

Summary of product characteristics for a biocidal product family

Family name: Boumatic Iodine product family

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

Authorisation number: EU-0020541-0000

R4BP 3 asset reference number: IS-0022011-0000

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Part I.- First information level

1. Administrative information

1.1. Family name

Boumatic Iodine product family

1.2. Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

1.3. Authorisation holder

Name and address of the authorisation holder

Name	Boumatic
Address	31, Rue Jules Melotte 4350 Remicourt Belgium

Authorisation number

EU-0020541-0000

R4BP 3 asset reference number

IS-0022011-0000

Date of the authorisation

18/11/2019

Expiry date of the authorisation

31/10/2029

1.4. Manufacturer(s) of the biocidal products

Name of the manufacturer

Christeyns n.v.

Address of the manufacturer

Afrikalaan 182 9000 Ghent Belgium

Location of manufacturing sites

Afrikalaan 182 9000 Ghent Belgium

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

Active substance	1319 - Iodine
Name of the manufacturer	Christeyns n.v.
Address of the manufacturer	Afrikalaan 182 9000 Ghent Belgium
Location of manufacturing sites	Cosayach Nitratos S.AO, Oficina Cala Cala S/N Pozo Almonte Iquique Chile

2. Product family composition and formulation

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,26 - 0,5
Fatty alcohol ethoxylate			69011-36-5	500-241-6	1 - 2,99

2.2. Type(s) of formulation

AL - Any other liquid

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

1. Meta SPC administrative information

1.1. Meta SPC identifier

meta SPC 1

1.2. Suffix to the authorisation number

1-1

1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

2. Meta SPC composition

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,44 - 0,5
Fatty alcohol ethoxylate			69011-36-5	500-241-6	1 - 2,99

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

Formulation(s)

AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

Hazard statements

Causes serious eye irritation.
Harmful to aquatic life with long lasting effects.

Precautionary statements

Wash hands thoroughly after handling.
Wear eye protection.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice.
Avoid release to the environment.

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - Use # 1.1 – Manual dip treatment, pre- or post-milking teat disinfectants

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: Scientific name: Yeasts Common name: Yeasts Development stage:
Field(s) of use	Indoor Teat disinfectants for pre- or post-milking manual dip treatment of cow teats
Application method(s)	Open system: dip treatment - for pre-milking: min. 1 minute contact time for post-milking min. 5 minutes contact time
Application rate(s) and frequencies	Apply an amount of product that is sufficient to cover the entire teat, at the maximum 10 ml per treatment - Product is ready to use - 2 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	20kg, 60kg, 200kg, 210kg HDPE drum and 1000kg HDPE

4.1.1 Use-specific instructions for use

Product for disinfection of cow teat by dipping treatment, before or after milking.
Apply an amount of product that is sufficient to cover the entire teat, at the maximum 10 ml per dip treatment.
Fill the dipping cup with indicated quantity of undiluted product straight from the original packaging. With every treatment, care

should be taken to the volume of treatment product in the dipping cup. To reduce dermal exposure, the use of a dosing pump for filling the product into the application equipment is recommended.

4.1.2 Use-specific risk mitigation measures

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

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 of the meta SPC 1

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

See general directions for use of the meta SPC 1

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 of the meta SPC 1

4.2 Use description

Use 2 - Use # 1.2 – Manual spraying treatment pre- or post-milking teat disinfectants

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:

Scientific name: yeast
Common name: Yeasts
Development stage:

Field(s) of use	Indoor Teat disinfectants for pre- or post-milking, manual spray treatment of cow teat
Application method(s)	Open system: spray treatment - for pre-milking: min. 1 minute contact time, for post-milking min. 5 minutes contact time.
Application rate(s) and frequencies	Apply an amount of product that is sufficient to cover the entire teat, at the maximum 15ml per spray - Product is ready to use - 2 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	20kg, 60kg, 200kg, 210kg HDPE drum and 1000kg HDPE IBC

4.2.1 Use-specific instructions for use

Product for disinfection of cow teat by spraying, before or after milking.

Apply an amount of product that is sufficient to cover the entire teat at the maximum 15 ml per spray treatment. Fill the spray flask with the indicated quantity of undiluted product straight from the original packaging. To reduce dermal exposure, the use of a dosing pump for filling the product into the application equipment is recommended.

4.2.2 Use-specific risk mitigation measures

Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), protective clothing, chemical resistant boots, and eye protection.

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 of the meta SPC 1

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

See general directions for use of the meta SPC 1

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 of the meta SPC 1

4.3 Use description

Use 3 - Use # 1.3 – Automated dip treatment, pre- or post-milking teat disinfectants

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:

Scientific name: yeast
Common name: Yeasts
Development stage:

Field(s) of use

Indoor

Teat disinfectants for pre- or post-milking, automated dip treatment of cow teat

Application method(s)

Open system: dip treatment -
for pre-milking: min. 1 minute contact time,
for post-milking min. 5 minutes contact time.

Application rate(s) and frequencies

Apply an amount of product that is sufficient to cover the entire teat, at the maximum 10 ml per dip - Product is ready to use - 3 times per day

Category(ies) of users

Professional

Pack sizes and packaging material

20kg, 60kg, 200kg, 210kg HDPE drum and 1000kg HDPE IBC

4.3.1 Use-specific instructions for use

Product for disinfection of cow teat by dipping, before or after milking.

Apply an amount of product that is sufficient to cover the entire teat, at the maximum 10 ml per dip treatment.

Use the undiluted product straight from the original packaging. To reduce dermal exposure, the use of a dosing pump for filling the product into the application equipment is recommended.

4.3.2 Use-specific risk mitigation measures

See general directions for use of the meta SPC 1

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 of the meta SPC 1

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

See general directions for use of the meta SPC 1

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 of the meta SPC 1

4.4 Use description

Use 4 - Use # 1.4 – Automated spraying treatment, pre- or post-milking teat disinfectants

Product type

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

-

Target organism(s) (including development stage)	<p>Scientific name: Bacteria Common name: Bacteria Development stage:</p> <p>Scientific name: yeast Common name: Yeasts Development stage:</p>
Field(s) of use	<p>Indoor</p> <p>Teat disinfectants for pre- or post-milking, automated spray treatment of cow teat</p>
Application method(s)	<p>Open system: spray treatment - for pre-milking: min. 1 minute contact time, for post-milking min. 5 minutes contact time.</p>
Application rate(s) and frequencies	<p>Apply an amount of product that is sufficient to cover the entire teat, at the maximum 15ml per spray - Product is ready to use - 3 times per day</p>
Category(ies) of users	<p>Professional</p>
Pack sizes and packaging material	<p>20kg, 60kg, 200kg, 210kg HDPE drum and 1000kg HDPE IBC</p>

4.4.1 Use-specific instructions for use

<p>Product for disinfection of cow teat by spraying, before or after milking.</p> <p>Apply an amount of product that is sufficient to cover the entire teat, at the maximum of 15 ml per spray treatment.</p> <p>Use the undiluted product straight from the original packaging. To reduce dermal exposure, the use of a dosing pump for filling the product into the application equipment is recommended.</p>

4.4.2 Use-specific risk mitigation measures

<p>See general directions for use of the meta SPC 1</p>

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 of the meta SPC 1

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

See general directions for use of the meta SPC 1

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 of the meta SPC 1

5. General directions for use of the meta SPC

5.1. Instructions for use

The products must be brought to temperatures above 20°C before use.
For pre-milking treatment: treat the entire teat with the product, let act 60 seconds and wipe teats dry using single-use towels to avoid any contamination of milk.
For the post-milking treatment: The teats should be treated as soon as possible after milking in such a way that the teats are fully covered. Let the teats air dry. The cows should be kept in a standing position until the product is fully dried (at least 5 minutes).

5.2. Risk mitigation measures

In case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered either for pre- or post-milking disinfection.
Keep out of reach of children.

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

First aid: general information: immediately remove any clothing soiled by the product
After inhalation: Supply fresh air; consult doctor in case of complaints.
After skin contact: Wash skin thoroughly. Generally the product does not irritate the skin.

After eye contact: Rinse opened eye for several minutes under running water. Remove contact lenses, if present and easy to do. Continue rinsing.
After swallowing: Rinse out mouth and then drink water. If you feel unwell, get medical advice/attention.
If medical advice is needed, have product container or label at hand.
Do not allow product to enter sewers/ surface or ground water.

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

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

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

Protect from frost. Store in a cool, dry place, away from direct sunlight and out of reach from children.

Shelf life: 2 years

6. Other information

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

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

Trade name(s)

Udder Dip	Market area: EU
Udder Dip Max	Market area: EU
Udder D Max	Market area: EU
Udderdine Dip	Market area: EU
Uddine Dip	Market area: EU
Udderdine DP	Market area: EU

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

Uddine DP	Market area: EU
Udderdine DS	Market area: EU
IS-0022011-0001 1-1	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,5
Fatty alcohol ethoxylate			69011-36-5	500-241-6	2,99

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

meta SPC 2

1.2. Suffix to the authorisation number

1-2

1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

2. Meta SPC composition

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,26 - 0,38
Fatty alcohol ethoxylate			69011-36-5	500-241-6	1 - 2,99

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

Formulation(s)

AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

Hazard statements

Causes serious eye irritation.
Harmful to aquatic life with long lasting effects.

Precautionary statements

Wash hands thoroughly after handling.
Wear eye protection.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice.
Avoid release to the environment.

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - Use # 2.1 – Manual dip treatment, post milking teat disinfectants

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:

Scientific name: yeasts
Common name: Yeasts
Development stage:

Field(s) of use

Indoor

Teat disinfection for post –milking, manual dip treatment of cow teats

Application method(s)

Open system: dip treatment -

For post-milking min. 5 minutes contact time

Application rate(s) and frequencies

Apply an amount of product that is sufficient to cover the entire teat, at the maximum 10 ml per treatment - Product is ready to use -
2 times per day

Category(ies) of users

Professional

Pack sizes and packaging material

20kg, 60kg, 200kg, 210kg HDPE drum and 1000kg HDPE IBC

4.1.1 Use-specific instructions for use

Product for disinfection of cow teat by dipping treatment, after milking.

Fill the dipping cup with the indicated quantity of undiluted product straight from the original packaging. With every treatment, care should be taken to the volume of treatment product in the dipping cup. To reduce dermal exposure, the use of a dosing pump for filling the product into the application equipment is recommended.

4.1.2 Use-specific risk mitigation measures

Wear eye protection.

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 of the meta SPC 2

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

See general directions for use of the meta SPC 2

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 of the meta SPC 2

4.2 Use description

Use 2 - Use # 2.2 – Manual spraying treatment, post milking teat disinfectants

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:

Scientific name: yeasts
Common name: Yeasts
Development stage:

Field(s) of use

Indoor

Teat disinfection for post – milking, Manual spray treatment of cow teats

Application method(s)

Open system: spray treatment -
For post-milking min. 5 minutes contact time

Application rate(s) and frequencies

Apply an amount of product that is sufficient to cover the entire teat, at the maximum 15ml per spray treatment - Product is ready to use - 2 times per day

Category(ies) of users

Professional

Pack sizes and packaging material

20kg, 60kg, 200kg, 210kg HDPE drum and 1000kg HDPE IBC

4.2.1 Use-specific instructions for use

Product for disinfection of cow teat by spraying, after milking.
Apply an amount of product that is sufficient to cover the entire teat, a the maximum 15 ml per spray treatment.

Fill the spray flask with the indicated quantity of undiluted product straight from the original packaging.To reduce dermal exposure, the use of a dosing pump for filling the product into the application equipment is recommended.

4.2.2 Use-specific risk mitigation measures

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

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 of the meta SPC 2

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

See general directions for use of the meta SPC 2

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 of the meta SPC 2

4.3 Use description

Use 3 - Use # 2.3 – Automated dip treatment, post-milking teat disinfectants

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: Scientific name: yeasts Common name: Yeasts Development stage:
Field(s) of use	Indoor Teat disinfection for post – milking, Automated dip treatment of cow teats
Application method(s)	Open system: dip treatment - For post-milking min. 5 minutes contact time .
Application rate(s) and frequencies	Apply an amount of product that is sufficient to cover the entire teat, at the maximum 10ml per dip treatment - Product is ready to use. - 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	20kg, 60kg, 200kg, 210kg HDPE drum and 1000kg HDPE IBC

4.3.1 Use-specific instructions for use

Product for disinfection of cow teat by dipping, after milking.

Apply an amount of product that is sufficient to cover the entire teat, at the maximum 10 ml per dip treatment.

Use the undiluted product straight from the original packaging. To reduce dermal exposure, the use of a dosing pump for filling the product into the application equipment is recommended.

4.3.2 Use-specific risk mitigation measures

See general directions for use of the meta SPC 2

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 of the meta SPC 2

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

See general directions for use of the meta SPC 2

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 of the meta SPC 2

4.4 Use description

Use 4 - Use # 2.4 – Automated spraying treatment, post-milking teat disinfectants

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: Scientific name: yeasts Common name: Yeasts Development stage:
Field(s) of use	Indoor Teat disinfection for post – milking, Automated spray treatment of cow teats

Application method(s)	Open system: spray treatment - For post-milking min. 5 minutes contact time..
Application rate(s) and frequencies	Apply an amount of product that is sufficient to cover the entire teat, at the maximum 15ml per spray treatment - Product is ready to use - 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	20kg, 60kg, 200kg, 210kg HDPE drum and 1000kg HDPE IBC

4.4.1 Use-specific instructions for use

Product for disinfection of cow teat by spraying, after milking. Apply an amount of product that is sufficient to cover the entire teat, at the maximum of 15 ml per spray treatment Use the undiluted product straight from the original packaging. To reduce dermal exposure, the use of a dosing pump for filling the product into the application equipment is recommended.

4.4.2 Use-specific risk mitigation measures

See general directions for use of the meta SPC 2
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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 of the meta SPC 2
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4.4.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use of the meta SPC 2
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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 of the meta SPC 2

5. General directions for use of the meta SPC

5.1. Instructions for use

The products must be brought to temperatures above 20°C before use.

For the post-milking treatment: The teats should be treated as soon as possible after milking in such a way that the teats are fully covered. Let the teats air dry. The cows should be kept in a standing position until the product is fully dried (at least 5 minutes).

5.2. Risk mitigation measures

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

Keep out of reach of children.

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

First aid: general information: immediately remove any clothing soiled by the product

After inhalation: Supply fresh air; consult doctor in case of complaints.

After skin contact: Wash skin thoroughly. Generally the product does not irritate the skin.

After eye contact: Rinse opened eye for several minutes under running water. Remove contact lenses, if present and easy to do. Continue rinsing.

After swallowing: Rinse out mouth and then drink water. If you feel unwell, get medical advice/attention.

If medical advice is needed, have product container or label at hand.

Do not allow product to enter sewers/ surface or ground water.

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

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

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

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

Protect from frost. Store in a cool, dry place, away from direct sunlight and out of reach from children.
Shelf life: 1 year

6. Other information

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

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

Trade name(s)

Gladiator RTU	Market area: EU
Udder Max Barrier	Market area: EU
Gladiator Max Barrier	Market area: EU
Udderdine BARRIER	Market area: EU
Uddine BARRIER	Market area: EU
Udderdine RTU	Market area: EU

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

Uddine RTU	Market area: EU
Udderdine BR	Market area: EU
IS-0022011-0002 1-2	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,26
Fatty alcohol ethoxylate			69011-36-5	500-241-6	1,2

Trade name(s)

Udder Star Spray	Market area: EU
Udder Spray Max	Market area: EU
Udderdine Spray	Market area: EU
Uddine Spray	Market area: EU
Udderdine SP	Market area: EU
Uddine SP	Market area: EU

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

IS-0022011-0003 1-2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,29
Fatty alcohol ethoxylate			69011-36-5	500-241-6	2,99

1. Meta SPC administrative information

1.1. Meta SPC identifier

meta SPC 3

1.2. Suffix to the authorisation number

1-3

1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

2. Meta SPC composition

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,43 - 0,5
Fatty alcohol ethoxylate			69011-36-5	500-241-6	1 - 2,99

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

Formulation(s)

AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

Hazard statements

Causes serious eye irritation.
Harmful to aquatic life with long lasting effects.

Precautionary statements

Wash hands thoroughly after handling.
Wear eye protection.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice.
Avoid release to the environment.

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - Use # 3.1 – Manual dip treatment, post milking teat disinfectants

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:

	<p>Scientific name: yeasts Common name: Yeasts Development stage:</p>
Field(s) of use	<p>Indoor</p> <p>Teat disinfection for post –milking, manual dip treatment of cow teats</p>
Application method(s)	<p>Open system: dip treatment -</p> <p>For post-milking min. 5 minutes contact time</p>
Application rate(s) and frequencies	<p>Apply an amount of product that is sufficient to cover the entire teat, at the maximum 10 ml per treatment - Product is ready to use - 2 times per day</p>
Category(ies) of users	<p>Professional</p>
Pack sizes and packaging material	<p>20kg, 60kg, 200kg, 210kg HDPE drum and 1000kg HDPE IBC</p>

4.1.1 Use-specific instructions for use

<p>Product for disinfection of cow teat by dipping treatment, after milking.</p> <p>Fill the dipping cup with the indicated quantity of undiluted product straight from the original packaging. With every treatment, care should be taken to the volume of treatment product in the dipping cup. To reduce dermal exposure, the use of a dosing pump for filling the product into the application equipment is recommended.</p>
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4.1.2 Use-specific risk mitigation measures

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

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 of the meta SPC 3

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

See general directions for use of the meta SPC 3

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 of the meta SPC 3

4.2 Use description

Use 2 - Use # 3.2 – Manual spraying treatment, post milking teat disinfectants

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: Scientific name: yeasts Common name: Yeasts Development stage:
Field(s) of use	Indoor Teat disinfection for post – milking, manual spray treatment of cow teats
Application method(s)	Open system: spray treatment - For post-milking min. 5 minutes contact time .

Application rate(s) and frequencies

Apply an amount of product that is sufficient to cover the entire teat, at the maximum 15ml per spray treatment - Product is ready to use - 2 times per day

Category(ies) of users

Professional

Pack sizes and packaging material

20kg, 60kg, 200kg, 210kg HDPE drum and 1000kg HDPE IBC

4.2.1 Use-specific instructions for use

Product for disinfection of cow teat by spraying, after milking.

Apply an amount of product that is sufficient to cover the entire teat, at the maximum 15 ml per spray treatment

Fill the spray flask with the indicated quantity of undiluted product straight from the original packaging. To reduce dermal exposure, the use of a dosing pump for filling the product into the application equipment is recommended.

4.2.2 Use-specific risk mitigation measures

Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), protective clothing, chemical resistant boots, and eye protection.

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 of the meta SPC 3

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

See general directions for use of the meta SPC 3

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 of the meta SPC 3

4.3 Use description

Use 3 - Use # 3.3 – Automated dip treatment, post-milking teat disinfectants

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: Scientific name: yeasts Common name: Yeasts Development stage:
Field(s) of use	Indoor Teat disinfection for post – milking, automated dip treatment of cow teats
Application method(s)	Open system: dip treatment - For post-milking min. 5 minutes contact time.
Application rate(s) and frequencies	Apply an amount of product that is sufficient to cover the entire teat, at the maximum 10ml per dip treatment - Product is ready to use. - 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	20kg, 60kg, 200kg, 210kg HDPE drum and 1000kg HDPE IBC

4.3.1 Use-specific instructions for use

Product for disinfection of cow teat by dipping, after milking.

Apply an amount of product that is sufficient to cover the entire teat, at the maximum 10 ml per dip treatment.

Use the undiluted product straight from the original packaging. To reduce dermal exposure, the use of a dosing pump for filling the product into the application equipment is recommended.

4.3.2 Use-specific risk mitigation measures

See general directions for use of the meta SPC 3

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 of the meta SPC 3

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

See general directions for use of the meta SPC 3

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 of the meta SPC 3

4.4 Use description

Use 4 - Use # 3.4 – Automated spraying treatment, post-milking teat disinfectants

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:

Scientific name: yeasts
Common name: Yeasts

	Development stage:
Field(s) of use	Indoor Teat disinfection for post – milking, automated spray treatment of cow teats
Application method(s)	Open system: spray treatment - For post-milking min. 5 minutes contact time.
Application rate(s) and frequencies	15 ml per spray treatment - Product is ready to use - 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	20kg, 60kg, 200kg, 210kg HDPE drum and 1000kg HDPE IBC

4.4.1 Use-specific instructions for use

Product for disinfection of cow teat by spraying, after milking.

Apply an amount of product that is sufficient to cover the entire teat, at the maximum of 15 ml per spray treatment.

Use the undiluted product straight from the original packaging. To reduce dermal exposure, the use of a dosing pump for filling the product into the application equipment is recommended.

4.4.2 Use-specific risk mitigation measures

See general directions for use of the meta SPC 3

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 of the meta SPC 3

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

See general directions for use of the meta SPC 3

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 of the meta SPC 3

5. General directions for use of the meta SPC

5.1. Instructions for use

The products must be brought to temperatures above 20°C before use.

For the post-milking treatment: The teats should be treated as soon as possible after milking in such a way that the teats are fully covered. Let the teats air dry. The cows should be kept in a standing position until the product is fully dried (at least 5 minutes).

5.2. Risk mitigation measures

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

Keep out of reach of children.

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

First aid: general information: immediately remove any clothing soiled by the product

After inhalation: Supply fresh air; consult doctor in case of complaints.

After skin contact: Wash skin thoroughly. Generally the product does not irritate the skin.

After eye contact: Rinse opened eye for several minutes under running water. Remove contact lenses, if present and easy to do. Continue rinsing.

After swallowing: Rinse out mouth and then drink water. If you feel unwell, get medical advice/attention.

If medical advice is needed, have product container or label at hand.

Do not allow product to enter sewers/ surface or ground water.

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

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

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

Protect from frost. Store in a cool, dry place, away from direct sunlight and out of reach from children.
Shelf life: 2 years.

6. Other information

Hazard and precautionary statements in Icelandic

H319: Veldur alvarlegri augnertingu.

H412: Skaðlegt lífi í vatni, hefur langvinn áhrif.

P264: Þvoðið hendur vandlega eftir meðhöndlun.

P280: Notið augnhlífir.

P305+P351+P338: BERIST EFNID Í AUGU: Skolið varlega með vatni í nokkrar mínútur. Fjarlægjið snertilinsur ef það er auðvelt. Skolið áfram.

P337+P313: Ef augnerting er viðvarandi: Leitið lækni.

P273: Forðist losun út í umhverfi.

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)

Udder Star	Market area: EU
Udder Star Max	Market area: EU
Udder S Max	Market area: EU
Udderdine Star	Market area: EU

Uddine Star	Market area: EU
Udderine ST	Market area: EU
Uddine ST	Market area: EU
IS-0022011-0004 1-3	

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,5
Fatty alcohol ethoxylate			69011-36-5	500-241-6	2,5