

# Summary of product characteristics for a biocidal product family

**Family name:** Iodine Teat dip products

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

**Authorisation number:** EU-0020125-0000

**R4BP 3 asset reference number:** IS-0026281-0000

## Table Of Contents

|  |    |
|--|----|
| Part I.- First information level   | 1  |
| 1. Administrative information  | 1  |
| 2. Product family composition and formulation  | 3  |
| Part II.- Second information level - meta SPC(s)   | 3  |
| 1. Meta SPC administrative information - <b>Meta SPC 1 - Concentrates - Professional concentrates with 1:3, 1:4 and 1:7 dilution rates</b>             | 3  |
| 2. Meta SPC composition  | 3  |
| 3. Hazard and precautionary statements of the meta SPC   | 4  |
| 4. Authorised use(s) of the meta SPC   | 4  |
| 5. General directions for use of the meta SPC  | 11 |
| 6. Other information   | 12 |
| 7. Third information level: individual products in the meta SPC  | 13 |
| 1. Meta SPC administrative information - <b>Meta SPC 2 - RTU Products - Professional RTU Liquid for application pre and post milking</b>               | 15 |
| 2. Meta SPC composition  | 15 |
| 3. Hazard and precautionary statements of the meta SPC   | 16 |
| 4. Authorised use(s) of the meta SPC   | 16 |
| 5. General directions for use of the meta SPC  | 34 |
| 6. Other information   | 35 |
| 7. Third information level: individual products in the meta SPC  | 35 |
| 1. Meta SPC administrative information - <b>Meta SPC 3 - RTU Products - Professional RTU Liquid for application pre and post milking (LuxSpray 15)</b> | 38 |
| 2. Meta SPC composition  | 38 |
| 3. Hazard and precautionary statements of the meta SPC   | 39 |
| 4. Authorised use(s) of the meta SPC   | 39 |
| 5. General directions for use of the meta SPC  | 57 |
| 6. Other information   | 58 |
| 7. Third information level: individual products in the meta SPC  | 58 |

## Part I.- First information level

### 1. Administrative information

#### 1.1. Family name

Iodine Teat dip products

#### 1.2. Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

#### 1.3. Authorisation holder

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

|         |   |
|---------|---|
| Name    | GEA Farm Technologies GmbH              |
| Address | Siemensstraße 25-27 59199 Bönen Germany |

##### Authorisation number

EU-0020125-0000

##### R4BP 3 asset reference number

IS-0026281-0000

##### Date of the authorisation

19/11/2019

##### Expiry date of the authorisation

31/10/2029

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

|  |  |
|--|--|
| <b>Name of the manufacturer</b>        | GEA Farm Technologies  |
| <b>Address of the manufacturer</b>     | Wyllye Works BA12 9HT Warminster United Kingdom              |
| <b>Location of manufacturing sites</b> | Wyllye Works, Watery Lane BA12 9HT Warminster United Kingdom |
|  | Gewerbestraße 5 5325 Plainfeld Austria                       |
|  | ul. Ołowiana 10 85-461 Bydgoszcz Poland                      |

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

|  |  |
|--|--|
| <b>Active substance</b>                | 1319 - Iodine  |
| <b>Name of the manufacturer</b>        | SQM Europe N.V.  |
| <b>Address of the manufacturer</b>     | St Pietersvliet 7, bus 8 2000 Antwerp Belgium                                      |
| <b>Location of manufacturing sites</b> | Sociedad Quimica y Minera SA, Los Militares, Las Condes 4290 Piso 4 Santiago Chile |

|  |   |
|--|---|
| <b>Active substance</b>                | 1319 - Iodine   |
| <b>Name of the manufacturer</b>        | Nihon Tennen Gas Co., Ltd (Via Mitsui & Co Europe PLC)                                |
| <b>Address of the manufacturer</b>     | Chiba Plant, 2508 Minami-Hinata, Shirako-Machi, Chosei-Gun, 299-4205 Chosei-Gun Japan |
| <b>Location of manufacturing sites</b> | Chiba Plant, 2508 Minami-Hinata, Shirako-Machi, Chosei-Gun, 299-4205 Chosei-Gun Japan |

|  |  |
|--|--|
| <b>Active substance</b>                | 1319 - Iodine  |
| <b>Name of the manufacturer</b>        | Norkem Ltd   |
| <b>Address of the manufacturer</b>     | Norkem House, Bexton Lane, WA16 9FB Knutsford United Kingdom |
| <b>Location of manufacturing sites</b> | OFICINA CALA CALA S/N Unknown POZO ALMONTE 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 | 0,16 - 2,47 |
| C9-11 Alcohol Ethoxylate | C 9-11 alcohol with 6 moles of ethoxylate. Various brand names available including Imbentin C-91-060 | Non-active substance | 68439-46-3 | 614-482-0 | 0 - 2,35    |

### 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 - Concentrates - Professional concentrates with 1:3, 1:4 and 1:7 dilution rates

#### 1.2. Suffix to the authorisation number

1-1

#### 1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

## 2. Meta SPC composition

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

| Common name              | IUPAC name   | Function             | CAS number | EC number | Content (%) |
|--------------------------|--|----------------------|------------|-----------|-------------|
| Iodine                   |  | Active Substance     | 7553-56-2  | 231-442-4 | 1,58 - 2,47 |
| C9-11 Alcohol Ethoxylate | C 9-11 alcohol with 6 moles of ethoxylate. Various brand names available including Imbentin C-91-060 | Non-active substance | 68439-46-3 | 614-482-0 | 1,51 - 2,35 |

## 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.  
 May cause damage to organs Thyroid gland through prolonged or repeated exposure .  
 May be corrosive to metals.  
 Toxic to aquatic life with long lasting effects.

Precautionary statements

Do not breathe vapours.  
 Wash hands thoroughly after handling.  
 Wear protective gloves.  
 Wear protective clothing.  
 Wear eye protection.  
 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
 Get medical attention if you feel unwell.  
 If eye irritation persists: Get medical advice.  
 Collect spillage.  
 Dispose of container to according to local regulations.  
 Dispose of contents to according to local regulations.

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

#### 4.1 Use description

##### Use 1 - Concentrates - Professional concentrates with 1:3, 1:4 and 1:7 dilution rates, for post milking - Dipping

|   |   |
|---|---|
| <b>Product type</b>   | PT03 - Veterinary hygiene (Disinfectants)   |
| <b>Where relevant, an exact description of the authorised use</b> | -   |
| <b>Target organism(s) (including development stage)</b>           | Scientific name: Bacteria<br>Common name: Bacteria<br>Development stage: All<br><br>Scientific name: Other: Yeast<br>Common name: Other: Yeast<br>Development stage: All  |
| <b>Field(s) of use</b>  | Indoor<br><br>-   |
| <b>Application method(s)</b>                                      | Method: Open system: dip treatment<br>Detailed description:<br><br>Application via dip Cup: Using a traditional dip cup with non-return valves, dispense diluted product into the reservoir. Screw down the applicator portion. Squeeze the reservoir to fill the applicator. Cover the bottom two thirds of each teat with material. Dispose of unused material after each milking<br><br>The same solution can be applied to multiple animals during the same milking session. Cups should be refilled with fresh solution before starting new milking session                              |
| <b>Application rate(s) and frequencies</b>                        | Application Rate: Quantity of diluted product to be applied per application; - cows and buffaloes: 3 to 10ml (5 ml recommended) - sheep 1.5 to 5 ml (1.5 ml recommended) - goats 2.5 to 6 ml (2.5 ml recommended)<br>Dilution (%): Product to be diluted by the relevant rate stated on the label. Either; 25% (1 part product to 3 parts water) 20 % (1 part product to 4 parts water) 12.5% (1 part product to 7 parts water) In use concentration of products between 0.29 and 0.52% (w/w) iodine.<br>Number and timing of application:<br>2 post milking applications per animal, per day |
| <b>Category(ies) of users</b>                                     | Trained professional<br><br>Professional  |
| <b>Pack sizes and packaging material</b>                          | Drum, Plastic: HDPE , 10 l<br>Drum, Plastic: HDPE , 20 l<br>Drum, Plastic: HDPE , 25 l  |

Drum, Plastic: HDPE , 200 l  
IBC (intermediate bulk container), Plastic: HDPE , 1000 l  
Drum, Plastic: HDPE , 5 l

All drums excepting 200 l (200 kg) and 1000 l (1000 kg) could be either silver or natural (white translucent) in colour. 200 l (200 kg) drums are either silver or blue in colour. IBCs are natural coloured.

All drums are capped with tamper evident caps or bungs and are UN certified.

#### 4.1.1 Use-specific instructions for use

Dip at least 2/3 of the teat length with diluted product immediately after milking

#### 4.1.2 Use-specific risk mitigation measures

Wear protective chemical resistant gloves and eye protection when handling the concentrate (glove material to be specified by the authorisation holder within the product information).

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

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

See general directions for use

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

See general directions for use

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

See general directions for use



## 4.2 Use description

### Use 2 - Concentrates - Professional concentrates with 1:3, 1:4 and 1:7 dilution rates, for post milking - Spraying

|   |   |
|---|---|
| <b>Product type</b>   | PT03 - Veterinary hygiene (Disinfectants)   |
| <b>Where relevant, an exact description of the authorised use</b> | -   |
| <b>Target organism(s) (including development stage)</b>           | Scientific name: Bacteria<br>Common name: Bacteria<br>Development stage: All<br><br>Scientific name: Yeast<br>Common name: yeast<br>Development stage: All  |
| <b>Field(s) of use</b>  | Indoor<br><br>-   |
| <b>Application method(s)</b>                                      | Method: Open system: spray treatment<br>Detailed description:<br>Application via pneumatic sprayer: Uptake lance of spray system is placed in the container of the diluted product. The diluted product is then pumped to a spray lance located in the milking parlour. The spray lance is then used to cover the bottom two thirds of teats in the diluted product<br><br>Application via manual trigger spray: Fill trigger spray bottle with diluted product. Use trigger spray to cover the bottom two thirds of each teat with diluted product   |
| <b>Application rate(s) and frequencies</b>                        | Application Rate: Quantity of diluted product to be applied per application; - cows and buffaloes: 3 to 10ml (5 ml recommended) - sheep 1.5 to 5 ml (1.5 ml recommended) - goats 2.5 to 6 ml (2.5 ml recommended)<br>Dilution (%): Product to be diluted by the relevant rate stated on the label. Either; 25% (1 part product to 3 parts water) 20 % (1 part product to 4 parts water) 12.5% (1 part product to 7 parts water) In use concentration of products between 0.29 and 0.52% (w/w) iodine.<br>Number and timing of application:<br>2 post milking applications per animal, per day |
| <b>Category(ies) of users</b>                                     | Trained professional<br><br>Professional  |

## Pack sizes and packaging material

Drum, Plastic: HDPE , 10 l  
Drum, Plastic: HDPE , 20 l  
Drum, Plastic: HDPE , 25 l  
Drum, Plastic: HDPE , 200 l  
IBC (intermediate bulk container), Plastic: HDPE , 1000 l  
Drum, Plastic: HDPE , 5 l

All drums excepting 200 l (200 kg) and 1000 l (1000 kg) could be either silver or natural (white translucent) in colour. 200 l (200 kg) drums are either silver or blue in colour. IBCs are natural coloured.  
All drums are capped with tamper evident caps or bungs and are UN certified.

### 4.2.1 Use-specific instructions for use

Spray at least 2/3 of the teat length with diluted product immediately after milking

### 4.2.2 Use-specific risk mitigation measures

Wear protective chemical resistant gloves and eye protection when handling the concentrate (glove material to be specified by the authorisation holder within the product information).  
Wear protective chemical resistant gloves and boots when applying the product by manual spraying (glove material to be specified by the authorisation holder within the product information)

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

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

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

See general directions for use

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

See general directions for use

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

See general directions for use

### 4.3 Use description

#### Use 3 - Concentrates - Professional concentrates with 1:3, 1:4 and 1:7 dilution rates, for post milking - Foaming

**Product type**

PT03 - Veterinary hygiene (Disinfectants)

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

-

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

Scientific name: Bacteria  
Common name: Bacteria  
Development stage: All

Scientific name: yeast  
Common name: yeast  
Development stage: All

**Field(s) of use**

Indoor

-

**Application method(s)**

Method: Open system: dip treatment  
Detailed description:

Application via foaming Dip cup: As for dip cup, however, when squeezed, the liquid is forced through a fine mesh, mixing with air and forming foam. This is then applied to the bottom two thirds of the cow's udder

The same solution can be applied to multiple animals during the same milking session.

**Application rate(s) and frequencies**

Application Rate: Quantity of diluted product to be applied per application; - cows and buffaloes: 3 to 10ml (5 ml recommended) - sheep 1.5 to 5 ml (1.5 ml recommended) - goats 2.5 to 6 ml (2.5 ml recommended)  
Dilution (%): Product to be diluted by the relevant rate stated on the label. Either; 25% (1 part product to 3 parts water) 20% (1 part product to 4 parts water) 12.5% (1 part product to 7 parts water) In use concentration of products between 0.29 and 0.52% (w/w) iodine.

|  |  |
|--|--|
|  | Number and timing of application:<br>2 post milking applications per animal, per day   |
| <b>Category(ies) of users</b>            | Trained professional<br><br>Professional   |
| <b>Pack sizes and packaging material</b> | Drum, Plastic: HDPE , 10 l<br>Drum, Plastic: HDPE , 20 l<br>Drum, Plastic: HDPE , 25 l<br>Drum, Plastic: HDPE , 200 l<br>IBC (intermediate bulk container), Plastic: HDPE , 1000 l<br>Drum, Plastic: HDPE , 5 l<br><br>All drums excepting 200 l (200 kg) and 1000 l (1000 kg) could be either silver or natural (white translucent) in colour. 200 l (200 kg) drums are either silver or blue in colour. IBCs are natural coloured.<br>All drums are capped with tamper evident caps or bungs and are UN certified. |

#### 4.3.1 Use-specific instructions for use

Dip at least 2/3 of the teat length with diluted product immediately after milking

#### 4.3.2 Use-specific risk mitigation measures

Wear protective chemical resistant gloves and eye protection when handling the concentrate (glove material to be specified by the authorisation holder within the product information).

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

#### 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

See general directions for use

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

See general directions for use

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

See general directions for use

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

#### 5.1. Instructions for use

Keep out of reach of children  
Always read the label or leaflet before use and follow all the instructions provided.  
The product must be brought to a temperature above 20°C before use.  
Dilute product before application according to the ratio specified on the product label

For manual dilution of the concentrate; Add the ratio of concentrate and water, specified on the product label, to a suitably sized container to achieve the required dilution rate. Mix to a uniform solution.  
Before attaching the milking cluster, all teat-dip residues should be removed with either a single use towel or re-usable cloth. One cloth should be used per cow

For effective use against bacteria and yeast, product must be left in contact with the skin for at least 60 seconds

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

#### 5.2. Risk mitigation measures

See section 2.1.4.2 of the relevant use

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

Remove and wash contaminated clothing before re-use.  
After inhalation: Move to fresh air in case of accidental inhalation of fumes from overheating or combustion.  
If you feel unwell, seek medical advice.  
After contact with skin: Wash with water and soap as a precaution. Consult a doctor if skin irritation persists.  
After contact with eyes: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Seek medical treatment by eye specialist.  
After ingestion: Rinse out mouth and give plenty of water to drink. Never give anything by mouth to an unconscious person. Consult a physician.

Large spills should be contained using a chemical spill kit, soaked up using absorbent material such as kieselguhr and disposed of as Hazardous waste.

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

At the end of the treatment, dispose of 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 farm based waste water treatment plant.

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

Protect from frost

Do not store at temperatures above 30 °C

Shelf life 12 months

## 6. Other information

The signal word, hazard- and precautionary statements shall be in Icelandic on the product label.

Signal word:

**Varúð**

Hazard statements:

- H319** Veldur alvarlegri augnertingu.
- H373** Getur skaðað líffæri (skjaldkirtill) við langvinn eða endurtekin áhrif.
- H290** Getur verið ætandi fyrir málma.
- H411** Eitrað lífi í vatni, hefur langvinn áhrif.

Precautionary statements:

- P260** Andið ekki að ykkur gufu.
- P264** Þvoið hendur vandlega eftir meðhöndlun.
- P280** Notið hlífðarhanska.
- P280** Notið hlífðarfatnað.
- P280** Notið augnhlífur.
- P305 + P351 + P338** BERIST EFNID Í AUGU: Skolið varlega með vatni í nokkrar mínútur. Fjarlægjið snertilinsur ef það er auðvelt. Skolið áfram.
- P314** Leitið lækni ef lasleika verður vart.
- P337 + P313** Ef augnerting er viðvarandi: Leitið lækni.
- P391** Safnið upp því sem hellist niður.
- P501** Fargið ílát í samræmi við staðbundnar reglur.

P501 Fargið innihaldi í samræmi við staðbundnar reglur.

## 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)

Ioklene Concentrate, Coars Dual

Market area: EU

#### Authorisation number

IS-0026281-0001 1-1

(R4BP 3 asset reference number - National Authorisation)

| Common name              | IUPAC name   | Function             | CAS number | EC number | Content (%) |
|--------------------------|--|----------------------|------------|-----------|-------------|
| Iodine                   |  | Active Substance     | 7553-56-2  | 231-442-4 | 1,58        |
| C9-11 Alcohol Ethoxylate | C 9-11 alcohol with 6 moles of ethoxylate. Various brand names available including Imbentin C-91-060 | Non-active substance | 68439-46-3 | 614-482-0 | 1,51        |

#### Trade name(s)

Maxadine C, Clinidip L Concentrate, Diamond 3:1 Concentrate, Kristal 321, IO Spray 3:1 Concentrate, Coars Shield

Market area: EU

#### Authorisation number

IS-0026281-0002 1-1

(R4BP 3 asset reference number - National Authorisation)

| Common name              | IUPAC name   | Function             | CAS number | EC number | Content (%) |
|--------------------------|--|----------------------|------------|-----------|-------------|
| Iodine                   |  | Active Substance     | 7553-56-2  | 231-442-4 | 2,06        |
| C9-11 Alcohol Ethoxylate | C 9-11 alcohol with 6 moles of ethoxylate. Various brand names available including Imbentin C-91-060 | Non-active substance | 68439-46-3 | 614-482-0 | 1,96        |

**Trade name(s)**

Dunglison Super IO 421 Concentrate, Clinidip Superconcentrate, Ceanodine 4:1, Iodosan

Market area: EU

**Authorisation number**

(R4BP 3 asset reference number - National Authorisation)

IS-0026281-0003 1-1

| Common name              | IUPAC name   | Function             | CAS number | EC number | Content (%) |
|--------------------------|--|----------------------|------------|-----------|-------------|
| Iodine                   |  | Active Substance     | 7553-56-2  | 231-442-4 | 2,47        |
| C9-11 Alcohol Ethoxylate | C 9-11 alcohol with 6 moles of ethoxylate. Various brand names available including Imbentin C-91-060 | Non-active substance | 68439-46-3 | 614-482-0 | 2,35        |

**Trade name(s)**

Priodine, Diamond Predip

Market area: EU

**Authorisation number**

(R4BP 3 asset reference number - National Authorisation)

IS-0026281-0004 1-1



| Common name              | IUPAC name   | Function             | CAS number | EC number | Content (%) |
|--------------------------|--|----------------------|------------|-----------|-------------|
| Iodine                   |  | Active Substance     | 7553-56-2  | 231-442-4 | 2,32        |
| C9-11 Alcohol Ethoxylate | C 9-11 alcohol with 6 moles of ethoxylate. Various brand names available including Imbentin C-91-060 | Non-active substance | 68439-46-3 | 614-482-0 | 2,21        |

## 1. Meta SPC administrative information

### 1.1. Meta SPC identifier

Meta SPC 2 - RTU Products - Professional RTU Liquid for application pre and post milking

### 1.2. Suffix to the authorisation number

1-2

### 1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

## 2. Meta SPC composition

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

| Common name              | IUPAC name   | Function             | CAS number | EC number | Content (%) |
|--------------------------|--|----------------------|------------|-----------|-------------|
| Iodine                   |  | Active Substance     | 7553-56-2  | 231-442-4 | 0,16 - 0,5  |
| C9-11 Alcohol Ethoxylate | C 9-11 alcohol with 6 moles of ethoxylate. Various brand names available including Imbentin C-91-060 | Non-active substance | 68439-46-3 | 614-482-0 | 0 - 0,56    |

## 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

May be corrosive to metals.  
Harmful to aquatic life with long lasting effects.

Precautionary statements

Avoid release to the environment.  
Collect spillage.  
Dispose of contents to in accordance with local regulations.  
Dispose of container to in accordance with local regulations.

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

### 4.1 Use description

#### Use 1 - RTU Products - Professional RTU Liquid, for application pre-milking - Dipping

Product type

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

-

Target organism(s) (including development stage)

Scientific name: Bacteria  
Common name: Bacteria  
Development stage: All

Scientific name: YEAST  
Common name: yeast  
Development stage: All

Field(s) of use

Indoor

-

Application method(s)

Method: Open system: dip treatment  
Detailed description:

Application via dip Cup: Using a traditional dip cup with non-return valves, dispense RTU product into the reservoir. Screw down the applicator portion. Squeeze the reservoir to fill the applicator. Cover the bottom two thirds of each teat with material.

|  |   |
|--|---|
|  | <p>Dispose of unused material after each milking</p> <p>The same solution can be applied to multiple animals during the same milking session.</p>   |
| <b>Application rate(s) and frequencies</b> | <p>Application Rate: Quantity of RTU product to be applied per application; - cows and buffaloes: 3 to 10ml (5 ml recommended) - sheep 1.5 to 5 ml (1.5 ml recommended) - goats 2.5 to 6 ml (2.5 ml recommended)</p> <p>Dilution (%): Ready to use formulation In use concentration 0.16-0.30% (w/w) iodine.</p> <p>Number and timing of application:<br/>2 pre milking applications per animal, per day</p>  |
| <b>Category(ies) of users</b>              | <p>Trained professional</p> <p>Professional</p>   |
| <b>Pack sizes and packaging material</b>   | <p>Drum, Plastic: HDPE , 10 l<br/> Drum, Plastic: HDPE , 20 l<br/> Drum, Plastic: HDPE , 25 l<br/> Drum, Plastic: HDPE , 200 l<br/> IBC (intermediate bulk container), Plastic: HDPE , 1000 l<br/> Drum, Plastic: HDPE , 5 l</p> <p>All drums excepting 200 l (200 kg) and 1000 l (1000 kg) could be either silver or natural (white translucent) in colour. 200 l (200 kg) drums are either silver or blue in colour. IBCs are natural coloured.</p> <p>All drums are capped with tamper evident caps or bungs and are UN certified.</p> |

#### 4.1.1 Use-specific instructions for use

See general directions for use

#### 4.1.2 Use-specific 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 post milking disinfection

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

See general directions for use

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

See general directions for use

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

See general directions for use

**4.2 Use description**

**Use 2 - RTU Products - Professional RTU Liquid, for application pre milking - Spraying**

**Product type**

PT03 - Veterinary hygiene (Disinfectants)

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

-

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

Scientific name: Bacteria  
Common name: Bacteria  
Development stage: All

Scientific name: yeast  
Common name: yeast  
Development stage: All

**Field(s) of use**

Indoor

-

**Application method(s)**

Method: Open system: spray treatment  
Detailed description:

Application via pneumatic sprayer: Uptake lance of spray system is placed in the container of the RTU product. The RTU product is then pumped to a spray lance located in the milking parlour. The spray lance is then used to cover the bottom two

|   |   |
|---|---|
|   | <p>thirds of teats in the RTU product</p> <p>Application via manual trigger spray: Fill trigger spray bottle with RTU product. Use trigger spray to cover the bottom two thirds of each teat with RTU product</p>   |
| <p><b>Application rate(s) and frequencies</b></p> | <p>Application Rate: Quantity of RTU product to be applied per application; - cows and buffaloes: 3 to 10ml (5 ml recommended) - sheep 1.5 to 5 ml (1.5 ml recommended) - goats 2.5 to 6 ml (2.5 ml recommended)</p> <p>Dilution (%): Ready to use formulation In use concentration 0.16-0.30% (w/w) iodine.</p> <p>Number and timing of application:<br/>2 pre milking applications per animal, per day</p>  |
| <p><b>Category(ies) of users</b></p>              | <p>Trained professional</p> <p>Professional</p>   |
| <p><b>Pack sizes and packaging material</b></p>   | <p>Drum, Plastic: HDPE , 10 l<br/> Drum, Plastic: HDPE , 20 l<br/> Drum, Plastic: HDPE , 25 l<br/> Drum, Plastic: HDPE , 200 l<br/> IBC (intermediate bulk container), Plastic: HDPE , 1000 l<br/> Drum, Plastic: HDPE , 5 l</p> <p>All drums excepting 200 l (200 kg) and 1000 l (1000 kg) could be either silver or natural (white translucent) in colour. 200 l (200 kg) drums are either silver or blue in colour. IBCs are natural coloured.</p> <p>All drums are capped with tamper evident caps or bungs and are UN certified.</p> |

#### 4.2.1 Use-specific instructions for use

See general directions for use

#### 4.2.2 Use-specific risk mitigation measures

Wear protective chemical resistant gloves when applying the product by manual spraying (glove material to be specified by the authorisation holder within the product information)

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

considered for post milking disinfection

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

See general directions for use

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

See general directions for use

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

See general directions for use

### 4.3 Use description

#### Use 3 - RTU Products - Professional RTU Liquid, for application pre milking – Foaming

|   |   |
|---|---|
| <b>Product type</b>   | PT03 - Veterinary hygiene (Disinfectants)   |
| <b>Where relevant, an exact description of the authorised use</b> | -   |
| <b>Target organism(s) (including development stage)</b>           | Scientific name: Bacteria<br>Common name: Bacteria<br>Development stage: All<br><br>Scientific name: yeast<br>Common name: yeast<br>Development stage: All  |
| <b>Field(s) of use</b>  | Indoor<br><br>-   |
| <b>Application method(s)</b>                                      | Method: Open system: dip treatment<br>Detailed description:<br>Application via foaming Dip cup: As for dip cup, however, when squeezed, the liquid is forced through a fine mesh, mixing with air and forming foam. This is then applied to the |

|  |  |
|--|--|
|  | <p>bottom two thirds of the cow's udder<br/>The same solution can be applied to multiple animals during the same milking session.</p>  |
| <b>Application rate(s) and frequencies</b> | <p>Application Rate: Quantity of RTU product to be applied per application; - cows and buffaloes: 3 to 10ml (5 ml recommended) - sheep 1.5 to 5 ml (1.5 ml recommended) - goats 2.5 to 6 ml (2.5 ml recommended)<br/>Dilution (%): Ready to use formulation In use concentration 0.16-0.30% (w/w) iodine.<br/>Number and timing of application:<br/>2 pre milking applications per animal, per day</p>   |
| <b>Category(ies) of users</b>              | <p>Trained professional<br/><br/>Professional</p>  |
| <b>Pack sizes and packaging material</b>   | <p>Drum, Plastic: HDPE , 10 l<br/>Drum, Plastic: HDPE , 20 l<br/>Drum, Plastic: HDPE , 25 l<br/>Drum, Plastic: HDPE , 200 l<br/>IBC (intermediate bulk container), Plastic: HDPE , 1000 l<br/>Drum, Plastic: HDPE , 5 l</p> <p>All drums excepting 200 l (200 kg) and 1000 l (1000 kg) could be either silver or natural (white translucent) in colour. 200 l (200 kg) drums are either silver or blue in colour. IBCs are natural coloured.</p> <p>All drums are capped with tamper evident caps or bungs and are UN certified.</p> |

#### 4.3.1 Use-specific instructions for use

See general directions for use

#### 4.3.2 Use-specific 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 post milking disinfection

**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**

See general directions for use

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

See general directions for use

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

See general directions for use

**4.4 Use description**

**Use 4 - RTU Products - Professional RTU Liquid, for application post milking – Dipping**

|   |   |
|---|---|
| <b>Product type</b>   | PT03 - Veterinary hygiene (Disinfectants)   |
| <b>Where relevant, an exact description of the authorised use</b> | -   |
| <b>Target organism(s) (including development stage)</b>           | <p>Scientific name: Bacteria<br/> Common name: Bacteria<br/> Development stage: All</p> <p>Scientific name: yeast<br/> Common name: yeast<br/> Development stage: All</p>   |
| <b>Field(s) of use</b>  | <p>Indoor</p> <p>-</p>  |
| <b>Application method(s)</b>                                      | <p>Method: Open system: dip treatment<br/> Detailed description:<br/> Application via dip Cup: Using a traditional dip cup with non-return valves, dispense RTU product into the reservoir. Screw down the applicator portion. Squeeze the reservoir to fill the applicator. Cover the bottom two thirds of each teat with material. Dispose of unused material after each milking<br/> The same solution can be applied to multiple animals during the same milking session.</p> |



**Application rate(s) and frequencies**

Application Rate: Quantity of RTU product to be applied per application; - cows and buffaloes: 3 to 10ml (5 ml recommended) - sheep 1.5 to 5 ml (1.5 ml recommended) - goats 2.5 to 6 ml (2.5 ml recommended)  
Dilution (%): Ready to use formulation In use concentration 0.16-0.50% (w/w) iodine.  
Number and timing of application:  
2 post milking applications per animal, per day

**Category(ies) of users**

Trained professional  
Professional

**Pack sizes and packaging material**

Drum, Plastic: HDPE , 10 l  
Drum, Plastic: HDPE , 20 l  
Drum, Plastic: HDPE , 25 l  
Drum, Plastic: HDPE , 200 l  
IBC (intermediate bulk container), Plastic: HDPE , 1000 l  
Drum, Plastic: HDPE , 5 l

All drums excepting 200 l (200 kg) and 1000 l (1000 kg) could be either silver or natural (white translucent) in colour. 200 l (200 kg) drums are either silver or blue in colour. IBCs are natural coloured.

All drums are capped with tamper evident caps or bungs and are UN certified.

**4.4.1 Use-specific instructions for use**

Dip at least 2/3 of the teat length with RTU product immediately after milking

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

**4.4.2 Use-specific 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

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

See general directions for use

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

See general directions for use

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

See general directions for use

### 4.5 Use description

#### Use 5 - RTU Products - Professional RTU Liquid, for application post milking – Spraying

##### Product type

PT03 - Veterinary hygiene (Disinfectants)

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

-

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

Scientific name: Bacteria  
Common name: Bacteria  
Development stage: All

Scientific name: yeast  
Common name: yeast  
Development stage: All

##### Field(s) of use

Indoor

-

##### Application method(s)

Method: Open system: spray treatment

Detailed description:

Application via pneumatic sprayer: Uptake lance of spray system is placed in the container of the RTU product. The RTU product is then pumped to a spray lance located in the milking parlour. The spray lance is then used to cover the bottom two thirds of teats in the RTU product

Application via manual trigger spray: Fill trigger spray bottle with RTU product. Use trigger spray to cover the bottom two thirds of each teat with RTU product

**Application rate(s) and frequencies**

Application Rate: Quantity of RTU product to be applied per application; - cows and buffaloes: 3 to 10ml (5 ml recommended) - sheep 1.5 to 5 ml (1.5 ml recommended) - goats 2.5 to 6 ml (2.5 ml recommended)  
Dilution (%): Ready to use formulation In use concentration 0.16-0.50% (w/w) iodine.  
Number and timing of application:  
2 post milking applications per animal, per day

**Category(ies) of users**

Trained professional  
Professional

**Pack sizes and packaging material**

Drum, Plastic: HDPE , 10 l  
Drum, Plastic: HDPE , 20 l  
Drum, Plastic: HDPE , 25 l  
Drum, Plastic: HDPE , 200 l  
IBC (intermediate bulk container), Plastic: HDPE , 1000 l  
Drum, Plastic: HDPE , 5 l

All drums excepting 200 l (200 kg) and 1000 l (1000 kg) could be either silver or natural (white translucent) in colour. 200 l (200 kg) drums are either silver or blue in colour. IBCs are natural coloured.

All drums are capped with tamper evident caps or bungs and are UN certified.

**4.5.1 Use-specific instructions for use**

Spray at least 2/3 of the teat length with RTU product immediately after milking

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

**4.5.2 Use-specific risk mitigation measures**

Wear protective chemical resistant gloves and boots when applying the product by manual spraying (glove material to be specified by the authorisation holder within the product information)

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

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

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

See general directions for use

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

See general directions for use

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

See general directions for use

#### 4.6 Use description

##### Use 6 - RTU Products - Professional RTU Liquid, for application post milking – Foaming

###### Product type

PT03 - Veterinary hygiene (Disinfectants)

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

-

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

Scientific name: Bacteria  
Common name: Bacteria  
Development stage: All

Scientific name: yeast  
Common name: yeast  
Development stage: All

###### Field(s) of use

Indoor

-

###### Application method(s)

Method: Open system: dip treatment  
Detailed description:

Application via foaming Dip cup: As for dip cup, however, when squeezed, the liquid is forced through a fine mesh, mixing with air and forming foam. This is then applied to the bottom two thirds of the cow's udder

The same solution can be applied to multiple animals during the same milking session.

**Application rate(s) and frequencies**

Application Rate: Quantity of RTU product to be applied per application; - cows and buffaloes: 3 to 10ml (5 ml recommended) - sheep 1.5 to 5 ml (1.5 ml recommended) - goats 2.5 to 6 ml (2.5 ml recommended)  
Dilution (%): Ready to use formulation In use concentration 0.16-0.50% (w/w) iodine.  
Number and timing of application:  
2 post milking applications per animal, per day

**Category(ies) of users**

Trained professional  
Professional

**Pack sizes and packaging material**

Drum, Plastic: HDPE , 10 l  
Drum, Plastic: HDPE , 20 l  
Drum, Plastic: HDPE , 25 l  
Drum, Plastic: HDPE , 200 l  
IBC (intermediate bulk container), Plastic: HDPE , 1000 l  
Drum, Plastic: HDPE , 5 l

All drums excepting 200 l (200 kg) and 1000 l (1000 kg) could be either silver or natural (white translucent) in colour. 200 l (200 kg) drums are either silver or blue in colour. IBCs are natural coloured.

All drums are capped with tamper evident caps or bungs and are UN certified.

**4.6.1 Use-specific instructions for use**

Dip at least 2/3 of the teat length with RTU product immediately after milking  
To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).

**4.6.2 Use-specific 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

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

See general directions for use

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

See general directions for use

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

See general directions for use

#### 4.7 Use description

##### Use 7 - RTU Products - Professional RTU Liquid, for application pre and post milking-Dipping

|   |  |
|---|--|
| <b>Product type</b>   | PT03 - Veterinary hygiene (Disinfectants)  |
| <b>Where relevant, an exact description of the authorised use</b> | -  |
| <b>Target organism(s) (including development stage)</b>           | Scientific name: Bacteria<br>Common name: Bacteria<br>Development stage: All<br><br>Scientific name: yeast<br>Common name: yeast<br>Development stage: All   |
| <b>Field(s) of use</b>  | Indoor<br><br>-  |
| <b>Application method(s)</b>                                      | Method: Open system: dip treatment<br>Detailed description:<br><br>Application via dip Cup: Using a traditional dip cup with non-return valves, dispense RTU product into the reservoir. Screw down the applicator portion. Squeeze the reservoir to fill the applicator. Cover the bottom two thirds of each teat with material. Dispose of unused material after each milking<br><br>The same solution can be applied to multiple animals during the same milking session. |
| <b>Application rate(s) and frequencies</b>                        | Application Rate: Quantity of RTU product to be applied per application; - cows and buffaloes: 3 to 10ml (5 ml recommended) - sheep 1.5 to 5 ml (1.5 ml recommended) - goats 2.5 to 6 ml (2.5 ml recommended)<br>Dilution (%): Ready to use formulation In use concentration 0.16-0.30% (w/w) iodine.<br>Number and timing of application:<br>2 pre milking applications per animal, per day<br>2 post milking applications per animal, per day                              |

**Category(ies) of users**

Trained professional  
Professional

**Pack sizes and packaging material**

Drum, Plastic: HDPE , 10 l  
Drum, Plastic: HDPE , 20 l  
Drum, Plastic: HDPE , 25 l  
Drum, Plastic: HDPE , 200 l  
IBC (intermediate bulk container), Plastic: HDPE , 1000 l  
Drum, Plastic: HDPE , 5 l

All drums excepting 200 l (200 kg) and 1000 l (1000 kg) could be either silver or natural (white translucent) in colour. 200 l (200 kg) drums are either silver or blue in colour. IBCs are natural coloured.

All drums are capped with tamper evident caps or bungs and are UN certified.

**4.7.1 Use-specific instructions for use**

Post milking:

Dip at least 2/3 of the teat length with RTU product immediately after milking  
To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).

**4.7.2 Use-specific risk mitigation measures**

Wear protective chemical resistant gloves when applying the product by dipping (glove material to be specified by the authorisation holder within the product information).  
This product can be used for pre- and post-milking disinfection in combination. However, it should not be used in combination with a different iodine-based product.

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

See general directions for use

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

See general directions for use

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

See general directions for use

### 4.8 Use description

#### Use 8 - RTU Products - Professional RTU Liquid, for application pre and post milking- Spraying

|   |   |
|---|---|
| <b>Product type</b>   | PT03 - Veterinary hygiene (Disinfectants)   |
| <b>Where relevant, an exact description of the authorised use</b> | -   |
| <b>Target organism(s) (including development stage)</b>           | Scientific name: Bacteria<br>Common name: Bacteria<br>Development stage: All<br><br>Scientific name: yeast<br>Common name: yeast<br>Development stage: All  |
| <b>Field(s) of use</b>  | Indoor<br><br>-   |
| <b>Application method(s)</b>                                      | Method: Open system: spray treatment<br>Detailed description:<br><br>Application via pneumatic sprayer: Uptake lance of spray system is placed in the container of the RTU product. The RTU product is then pumped to a spray lance located in the milking parlour. The spray lance is then used to cover the bottom two thirds of teats in the RTU product<br><br>Application via manual trigger spray: Fill trigger spray bottle with RTU product. Use trigger spray to cover the bottom two thirds of each teat with RTU product |
| <b>Application rate(s) and frequencies</b>                        | Application Rate: Quantity of RTU product to be applied per application; - cows and buffaloes: 3 to 10ml (5 ml recommended) - sheep 1.5 to 5 ml (1.5 ml recommended) - goats 2.5 to 6 ml (2.5 ml recommended)   |



|  |  |
|--|--|
|  | <p>Dilution (%): Ready to use formulation In use concentration 0.16-0.30% (w/w) iodine.<br/>Number and timing of application:</p> <p>2 pre milking applications per animal, per day<br/>2 post milking applications per animal, per day</p>  |
| <b>Category(ies) of users</b>            | <p>Trained professional</p> <p>Professional</p>  |
| <b>Pack sizes and packaging material</b> | <p>Drum, Plastic: HDPE , 10 l<br/>Drum, Plastic: HDPE , 20 l<br/>Drum, Plastic: HDPE , 25 l<br/>Drum, Plastic: HDPE , 200 l<br/>IBC (intermediate bulk container), Plastic: HDPE , 1000 l<br/>Drum, Plastic: HDPE , 5 l</p> <p>All drums excepting 200 l (200 kg) and 1000 l (1000 kg) could be either silver or natural (white translucent) in colour. 200 l (200 kg) drums are either silver or blue in colour. IBCs are natural coloured.</p> <p>All drums are capped with tamper evident caps or bungs and are UN certified.</p> |

#### 4.8.1 Use-specific instructions for use

|  |
|--|
| <p>Post milking:</p> <p>Spray at least 2/3 of the teat length with RTU product immediately after milking<br/>To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).</p> |
|--|

#### 4.8.2 Use-specific risk mitigation measures

|  |
|--|
| <p>Wear protective chemical resistant gloves and boots when applying the product by manual spraying (glove material to be specified by the authorisation holder within the product information)</p> <p>A protective coverall (at least type 6, EN 13034) shall be worn</p> <p>This product can be used for pre- and post-milking disinfection in combination. However, it should not be used in combination with a different iodine-based product.</p> |
|--|

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

See general directions for use

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

See general directions for use

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

See general directions for use

**4.9 Use description**

**Use 9 - RTU Products - Professional RTU Liquid, for application pre and post milking - Foaming**

|   |   |
|---|---|
| <b>Product type</b>   | PT03 - Veterinary hygiene (Disinfectants)   |
| <b>Where relevant, an exact description of the authorised use</b> | -   |
| <b>Target organism(s) (including development stage)</b>           | Scientific name: Bacteria<br>Common name: Bacteria<br>Development stage: All<br><br>Scientific name: yeast<br>Common name: yeast<br>Development stage: All  |
| <b>Field(s) of use</b>  | Indoor<br><br>-   |
| <b>Application method(s)</b>                                      | Method: Open system: dip treatment<br>Detailed description:<br>Application via foaming Dip cup: As for dip cup, however, when squeezed, the liquid is forced through a fine mesh, mixing with air and forming foam. This is then applied to the bottom two thirds of the cow's udder<br><br>The same solution can be applied to multiple animals during the same milking session. |

**Application rate(s) and frequencies**

Application Rate: Quantity of RTU product to be applied per application; - cows and buffaloes: 3 to 10ml (5 ml recommended) - sheep 1.5 to 5 ml (1.5 ml recommended) - goats 2.5 to 6 ml (2.5 ml recommended)  
Dilution (%): Ready to use formulation In use concentration 0.16-0.30% (w/w) iodine.  
Number and timing of application:  
  
2 pre milking applications per animal, per day  
2 post milking applications per animal, per day

**Category(ies) of users**

Trained professional  
  
Professional

**Pack sizes and packaging material**

Drum, Plastic: HDPE , 10 l  
Drum, Plastic: HDPE , 20 l  
Drum, Plastic: HDPE , 25 l  
Drum, Plastic: HDPE , 200 l  
IBC (intermediate bulk container), Plastic: HDPE , 1000 l  
Drum, Plastic: HDPE , 5 l  
  
All drums excepting 200 l (200 kg) and 1000 l (1000 kg) could be either silver or natural (white translucent) in colour. 200 l (200 kg) drums are either silver or blue in colour. IBCs are natural coloured.  
  
All drums are capped with tamper evident caps or bungs and are UN certified.

**4.9.1 Use-specific instructions for use**

Post milking:  
  
Dip at least 2/3 of the teat length with RTU product immediately after milking  
  
To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).

**4.9.2 Use-specific risk mitigation measures**

Wear protective chemical resistant gloves when applying the product by foaming application method (glove material to be specified by the authorisation holder within the product information).  
This product can be used for pre- and post-milking disinfection in combination. However, it should not be used in combination with a

different iodine-based product.

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

See general directions for use

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

See general directions for use

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

See general directions for use

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

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

Keep out of reach of children  
Always read the label or leaflet before use and follow all the instructions provided.  
The product must be brought to a temperature above 20°C before use.  
Product can be used during the entire lactation period  
Before attaching the milking cluster, all teat-dip residues should be removed with either a single use towel or re-usable cloth. One cloth should be used per cow  
For effective use against bacteria and yeast, product must be left in contact with the skin for at least 60 seconds

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

See section 4.2 of the relevant use

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

Remove and wash contaminated clothing before re-use.  
After inhalation: Move to fresh air in case of accidental inhalation of fumes from overheating or combustion.  
If you feel unwell, seek medical advice.  
After contact with skin: Wash with water and soap as a precaution. Consult a doctor if skin irritation persists.

After contact with eyes: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Seek medical treatment by eye specialist.  
After ingestion: Rinse out mouth and give plenty of water to drink. Never give anything by mouth to an unconscious person. Consult a physician.

Large spills should be contained using a chemical spill kit, soaked up using absorbent material such as kieselguhr and disposed of as Hazardous waste.

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

At the end of the treatment, dispose of 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 farm based waste water treatment plant.

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

Protect from frost

Do not store at temperatures above 30 °C

Shelf life 12 months

#### 6. Other information

The hazard- and precautionary statements shall be in Icelandic on the product label.

Hazard statements:

**H290** Getur verið ætandi fyrir málma.

**H412** Skaðlegt lífi í vatni, hefur langvinn áhrif.

Precautionary statements:

**P273** Forðist losun út í umhverfi.

**P391** Safnið upp því sem hellist niður.

**P501** Fargið innhaldi í samræmi við staðbundnar reglur.

**P501** Fargið íláti í samræmi við staðbundnar reglur.

#### 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)

LuxSpray 30, Ioklene RTU, Corston Pre/Post Sprayable, Kristal Iocare Plus, PrePost, Autodine, Coars Super Pre

Market area: EU

### Authorisation number

(R4BP 3 asset reference number - National Authorisation)

IS-0026281-0005 1-2

| Common name              | IUPAC name   | Function             | CAS number | EC number | Content (%) |
|--------------------------|--|----------------------|------------|-----------|-------------|
| Iodine                   |  | Active Substance     | 7553-56-2  | 231-442-4 | 0,3         |
| C9-11 Alcohol Ethoxylate | C 9-11 alcohol with 6 moles of ethoxylate. Various brand names available including Imbentin C-91-060 | Non-active substance | 68439-46-3 | 614-482-0 | 0,305       |

### Trade name(s)

LuxSpray 50, Silkidip, Ceanodine, IoSpray 10, Maxadine RTU, Diamond Superdip, Kristal Iocare Post, KiwiDip, Superdip Excel, Ioguard RTU, Shepherd's IoSpray 50

Market area: EU

### Authorisation number

(R4BP 3 asset reference number - National Authorisation)

IS-0026281-0006 1-2

| Common name              | IUPAC name   | Function             | CAS number | EC number | Content (%) |
|--------------------------|--|----------------------|------------|-----------|-------------|
| Iodine                   |  | Active Substance     | 7553-56-2  | 231-442-4 | 0,5         |
| C9-11 Alcohol Ethoxylate | C 9-11 alcohol with 6 moles of ethoxylate. Various brand names available including Imbentin C-91-060 | Non-active substance | 68439-46-3 | 614-482-0 | 0,56        |

**Trade name(s)**

LuxDip 50B, Postguard

Market area: EU

**Authorisation number**

(R4BP 3 asset reference number - National Authorisation)

IS-0026281-0007 1-2

| Common name              | IUPAC name   | Function             | CAS number | EC number | Content (%) |
|--------------------------|--|----------------------|------------|-----------|-------------|
| Iodine                   |  | Active Substance     | 7553-56-2  | 231-442-4 | 0,5         |
| C9-11 Alcohol Ethoxylate | C 9-11 alcohol with 6 moles of ethoxylate. Various brand names available including Imbentin C-91-060 | Non-active substance | 68439-46-3 | 614-482-0 | 0           |

**Trade name(s)**

LuxDip 25, Kote It, Corston Barracide Post Film Forming Dip, Pro-Tect, Kristal locare Film, Coars Iodinegel, Coars Iodogel, LuxDip 20B

Market area: EU

**Authorisation number**

(R4BP 3 asset reference number - National Authorisation)

IS-0026281-0008 1-2

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

|                          |  |                      |            |           |     |
|--------------------------|--|----------------------|------------|-----------|-----|
| C9-11 Alcohol Ethoxylate | C 9-11 alcohol with 6 moles of ethoxylate. Various brand names available including Imbentin C-91-060 | Non-active substance | 68439-46-3 | 614-482-0 | 0,5 |
|--------------------------|--|----------------------|------------|-----------|-----|

## 1. Meta SPC administrative information

### 1.1. Meta SPC identifier

**Meta SPC 3 - RTU Products - Professiona RTU Liquid for application pre and post milking (LuxSpray 15)**

### 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 | 0,16 - 0,16   |
| C9-11 Alcohol Ethoxylate | C 9-11 alcohol with 6 moles of ethoxylate. Various brand names available including Imbentin C-91-060 | Non-active substance | 68439-46-3 | 614-482-0 | 0,166 - 0,166 |

### 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**

May be corrosive to metals.

**Precautionary statements**

Avoid release to the environment.

Collect spillage.

Dispose of contents to in accordance with local regulations.

Dispose of container to in accordance with local regulations.

**4. Authorised use(s) of the meta SPC****4.1 Use description****Use 1 - RTU Products - Professional RTU Liquid, for application pre-milking - Dipping****Product type**

PT03 - Veterinary hygiene (Disinfectants)

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

-

**Target organism(s) (including development stage)**Scientific name: Bacteria  
Common name: Bacteria  
Development stage: AllScientific name: YEAST  
Common name: yeast  
Development stage: All**Field(s) of use**

Indoor

-

**Application method(s)**Method: Open system: dip treatment  
Detailed description:

Application via dip Cup: Using a traditional dip cup with non-return valves, dispense RTU product into the reservoir. Screw down the applicator portion. Squeeze the reservoir to fill the applicator. Cover the bottom two thirds of each teat with material. Dispose of unused material after each milking

The same solution can be applied to multiple animals during the same milking session.

**Application rate(s) and frequencies**

Application Rate: Quantity of RTU product to be applied per application; - cows and buffaloes: 3 to 10ml (5 ml recommended) - sheep 1.5 to 5 ml (1.5 ml recommended) - goats 2.5 to 6 ml (2.5 ml recommended)  
Dilution (%): Ready to use formulation In use concentration 0.16% (w/w) iodine.  
Number and timing of application:  
2 pre milking applications per animal, per day

**Category(ies) of users**

Trained professional  
Professional

**Pack sizes and packaging material**

Drum, Plastic: HDPE , 10 l  
Drum, Plastic: HDPE , 20 l  
Drum, Plastic: HDPE , 25 l  
Drum, Plastic: HDPE , 200 l  
IBC (intermediate bulk container), Plastic: HDPE , 1000 l  
Drum, Plastic: HDPE , 5 l

All drums excepting 200 l (200 kg) and 1000 l (1000 kg) could be either silver or natural (white translucent) in colour. 200 l (200 kg) drums are either silver or blue in colour. IBCs are natural coloured.

All drums are capped with tamper evident caps or bungs and are UN certified.

**4.1.1 Use-specific instructions for use**

See general directions for use

**4.1.2 Use-specific 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 post milking disinfection

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

See general directions for use

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

See general directions for use

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

See general directions for use

### 4.2 Use description

#### Use 2 - RTU Products - Professional RTU Liquid, for application pre milking - Spraying

##### Product type

PT03 - Veterinary hygiene (Disinfectants)

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

-

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

Scientific name: Bacteria  
Common name: Bacteria  
Development stage: All

Scientific name: yeast  
Common name: yeast  
Development stage: All

##### Field(s) of use

Indoor

-

##### Application method(s)

Method: Open system: spray treatment  
Detailed description:

Application via pneumatic sprayer: Uptake lance of spray system is placed in the container of the RTU product. The RTU product is then pumped to a spray lance located in the milking parlour. The spray lance is then used to cover the bottom two thirds of teats in the RTU product

Application via manual trigger spray: Fill trigger spray bottle with RTU product. Use trigger spray to cover the bottom two thirds of each teat with RTU product

**Application rate(s) and frequencies**

Application Rate: Quantity of RTU product to be applied per application; - cows and buffaloes: 3 to 10ml (5 ml recommended) - sheep 1.5 to 5 ml (1.5 ml recommended) - goats 2.5 to 6 ml (2.5 ml recommended)  
Dilution (%): Ready to use formulation In use concentration 0.16% (w/w) iodine.  
Number and timing of application:  
2 pre milking applications per animal, per day

**Category(ies) of users**

Trained professional  
Professional

**Pack sizes and packaging material**

Drum, Plastic: HDPE , 10 l  
Drum, Plastic: HDPE , 20 l  
Drum, Plastic: HDPE , 25 l  
Drum, Plastic: HDPE , 200 l  
IBC (intermediate bulk container), Plastic: HDPE , 1000 l  
Drum, Plastic: HDPE , 5 l

All drums excepting 200 l (200 kg) and 1000 l (1000 kg) could be either silver or natural (white translucent) in colour. 200 l (200 kg) drums are either silver or blue in colour. IBCs are natural coloured.

All drums are capped with tamper evident caps or bungs and are UN certified.

**4.2.1 Use-specific instructions for use**

See general directions for use

**4.2.2 Use-specific risk mitigation measures**

Wear protective chemical resistant gloves when applying the product by manual spraying (glove material to be specified by the authorisation holder within the product information)

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

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

See general directions for use

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

See general directions for use

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

See general directions for use

### 4.3 Use description

#### Use 3 - RTU Products - Professional RTU Liquid, for application pre milking – Foaming

|   |   |
|---|---|
| <b>Product type</b>   | PT03 - Veterinary hygiene (Disinfectants)   |
| <b>Where relevant, an exact description of the authorised use</b> | -   |
| <b>Target organism(s) (including development stage)</b>           | Scientific name: Bacteria<br>Common name: Bacteria<br>Development stage: All<br><br>Scientific name: yeast<br>Common name: yeast<br>Development stage: All  |
| <b>Field(s) of use</b>  | Indoor<br><br>-   |
| <b>Application method(s)</b>                                      | Method: Open system: dip treatment<br>Detailed description:<br>Application via foaming Dip cup: As for dip cup, however, when squeezed, the liquid is forced through a fine mesh, mixing with air and forming foam. This is then applied to the bottom two thirds of the cow's udder<br>The same solution can be applied to multiple animals during the same milking session. |

**Application rate(s) and frequencies**

Application Rate: Quantity of RTU product to be applied per application; - cows and buffaloes: 3 to 10ml (5 ml recommended) - sheep 1.5 to 5 ml (1.5 ml recommended) - goats 2.5 to 6 ml (2.5 ml recommended)  
Dilution (%): Ready to use formulation In use concentration 0.16% (w/w) iodine.  
Number and timing of application:  
2 pre milking applications per animal, per day

**Category(ies) of users**

Trained professional  
Professional

**Pack sizes and packaging material**

Drum, Plastic: HDPE , 10 l  
Drum, Plastic: HDPE , 20 l  
Drum, Plastic: HDPE , 25 l  
Drum, Plastic: HDPE , 200 l  
IBC (intermediate bulk container), Plastic: HDPE , 1000 l  
Drum, Plastic: HDPE , 5 l

All drums excepting 200 l (200 kg) and 1000 l (1000 kg) could be either silver or natural (white translucent) in colour. 200 l (200 kg) drums are either silver or blue in colour. IBCs are natural coloured.

All drums are capped with tamper evident caps or bungs and are UN certified.

**4.3.1 Use-specific instructions for use**

See general directions for use

**4.3.2 Use-specific 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 post milking disinfection

**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**

See general directions for use

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

See general directions for use

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

See general directions for use

#### 4.4 Use description

##### Use 4 - RTU Products - Professional RTU Liquid, for application post milking – Dipping

##### Product type

PT03 - Veterinary hygiene (Disinfectants)

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

-

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

Scientific name: Bacteria  
Common name: Bacteria  
Development stage: All

Scientific name: yeast  
Common name: yeast  
Development stage: All

##### Field(s) of use

Indoor

-

##### Application method(s)

Method: Open system: dip treatment

Detailed description:

Application via dip Cup: Using a traditional dip cup with non-return valves, dispense RTU product into the reservoir. Screw down the applicator portion. Squeeze the reservoir to fill the applicator. Cover the bottom two thirds of each teat with material. Dispose of unused material after each milking  
The same solution can be applied to multiple animals during the same milking session.

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

Application Rate: Quantity of RTU product to be applied per application; - cows and buffaloes: 3 to 10ml (5 ml recommended) - sheep 1.5 to 5 ml (1.5 ml recommended) - goats 2.5 to 6 ml (2.5 ml recommended)  
Dilution (%): Ready to use formulation In use concentration 0.16% (w/w) iodine.  
Number and timing of application:

|  |  |
|--|--|
|  | 2 post milking applications per animal, per day  |
| <b>Category(ies) of users</b>            | Trained professional<br>Professional   |
| <b>Pack sizes and packaging material</b> | Drum, Plastic: HDPE , 10 l<br>Drum, Plastic: HDPE , 20 l<br>Drum, Plastic: HDPE , 25 l<br>Drum, Plastic: HDPE , 200 l<br>IBC (intermediate bulk container), Plastic: HDPE , 1000 l<br>Drum, Plastic: HDPE , 5 l<br><br>All drums excepting 200 l (200 kg) and 1000 l (1000 kg) could be either silver or natural (white translucent) in colour. 200 l (200 kg) drums are either silver or blue in colour. IBCs are natural coloured.<br><br>All drums are capped with tamper evident caps or bungs and are UN certified. |

#### 4.4.1 Use-specific instructions for use

Dip at least 2/3 of the teat length with RTU product immediately after milking

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

#### 4.4.2 Use-specific 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

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

See general directions for use

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



See general directions for use

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

See general directions for use

### 4.5 Use description

#### Use 5 - RTU Products - Professional RTU Liquid, for application post milking – Spraying

|   |   |
|---|---|
| <b>Product type</b>   | PT03 - Veterinary hygiene (Disinfectants)   |
| <b>Where relevant, an exact description of the authorised use</b> | -   |
| <b>Target organism(s) (including development stage)</b>           | Scientific name: Bacteria<br>Common name: Bacteria<br>Development stage: All<br><br>Scientific name: yeast<br>Common name: yeast<br>Development stage: All  |
| <b>Field(s) of use</b>  | Indoor<br><br>-   |
| <b>Application method(s)</b>                                      | Method: Open system: spray treatment<br>Detailed description:<br>Application via pneumatic sprayer: Uptake lance of spray system is placed in the container of the RTU product. The RTU product is then pumped to a spray lance located in the milking parlour. The spray lance is then used to cover the bottom two thirds of teats in the RTU product<br>Application via manual trigger spray: Fill trigger spray bottle with RTU product. Use trigger spray to cover the bottom two thirds of each teat with RTU product |
| <b>Application rate(s) and frequencies</b>                        | Application Rate: Quantity of RTU product to be applied per application; - cows and buffaloes: 3 to 10ml (5 ml recommended) - sheep 1.5 to 5 ml (1.5 ml recommended) - goats 2.5 to 6 ml (2.5 ml recommended)<br>Dilution (%): Ready to use formulation In use concentration 0.16% (w/w) iodine.<br>Number and timing of application:<br>2 post milking applications per animal, per day  |

|  |  |
|--|--|
| <b>Category(ies) of users</b>            | Trained professional<br><br>Professional   |
| <b>Pack sizes and packaging material</b> | Drum, Plastic: HDPE , 10 l<br>Drum, Plastic: HDPE , 20 l<br>Drum, Plastic: HDPE , 25 l<br>Drum, Plastic: HDPE , 200 l<br>IBC (intermediate bulk container), Plastic: HDPE , 1000 l<br>Drum, Plastic: HDPE , 5 l<br><br>All drums excepting 200 l (200 kg) and 1000 l (1000 kg) could be either silver or natural (white translucent) in colour. 200 l (200 kg) drums are either silver or blue in colour. IBCs are natural coloured.<br><br>All drums are capped with tamper evident caps or bungs and are UN certified. |

#### 4.5.1 Use-specific instructions for use

Spray at least 2/3 of the teat length with RTU product immediately after milking

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

#### 4.5.2 Use-specific risk mitigation measures

Wear protective chemical resistant gloves and boots when applying the product by manual spraying (glove material to be specified by the authorisation holder within the product information)

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

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

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

See general directions for use

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

See general directions for use

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

See general directions for use

#### 4.6 Use description

##### Use 6 - RTU Products - Professional RTU Liquid, for application post milking – Foaming

**Product type**

PT03 - Veterinary hygiene (Disinfectants)

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

-

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

Scientific name: Bacteria  
Common name: Bacteria  
Development stage: All

Scientific name: yeast  
Common name: yeast  
Development stage: All

**Field(s) of use**

Indoor

-

**Application method(s)**

Method: Open system: dip treatment  
Detailed description:

Application via foaming Dip cup: As for dip cup, however, when squeezed, the liquid is forced through a fine mesh, mixing with air and forming foam. This is then applied to the bottom two thirds of the cow's udder

The same solution can be applied to multiple animals during the same milking session.

**Application rate(s) and frequencies**

Application Rate: Quantity of RTU product to be applied per application; - cows and buffaloes: 3 to 10ml (5 ml recommended) - sheep 1.5 to 5 ml (1.5 ml recommended) - goats 2.5 to 6 ml (2.5 ml recommended)

Dilution (%): Ready to use formulation In use concentration 0.16% (w/w) iodine.

Number and timing of application:

2 post milking applications per animal, per day

|  |  |
|--|--|
| <b>Category(ies) of users</b>            | Trained professional<br><br>Professional   |
| <b>Pack sizes and packaging material</b> | Drum, Plastic: HDPE , 10 l<br>Drum, Plastic: HDPE , 20 l<br>Drum, Plastic: HDPE , 25 l<br>Drum, Plastic: HDPE , 200 l<br>IBC (intermediate bulk container), Plastic: HDPE , 1000 l<br>Drum, Plastic: HDPE , 5 l<br><br>All drums excepting 200 l (200 kg) and 1000 l (1000 kg) could be either silver or natural (white translucent) in colour. 200 l (200 kg) drums are either silver or blue in colour. IBCs are natural coloured.<br><br>All drums are capped with tamper evident caps or bungs and are UN certified. |

#### 4.6.1 Use-specific instructions for use

Dip at least 2/3 of the teat length with RTU product immediately after milking  
To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).

#### 4.6.2 Use-specific 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

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

See general directions for use

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

See general directions for use

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

See general directions for use

#### 4.7 Use description

##### Use 7 - RTU Products - Professional RTU Liquid, for application pre and post milking-Dipping

###### Product type

PT03 - Veterinary hygiene (Disinfectants)

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

-

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

Scientific name: Bacteria  
Common name: Bacteria  
Development stage: All

Scientific name: yeast  
Common name: yeast  
Development stage: All

###### Field(s) of use

Indoor

-

###### Application method(s)

Method: Open system: dip treatment  
Detailed description:

Application via dip Cup: Using a traditional dip cup with non-return valves, dispense RTU product into the reservoir. Screw down the applicator portion. Squeeze the reservoir to fill the applicator. Cover the bottom two thirds of each teat with material. Dispose of unused material after each milking

The same solution can be applied to multiple animals during the same milking session.

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

Application Rate: Quantity of RTU product to be applied per application; - cows and buffaloes: 3 to 10ml (5 ml recommended) - sheep 1.5 to 5 ml (1.5 ml recommended) - goats 2.5 to 6 ml (2.5 ml recommended)

Dilution (%): Ready to use formulation In use concentration 0.16% (w/w) iodine.

Number and timing of application:

2 pre milking applications per animal, per day

2 post milking applications per animal, per day

|  |  |
|--|--|
| <b>Category(ies) of users</b>            | Trained professional<br><br>Professional   |
| <b>Pack sizes and packaging material</b> | Drum, Plastic: HDPE , 10 l<br>Drum, Plastic: HDPE , 20 l<br>Drum, Plastic: HDPE , 25 l<br>Drum, Plastic: HDPE , 200 l<br>IBC (intermediate bulk container), Plastic: HDPE , 1000 l<br>Drum, Plastic: HDPE , 5 l<br><br>All drums excepting 200 l (200 kg) and 1000 l (1000 kg) could be either silver or natural (white translucent) in colour. 200 l (200 kg) drums are either silver or blue in colour. IBCs are natural coloured.<br><br>All drums are capped with tamper evident caps or bungs and are UN certified. |

#### 4.7.1 Use-specific instructions for use

Post milking:  
Dip at least 2/3 of the teat length with RTU product immediately after milking  
To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).

#### 4.7.2 Use-specific risk mitigation measures

Wear protective chemical resistant gloves when applying the product by dipping (glove material to be specified by the authorisation holder within the product information).  
This product can be used for pre- and post-milking disinfection in combination. However, it should not be used in combination with a different iodine-based product.

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

See general directions for use

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

See general directions for use

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

See general directions for use

#### 4.8 Use description

##### Use 8 - RTU Products - Professional RTU Liquid, for application pre and post milking- Spraying

###### Product type

PT03 - Veterinary hygiene (Disinfectants)

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

-

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

Scientific name: Bacteria  
Common name: Bacteria  
Development stage: All

Scientific name: yeast  
Common name: yeast  
Development stage: All

###### Field(s) of use

Indoor

-

###### Application method(s)

Method: Open system: spray treatment  
Detailed description:

Application via pneumatic sprayer: Uptake lance of spray system is placed in the container of the RTU product. The RTU product is then pumped to a spray lance located in the milking parlour. The spray lance is then used to cover the bottom two thirds of teats in the RTU product

Application via manual trigger spray: Fill trigger spray bottle with RTU product. Use trigger spray to cover the bottom two thirds of each teat with RTU product

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

Application Rate: Quantity of RTU product to be applied per application; - cows and buffaloes: 3 to 10ml (5 ml recommended) - sheep 1.5 to 5 ml (1.5 ml recommended) - goats 2.5 to 6 ml (2.5 ml recommended)

Dilution (%): Ready to use formulation In use concentration 0.16% (w/w) iodine.

Number and timing of application:

|  |  |
|--|--|
|  | 2 pre milking applications per animal, per day<br>2 post milking applications per animal, per day  |
| <b>Category(ies) of users</b>            | Trained professional<br><br>Professional   |
| <b>Pack sizes and packaging material</b> | Drum, Plastic: HDPE , 10 l<br>Drum, Plastic: HDPE , 20 l<br>Drum, Plastic: HDPE , 25 l<br>Drum, Plastic: HDPE , 200 l<br>IBC (intermediate bulk container), Plastic: HDPE , 1000 l<br>Drum, Plastic: HDPE , 5 l<br><br>All drums excepting 200 l (200 kg) and 1000 l (1000 kg) could be either silver or natural (white translucent) in colour. 200 l (200 kg) drums are either silver or blue in colour. IBCs are natural coloured.<br><br>All drums are capped with tamper evident caps or bungs and are UN certified. |

#### 4.8.1 Use-specific instructions for use

|  |
|--|
| <p>Post milking:</p> <p>Spray at least 2/3 of the teat length with RTU product immediately after milking<br/>To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).</p> |
|--|

#### 4.8.2 Use-specific risk mitigation measures

|  |
|--|
| <p>Wear protective chemical resistant gloves and boots when applying the product by manual spraying (glove material to be specified by the authorisation holder within the product information)</p> <p>A protective coverall (at least type 6, EN 13034) shall be worn</p> <p>This product can be used for pre- and post-milking disinfection in combination. However, it should not be used in combination with a different iodine-based product.</p> |
|--|

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



See general directions for use

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

See general directions for use

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

See general directions for use

#### 4.9 Use description

##### Use 9 - RTU Products - Professional RTU Liquid, for application pre and post milking - Foaming

##### Product type

PT03 - Veterinary hygiene (Disinfectants)

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

-

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

Scientific name: Bacteria  
Common name: Bacteria  
Development stage: All

Scientific name: yeast  
Common name: yeast  
Development stage: All

##### Field(s) of use

Indoor

-

##### Application method(s)

Method: Open system: dip treatment

Detailed description:

Application via foaming Dip cup: As for dip cup, however, when squeezed, the liquid is forced through a fine mesh, mixing with air and forming foam. This is then applied to the bottom two thirds of the cow's udder

The same solution can be applied to multiple animals during the same milking session.

**Application rate(s) and frequencies**

Application Rate: Quantity of RTU product to be applied per application; - cows and buffaloes: 3 to 10ml (5 ml recommended) - sheep 1.5 to 5 ml (1.5 ml recommended) - goats 2.5 to 6 ml (2.5 ml recommended)  
Dilution (%): Ready to use formulation In use concentration 0.16% (w/w) iodine.  
Number and timing of application:  
  
2 pre milking applications per animal, per day  
2 post milking applications per animal, per day

**Category(ies) of users**

Trained professional  
  
Professional

**Pack sizes and packaging material**

Drum, Plastic: HDPE , 10 l  
Drum, Plastic: HDPE , 20 l  
Drum, Plastic: HDPE , 25 l  
Drum, Plastic: HDPE , 200 l  
IBC (intermediate bulk container), Plastic: HDPE , 1000 l  
Drum, Plastic: HDPE , 5 l  
  
All drums excepting 200 l (200 kg) and 1000 l (1000 kg) could be either silver or natural (white translucent) in colour. 200 l (200 kg) drums are either silver or blue in colour. IBCs are natural coloured.  
  
All drums are capped with tamper evident caps or bungs and are UN certified.

**4.9.1 Use-specific instructions for use**

Post milking:  
  
Dip at least 2/3 of the teat length with RTU product immediately after milking  
  
To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).

**4.9.2 Use-specific risk mitigation measures**

Wear protective chemical resistant gloves when applying the product by foaming application method (glove material to be specified by the authorisation holder within the product information).  
This product can be used for pre- and post-milking disinfection in combination. However, it should not be used in combination with a different iodine-based product.

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

See general directions for use

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

See general directions for use

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

See general directions for use

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

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

Keep out of reach of children  
Always read the label or leaflet before use and follow all the instructions provided.  
The product must be brought to a temperature above 20°C before use.  
Product can be used during the entire lactation period  
Before attaching the milking cluster, all teat-dip residues should be removed with either a single use towel or re-usable cloth. One cloth should be used per cow  
For effective use against bacteria and yeast, product must be left in contact with the skin for at least 60 seconds

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

See section 4.2 of the relevant use

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

Remove and wash contaminated clothing before re-use.  
After inhalation: Move to fresh air in case of accidental inhalation of fumes from overheating or combustion.  
If you feel unwell, seek medical advice.  
After contact with skin: Wash with water and soap as a precaution. Consult a doctor if skin irritation persists.  
After contact with eyes: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Seek medical treatment by eye specialist.  
After ingestion: Rinse out mouth and give plenty of water to drink. Never give anything by mouth to an unconscious person. Consult a physician.

Large spills should be contained using a chemical spill kit, soaked up using absorbent material such as kieselguhr and disposed of as Hazardous waste.

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

At the end of the treatment, dispose of 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 farm based waste water treatment plant.

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

Protect from frost

Do not store at temperatures above 30 °C

Shelf life 12 months

## 6. Other information

The hazard- and precautionary statements shall be in Icelandic on the product label.

Hazard statements:

**H290** Getur verið ætandi fyrir málma.

Precautionary statements:

**P273** Forðist losun út í umhverfi.

**P391** Safnið upp því sem hellist niður.

**P501** Fargið innhaldi í samræmi við staðbundnar reglur.

**P501** Fargið íláti í samræmi við staðbundnar reglur.

## 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)**LuxSpray 15, Kristal Iocare Pre, Super Pre,  
Priodine RTU

Market area: EU

**Authorisation number**(R4BP 3 asset reference number - National  
Authorisation)

IS-0026281-0009 1-3

---

| Common name              | IUPAC name   | Function                | CAS number | EC number | Content (%) |
|--------------------------|--|-------------------------|------------|-----------|-------------|
| Iodine                   |  | Active Substance        | 7553-56-2  | 231-442-4 | 0,16        |
| C9-11 Alcohol Ethoxylate | C 9-11 alcohol with 6<br>moles of ethoxylate.<br>Various brand names<br>available including<br>Imbentin C-91-060 | Non-active<br>substance | 68439-46-3 | 614-482-0 | 0,166       |

---