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: EU-0020125-0000

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Part I.- First information level

1. Administrative information

1.1. Family name

lodine Teat dip products		
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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	
ELL 0020125 0000		

Authorisation number

EU-0020125-0000

R4BP 3 asset reference number

EU-0020125-0000

Date of the authorisation

19/11/2019

Expiry date of the authorisation

31/10/2029

1.4. Manufacturer(s) of the biocidal products

Name of the manufacturer	GEA Farm Technologies	
Address of the manufacturer	Wylye Works BA12 9HT Warminster United Kingdom	
Location of manufacturing sites	Wylye Works, Watery Lane BA12 9HT Warminster United Kingdom	
	Gewerbestraße 5 5325 Plainfeld Austria	
	ul. Olowiana 10 85-461 Bydgoszcz Poland	

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

gium
ares, Las Condes 4290 Piso 4 Santiago Chile
c Co Europe PLC)
o-Machi, Chosei-Gun, 299-4205 Chosei-Gun
o-Machi, Chosei-Gun, 299-4205 Chosei-Gun
3 Knutsford United Kingdom
ZO 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 (%)
lodine		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



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 (%)
lodine		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

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: Other: Yeast Common name: Other: Yeast Development stage: All
Field(s) of use	Indoor
. iola(e) of abo	-
Application method(s)	Method: Open system: dip treatment Detailed description:
	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 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: 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 I

IBC (intermediate bulk container), Plastic: HDPE, 1000 I

Drum, Plastic: HDPE, 51

All drums excepting 200 I (200 kg) and 1000 I (1000 kg) could be either silver or natural (white translucent) in colour. 200 I (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

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 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 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: 2 post milking applications per animal, per day
Category(ies) of users	Trained professional Professional

Pack sizes and packaging material

Drum, Plastic: HDPE, 10 | Drum, Plastic: HDPE, 20 | Drum, Plastic: HDPE, 25 | Drum, Plastic: HDPE, 200 |

IBC (intermediate bulk container), Plastic: HDPE, 1000 I

Drum, Plastic: HDPE , 5 I

All drums excepting 200 I (200 kg) and 1000 I (1000 kg) could be either silver or natural (white translucent) in colour. 200 I (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 us under normal conditions of s	se, the conditions of storage and shelf-life of the product torage	
See general directions for use		
4.3 Use description		
·	onal concentrates with 1:3, 1:4 and 1:7 dilution rates, for post	
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: 2 post milking applications per animal, per day Trained professional Category(ies) of users Professional Pack sizes and packaging material Drum, Plastic: HDPE, 10 I Drum, Plastic: HDPE, 20 I Drum, Plastic: HDPE, 25 I Drum, Plastic: HDPE, 200 I IBC (intermediate bulk container), Plastic: HDPE, 1000 I Drum, Plastic: HDPE, 5 I All drums excepting 200 I (200 kg) and 1000 I (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

See general directions for use	
.3.5 Where specific to nder normal condition	the use, the conditions of storage and shelf-life of the product is of storage
See general directions for use	
. General directions	for use of the meta SPC
.1. Instructions for us	e
	pefore use and follow all the instructions provided.
The product must be brought to	a lemberance above 70 C beible use.
Dilute product before application	according to the ratio specified on the product label
Formanual dilution of the concer container to achieve the required dilution rate	according to the ratio specified on the product label ntrate; Add the ratio of concentrate and water, specified on the product label, to a suitably sized e. Mix to a uniform solution.
Formanual dilution of the concer container to achieve the required dilution rate Before attaching the milking clus	according to the ratio specified on the product label ntrate; Add the ratio of concentrate and water, specified on the product label, to a suitably sized
Formanual dilution of the concer container to achieve the required dilution rate Before attaching the milking clus cloth should be used per cow	ntrate; Add the ratio of concentrate and water, specified on the product label, to a suitably sized e. Mix to a uniform solution. Ster, all teat-dip residues should be removed with either a single use towel or re-usable cloth. One
Formanual dilution of the concer container to achieve the required dilution rate Before attaching the milking clus cloth should be used per cow For effective use against bacteri	according to the ratio specified on the product label ntrate; Add the ratio of concentrate and water, specified on the product label, to a suitably sized e. Mix to a uniform solution.
Formanual dilution of the concer container to achieve the required dilution rate Before attaching the milking clus cloth should be used per cow For effective use against bacteri	ntrate; Add the ratio of concentrate and water, specified on the product label, to a suitably sized e. Mix to a uniform solution. Ster, all teat-dip residues should be removed with either a single use towel or re-usable cloth. One a and yeast, product must be left in contact with the skin for at least 60 seconds e, care should be taken that the product is not removed after application (e.g. keep the cows standing).
Formanual dilution of the concer container to achieve the required dilution rate Before attaching the milking clus cloth should be used per cow For effective use against bacteri To ensure sufficient contact time at least 5 minutes).	ntrate; Add the ratio of concentrate and water, specified on the product label, to a suitably sized e. Mix to a uniform solution. Ster, all teat-dip residues should be removed with either a single use towel or re-usable cloth. One a and yeast, product must be left in contact with the skin for at least 60 seconds e, care should be taken that the product is not removed after application (e.g. keep the cows standing entire lactation period
Formanual dilution of the concercontainer to achieve the required dilution rate Before attaching the milking clus cloth should be used per cow For effective use against bactering to ensure sufficient contact time at least 5 minutes). Product can be used during the	ntrate; Add the ratio of concentrate and water, specified on the product label, to a suitably sized e. Mix to a uniform solution. Ster, all teat-dip residues should be removed with either a single use towel or re-usable cloth. One a and yeast, product must be left in contact with the skin for at least 60 seconds e, care should be taken that the product is not removed after application (e.g. keep the cows standing entire lactation period

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. C	onsult
a physician.	
Large spills should be contained using a chemical spill kit, soaked up using absorbent material such as kieselguhr and dispos	ed 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 produ	ct can
be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an	ci can
individual farm based waste water treatment plant.	
.5. Conditions of storage and shelf-life of the product under normal conditions of stor	rage
Protect from frost	
Flotect noin nost	
Do not store at temperatures above 30 °C	
Shelf life 12 months	
5. Other information	
5. Other information	
7. Third information level: individual products in the meta SPC	

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

Trade name(s)

Ioklene Concentrate, Coars Dual

Market area: EU

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

EU-0020125-0001 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		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

(R4BP 3 asset reference number - National Authorisation)

EU-0020125-0002 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		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)

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

Market area: EU

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

EU-0020125-0003 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		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)

EU-0020125-0004 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		Active Substance	7553-56-2	231-442-4	2,32

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 (%)
lodine		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. 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 0.16-0.30% (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 $\rm I$

Drum, Plastic: HDPE, 51

All drums excepting 200 I (200 kg) and 1000 I (1000 kg) could be either silver or natural (white translucent) in colour. 200 I (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 u	se, the instructions for safe disposal of the product and its
See general directions for use	
I.1.5 Where specific to the us under normal conditions of s	se, the conditions of storage and shelf-life of the product torage
See general directions for use	
4.2 Use description	
Jse 2 - RTU Products - Profess	ional 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
	Indoor
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 requencies	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
Category(ies) of users	Trained professional
Jacogory (100) or allocio	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 instructio	ons for use
See general directions for use	
1.2.2 Use-specific risk mitig	jation measures
Wear protective chemical resistant glovauthorisation holder within the product	ves when applying the product by manual spraying (glove material to be specified by the information)
In case a combination of pre- and post- considered for post milking disinfection	-milking disinfection is necessary, using another product not containing iodine has to be

	se, the particulars of likely direct or indirect effects, first aid measures to protect the environment
See general directions for use	
4.2.4 Where specific to the u packaging	se, the instructions for safe disposal of the product and its
See general directions for use	
under normal conditions of s	se, the conditions of storage and shelf-life of the product storage
See general directions for use	
4.3 Use description Use 3 - RTU Products - Profess	ional 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)	Scientific name: Bacteria Common name: Bacteria Development stage: All
	Scientific name: yeast Common name: yeast Development stage: All
	Indoor
Field(s) of use	-
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 0.16-0.30% (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 4.3.1 Use-specific instruction	Drum, Plastic: HDPE , 10 I Drum, Plastic: HDPE , 20 I Drum, Plastic: HDPE , 25 I Drum, Plastic: HDPE , 200 I IBC (intermediate bulk container), Plastic: HDPE , 1000 I Drum, Plastic: HDPE , 5 I All drums excepting 200 I (200 kg) and 1000 I (1000 kg) could be either silver or natural (white translucent) in colour. 200 I (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.
See general directions for use	
4.3.2 Use-specific risk mitiga	tion measures
In case a combination of pre- and post-m considered for post milking disinfection	ilking disinfection is necessary, using another product not containing iodine has to be

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 u packaging	se, the instructions for safe disposal of the product and its
See general directions for use	
under normal conditions of s	se, the conditions of storage and shelf-life of the product storage
See general directions for use	
4.4.Llca decarintian	
4.4 Use description	
Use 4 - RTU Products - Profess	ional 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 0.16-0.50% (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 | Drum, Plastic: HDPE , 20 | Drum, Plastic: HDPE , 25 | Drum, Plastic: HDPE , 200 |

IBC (intermediate bulk container), Plastic: HDPE, 1000 I

Drum, Plastic: HDPE, 51

All drums excepting 200 I (200 kg) and 1000 I (1000 kg) could be either silver or natural (white translucent) in colour. 200 I (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 usunder normal conditions of s	se, the conditions of storage and shelf-life of the product storage
See general directions for use	
4.5 Use description	
Use 5 - RTU Products - Profess	ional 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 | Drum, Plastic: HDPE, 20 | Drum, Plastic: HDPE, 25 | Drum, Plastic: HDPE, 200 |

IBC (intermediate bulk container), Plastic: HDPE, 1000 I

Drum, Plastic: HDPE, 51

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 usunder normal conditions of s	se, the conditions of storage and shelf-life of the product
See general directions for use	
4.6 Use description	
Use 6 - RTU Products - Profess	ional 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 mosh, mixing with air and forming foam. This is then applied to the
	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 | Drum, Plastic: HDPE, 20 | Drum, Plastic: HDPE, 25 | Drum, Plastic: HDPE, 200 |

IBC (intermediate bulk container), Plastic: HDPE, 1000 I

Drum, Plastic: HDPE , 5 I

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 - Professi	ional 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 0.16-0.30% (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 | Drum, Plastic: HDPE, 20 | Drum, Plastic: HDPE, 25 | Drum, Plastic: HDPE, 200 |

IBC (intermediate bulk container), Plastic: HDPE, 1000 I

Drum, Plastic: HDPE, 51

All drums excepting 200 I (200 kg) and 1000 I (1000 kg) could be either silver or natural (white translucent) in colour. 200 I (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

Product type

Where relevant, an exact description of the authorised use

Target organism(s) (including development stage)

PT03 - Veterinary hygiene (Disinfectants)

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

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

Field(s) of use

Application method(s)

Indoor

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 0.16-0.30% (w/w) iodine. Number and timing of application:

2 pre milking applications per animal, per day 2 post milking applications per animal, per day

Trained professional Category(ies) of users Professional Drum, Plastic: HDPE, 10 I Pack sizes and packaging Drum, Plastic: HDPE, 20 I material Drum, Plastic: HDPE, 25 I Drum, Plastic: HDPE, 200 I IBC (intermediate bulk container), Plastic: HDPE, 1000 I Drum, Plastic: HDPE, 51 All drums excepting 200 I (200 kg) and 1000 I (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	
under normal conditions of s	se, the conditions of storage and shelf-life of the product storage
See genarl directions for use	
4.9 Use description	
Use 9 - RTU Products - Profess	ional 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 0.16-0.30% (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 | Drum, Plastic: HDPE, 20 | Drum, Plastic: HDPE, 25 | Drum, Plastic: HDPE, 200 |

IBC (intermediate bulk container), Plastic: HDPE, 1000 I

Drum, Plastic: HDPE, 5 I

All drums excepting 200 I (200 kg) and 1000 I (1000 kg) could be either silver or natural (white translucent) in colour. 200 I (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

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

At the end of the treatment, dispose of un be flushed to the municipal sewer or dispo individual farm based waste water treatm	rused product and the packaging in accordance vosed to the manure deposit depending on local reent plant.	vith local requirements. Used product can equirements. Avoid release to an
5.5. Conditions of storage and	d shelf-life of the product under n	ormal 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 met	a SPC
7.1 Trade name(s), authorisat product	tion number and specific compos	ition of each individual
Trade name(s)	LuxSpray 30, loklene RTU, Corston Pre/Post Sprayable, Kristal locare Plus, PrePost, Autodine, Coars Super Pre	Market area: EU
Authorisation number		
(R4BP 3 asset reference number - National Authorisation)	EU-0020125-0005 1-2	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		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)

EU-0020125-0006 1-2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		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)

EU-0020125-0007 1-2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		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 Iocare Film, Coars Iodinegel, Coars Iodogel, LuxDip 20B

Market area: EU

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

EU-0020125-0008 1-2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		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 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

2. Meta SPC composition

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		Active Substance	7553-56-2	231-442-4	0,16 - 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

PT03 - Veterinary hygiene (Disinfectants) Product type Where relevant, an exact description of the authorised Scientific name: Bacteria Common name: Bacteria Development stage: All Target organism(s) (including development stage) Scientific name: YEAST Common name: yeast Development stage: All Indoor Field(s) of use Method: Open system: dip treatment Application method(s) 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: Quantity of RTU product to be applied per application; - cows and Application rate(s) and buffaloes: 3 to 10ml (5 ml recommended) - sheep 1.5 to 5 ml (1.5 ml recommended) frequencies 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 Trained professional Category(ies) of users Professional Drum, Plastic: HDPE, 10 I Pack sizes and packaging Drum, Plastic: HDPE , 20 I material Drum, Plastic: HDPE, 25 I Drum, Plastic: HDPE, 200 I IBC (intermediate bulk container), Plastic: HDPE, 1000 I Drum, Plastic: HDPE, 5 I

All drums excepting 200 I (200 kg) and 1000 I (1000 kg) could be either silver or natural (white translucent) in colour. 200 I (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

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 I Drum, Plastic: HDPE, 20 I Drum, Plastic: HDPE, 25 l Drum, Plastic: HDPE , 200 I

IBC (intermediate bulk container), Plastic: HDPE, 1000 I

Drum, Plastic: HDPE, 5 I

All drums excepting 200 I (200 kg) and 1000 I (1000 kg) could be either silver or natural

See general directions for use	
I.2.2 Use-specific risk r	nitigation measures
Wear protective chemical resistar authorisation holder within the pro	nt gloves when applying the product by manual spraying (glove material to be specified by the oduct information)
In case a combination of pre- and considered for post milking disinf	post-milking disinfection is necessary, using another product not containing iodine has to be
sorisidered for post minking dismi	ection
.2.3 Where specific to	the use, the particulars of likely direct or indirect effects, first aid ency measures to protect the environment
.2.3 Where specific to nstructions and emerg	the use, the particulars of likely direct or indirect effects, first aid
.2.3 Where specific to a structions and emerg See general directions for use	the use, the particulars of likely direct or indirect effects, first aid
A.2.3 Where specific to nstructions and emerg	the use, the particulars of likely direct or indirect effects, first aid ency measures to protect the environment
.2.3 Where specific to a structions and emergon see general directions for use .2.4 Where specific to ackaging	the use, the particulars of likely direct or indirect effects, first aid ency measures to protect the environment the use, the instructions for safe disposal of the product and its

(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 Use description

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

PT03 - Veterinary hygiene (Disinfectants) Product type Where relevant, an exact description of the authorised Scientific name: Bacteria Common name: Bacteria Development stage: All Target organism(s) (including development stage) Scientific name: yeast Common name: yeast Development stage: All Indoor Field(s) of use Method: Open system: dip treatment Application method(s) 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: Quantity of RTU product to be applied per application; - cows and Application rate(s) and buffaloes: 3 to 10ml (5 ml recommended) - sheep 1.5 to 5 ml (1.5 ml recommended) frequencies 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 Trained professional Category(ies) of users Professional Drum, Plastic: HDPE, 10 I Pack sizes and packaging Drum, Plastic: HDPE, 20 I material Drum, Plastic: HDPE, 25 I Drum, Plastic: HDPE, 200 I IBC (intermediate bulk container), Plastic: HDPE, 1000 I Drum, Plastic: HDPE, 5 I

IBCs are natural coloured.

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

All drums are capped with tamper evident caps or bungs and are UN certified	۱.

4.3.1 Use-specific instructions for use
See general directions for use
4.3.2 Use-specific risk mitigation measures
no - coo cpecino nen muganen menerina
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

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 I

Drum, Plastic: HDPE, 5 I

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

Where relevant, an exact description of the authorised use

Target organism(s) (including development stage)

PT03 - Veterinary hygiene (Disinfectants)

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 post milking applications per animal, per day

Category(ies) of users

Trained professional

Professional

Pack sizes and packaging material

Drum, Plastic: HDPE, 10 I Drum, Plastic: HDPE , 20 I Drum, Plastic: HDPE, 25 I Drum, Plastic: HDPE, 200 I

IBC (intermediate bulk container), Plastic: HDPE, 1000 I

Drum, Plastic: HDPE , 5 I

All drums excepting 200 I (200 kg) and 1000 I (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 jodine 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

Product type

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

Where relevant, an exact

description of the authorised

Target organism(s) (including development stage)

PT03 - Veterinary hygiene (Disinfectants)

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

Category(ies) of users

Trained professional

Professional

Pack sizes and packaging material

Drum, Plastic: HDPE, 10 I Drum, Plastic: HDPE , 20 I Drum, Plastic: HDPE, 25 I Drum, Plastic: HDPE, 200 I

IBC (intermediate bulk container), Plastic: HDPE , 1000 $\rm I$

Drum, Plastic: HDPE , 5 I

All drums excepting 200 I (200 kg) and 1000 I (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 jodine 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

Where relevant, an exact description of the authorised use

Target organism(s) (including development stage)

PT03 - Veterinary hygiene (Disinfectants)

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

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

Field(s) of use

Indoor

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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

Category(ies) of users

Trained professional

Professional

Pack sizes and packaging material

Drum, Plastic: HDPE, 10 | Drum, Plastic: HDPE, 20 | Drum, Plastic: HDPE, 25 | Drum, Plastic: HDPE, 200 |

IBC (intermediate bulk container), Plastic: HDPE , 1000 I

Drum, Plastic: HDPE, 5 I

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 PT03 - Veterinary hygiene (Disinfectants)

Product type Where relevant, an exact description of the authorised Scientific name: Bacteria Common name: Bacteria Development stage: All Target organism(s) (including development stage) Scientific name: yeast Common name: yeast Development stage: All

Field(s) of use

Indoor

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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 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 \mbox{I}

Drum, Plastic: HDPE , 5 I

All drums excepting 200 I (200 kg) and 1000 I (1000 kg) could be either silver or natural (white translucent) in colour. 200 I (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 standi 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 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

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

PT03 - Veterinary hygiene (Disinfectants)

Product type

Where relevant, an exact description of the authorised

Target organism(s) (including development stage)

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

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

Field(s) of use

Indoor

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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 I

Drum, Plastic: HDPE, 51

All drums excepting 200 I (200 kg) and 1000 I (1000 kg) could be either silver or natural (white translucent) in colour. 200 I (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
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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6.	Other	inform	ation

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 locare Pre, Super Pre, Priodine RTU

Market

Market area: EU

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

EU-0020125-0009 1-3

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