conditions of so  4.2 Use description | ee 5.3 for general instructions.  se, the instructions for safe disposal of the product and its  ee 5.4 for general instructions.  se, the conditions of storage and shelf-life of the product         |  |  |  |
| 4.1.4 Where specific to the upackaging  There are no use specific instructions. So  4.1.5 Where specific to the usunder normal conditions of so  4.2 Use description | ee 5.3 for general instructions.  se, the instructions for safe disposal of the product and its  ee 5.4 for general instructions.  se, the conditions of storage and shelf-life of the product storage |  |  |  |

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

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

Teat disinfectant

Scientific name: Common name: Bacteria Development stage:

Scientific name: Common name: Yeast Development stage:

Scientific name: Common name: Viruses Development stage:

### Field(s) of use

#### Indoor

The product is intended for post-milking teat disinfection.

The product is applied directly after milking on the teats of lactating animals

#### Application method(s)

post-milking teat disinfection of udder teats with ready-to-use products -

The product is applied manually after milking on the teats by spraying using a spray container.

### Application rate(s) and frequencies

ca. 5 ml per cow; ca. 2.5 ml per sheep or goat - 0% -

To be applied after milking, 2 times per day. The products can be used all year during the lactation period.

### Category(ies) of users

#### Professional

#### Pack sizes and packaging material

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

### 4.2.1 Use-specific instructions for use

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

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

Directions for use:

For manual application: use a clean applicator.

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

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

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

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

### 4.2.2 Use-specific risk mitigation measures

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

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

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

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

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

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

-

### 4.3 Use description

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

### **Product type**

Where relevant, an exact description of the authorised use

Target organism(s) (including development stage)

PT03 - Veterinary hygiene (Disinfectants)

Teat disinfectant

Scientific name: Common name: Bacteria Development stage:

Scientific name: Common name: Yeasts Development stage:

Scientific name: Common name: Viruses Development stage:

Field(s) of use

Indoor

The product is intended for post-milking teat disinfection.

The product is applied directly after milking on the teats of lactating animals

### Application method(s)

Post-milking teat disinfection of udder teats with ready-to-use products. -

The product is applied automatically by milking machines after milking on the teats by integrated dipping or spraying device.

### Application rate(s) and frequencies

ca. 5 ml per cow; ca. 2.5 ml per sheep or goat - 0% -

To be applied after milking, 3 times per day. The products can be used all year during the lactation period.

### Category(ies) of users

Professional

### Pack sizes and packaging material

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

### 4.3.1 Use-specific instructions for use

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

### 4.3.2 Use-specific risk mitigation measures

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

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

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

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

| There are no use specific instructions. See 5.4 for general instructions.   |  |  |  |  |
|---|--|--|--|--|
| 4.3.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage   |  |  |  |  |
| -   |  |  |  |  |
|   |  |  |  |  |
| 5. General directions for use of the meta SPC   |  |  |  |  |
| 5.1. Instructions for use   |  |  |  |  |
| There are no general instructions for use. See the use specific instructions for use.   |  |  |  |  |
| 5.2. Risk mitigation measures   |  |  |  |  |
| In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.  |  |  |  |  |
| 5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment   |  |  |  |  |
| DIRECT/INDIRECT EFFECTS:  According to our experience and to the information provided to us, the product does not have any adverse effects if it is used and handled as specified.  |  |  |  |  |
| FIRST AID MEASURES: Eye contact: Rinse thoroughly with plenty of water for at least 15 minutes. If eye irritation persists: Get medical advice/attention. Skin contact: Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes. Ingestion: Wash out mouth with water. Seek medical advice immediately if symptoms occur and/or large quantities have been ingested. |  |  |  |  |
| Inhalation: Move to fresh air.  EMERGENCY MEASURES TO PROTECT THE ENVIRONMENT:  Prevent further leakage or spillage if safe to do so. Methods and materials for containment and clean-up: Dam up. Soak up with inert absorbent material. Prevent product from entering drains. Keep in suitable and closed containers for disposal.   |  |  |  |  |
| 5.4. Instructions for safe disposal of the product and its packaging  |  |  |  |  |
| At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.  |  |  |  |  |

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

| Shelf-life: 1 year.   |                                |                           |
|---|--------------------------------|---------------------------|
|   |                                |                           |
| 6. Other information  |                                |                           |
|   |                                |                           |
| 7. Third information level:   | individual products in the me  | ta SPC                    |
| 7.1 Trade name(s), authorisa<br>product                                       | tion number and specific compo | sition of each individual |
| Trade name(s)   | Tri-Fender                     | Market area: EU           |
|   | Tri-Fender                     | Market area: CH           |
|   | Tri-Fender                     | Market area: IS           |
|   | Tri-Fender                     | Market area: NO           |
| Authorisation number (R4BP 3 asset reference number - National Authorisation) | NL-0013188-0001 1-1            |                           |
|   |                                |                           |

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

| Common name        | IUPAC name | Function         | CAS number | EC number | Content (%) |
|--------------------|------------|------------------|------------|-----------|-------------|
| Iodine             |            | Active Substance | 7553-56-2  | 231-442-4 | 0,25        |
| Alcohol ethoxylate |            |                  | 68439-46-3 |           | 0           |

Sodium iodide 7681-82-5 231-679-3 0,12

Trade name(s)

TriActive Market area: DK

**Authorisation number** 

(R4BP 3 asset reference number - National Authorisation)

NL-0013188-0002 1-1

| Common name        | IUPAC name | Function         | CAS number | EC number | Content (%) |
|--------------------|------------|------------------|------------|-----------|-------------|
| lodine             |            | Active Substance | 7553-56-2  | 231-442-4 | 0,214       |
| Alcohol ethoxylate |            |                  | 68439-46-3 |           | 0           |
| Sodium iodide      |            |                  | 7681-82-5  | 231-679-3 | 0,092       |

### 1. Meta SPC administrative information

#### 1.1. Meta SPC identifier

meta SPC 2: Metafamily 2

### 1.2. Suffix to the authorisation number

1-2

### 1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

### 2. Meta SPC composition

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

| Common name        | IUPAC name | Function         | CAS number | EC number | Content (%)  |
|--------------------|------------|------------------|------------|-----------|--------------|
| lodine             |            | Active Substance | 7553-56-2  | 231-442-4 | 0,23 - 0,25  |
| Alcohol ethoxylate |            |                  | 68439-46-3 |           | 0 - 0        |
| Sodium iodide      |            |                  | 7681-82-5  | 231-679-3 | 0,097 - 0,11 |

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

Formulation(s)

AL - Any other liquid

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

**Hazard statements** 

Contains sodium iodate. May produce an allergic reaction.

Harmful to aquatic life with long lasting effects.

**Precautionary statements** 

Keep out of reach of children.

Avoid release to the environment.

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

### 4.1 Use description

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

#### **Product type**

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised

Teat disinfectant

Target organism(s) (including development stage)

Scientific name: Common name: Bacteria Development stage:

Scientific name: Common name: Yeasts Development stage:

Scientific name: Common name: Viruses Development stage:

Field(s) of use

Indoor

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

Application method(s)

Post-milking teat disinfection of udder teats with ready-to-use products. -

The product is applied manually after milking on the teats by manual dipping using a dip

Application rate(s) and frequencies

ca. 5 ml per cow; ca. 2.5 ml per sheep or goat - 0% -

To be applied after milking, 2 times per day. The products can be used all year during the lactation period.

Category(ies) of users

Professional

Pack sizes and packaging material

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

### 4.1.1 Use-specific instructions for use

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

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

Directions for use:

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

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

| DIP: dip every teat in the product. Ensure that the teat is covered to at least three quarters length and replenish the dip cup as necessary; Allow teats to dry after application during at least 5 min and keep the animals standing during this period. |   |  |  |  |  |  |  |
|--|---|--|--|--|--|--|--|
| 4.1.2 Use-specific risk mitiga   | ation measures  |  |  |  |  |  |  |
| There are no use specific risk mitigation  | measures. See 5.2 for general instructions.   |  |  |  |  |  |  |
| -  | se, the particulars of likely direct or indirect effects, first aid measures to protect the environment |  |  |  |  |  |  |
| There are no use specific instructions. Se   | ee 5.3 for general instructions.  |  |  |  |  |  |  |
| 4.1.4 Where specific to the uspeckaging  | se, the instructions for safe disposal of the product and its   |  |  |  |  |  |  |
| There are no use specific instructions. Se   | ee 5.4 for general instructions.  |  |  |  |  |  |  |
| 4.1.5 Where specific to the us<br>under normal conditions of s   | se, the conditions of storage and shelf-life of the product<br>torage                                   |  |  |  |  |  |  |
| -  |   |  |  |  |  |  |  |
| 4.2 Use description  |   |  |  |  |  |  |  |
| Use 2 - Teat disinfection, Ready   | v-to-use spray products applied manually  |  |  |  |  |  |  |
| Product type   | PT03 - Veterinary hygiene (Disinfectants)   |  |  |  |  |  |  |
| Where relevant, an exact<br>description of the authorised<br>use   | escription of the authorised  |  |  |  |  |  |  |
| Target organism(s) (including development stage)   | Scientific name:<br>Common name: Bacteria<br>Development stage:   |  |  |  |  |  |  |
|  | Scientific name:<br>Common name: Yeasts<br>Development stage:   |  |  |  |  |  |  |
|  | Scientific name:<br>Common name: Viruses  |  |  |  |  |  |  |

Development stage:

### Field(s) of use

#### Indoor

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

### Application method(s)

Post-milking teat disinfection of udder teats with ready-to-use products. -

The product is applied manually after milking on the teats by spraying using a spray container.

### Application rate(s) and frequencies

ca 5 ml per cow; ca 2.5 ml per sheep or goat - 0% -

To be applied after milking, 2 times per day. The products can be used all year during the lactation period

### Category(ies) of users

#### Professional

### Pack sizes and packaging material

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

### 4.2.1 Use-specific instructions for use

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

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

Directions for use:

For manual application: use a clean applicator.

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

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

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

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

### 4.2.2 Use-specific risk mitigation measures

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

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

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

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

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

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

-

### 4.3 Use description

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

| D   | 4    |      |
|-----|------|------|
| Pro | auct | type |

Where relevant, an exact description of the authorised

Target organism(s) (including development stage)

PT03 - Veterinary hygiene (Disinfectants)

Teat disinfectant

Scientific name: Common name: Bacteria Development stage:

Scientific name: Common name: Yeasts Development stage:

Scientific name: Common name: Viruses Development stage:

Field(s) of use

Indoor

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

Application method(s)

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

Application rate(s) and frequencies

ca. 5 ml per cow; ca. 2.5 ml per sheep or goat - 0% -

To be applied after milking, 3 times per day. The products can be used all year during

|   | the lactation period.  |  |  |  |  |
|---|--|--|--|--|--|
| Category(ies) of users  | Professional   |  |  |  |  |
| Pack sizes and packaging<br>material  | Can, Plastic: HDPE , 5L Can, Plastic: HDPE , 10L Can, Plastic: HDPE , 20L Can, Plastic: HDPE , 60L Drum, Plastic: HDPE , 200L IBC, Plastic: HDPE , 1000L |  |  |  |  |
| 4.3.1 Use-specific instruction  | ns for use   |  |  |  |  |
| The product is a ready-to-use product and is used undiluted. The product must be brought to a temperature above 20°C before use.                                |  |  |  |  |  |
| 4.3.2 Use-specific risk mitigation measures   |  |  |  |  |  |
| There are no use specific risk mitigation measures. See 5.2 for general instructions.   |  |  |  |  |  |
| 4.3.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment |  |  |  |  |  |
| There are no use specific instructions. See 5.3 for general instructions.   |  |  |  |  |  |
| 4.3.4 Where specific to the use, the instructions for safe disposal of the product and its packaging  |  |  |  |  |  |
| There are no use specific instructions. See 5.4 for general instructions.   |  |  |  |  |  |

| •  | fic to the use, the conditions of storage and shelf-life of the product ditions of storage  |
|--|---|
| -  |   |
|  |   |
| 5. General direc   | tions for use of the meta SPC   |
| 5.1. Instructions f  | or use  |
| There are no general ins   | structions for use. See the use specific instructions for use.  |
| 5.2. Risk mitigatio  | on measures   |
| In case a combination of considered for pre-milking  | pre- and post-milking disinfection is necessary, using another product not containing iodine has to be g disinfection.  |
| measures to prot   | likely direct or indirect effects, first aid instructions and emergency ect the environment   |
| DIRECT/INDIRECT EFF<br>According to our experie<br>handled as specified.<br>FIRST AID MEASURES | nce and to the information provided to us, the product does not have any adverse effects if it is used and  |
| Eye contact: Rinse thoro<br>Skin contact: Wash off in  | ughly with plenty of water for at least 15 minutes. If eye irritation persists: Get medical advice/attention. mmediately with soap and plenty of water removing all contaminated clothes and shoes. uth with water. Seek medical advice immediately if symptoms occur and/or large quantities have been |
| Inhalation: Move to fresh<br>EMERGENCY MEASUR<br>Prevent further leakage                       | n air.<br>RES TO PROTECT THE ENVIRONMENT:<br>or spillage if safe to do so. Methods and materials for containment and clean-up: Dam up. Soak up with iner<br>rent product from entering drains. Keep in suitable and closed containers for disposal.   |
|  |   |
| 5.4. Instructions f  | or safe disposal of the product and its packaging   |
|  | ent, dispose unused product and the packaging in accordance with local requirements. Used product can be sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual ant.   |
|  |   |

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

| Storage: Store upright in the tightly close<br>Shelf-life: 1 year             | d original container. Protect from direct light, tem | peratures above 30°C and frost. |
|---|--|---------------------------------|
| 6. Other information  |  |                                 |
|   | individual products in the me                        |                                 |
| Trade name(s)   | Blockade   | Market area: HR                 |
|   | Blockade   | Market area: DK                 |
|   | Blockade   | Market area: FR                 |
|   | Blockade   | Market area: IT                 |
|   | Blockade   | Market area: ES                 |
| Authorisation number (R4BP 3 asset reference number - National Authorisation) | NL-0013188-0003 1-2                                  |                                 |

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

### Trade name(s)

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

| IodoFence | Market area: HU |
|-----------|-----------------|
| IodoFence | Market area: IE |
| IodoFence | Market area: IT |
| IodoFence | Market area: LV |
| IodoFence | Market area: LT |
| IodoFence | Market area: LU |
| IodoFence | Market area: MT |
| IodoFence | Market area: NL |
| IodoFence | Market area: PL |
| IodoFence | Market area: PT |
| IodoFence | Market area: RO |
| IodoFence | Market area: SK |
| IodoFence | Market area: SI |
| IodoFence | Market area: ES |
| IodoFence | Market area: SE |
| lodoFence | Market area: GB |

| IodoFence           | Market area: CH |
|---------------------|-----------------|
| IodoFence           | Market area: NO |
| NL-0013188-0004 1-2 |                 |

#### **Authorisation number**

(R4BP 3 asset reference number - National Authorisation)

| Common name        | IUPAC name | Function         | CAS number | EC number | Content (%) |
|--------------------|------------|------------------|------------|-----------|-------------|
| lodine             |            | Active Substance | 7553-56-2  | 231-442-4 | 0,25        |
| Alcohol ethoxylate |            |                  | 68439-46-3 |           | 0           |
| Sodium iodide      |            |                  | 7681-82-5  | 231-679-3 | 0,11        |

### Trade name(s)

| Fortex | Market area: AT |
|--------|-----------------|
| Fortex | Market area: HR |
| Fortex | Market area: CZ |
| Fortex | Market area: DK |
| Fortex | Market area: EE |
| Fortex | Market area: FI |
|        |                 |

| Fortex | Market area: FR |
|--------|-----------------|
| Fortex | Market area: DE |
| Fortex | Market area: HU |
| Fortex | Market area: IT |
| Fortex | Market area: LV |
| Fortex | Market area: LT |
| Fortex | Market area: LU |
| Fortex | Market area: NL |
| Fortex | Market area: PL |
| Fortex | Market area: PT |
| Fortex | Market area: ES |
| Fortex | Market area: SE |
| Fortex | Market area: CH |
| Fortex | Market area: NO |
| Fortex | Market area: IS |

**Authorisation number** 

NL-0013188-0005 1-2

(R4BP 3 asset reference number - National Authorisation)

| Common name        | IUPAC name | Function         | CAS number | EC number | Content (%) |
|--------------------|------------|------------------|------------|-----------|-------------|
| lodine             |            | Active Substance | 7553-56-2  | 231-442-4 | 0,23        |
| Alcohol ethoxylate |            |                  | 68439-46-3 |           | 0           |
| Sodium iodide      |            |                  | 7681-82-5  | 231-679-3 | 0,097       |

### 1. Meta SPC administrative information

#### 1.1. Meta SPC identifier

meta SPC 3: Metafamily 3

#### 1.2. Suffix to the authorisation number

1-3

### 1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

### 2. Meta SPC composition

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

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

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

Formulation(s) AL - Any other liquid

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

| Hazard statements        |                                |
|--------------------------|--------------------------------|
| Precautionary statements | Keep out of reach of children. |

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

### 4.1 Use description

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

# Product type Where relevant, an exact description of the authorised use Product type Teat disinfectant

Target organism(s) (including development stage)

Scientific name: Common name: Bacteria Development stage:

Scientific name: Common name: Yeasts Development stage:

Scientific name: Common name: Viruses Development stage:

### Field(s) of use

Indoor

The product is intended for post-milking teat disinfection.

The product is applied directly after milking on the teats of lactating animals

Application method(s)

Post-milking teat disinfection of udder teats with ready-to-use products -

The product is applied manually after milking on the teats by manual dipping using a dip

### Application rate(s) and frequencies

ca. 5 ml per cow; ca. 2.5 ml per sheep or goat - 0% -

To be applied after milking, 2 times per day. The products can be used all year during

the lactation period.

### Category(ies) of users

Professional

#### Pack sizes and packaging material

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

### 4.1.1 Use-specific instructions for use

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

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

Directions for use:

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

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

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

### 4.1.2 Use-specific risk mitigation measures

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

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

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

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

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

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

-

### 4.2 Use description

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

| D   | 4    |      |
|-----|------|------|
| Pro | auct | type |

Where relevant, an exact description of the authorised

Target organism(s) (including development stage)

PT03 - Veterinary hygiene (Disinfectants)

Teat disinfectant

Scientific name: Common name: Bacteria Development stage:

Scientific name: Common name: Yeast Development stage:

Scientific name: Common name: Viruses Development stage:

Field(s) of use

Indoor

The product is intended for post-milking teat disinfection.

The product is applied directly after milking on the teats of lactating animals

Application method(s)

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

container.

Application rate(s) and frequencies

ca. 5 ml per cow; ca. 2.5 ml per sheep or goat - 0% -

To be applied after milking, 2 times per day. The products can be used all year during

Category(ies) of users

Professional

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

### 4.2.1 Use-specific instructions for use

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

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

Directions for use:

For manual application: use a clean applicator.

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

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

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

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

### 4.2.2 Use-specific risk mitigation measures

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

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

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

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

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

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

-

### 4.3 Use description

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

### **Product type**

Where relevant, an exact description of the authorised use

Target organism(s) (including development stage)

PT03 - Veterinary hygiene (Disinfectants)

Teat disinfectant

Scientific name: Common name: Bacteria Development stage:

Scientific name: Common name: Yeasts Development stage:

Scientific name: Common name: Viruses Development stage:

### Field(s) of use

Indoor

The product is intended for post-milking teat disinfection.

The product is applied directly after milking on the teats of lactating animals

### Application method(s)

Post-milking teat disinfection of udder teats with ready-to-use products - The product is applied automatically by milking machines after milking on the teats by

integrated dipping or spraying device.

### Application rate(s) and frequencies

ca. 5 ml per cow; ca. 2.5 ml per sheep or goat - 0% -

To be applied after milking, 3 times per day. The products can be used all year during the lactation period.

### Category(ies) of users

Professional

### Pack sizes and packaging material

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

| 4.3.1 Use-specific instructions for use   |
|---|
| The product is a ready-to-use product and is used undiluted. The product must be brought to a temperature above 20°C before use.                                |
|   |
| 4.3.2 Use-specific risk mitigation measures   |
| There are no use specific risk mitigation measures. See 5.2 for general instructions.   |
| 4.3.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment |
| There are no use specific instructions. See 5.3 for general instructions.   |
| 4.3.4 Where specific to the use, the instructions for safe disposal of the product and its packaging  |
| There are no use specific instructions. See 5.4 for general instructions.   |
| 4.3.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage                                     |
| -   |
|   |
| 5. General directions for use of the meta SPC   |
| 5.1. Instructions for use   |
| There are no general instructions for use. See the use specific instructions for use.   |
| 5.2. Risk mitigation measures   |
| In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be                                 |

| neasures to prote  | flikely direct or indirect effects, first aid instructions and emergency ect the environment   |
|--|--|
| DIRECT/INDIRECT EFF  |  |
| According to our experie handled as specified.   | ence and to the information provided to us, the product does not have any adverse effects if it is used and  |
| Skin contact: Wash off ir<br>Ingestion: Wash out mot<br>ingested.<br>Inhalation: Move to fresh<br>EMERGENCY MEASUR | oughly with plenty of water for at least 15 minutes. If eye irritation persists: Get medical advice/attention  mmediately with soap and plenty of water removing all contaminated clothes and shoes.  uth with water. Seek medical advice immediately if symptoms occur and/or large quantities have been  n air.  RES TO PROTECT THE ENVIRONMENT: |
|  | or spillage if safe to do so. Methods and materials for containment and clean-up: Dam up. Soak up with inert<br>/ent product from entering drains. Keep in suitable and closed containers for disposal.  |
| 5.4. Instructions f  | or safe disposal of the product and its packaging  |
|  | ent, dispose unused product and the packaging in accordance with local requirements. Used product can be sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual lant.   |
|  |  |
|  |  |
|  |  |
|  |  |
| F. Conditions of   | storage and shelf life of the product under normal conditions of storage   |
|  | storage and shelf-life of the product under normal conditions of storage   |
| Storage: Store upright in  | storage and shelf-life of the product under normal conditions of storage in the tightly closed original container. Protect from direct light, temperatures above 30°C and frost.   |
| Storage: Store upright in  | -  |
| Storage: Store upright in  | -  |
| Storage: Store upright in  | -  |
| Storage: Store upright in<br>Shelf-life: 1 year.   | the tightly closed original container. Protect from direct light, temperatures above 30°C and frost.   |
| Storage: Store upright in<br>Shelf-life: 1 year.   | the tightly closed original container. Protect from direct light, temperatures above 30°C and frost.   |
| Storage: Store upright in<br>Shelf-life: 1 year.   | the tightly closed original container. Protect from direct light, temperatures above 30°C and frost.   |
| Storage: Store upright in<br>Shelf-life: 1 year.   | the tightly closed original container. Protect from direct light, temperatures above 30°C and frost.   |
|  | the tightly closed original container. Protect from direct light, temperatures above 30°C and frost.   |
| Storage: Store upright in<br>Shelf-life: 1 year.   | n the tightly closed original container. Protect from direct light, temperatures above 30°C and frost.  Ation  |
| Storage: Store upright in<br>Shelf-life: 1 year.   | the tightly closed original container. Protect from direct light, temperatures above 30°C and frost.   |

Trade name(s)

Dipal RTU Market area: AT

| Dipal RTU | Market area: HR |
|-----------|-----------------|
| Dipal RTU | Market area: CY |
| Dipal RTU | Market area: DK |
| Dipal RTU | Market area: EE |
| Dipal RTU | Market area: FI |
| Dipal RTU | Market area: FR |
| Dipal RTU | Market area: DE |
| Dipal RTU | Market area: GR |
| Dipal RTU | Market area: LT |
| Dipal RTU | Market area: MT |
| Dipal RTU | Market area: NL |
| Dipal RTU | Market area: BE |
| Dipal RTU | Market area: PT |
| Dipal RTU | Market area: SI |
| Dipal RTU | Market area: ES |
| Dipal RTU | Market area: SE |

| Dipal RTU           | Market area: NO |
|---------------------|-----------------|
| NL-0013188-0006 1-3 |                 |

#### **Authorisation number**

(R4BP 3 asset reference number - National Authorisation)

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

### 1. Meta SPC administrative information

### 1.1. Meta SPC identifier

meta SPC 4: Metafamily 4

#### 1.2. Suffix to the authorisation number

1-4

### 1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

### 2. Meta SPC composition

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

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

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

Formulation(s)

AL - Any other liquid

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

**Hazard statements** 

Causes serious eye irritation.

**Precautionary statements** 

Keep out of reach of children.

Wear eye protection.

Wear face protection.

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

Wash hands thoroughly after handling.

If eye irritation persists:Get medical advice.

If eye irritation persists:Get medical attention.

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

## 4.1 Use description

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

**Product type** 

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised

Target organism(s) (including development stage)

Teat disinfectant

Scientific name: Common name: Bacteria Development stage:

Scientific name: Common name: Yeasts Development stage:

Scientific name: Common name: Viruses Development stage:

Field(s) of use

Indoor

The product is intended for post-milking teat disinfection.

The product is applied directly after milking on the teats of lactating animals

Application method(s)

Post-milking teat disinfection of udder teats with ready-to-use products. -

The product is applied manually after milking on the teats by manual dipping using a dip

Application rate(s) and frequencies

ca. 5 ml per cow; ca. 2.5 ml per sheep or goat - 0% -

To be applied after milking, 2 times per day. The products can be used all year during

the lactation period.

Category(ies) of users

Professional

Pack sizes and packaging material

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

### 4.1.1 Use-specific instructions for use

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

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

Directions for use:

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

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

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

| 4.1.2 Use-specific risk mitiga  | ation measures  |  |  |  |  |  |  |  |
|---|---|--|--|--|--|--|--|--|
| Use eye/face protection during post-milking teat disinfection by manual dipping. See 5.2 for general instructions.  |   |  |  |  |  |  |  |  |
| 4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment |   |  |  |  |  |  |  |  |
| There are no use specific instructions. So  | ee 5.3 for general instructions.                                |  |  |  |  |  |  |  |
| 4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging  |   |  |  |  |  |  |  |  |
| There are no use specific instructions. So  | ee 5.4 for general instructions.                                |  |  |  |  |  |  |  |
| 4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage                                     |   |  |  |  |  |  |  |  |
| 4.2 Use description   |   |  |  |  |  |  |  |  |
| Use 2 - Teat disinfection, Ready  | v-to-use spray products applied manually                        |  |  |  |  |  |  |  |
| Product type  | PT03 - Veterinary hygiene (Disinfectants)                       |  |  |  |  |  |  |  |
| Where relevant, an exact description of the authorised use  |   |  |  |  |  |  |  |  |
| Target organism(s) (including development stage)  | Scientific name:<br>Common name: Bacteria<br>Development stage: |  |  |  |  |  |  |  |
|   | Scientific name:<br>Common name: Yeast<br>Development stage:    |  |  |  |  |  |  |  |
|   | Scientific name:<br>Common name: Viruses<br>Development stage:  |  |  |  |  |  |  |  |

Field(s) of use

Indoor

The product is intended for post-milking teat disinfection.

The product is applied directly after milking on the teats of lactating animals

Application method(s)

post-milking teat disinfection of udder teats with ready-to-use products -

The product is applied manually after milking on the teats by spraying using a spray

container.

Application rate(s) and frequencies

ca. 5 ml per cow; ca. 2.5 ml per sheep or goat - 0% -

To be applied after milking, 2 times per day. The products can be used all year during

the lactation period.

Category(ies) of users

Professional

Pack sizes and packaging material

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

## 4.2.1 Use-specific instructions for use

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

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

Directions for use:

For manual application: use a clean applicator.

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

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

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

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

### 4.2.2 Use-specific risk mitigation measures

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

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

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

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

There are no use specific instructions. See 5.4 for general instructions. 4.2.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage 4.3 Use description Use 3 - Teat disinfection, Ready-to-use dip or spray products applied automatically PT03 - Veterinary hygiene (Disinfectants) **Product type** Where relevant, an exact Teat disinfectant description of the authorised Scientific name: Common name: Bacteria Target organism(s) (including development stage) Development stage: Scientific name: Common name: Yeasts Development stage: Scientific name: Common name: Viruses Development stage: Indoor Field(s) of use The product is intended for post-milking teat disinfection. The product is applied directly after milking on the teats of lactating animals Post-milking teat disinfection of udder teats with ready-to-use products. -Application method(s) The product is applied automatically by milking machines after milking on the teats by integrated dipping or spraying device. ca. 5 ml per cow; ca. 2.5 ml per sheep or goat - 0% -Application rate(s) and To be applied after milking, 3 times per day. The products can be used all year during frequencies the lactation period. Professional Category(ies) of users

| Pack sizes and packaging<br>material   | Can, Plastic: HDPE , 5L Can, Plastic: HDPE , 10L Can, Plastic: HDPE , 20L Can, Plastic: HDPE , 60L Drum, Plastic: HDPE , 200L IBC, Plastic: HDPE , 1000L |  |  |  |  |  |
|--|--|--|--|--|--|--|
| 4.3.1 Use-specific instruction   | ns for use   |  |  |  |  |  |
| The product is a ready-to-use product an The product must be brought to a temper |  |  |  |  |  |  |
| 4.3.2 Use-specific risk mitiga   | ition measures   |  |  |  |  |  |
| Use eye/face protection during post-milki  | ing teat disinfection by automated dipping or spraying. See 5.2 for general instructions.  |  |  |  |  |  |
|  | se, the particulars of likely direct or indirect effects, first aid measures to protect the environment  |  |  |  |  |  |
| There are no use specific instructions. See 5.3 for general instructions.        |  |  |  |  |  |  |
| 4.3.4 Where specific to the uspackaging  | se, the instructions for safe disposal of the product and its  |  |  |  |  |  |
| There are no use specific instructions. Se                                       | ee 5.4 for general instructions.   |  |  |  |  |  |
| 4.3.5 Where specific to the us<br>under normal conditions of s                   | se, the conditions of storage and shelf-life of the product  |  |  |  |  |  |

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

### 5.1. Instructions for use

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

### 5.2. Risk mitigation measures

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

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

DIRECT/INDIRECT FEECTS:

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

FIRST AID MEASURES:

Eye contact: Rinse thoroughly with plenty of water for at least 15 minutes. If eye irritation persists: Get medical advice/attention. Skin contact: Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes.

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

Inhalation: Move to fresh air.

EMERGENCY MEASURES TO PROTECT THE ENVIRONMENT:

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

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

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

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

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

## 6. Other information

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

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

| Trade name(s)  | Dipal Plus          | Market area: NL |  |
|--|---------------------|-----------------|--|
| Authorisation number                                     | NL-0013188-0007 1-4 |                 |  |
| (R4BP 3 asset reference number - National Authorisation) |                     |                 |  |

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

## 1. Meta SPC administrative information

### 1.1. Meta SPC identifier

meta SPC 5: Metafamily 5

### 1.2. Suffix to the authorisation number

1-5

## 1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

## 2. Meta SPC composition

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

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

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

Formulation(s)

SL - Soluble concentrate

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

#### **Hazard statements**

Causes serious eye irritation.

Harmful to aquatic life with long lasting effects.

May cause damage to organs thyroid through prolonged or repeated exposure oral route.

## **Precautionary statements**

Keep out of reach of children.

Avoid release to the environment.

Wear eye protection.

Wear face protection.

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

Wash hands thoroughly after handling.

If eye irritation persists:Get medical advice.

If eye irritation persists:Get medical attention.

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

### 4.1 Use description

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

### **Product type**

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

Teat disinfectant

Target organism(s) (including development stage)

Scientific name: Common name: Bacteria Development stage:

Scientific name: Common name: Yeasts Development stage:

Scientific name: Common name: Viruses Development stage:

### Field(s) of use

Indoor

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

### Application method(s)

Post-milking disinfection of udder teats with diluted concentrate -

The product is applied manually after milking on the teats by manual dipping using a dip

## Application rate(s) and frequencies

ca. 5 ml per cow; ca. 2.5 ml per sheep or goat - 20%: Use concentration: 0.15% w/w iodine -

To be applied after milking, 2 times per day. The products can be used all year during the lactation period.

### Category(ies) of users

Professional

## Pack sizes and packaging material

Can, Plastic: HDPE, 5L Can, Plastic: HDPE, 10L Can, Plastic: HDPE, 20L Can, Plastic: HDPE, 60L Drum, Plastic: HDPE, 200L IBC, Plastic: HDPE, 1000L Bottle, Plastic, HDPE, 1L

## 4.1.1 Use-specific instructions for use

Directions for use:

It is recommended to wear gloves during milking and application to protect the skin and ensure hygienic milking condition.

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

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

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

For manual application: use a clean dip cup.

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

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

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

### 4.1.2 Use-specific risk mitigation measures

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

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

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

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

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

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

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#### 4.2 Use description

**Product type** 

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

Where relevant, an exact description of the authorised use

| PT03 - Veterinary h | nygiene | (Disinfectants) |
|---------------------|---------|-----------------|
|---------------------|---------|-----------------|

Teat disinfectant

Scientific name:

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

Common name: Bacteria Development stage:

Scientific name: Common name: Yeasts Development stage:

Scientific name: Common name: Viruses Development stage:

### Field(s) of use

frequencies

#### Indoor

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

### Application method(s)

Post-milking disinfection of udder teats with diluted concentrate -

The product is applied after manually milking on the teats by spraying using a spray container.

## Application rate(s) and

ca 5 ml per cow; ca. 2.5 ml per sheep or goat - 20%: Use concentration: 0.15% w/w

To be applied after milking 2 times per day. The product can be used all year during the lactation period.

### Category(ies) of users

#### Professional

### Pack sizes and packaging material

Can, Plastic: HDPE, 5L Can, Plastic: HDPE, 10L Can, Plastic: HDPE, 20L Can, Plastic: HDPE, 60L Drum, Plastic: HDPE, 200L IBC. Plastic: HDPE, 1000L Bottle, Plastic: HDPE, 1L

### 4.2.1 Use-specific instructions for use

Directions for use:

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

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

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

For manual application: use a clean applicator.

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

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

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

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

## 4.2.2 Use-specific risk mitigation measures

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

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

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

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

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

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

-

## 4.3 Use description

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

### **Product type**

Where relevant, an exact description of the authorised use

Target organism(s) (including development stage)

PT03 - Veterinary hygiene (Disinfectants)

Teat disinfectant

Scientific name: Common name: Bacteria Development stage:

Scientific name: Common name: Yeasts Development stage:

Scientific name: Common name: Viruses Development stage:

Field(s) of use

Indoor

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

### Application method(s)

Post-milking disinfection of udder teats with diluted concentrate -

The product is applied automatically by milking machines after milking on the teats by integrated dipping or spraying device.

## Application rate(s) and frequencies

ca. 5 ml per cow; ca. 2.5 ml per sheep or goat - 20%: Use concentration: 0.15% w/w inding -

To be applied after milking, 3 times per day. The products can be used all year during the lactation period.

### Category(ies) of users

Professional

## Pack sizes and packaging material

Can, Plastic: HDPE, 5L Can, Plastic: HDPE, 10L Can, Plastic: HDPE, 20L Can, Plastic: HDPE, 60L Drum, Plastic: HDPE, 200L IBC, Plastic: HDPE, 1000L Bottle, Plastic, HDPE, 1L

## 4.3.1 Use-specific instructions for use

Directions for use:

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

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

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

### 4.3.2 Use-specific risk mitigation measures

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

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

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

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

| There are no use specific instructions. See 5.4 for general instructions.   |
|---|
| 4.3.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage |
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|   |
| 5. General directions for use of the meta SPC   |
| 5.1. Instructions for use   |
| There are no general instructions for use. See section 4 for the use specific instructions for use.                         |

## 5.2. Risk mitigation measures

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

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

DIRECT/INDIRECT EFFECTS

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

FIRST AID MEASURES

Eye contact: Rinse thoroughly with plenty of water for at least 15 minutes. If eye irritation persists: Get medical advice/attention. Skin contact: Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes.

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

Inhalation: Move to fresh air.

EMERGENCY MEASURES TO PROTECT THE ENVIRONMENT

Prevent further leakage or spillage if safe to do so.

Methods and materials for containment and cleanup: Dam up. Soak up with inert absorbent material. Prevent product from entering drains. Keep in suitable and closed containers for disposal.

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

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

| waste water treatment plant. |
|------------------------------|
|------------------------------|

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

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

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

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

Trade name(s)

| lobac Conc | Market area: BE |
|------------|-----------------|
| Dipal Conc | Market area: BG |
| Dipal Conc | Market area: HR |
| Dipal Conc | Market area: CY |
| Dipal Conc | Market area: CZ |
| Dipal Conc | Market area: DK |
| Dipal Conc | Market area: EE |
| Dipal Conc | Market area: FI |
|            |                 |

| Dipal Conc           | Market area: FR |
|----------------------|-----------------|
| Dipal Conc           | Market area: HU |
| Dipal Conc           | Market area: LV |
| Dipal Conc           | Market area: LT |
| Dipal Conc           | Market area: LU |
| Dipal Conc           | Market area: PL |
| Dipal Conc           | Market area: RO |
| Dipal Conc           | Market area: SE |
| Dipal Conc           | Market area: NO |
| Dipal Conc           | Market area: IS |
| NI -0013188-0008 1-5 |                 |

## **Authorisation number**

(R4BP 3 asset reference number - National Authorisation)

NL-0013188-0008 1-5

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

## 1. Meta SPC administrative information

## 1.1. Meta SPC identifier

meta SPC 6: Metafamily 6

### 1.2. Suffix to the authorisation number

1-6

## 1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

## 2. Meta SPC composition

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

| Common name        | IUPAC name | Function         | CAS number | EC number | Content (%) |
|--------------------|------------|------------------|------------|-----------|-------------|
| lodine             |            | Active Substance | 7553-56-2  | 231-442-4 | 0,15 - 0,15 |
| Alcohol ethoxylate |            |                  | 68439-46-3 |           | 0 - 0       |
| Sodium iodide      |            |                  | 7681-82-5  | 231-679-3 | 0,07 - 0,07 |

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

Formulation(s)

AL - Any other liquid

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

Hazard statements

Harmful to aquatic life with long lasting effects.

May be corrosive to metals.

Keep out of reach of children.

Avoid release to the environment.

|  | Avoid release to the environment.  |  |  |
|--|--|--|--|
| 4. Authorised use(s) of the meta SPC                       |  |  |  |
| 4.1 Use description  |  |  |  |
| Use 1 - Teat disinfection, Ready                           | v-to-use dip products applied manually   |  |  |
| Product type   | PT03 - Veterinary hygiene (Disinfectants)  |  |  |
| Where relevant, an exact description of the authorised use | Teat disinfectant  |  |  |
| Target organism(s) (including development stage)           | Scientific name:<br>Common name: Bacteria<br>Development stage:  |  |  |
|  | Scientific name:<br>Common name: Yeasts<br>Development stage:  |  |  |
|  | Scientific name: Common name: Viruses Development stage:   |  |  |
|  | Indoor   |  |  |
| Field(s) of use  | Indoor   |  |  |
|  | The product is intended for post-milking teat disinfection. The product is applied directly after milking on the teats of lactating animals                            |  |  |
| Application method(s)                                      | Post-milking teat disinfection of udder teats with ready-to-use products The product is applied manually after milking on the teats by manual dipping using a dip cup. |  |  |
| Application rate(s) and frequencies                        | ca. 5 ml per cow; ca. 2.5 ml per sheep or goat - 0% - To be applied after milking, 2 times per day. The products can be used all year during the lactation period.     |  |  |
| Category(ies) of users                                     | Professional   |  |  |
|  |  |  |  |

## Pack sizes and packaging material

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

## 4.1.1 Use-specific instructions for use

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

Directions for use:

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

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

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

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

## 4.1.2 Use-specific risk mitigation measures

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

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

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

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

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

## 4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage 4.2 Use description Use 2 - Teat disinfection, Ready-to-use spray products applied manually PT03 - Veterinary hygiene (Disinfectants) **Product type** Where relevant, an exact Teat disinfectant description of the authorised Scientific name: Common name: Bacteria Development stage: Target organism(s) (including development stage) Scientific name: Common name: Yeast Development stage: Scientific name: Common name: Viruses Development stage: Indoor Field(s) of use The product is intended for post-milking teat disinfection. The product is applied directly after milking on the teats of lactating animals post-milking teat disinfection of udder teats with ready-to-use products -Application method(s) The product is applied manually after milking on the teats by spraying using a spray container. ca. 5 ml per cow; ca. 2.5 ml per sheep or goat - 0% -Application rate(s) and To be applied after milking, 2 times per day. The products can be used all year during frequencies the lactation period. Professional Category(ies) of users Can, Plastic: HDPE, 5L Pack sizes and packaging Can, Plastic: HDPE, 10L material Can, Plastic: HDPE , 20L Can, Plastic: HDPE, 60L Drum, Plastic: HDPE, 200L

IBC, Plastic: HDPE, 1000L

## 4.2.1 Use-specific instructions for use

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

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

Directions for use:

For manual application: use a clean applicator.

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

1) MANUAL TRIGGER SPRAY: spray every teat 1 sec. with the product. Ensure that the teat is covered to at least three quarters

length and replenish the spray container as necessary;

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

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

## 4.2.2 Use-specific risk mitigation measures

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

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

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

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

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

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

PT03 - Veterinary hygiene (Disinfectants)

#### 4.3 Use description

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

## Product type Where relevant and

Teat disinfectant

Where relevant, an exact description of the authorised use

Scientific name: Common name: Bacteria Development stage:

Target organism(s) (including development stage)

Scientific name: Common name: Yeasts Development stage:

Scientific name: Common name: Viruses Development stage:

Field(s) of use

Indoor

The product is intended for post-milking teat disinfection.

The product is applied directly after milking on the teats of lactating animals

Application method(s)

Post-milking teat disinfection of udder teats with ready-to-use products. -

The product is applied automatically by milking machines after milking on the teats by

integrated dipping or spraying device.

Application rate(s) and frequencies

ca. 5 ml per cow; ca. 2.5 ml per sheep or goat - 0% -

To be applied after milking, 3 times per day. The products can be used all year during

the lactation period.

Category(ies) of users

Professional

Pack sizes and packaging material

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

## 4.3.1 Use-specific instructions for use

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

4.3.2 Use-specific risk mitigation measures

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

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

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

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

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

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

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

#### 5.1. Instructions for use

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

### 5.2. Risk mitigation measures

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

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

DIRECT/INDIRECT EFFECTS:

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

#### FIRST AID MEASURES:

Eye contact: Rinse thoroughly with plenty of water for at least 15 minutes. If eye irritation persists: Get medical advice/attention. Skin contact: Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes.

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

Inhalation: Move to fresh air.

EMERGENCY MEASURES TO PROTECT THE ENVIRONMENT:

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

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

| At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant. |  |                           |  |  |  |
|--|--|---------------------------|--|--|--|
| .5. Conditions of storage and shelf-life of the product under normal conditions of storage   |  |                           |  |  |  |
| _  | Storage: Store upright in the tightly closed original container. Protect from direct light, temperatures above 30°C and frost. |                           |  |  |  |
| 6. Other information   |  |                           |  |  |  |
|  |  |                           |  |  |  |
| 7. Third information level:  | 7. Third information level: individual products in the meta SPC  |                           |  |  |  |
| 7.1 Trade name(s), authorisa<br>product  | tion number and specific compo   | sition of each individual |  |  |  |
| Trade name(s)  | Proactive Plus   | Market area: DK           |  |  |  |
|  | Proactive Plus   | Market area: FI           |  |  |  |
|  | Proactive Plus   | Market area: SE           |  |  |  |
|  | Proactive Plus   | Market area: NO           |  |  |  |
| Authorisation number (R4BP 3 asset reference number - National Authorisation)  | NL-0013188-0009 1-6  |                           |  |  |  |
|  |  |                           |  |  |  |

| Common name        | IUPAC name | Function         | CAS number | EC number | Content (%) |
|--------------------|------------|------------------|------------|-----------|-------------|
| lodine             |            | Active Substance | 7553-56-2  | 231-442-4 | 0,15        |
| Alcohol ethoxylate |            |                  | 68439-46-3 |           | 0           |
| Sodium iodide      |            |                  | 7681-82-5  | 231-679-3 | 0,07        |

## 1. Meta SPC administrative information

### 1.1. Meta SPC identifier

meta SPC 7: Metafamily 7

## 1.2. Suffix to the authorisation number

1-7

## 1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

## 2. Meta SPC composition

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

| Common name        | IUPAC name | Function         | CAS number | EC number | Content (%) |
|--------------------|------------|------------------|------------|-----------|-------------|
| lodine             |            | Active Substance | 7553-56-2  | 231-442-4 | 0,15 - 0,5  |
| Alcohol ethoxylate |            |                  | 68439-46-3 |           | 0 - 0       |
| Sodium iodide      |            |                  | 7681-82-5  | 231-679-3 | 0,06 - 0,06 |

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

Formulation(s)

AL - Any other liquid

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

**Hazard statements** 

Contains sodium iodate. May produce an allergic reaction.

Harmful to aquatic life with long lasting effects.

May be corrosive to metals.

**Precautionary statements** 

Keep out of reach of children.

Avoid release to the environment.

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

## 4.1 Use description

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

**Product type** 

Where relevant, an exact description of the authorised

Target organism(s) (including development stage)

PT03 - Veterinary hygiene (Disinfectants)

Teat disinfectant

Scientific name: Common name: Bacteria Development stage:

Scientific name: Common name: Yeasts Development stage:

Scientific name: Common name: Viruses Development stage:

Field(s) of use

Indoor

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

### Application method(s)

Post-milking teat disinfection of udder teats with ready-to-use products. -

The product is applied manually after milking on the teats by manual dipping using a dip cup.

## Application rate(s) and frequencies

ca. 5 ml per cow; ca. 2.5 ml per sheep or goat - 0% -

To be applied after milking, 2 times per day. The products can be used all year during the lactation period.

### Category(ies) of users

Professional

## Pack sizes and packaging material

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

## 4.1.1 Use-specific instructions for use

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

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

Directions for use:

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

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

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

## 4.1.2 Use-specific risk mitigation measures

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

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

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

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

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

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

#### 4.2 Use description

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

### **Product type**

Where relevant, an exact description of the authorised

Target organism(s) (including development stage)

PT03 - Veterinary hygiene (Disinfectants)

Teat disinfectant

Scientific name: Common name: Bacteria Development stage:

Scientific name: Common name: Yeasts Development stage:

Scientific name: Common name: Viruses Development stage:

## Field(s) of use

Indoor

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

### Application method(s)

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

## Application rate(s) and frequencies

ca 5 ml per cow; ca 2.5 ml per sheep or goat - 0% -

To be applied after milking, 2 times per day. The products can be used all year during the lactation period

## Category(ies) of users

Professional Can, Plastic: HDPE, 5L Pack sizes and packaging Can, Plastic: HDPE, 10L material Can, Plastic: HDPE, 20L Can, Plastic: HDPE, 60L Drum, Plastic: HDPE, 200L IBC, Plastic: HDPE, 1000L 4.2.1 Use-specific instructions for use The product is a ready-to-use product and is used undiluted. The product must be brought to a temperature above 20°C before use. Directions for use: For manual application: use a clean applicator. Ensure that teats are clean before use. Apply the ready-to-use solution of the product on each teat immediately after milking: 1) MANUAL TRIGGER SPRAY: spray every teat 1 sec. with the product. Ensure that the teat is covered to at least three quarters length and replenish the spray container as necessary; 2) AUTOMATIC SPRAYER: spray every teat 1 sec. with the product. Allow teats to dry after application during at least 5 min and keep the animals standing during this period. 4.2.2 Use-specific risk mitigation measures Use chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) during postmilking teat disinfection by manual spraying. See 5.2 for general instructions. 4.2.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment There are no use specific instructions. See 5.3 for general instructions. 4.2.4 Where specific to the use, the instructions for safe disposal of the product and its packaging There are no use specific instructions. See 5.4 for general instructions. 4.2.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

### 4.3 Use description

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

### **Product type**

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

Teat disinfectant

Target organism(s) (including development stage)

Scientific name: Common name: Bacteria Development stage:

Scientific name: Common name: Yeasts Development stage:

Scientific name: Common name: Viruses Development stage:

### Field(s) of use

Indoor

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

### Application method(s)

Post-milking teat disinfection of udder teats with ready-to-use products. -

The product is applied automatically by milking machines after milking on the teats by integrated dipping or spraying device.

## Application rate(s) and frequencies

ca. 5 ml per cow; ca. 2.5 ml per sheep or goat - 0% -

To be applied after milking, 3 times per day. The products can be used all year during the lactation period.

### Category(ies) of users

Professional

Pack sizes and packaging material

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

## 4.3.1 Use-specific instructions for use

| The product is a ready-to-use product and is used undiluted. The product must be brought to a temperature above 20°C before use.   |
|--|
|  |
|  |
| 4.3.2 Use-specific risk mitigation measures  |
| There are no use specific risk mitigation measures. See 5.2 for general instructions.  |
| 4.3.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment          |
| There are no use specific instructions. See 5.3 for general instructions.  |
| 4.3.4 Where specific to the use, the instructions for safe disposal of the product and its backaging   |
| There are no use specific instructions. See 5.4 for general instructions.  |
| 3.3.5 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  |
| There are no general instructions for use. See the use specific instructions for use.  |
| 5.2. Risk mitigation measures  |
| In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection. |
|  |

| 5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency   |
|---|
| DIRECT/INDIRECT EFFECTS: According to our experience and to the information provided to us, the product does not have any adverse effects if it is used and handled as specified. FIRST AID MEASURES: Eye contact: Rinse thoroughly with plenty of water for at least 15 minutes. If eye irritation persists: Get medical advice/attention. Skin contact: Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes. Ingestion: Wash out mouth with water. Seek medical advice immediately if symptoms occur and/or large quantities have been |
| ingested. Inhalation: Move to fresh air. EMERGENCY MEASURES TO PROTECT THE ENVIRONMENT: Prevent further leakage or spillage if safe to do so. Methods and materials for containment and clean-up: Dam up. Soak up with inert absorbent material. Prevent product from entering drains. Keep in suitable and closed containers for disposal.   |
| 5.4. Instructions for safe disposal of the product and its packaging  |
|   |
| At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.  |
|   |
| 5.5. Conditions of storage and shelf-life of the product under normal conditions of storage   |
| Storage: Store upright in the tightly closed original container. Protect from direct light, temperatures above 30°C and frost.  |
| Shelf-life: 1 year  |
|   |
| 6. Other information  |

- 7. Third information level: individual products in the meta SPC
- 7.1 Trade name(s), authorisation number and specific composition of each individual product

## Trade name(s)

| lobac RTU | Market area: BE |
|-----------|-----------------|
| Proactive | Market area: IT |
|           |                 |

## **Authorisation number**

(R4BP 3 asset reference number - National Authorisation)

| Common name        | IUPAC name | Function         | CAS number | EC number | Content (%) |
|--------------------|------------|------------------|------------|-----------|-------------|
| lodine             |            | Active Substance | 7553-56-2  | 231-442-4 | 0,15        |
| Alcohol ethoxylate |            |                  | 68439-46-3 |           | 0           |
| Sodium iodide      |            |                  | 7681-82-5  | 231-679-3 | 0,06        |

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