

## II

(Non-legislative acts)

## REGULATIONS

## COMMISSION IMPLEMENTING REGULATION (EU) 2020/202

of 4 October 2019

granting a Union authorisation for the biocidal product family 'Iodine Teat Dip Products'

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products <sup>(1)</sup>, and in particular Article 44(5) thereof,

Whereas:

- (1) On 20 August 2015, GEA Farm Technologies GmbH, submitted an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for authorisation of a biocidal product family named 'Iodine Teat Dip Products' ('the biocidal product family') of product-type 3, as described in Annex V to that Regulation. The competent authority of United Kingdom agreed to evaluate the application as referred to in Article 43(1) of Regulation (EU) No 528/2012. The application was recorded under the case number BC-AL019223-55 in the Register for Biocidal Products.
- (2) The biocidal product family contains iodine, as the active substance, which is included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012. Taking into account the intrinsic properties of the active substance, and the scientific criteria for the determination of endocrine-disrupting properties set out in Commission Delegated Regulation (EU) 2017/2100 <sup>(2)</sup>, the Commission will consider the need to review the approval of iodine, including polyvinylpyrrolidone iodine, in accordance with Article 15 of Regulation (EU) No 528/2012. Depending on the outcome of that review, the Commission will then consider whether the Union authorisations for products containing the active substance have to be reviewed in accordance with Article 48 of Regulation (EU) No 528/2012.
- (3) On 6 June 2018, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, the assessment report and the conclusions of its evaluation to the European Chemicals Agency ('the Agency').
- (4) On 18 January 2019, the Agency submitted to the Commission an opinion <sup>(3)</sup>, including the draft summary of the biocidal product characteristics ('SPC') of the biocidal product family and the final assessment report on the biocidal product family in accordance with Article 44(3) of Regulation (EU) No 528/2012. The opinion concludes that the biocidal product family falls within the definition of 'biocidal product family' laid down in Article 3(1)(s) of Regulation (EU) No 528/2012, that it is eligible for Union authorisation in accordance with Article 42(1) of that Regulation and that subject to compliance with the draft SPC, the biocidal product family meets the conditions laid down in Article 19(1) and (6) of that Regulation.

<sup>(1)</sup> OJ L 167, 27.6.2012, p. 1.

<sup>(2)</sup> Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council (OJ L 301, 17.11.2017, p. 1).

<sup>(3)</sup> ECHA opinion of 14 December 2018 on the Union authorisation of 'Iodine Teat Dip Products' (ECHA/BPC/217/2018).

- (5) On 20 May 2019, the Agency transmitted to the Commission the draft SPC in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.
- (6) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for the biocidal product family.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

*Article 1*

A Union authorisation is granted to GEA Farm Technologies GmbH for the making available on the market and use of the biocidal product family 'Iodine Teat Dip Products' with authorisation number EU-0020125-0000 in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 19 November 2019 until 31 October 2029.

*Article 2*

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 4 October 2019.

*For the Commission*  
*The President*  
Jean-Claude JUNCKER

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## ANNEX

**Summary of product characteristics for a biocidal product family**

Iodine Teat dip products

Product type 3 — Veterinary hygiene (Disinfectants)

Authorisation number: EU-0020125-0000

R4BP asset number: EU-0020125-0000

## PART I

**FIRST INFORMATION LEVEL**

## 1. ADMINISTRATIVE INFORMATION

1.1. **Family name**

Name	Iodine Teat dip products
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1.2. **Product type(s)**

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)
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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 asset number	EU-0020125-0000	
Date of the authorisation	19 November 2019	
Expiry date of the authorisation	31 October 2029	

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

Name of manufacturer	GEA Farm Technologies
Address of manufacturer	Wylle Works, BA12 9HT Warminster United Kingdom
Location of manufacturing sites	Wylle 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)**

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

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

Active substance	Iodine
Name of manufacturer	Norkem Ltd
Address of manufacturer	Norkem House, Bexton Lane,, WA16 9FB Knutsford United Kingdom
Location of manufacturing sites	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 (%)	
					Min	Max
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	0,0	2,35

### 2.2. Type(s) of formulation

Formulation(s)	AL — Any other liquid SL — Soluble concentrate
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## PART II

### SECOND INFORMATION LEVEL — META SPC(S)

#### META SPC 1

#### 1. META SPC 1 ADMINISTRATIVE INFORMATION

##### 1.1. Meta SPC 1 identifier

Identifier	Meta SPC 1 — Concentrates — Professional concentrates with 1:3, 1:4 and 1:7 dilution rates
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## 1.2. Suffix to the authorisation number

Number	1-1
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## 1.3. Product type(s)

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)
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## 2. META SPC 1 COMPOSITION

## 2.1. Qualitative and quantitative information on the composition of the meta SPC 1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
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 1

Formulation(s)	SL — Soluble concentrate
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## 3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

Hazard statements	Causes serious eye irritation. May cause damage to 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 according to local regulations. Dispose of contents according to local regulations.

## 4. AUTHORISED USE(S) OF THE META SPC 1

## 4.1. Use description

Table 1

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

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor
Application method(s)	Open system: dip treatment 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 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
Application rate(s) and frequency	Quantity of diluted product to be applied per application: — cows and buffaloes: 3 to 10 ml (5 ml recommended) — sheep 1,5 to 5 ml (1,5 ml recommended) — goats 2,5 to 6 ml (2,5 ml recommended) 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. 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.

## 4.1.1. 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**

Table 2

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

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor
Application method(s)	Open system: spray treatment 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 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
Application rate(s) and frequency	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) 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. 2 post milking applications per animal, per day
Category(ies) of users	Trained professional Professional

Pack sizes and packaging material	<p>Drum, Plastic: HDPE, 10 l</p> <p>Drum, Plastic: HDPE, 20 l</p> <p>Drum, Plastic: HDPE, 25 l</p> <p>Drum, Plastic: HDPE, 200 l</p> <p>IBC (intermediate bulk container), Plastic: HDPE, 1000 l</p> <p>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>
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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**

Table 3

**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)	Bacteria Yeast
Field(s) of use	Indoor
Application method(s)	<p>Open system: dip treatment</p> <p>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</p> <p>The same solution can be applied to multiple animals during the same milking session.</p>



Application rate(s) and frequency	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) 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. 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.

4.3.1. *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 <sup>(1)</sup> OF THE META SPC 1

### 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

Formanual 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 use specific risk mitigation measures

### 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

<sup>(1)</sup> Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 1.

## 7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1

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

Trade name(s)	Ioklene Concentrate. Coars Dual				
Authorisation number	EU-0020125-0001 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Sub- stance	7553-56-2	231-442-4	1,58
C9-11 Alcohol Ethoxy- late	C 9-11 alcohol with 6 moles of ethoxylate. Various brand names available including Im- bentin C-91-060	Non-active substance	68439-46-3	614-482-0	1,51

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

Trade name(s)	Clinidip L Concentrate, Maxadine C, Diamond 3:1 Concentrate, Kristal 321, IO Spray 3:1 Concentrate, Coars Shield				
Authorisation number	EU-0020125-0002 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Sub- stance	7553-56-2	231-442-4	2,06
C9-11 Alcohol Ethoxy- late	C 9-11 alcohol with 6 moles of ethoxylate. Various brand names available including Im- bentin C-91-060	Non-active substance	68439-46-3	614-482-0	1,96

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

Trade name(s)	Clinidip Superconcentrate, Dunglinson Super IO 421 Concentrate, Ceanodine 4:1, Iodosan				
Authorisation number	EU-0020125-0003 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Sub- stance	7553-56-2	231-442-4	2,47
C9-11 Alcohol Ethoxy- late	C 9-11 alcohol with 6 moles of ethoxylate. Various brand names available including Im- bentin C-91-060	Non-active substance	68439-46-3	614-482-0	2,35

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

Trade name(s)	Priodine, Diamond Predip				
Authorisation number	EU-0020125-0004 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

**META SPC 2**

## 1. META SPC 2 ADMINISTRATIVE INFORMATION

## 1.1. Meta SPC 2 identifier

Identifier	Meta SPC 2 — RTU Products — Professional RTU Liquid for application pre and post milking
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## 1.2. Suffix to the authorisation number

Number	1-2
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## 1.3. Product type(s)

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)
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## 2. META SPC 2 COMPOSITION

## 2.1. Qualitative and quantitative information on the composition of the meta SPC 2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
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	0,56

2.2. **Type(s) of formulation of the meta SPC 2**

Formulation(s)	AL — Any other liquid
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## 3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

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 in accordance with local regulations. Dispose of container in accordance with local regulations.

## 4. AUTHORISED USE(S) OF THE META SPC 2

4.1. **Use description**

Table 4

**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)	Bacteria Yeast
Field(s) of use	Indoor
Application method(s)	Open system: dip treatment 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 frequency	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) Ready to use formulation in use concentration 0,16-0,30 % (w/w) iodine. 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.
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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**

Table 5

**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)	Bacteria Yeast All
Field(s) of use	Indoor
Application method(s)	Open system: spray treatment 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 frequency	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) Ready to use formulation In use concentration 0,16-0,30 % (w/w) iodine. 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**

Table 6

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

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast All

Field(s) of use	Indoor
Application method(s)	Open system: dip treatment 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 frequency	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) Ready to use formulation. In use concentration 0,16-0,30 % (w/w) iodine. 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

Table 7

**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)	Bacteria Yeast
Field(s) of use	Indoor
Application method(s)	Open system: dip treatment 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 frequency	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) Ready to use formulation. In use concentration 0,16-0,50 % (w/w) iodine. 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**

Table 8

#### **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)	Bacteria Yeast
Field(s) of use	Indoor
Application method(s)	Open system: spray treatment 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 frequency	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) Ready to use formulation. In use concentration 0,16-0,50 % (w/w) iodine. 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**

Table 9

**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)	Bacteria Yeast
Field(s) of use	Indoor
Application method(s)	Open system: dip treatment 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 frequency	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) Ready to use formulation In use concentration 0,16-0,50 % (w/w) iodine. 2 post milking applications per animal, per day
Category(ies) of users	Trained professional Professional

Pack sizes and packaging material	<p>Drum, Plastic: HDPE, 10 l</p> <p>Drum, Plastic: HDPE, 20 l</p> <p>Drum, Plastic: HDPE, 25 l</p> <p>Drum, Plastic: HDPE, 200 l</p> <p>IBC (intermediate bulk container), Plastic: HDPE, 1000 l</p> <p>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>
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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**

Table 10

**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)	Bacteria Yeast
Field(s) of use	Indoor
Application method(s)	<p>Open system: dip treatment</p> <p>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</p> <p>The same solution can be applied to multiple animals during the same milking session.</p>

Application rate(s) and frequency	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) Ready to use formulation In use concentration 0,16-0,30 % (w/w) iodine. 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.

4.7.1. *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

Table 11

**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)	Bacteria Yeast
Field(s) of use	Indoor
Application method(s)	Open system: spray treatment 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 frequency	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) – Ready to use formulation In use concentration 0,16-0,30 % (w/w) iodine. 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.

## 4.8.1. Use-specific instructions for use

Post milking:

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).

## 4.8.2. 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

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.

4.8.3. *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

Table 12

#### 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)	Bacteria Yeast
Field(s) of use	Indoor
Application method(s)	Open system: dip treatment 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 frequency	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) Ready to use formulation In use concentration 0,16-0,30 % (w/w) iodine. 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 <sup>(?)</sup> OF THE META SPC 2

#### 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 reusable 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 use specific risk mitigation measures.

#### 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.

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<sup>(?)</sup> Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 2.



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

#### 7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 2

##### 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				
Authorisation number	EU-0020125-0005 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

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

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				
Authorisation number	EU-0020125-0006 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

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

Trade name(s)	LuxDip 50B, Postguard				
Authorisation number	EU-0020125-0007 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Sub-stance	7553-56-2	231-442-4	0,5

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

Trade name(s)	LuxDip 25, Kote It, Corston Barracide Post Film Forming Dip, Pro-Tect, Kristal Iocare Film, Coars Iodinegel, Coars Iodogel, LuxDip 20B				
Authorisation number	EU-0020125-0008 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Sub-stance	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

**META SPC 3**

## 1. META SPC 3 ADMINISTRATIVE INFORMATION

## 1.1. Meta SPC 3 identifier

Identifier	Meta SPC 3 — RTU Products — Professiona RTU Liquid for application pre and post milking (LuxSpray 15)
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## 1.2. Suffix to the authorisation number

Number	1-3
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## 1.3. Product type(s)

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)
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## 2. META SPC 3 COMPOSITION

## 2.1. Qualitative and quantitative information on the composition of the meta SPC 3

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
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 Im-bentin 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 3

Formulation(s)	AL — Any other liquid
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## 3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 3

Hazard statements	May be corrosive to metals.
Precautionary statements	Avoid release to the environment. Collect spillage. Dispose of contents in accordance with local regulations. Dispose of container in accordance with local regulations.

## 4. AUTHORISED USE(S) OF THE META SPC 3

## 4.1. Use description

Table 13

**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)	Bacteria Yeast
Field(s) of use	Indoor

Application method(s)	Open system: dip treatment 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 frequency	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) Ready to use formulation. In use concentration 0,16 % (w/w) iodine. 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

Table 14

## 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)	Bacteria Yeast
Field(s) of use	Indoor
Application method(s)	Open system: spray treatment 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 frequency	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) Ready to use formulation In use concentration 0,16 % (w/w) iodine. 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

Table 15

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

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor
Application method(s)	Open system: dip treatment 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 frequency	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) Ready to use formulation In use concentration 0,16 % (w/w) iodine. 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**

Table 16

**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)	Bacteria Yeast
Field(s) of use	Indoor
Application method(s)	Open system: dip treatment 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 frequency	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) Ready to use formulation In use concentration 0,16 % (w/w) iodine. 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.
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4.4.1. *Use-specific instructions for use*

Dip at least 2/3 of the teat length with diluted 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**

Table 17

**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)	Bacteria Yeast All
Field(s) of use	Indoor
Application method(s)	Open system: spray treatment 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 frequency	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) Ready to use formulation In use concentration 0,16 % (w/w) iodine. 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

Table 18

**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)	Bacteria Yeast
Field(s) of use	Indoor
Application method(s)	Open system: dip treatment 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 frequency	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) Ready to use formulation In use concentration 0,16 % (w/w) iodine. 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

Table 19

#### Use # 7 – Use # 3.7 – 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)	Bacteria Yeast
Field(s) of use	Indoor
Application method(s)	Open system: dip treatment 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 frequency	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) Ready to use formulation In use concentration 0,16 % (w/w) iodine. 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.

4.7.1. *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**

Table 20

**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)	Bacteria Yeast
Field(s) of use	Indoor
Application method(s)	Open system: spray treatment 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 frequency	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) Ready to use formulation In use concentration 0,16 % (w/w) iodine. 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.

4.8.1. *Use-specific instructions for use*

Post milking:

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).

4.8.2. *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

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.

4.8.3. *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**

Table 21

**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)	Bacteria Yeast
Field(s) of use	Indoor

Application method(s)	Open system: dip treatment 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 frequency	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) Ready to use formulation In use concentration 0,16 % (w/w) iodine. 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 <sup>(<sup>1</sup>)</sup> OF THE META SPC 3

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 reusable 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 use specific risk mitigation measures.

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

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<sup>(1)</sup> Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 3.

## 6. OTHER INFORMATION

## 7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 3

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

Trade name(s)	LuxSpray 15 — Priodine RTU/Kristal Iocare Pre/Super Pre				
Authorisation number	EU-0020125-0009 1-3				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Sub- stance	7553-56-2	231-442-4	0,16
C9-11 Alcohol Ethoxy- late	C 9-11 alcohol with 6 moles of ethoxylate. Various brand names available including Im- bentin C-91-060	Non-active substance	68439-46-3	614-482-0	0,166