

Summary of product characteristics for a biocidal product family

Family name: QUAT-CHEM's iodine based products

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

Authorisation number: EU-0018496-0000

R4BP 3 asset reference number: EU-0018496-0000

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Part I.- First information level

1. Administrative information

1.1. Family name

QUAT-CHEM's iodine based products

1.2. Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

1.3. Authorisation holder

Name and address of the authorisation holder

| | |
|---------|---|
| Name | Neogen Italia S.r.l. |
| Address | c/o REGUS Palazzo Bernini Centro Direzionale Milano Due, Via Fratelli Cervi snc 20054 Segrate, Milano Italy |

Authorisation number

EU-0018496-0000

R4BP 3 asset reference number

EU-0018496-0000

Date of the authorisation

11/10/2018

Expiry date of the authorisation

30/09/2028

1.4. Manufacturer(s) of the biocidal products

Name of the manufacturer

QUAT-CHEM LTD

Address of the manufacturer

Charter House 33 - Greek Street SK3 8AX Stockport United Kingdom

Location of manufacturing sites

QUAT-CHEM LTD - Charter House 33 - Greek Street SK3 8AX Stockport United Kingdom

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

| | |
|--|---|
| Active substance | 1319 - Iodine |
| Name of the manufacturer | COSAYACH : SCM Cía. Cosayach Minera Negreiros, Rut. N°96.625.710-5 |
| Address of the manufacturer | Terrenos de Elena S/N Terrenos de Elena S/N Huara, Región de Tarapacá Chile |
| Location of manufacturing sites | Mined at : S.C.M. Cía. Minera Negreiros, S.C.M. Cosayach Soledad. Refined at : S.C.M. Cía. Minera Negreiros. Pozo Almonte Chile |
| Active substance | 1319 - Iodine |
| Name of the manufacturer | ACF MINERA SA |
| Address of the manufacturer | San Martín 499 Iquique Chile |
| Location of manufacturing sites | Faena Lagunas KM. 1.722 Ruta A-5, Pozo Almonte Chile |
| Active substance | 1319 - Iodine |
| Name of the manufacturer | SOCIEDAD QUIMICA y MINERA SA |
| Address of the manufacturer | Los Militares 4290 SANTIAGO DE CHILE Chile |
| Location of manufacturing sites | Pedro de Valdivia (PV) Route B 180 Antofagasta Chile Nueva Victoria (NV) Route 5 North, Km 1925 Pozo Almonte Chile |

2. Product family composition and formulation

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

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|---|--|----------------------|------------|-----------|----------------|
| Iodine | | Active Substance | 7553-56-2 | 231-442-4 | 0,25 - 2,5 |
| Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio) | Poly(oxy-1,2-ethanediyl), -C12-14-(even numbered)-alkyl--hydroxy | Non-active substance | 68439-50-9 | | 2,697 - 24,199 |

2.2. Type(s) of formulation

AL - Any other liquid
SL - Soluble concentrate

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

1. Meta SPC administrative information

1.1. Meta SPC identifier

meta SPC 1 : Dipping products - ready to use

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 | 0,25 - 0,49 |
| Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio) | Poly(oxy-1,2-ethanediyl), -C12-14-(even numbered)-alkyl--hydroxy | Non-active substance | 68439-50-9 | | 2,697 - 4,993 |

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

Keep out of reach of children.
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.
If eye irritation persists: Get medical advice.
Get medical advice.

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - Use # 1.1 – Manual or automated dipping after milking

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:

Scientific name: Algae
Common name: Algae
Development stage:

Field(s) of use

Indoor
Disinfection of teats of milk producing animals by dipping after milking

| | |
|--|---|
| Application method(s) | <p>Method: Dipping Detailed description:</p> <p>Manual or automated disinfection of teats by dipping after milking. Dipping cup or automated dipping machine.</p> |
| Application rate(s) and frequencies | <p>Application Rate: - 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 (%): Number and timing of application: Frequency : 2 to 3 times per day</p> |
| Category(ies) of users | <p>Professional</p> |
| Pack sizes and packaging material | <p>HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L</p> <p>HDPE CONTAINER 1000L</p> |

4.1.1 Use-specific instructions for use

See general directions for use of meta SPC 1

4.1.2 Use-specific risk mitigation measures

See general directions for use of meta SPC 1

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 meta SPC 1

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

None : see directions for use 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 meta SPC 1

5. General directions for use of the meta SPC

5.1. Instructions for use

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.

The use of a dosing pump for filling the product into the application equipment is recommended.

Fill the dipping cup manually or automatically with the ready to use product.

Apply by dipping manually or automatically on animal's teats on the full length of the teat after milking.

- 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)

Leave the product until next milking. Keep the cows standing until the product has dried (at least 5 minutes).

At the next milking, use the teat cleaning and wiping method systematically before attaching the milking cluster.

Where necessary, repeat the application after each milking.

Clean the application equipment regularly with warm water.

5.2. Risk mitigation measures

Wear eye protection.

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.

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

Take the contaminated clothes and shoes off immediately. Wash them before wearing them again.

FIRST AID INSTRUCTIONS

- In the event of inhalation : Bring to fresh air.
- In the event of contact with the skin : Wash with water.
- In the event of contact with the eyes :
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/attention.
- In the event of ingestion : Rinse mouth. Do NOT induce vomiting. Get medical advice.
Refer to the safety data sheet available for professional user : it contains an emergency phone number.

Large spillage : Mark out, dyke up with an inert absorbant and pump in an emergency tank. Keep in suitable, properly labelled and closed containers for disposal. Never return spills in original containers for re-use.

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.
The paper towels used for removing the product and drying the teats are disposed in the normal and domestic waste.

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

Shelf life : 2 years in HDPE
Do not store at a temperature higher than 30°C.

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)

| | |
|---------------------|-----------------|
| Teatsan 2500 | Market area: EU |
| IODO GUARD 2500 | Market area: EU |
| EU-0018496-0001 1-1 | |

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 | 0,25 |
| Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio) | Poly(oxy-1,2-ethanediyl), -C12-14-(even numbered)-alkyl--hydroxy | Non-active substance | 68439-50-9 | | 2,697 |

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

meta SPC 2 : Dipping, foaming, spraying products - Ready to use

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 | 0,25 - 0,49 |
| Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio) | Poly(oxy-1,2-ethanediyl), -C12-14-(even numbered)-alkyl--hydroxy | Non-active substance | 68439-50-9 | | 2,697 - 4,69 |

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

Keep out of reach of children.
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.
If eye irritation persists: Get medical advice.
Get medical .

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - Use # 2.1 – Manual or automated dipping, foaming or spraying before milking

| | |
|---|--|
| 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: Yeasts Common name: Yeasts Development stage:</p> |
| Field(s) of use | <p>Indoor</p> <p>Disinfection of teats of milk producing animals by dipping, foaming or spraying before milking</p> |
| Application method(s) | <p>Method: Dipping, foaming or spraying before milking Detailed description:</p> <p>Manual or automated disinfection of teats by dipping, foaming or spraying before milking</p> <p>Dipping cup, foaming cup, teat sprayer, automated dipping machine, automated foaming machine or automated spraying machine</p> |
| Application rate(s) and frequencies | <p>Application Rate: - cows and buffaloes (3 to 10ml : 5 to 8 ml recommended) - sheep (1.5 to 5 ml : 1.5 to 3 ml recommended) - goats (2.5 to 6 ml : 2.5 to 4 ml recommended) Dilution (%): Number and timing of application: Frequency : 2 to 3 times per day</p> |
| Category(ies) of users | Professional |
| Pack sizes and packaging material | <p>HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L</p> <p>HDPE CONTAINER 1000L</p> |

4.1.1 Use-specific instructions for use

Eliminate all visible dirt before applying the product.

Manual or automatic dipping/foaming/spraying on animal's teats on the full length of the teat before milking.

Let the product act at least one minute.

Use the teat cleaning and wiping method systematically before attaching the milking cluster.

See also general instructions for use of meta SPC 2.

4.1.2 Use-specific risk mitigation measures

For manual dipping/foaming application : Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information)/ eye protection.

For manual spraying applications wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information)/protective clothing /eye protection.

In case a combination of pre- and post-milking disinfection is necessary, using another biocidal 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 of 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 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 meta SPC 2

4.2 Use description

Use 2 - Use # 2.2 – Manual or automated dipping, foaming or spraying after milking

| | |
|---|--|
| 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: Scientific name: Algae Common name: Algae Development stage: |
| Field(s) of use | Indoor Disinfection of teats of milk producing animals by dipping, foaming or spraying after milking |
| Application method(s) | Method: Dipping, foaming, spraying after milking Detailed description: Manual or automated disinfection of teats by dipping, foaming or spraying after milking Dipping cup, foaming cup, teat sprayer, automated dipping machine, automated foaming machine or automated spraying machine |
| Application rate(s) and frequencies | Application Rate: - cows and buffaloes (3 to 10ml : 5 to 8 ml recommended) - sheep (1.5 to 5 ml : 1.5 to 3 ml recommended) - goats (2.5 to 6 ml : 2.5 to 4 ml recommended) Dilution (%): Number and timing of application: Frequency : 2 to 3 times per day |
| Category(ies) of users | Professional |
| Pack sizes and packaging material | HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1000L |



4.2.1 Use-specific instructions for use

Manual or automatic dipping / foaming / spraying on animal's teats on the full length of the teat after milking.

Leave the product until next milking. Keep the cows standing until the product has dried. (at least 5 minutes)

At the next milking, use the teat cleaning and wiping method systematically before attaching the milking cluster.

See also general instructions for use of meta SPC 2.

4.2.2 Use-specific risk mitigation measures

For manual spraying applications wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information)/protective clothing /eye protection.
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.

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 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 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 meta SPC 2

5. General directions for use of the meta SPC

5.1. Instructions for use

See use-specific instructions for each use.
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.
The use of a dosing pump for filling the product into the application equipment is recommended. Fill the dipping/foaming cup/sprayer manually or automatically with the ready to use product.

Where necessary repeat the application at each milking
Clean the application equipment regularly with warm water.

5.2. Risk mitigation measures

See use-specific risk mitigation measures for each use.

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

Take the contaminated clothes and shoes off immediately. Wash them before wearing them again.

FIRST AID INSTRUCTIONS

- In the event of inhalation : Bring to fresh air.

- In the event of contact with the skin : Wash with water.

- In the event of contact with the eyes :

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/attention.

- In the event of ingestion : Rinse mouth. Do NOT induce vomiting. Get medical advice.

Refer to the safety data sheet available for professional user : it contains an emergency phone number.

Large spillage: Mark out, dyke up with an inert absorbant and pump in an emergency tank. Keep in suitable, properly labelled and closed containers for disposal. Never return spills in original containers for re-use.

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.
The paper towels used for removing the product and drying the teats are disposed in the normal and domestic waste.

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

Shelf life : 2 years in HDPE
Do not store at a temperature higher than 30°C.

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) | Teat Guard 2500 | Market area: EU |
| | IODO SPRAY 2500 | Market area: EU |
| Authorisation number <small>(R4BP 3 asset reference number - National Authorisation)</small> | EU-0018496-0002 1-2 | |

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|---|--|----------------------|------------|-----------|-------------|
| Iodine | | Active Substance | 7553-56-2 | 231-442-4 | 0,25 |
| Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio) | Poly(oxy-1,2-ethanediyl), -C12-14-(even numbered)-alkyl--hydroxy | Non-active substance | 68439-50-9 | | 2,697 |

1. Meta SPC administrative information

1.1. Meta SPC identifier

meta SPC 3 : Dipping, foaming, spraying concentrated products

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 | 2,5 - 2,5 |
| Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio) | Poly(oxy-1,2-ethanediyl), -C12-14-(even numbered)-alkyl--hydroxy | Non-active substance | 68439-50-9 | | 24,199 - 24,199 |

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 damage.
May cause damage to organs (thyroid) through prolonged or repeated exposure oral.
Toxic to aquatic life with long lasting effects.
May be corrosive to metals.

Precautionary statements

Keep out of reach of children.
Do not breathe mist.
Do not breathe vapours.
Do not breathe spray.
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.
Immediately call a poison center / doctor..
Get medical advice if you feel unwell.
Get medical attention if you feel unwell.
Dispose of contents to in accordance with local/ regional/ national/ international regulations.
Dispose of container to in accordance with local/ regional/ national/ international regulations.
Keep only in original packaging.
Absorb spillage to prevent material damage.

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - Use # 3.1 – Manual or automated dipping, foaming or spraying before milking

| | |
|---|--|
| 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 Disinfection of teats of milk producing animals by dipping, foaming or spraying before milking |
| Application method(s) | Method: Dipping, foaming, spraying Detailed description: Manual or automated disinfection of teats by dipping, foaming or spraying before milking. Dipping cup, foaming cup, teat sprayer, automated dipping machine, automated foaming machine or automated spraying machine |
| Application rate(s) and frequencies | Application Rate: A dilution at 10% (v/v) should be prepared Application rate for the diluted product:- cows and buffaloes (3 to 10ml : 5 to 8 ml recommended) - sheep (1.5 to 5 ml : 1.5 to 3 ml recommended) - goats (2.5 to 6 ml : 2.5 to 4 ml recommended) Dilution (%): Number and timing of application: Frequency : 2 to 3 times per day |
| Category(ies) of users | Professional |
| Pack sizes and packaging material | HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1000L |

4.1.1 Use-specific instructions for use

Prepare a dilution at 10% (v/v: 10 ml product, add water up to 100ml) for bactericidal and yeasticidal activity.

Fill the dipping / foaming cup / sprayer manually or automatically with the prepared dilution.

Eliminate all visible dirt before applying the product.

Manual or automatic dipping/foaming/spraying on animal's teats on the full length of the teat before milking.

Let the product act at least one minute.

Use the teat cleaning and wiping method systematically before attaching the milking cluster.

See also general directions for use of meta SPC 3.

4.1.2 Use-specific risk mitigation measures

For manual spraying applications wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information)/protective clothing /eye protection.

In case a combination of pre- and post-milking disinfection is necessary, using another biocidal 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 of 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 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 meta SPC 3

4.2 Use description

Use 2 - Use # 3.2 – Manual or automated dipping, foaming or spraying after milking

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:

Scientific name: Algae
Common name: Algae
Development stage:

Scientific name: Viruses
Common name: Viruses
Development stage:

Field(s) of use

Indoor

Disinfection of teats of milk producing animals by dipping, foaming or spraying after milking

Application method(s)

Method: Dipping, foaming, spraying
Detailed description:

Manual or automated disinfection of teats by dipping, foaming or spraying after milking.

Dipping cup, foaming cup, teat sprayer, automated dipping machine, automated foaming machine or automated spraying machine

Application rate(s) and frequencies

Application Rate: For disinfection of bacteria, yeasts and algae a dilution at 10% (v/v: 10 ml product, add water up to 100ml) should be prepared. For disinfection of viruses a dilution at 20% (v/v: 20 ml product, add water up to 100ml) should be prepared
Application rate for the diluted product:- cows and buffaloes (3 to 10ml : 5 to 8 ml recommended) - sheep (1.5 to 5 ml : 1.5 to 3 ml recommended) - goats (2.5 to 6 ml : 2.5 to 4 ml recommended)

Dilution (%):

Number and timing of application:

| | |
|--|---|
| | Frequency : 2 to 3 times per day |
| Category(ies) of users | Professional |
| Pack sizes and packaging material | HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1000L |

4.2.1 Use-specific instructions for use

Prepare a dilution at 10% (v/v: 10 ml product, add water up to 100ml) for bactericidal, yeasticidal and algaecidal activity or 20% (v/v: 20 ml product, add water up to 100ml) in case virucidal activity is also needed.

Fill the dipping / foaming cup / sprayer manually or automatically with the prepared dilution.

Manual or automatic dipping / foaming / spraying on animal's teats on the full length of the teat after milking.

Leave the product until next milking. Keep the cows standing until the product has dried (at least 5 minutes).

At the next milking, use the teat cleaning and wiping method systematically before attaching the milking cluster.

See also general directions for use of meta SPC 3.

4.2.2 Use-specific risk mitigation measures

For manual spraying applications wear chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) /protective clothing/eye protection.

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.

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 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 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 meta SPC 3

5. General directions for use of the meta SPC

5.1. Instructions for use

See use-specific instructions for each use.
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.

The use of a dosing pump for filling the product into the application equipment is recommended. Fill the dipping / foaming cup / sprayer manually or automatically with the prepared dilution.

Where necessary, repeat the application at each milking
Clean the application equipment regularly with warm water.

5.2. Risk mitigation measures

See use-specific risk mitigation measures for each use.

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

Take the contaminated clothes and shoes off immediately. Wash them before wearing them again.

In case of faintness, get medical advice/attention. Show this safety data sheet to the doctor.

FIRST AID INSTRUCTIONS

- In the event of inhalation : Bring to fresh air.
- In the event of contact with the skin : Wash with water.
- In the event of contact with the eyes : Rinse at once with a soft stream of water for at least 15 minutes, eyes wide open. Remove contact lenses if present and easy to do. Continue rinsing.
Immediately call a POISON CENTER or doctor/physician.

- In the event of ingestion : Rinse mouth. Do NOT induce vomiting. Get medical advice.
Refer to the safety data sheet available for professional user : it contains an emergency phone number.

Large spillage : Mark out, dyke up with an inert absorbant and pump in an emergency tank. Keep in suitable, properly labelled and closed containers for disposal. Never return spills in original containers for re-use.

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.

The paper towels used for removing the product and drying the teats are disposed in the normal and domestic waste.

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

Shelf life : 2 years in HDPE

Do not store at a temperature higher than 30°C.

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)

| | |
|----------------------------|-----------------|
| Teat Guard Concentrate 1:4 | Market area: EU |
| IODO GUARD CONCENTRATE 1:4 | Market area: EU |
| EU-0018496-0003 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 | 2,5 |
| Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio) | Poly(oxy-1,2-ethanediyl), -C12-14-(even numbered)-alkyl--hydroxy | Non-active substance | 68439-50-9 | | 24,199 |

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

meta SPC 4 : Dipping products reaching virucidal activity – Ready to use

1.2. Suffix to the authorisation number

1-4

1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

2. Meta SPC composition

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

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|---|--|----------------------|------------|-----------|---------------|
| Iodine | | Active Substance | 7553-56-2 | 231-442-4 | 0,5 - 0,5 |
| Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio) | Poly(oxy-1,2-ethanediyl), -C12-14-(even numbered)-alkyl--hydroxy | Non-active substance | 68439-50-9 | | 4,993 - 4,993 |

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

Keep out of reach of children.
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.
If eye irritation persists: Get medical advice.
Get medical .

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - Use # 4.1 – Manual or automated dipping after milking

| | |
|---|---|
| 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: Yeasts Common name: Yeasts Development stage:</p> <p>Scientific name: Algae Common name: Algae Development stage:</p> <p>Scientific name: Viruses Common name: Viruses Development stage:</p> |
| Field(s) of use | <p>Indoor</p> <p>Disinfection of teats of milk producing animals by dipping after milking</p> |
| Application method(s) | <p>Method: Dipping Detailed description:</p> <p>Manual or automated disinfection of teats by dipping after milking. Dipping cup or automated dipping machine.</p> |
| Application rate(s) and frequencies | <p>Application Rate: - 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 (%): Number and timing of application: Frequency : 2 to 3 times per day</p> |
| Category(ies) of users | Professional |
| Pack sizes and packaging material | <p>HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L</p> <p>HDPE CONTAINER 1000L</p> |

4.1.1 Use-specific instructions for use

See general directions for use of meta SPC 4

4.1.2 Use-specific risk mitigation measures

See general directions for use of meta SPC 4

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 meta SPC 4

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 meta SPC 4

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 meta SPC 4

5. General directions for use of the meta SPC

5.1. Instructions for use

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.

The use of a dosing pump for filling the product into the application equipment is recommended. Fill the dipping cup manually or automatically with the ready to use product.

Apply by dipping manually or automatically on animal's teats on the full length of the teat after milking.

- 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)

Leave the product until next milking. Keep the cows standing until the product has dried (at least 5 minutes).

At the next milking, use the teat cleaning and wiping method systematically before attaching the milking cluster.

Where necessary, repeat the application after each milking.
Clean the application equipment regularly with warm water.

5.2. Risk mitigation measures

Wear eye protection.

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.

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

Take the contaminated clothes and shoes off immediately. Wash them before wearing them again.

FIRST AID INSTRUCTIONS

- In the event of inhalation : Bring to fresh air.

- In the event of contact with the skin : Wash with water.

- In the event of contact with the eyes :

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/attention.

- In the event of ingestion : Rinse mouth. Do NOT induce vomiting. Get medical advice.

Refer to the safety data sheet available for professional user : it contains an emergency phone number.

Large spillage : Mark out, dyke up with an inert absorbant and pump in an emergency tank. Keep in suitable, properly labelled and closed containers for disposal. Never return spills in original containers for re-use.

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.

The paper towels used for removing the product and drying the teats are disposed in the normal and domestic waste.

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

Shelf life : 2 years in HDPE

Do not store at a temperature higher than 30°C.

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) | Teatsan 5000 | Market area: EU |
| | IODO GUARD 5000 | Market area: EU |
| Authorisation number <small>(R4BP 3 asset reference number - National Authorisation)</small> | EU-0018496-0004 1-4 | |

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|---|--|----------------------|------------|-----------|-------------|
| Iodine | | Active Substance | 7553-56-2 | 231-442-4 | 0,5 |
| Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio) | Poly(oxy-1,2-ethanediyl), -C12-14-(even numbered)-alkyl--hydroxy | Non-active substance | 68439-50-9 | | 4,993 |

1. Meta SPC administrative information

1.1. Meta SPC identifier

meta SPC 5 : Dipping, foaming, spraying products 5500 ppm – Ready to use

1.2. Suffix to the authorisation number

1-5

1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

2. Meta SPC composition

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

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|---|--|----------------------|------------|-----------|-------------|
| Iodine | | Active Substance | 7553-56-2 | 231-442-4 | 0,55 - 0,55 |
| Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio) | Poly(oxy-1,2-ethanediyl), -C12-14-(even numbered)-alkyl--hydroxy | Non-active substance | 68439-50-9 | | 4,69 - 4,69 |

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

Keep out of reach of children.
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.

If eye irritation persists: Get medical advice.

Get medical .

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - Use # 5.1 – Manual or automated dipping, foaming or spraying before milking

| | |
|---|---|
| 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 Disinfection of teats of milk producing animals by dipping, foaming or spraying before milking |
| Application method(s) | Method: Dipping, foaming, spraying Detailed description: Manual or automated disinfection of teats by dipping, foaming or spraying before milking Dipping cup, foaming cup, teat sprayer, automated dipping machine, automated foaming machine or automated spraying machine |
| Application rate(s) and frequencies | Application Rate: - cows and buffaloes (3 to 10ml : 5 to 8 ml recommended) - sheep (1.5 to 5 ml : 1.5 to 3 ml recommended) - goats (2.5 to 6 ml : 2.5 to 4 ml recommended) Dilution (%): Number and timing of application: Frequency : 2 to 3 times per day |
| Category(ies) of users | Professional |
| Pack sizes and packaging material | HDPE JERRYCAN 5, 10, 22 L |

HDPE DRUM 60, 120, 220 L
HDPE CONTAINER 1000L

4.1.1 Use-specific instructions for use

Fill the dipping / foaming cup / sprayer manually or automatically with the ready to use product.

Eliminate all visible dirt before applying the product.

Manual or automatic dipping / foaming / spraying on animal's teats on the full length of the teat before milking.

Let the product act at least one minute.

Use the teat cleaning and wiping method systematically before attaching the milking cluster.

See also general instructions for use of meta SPC5.

4.1.2 Use-specific risk mitigation measures

For manual dipping/foaming application : Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information)/ eye protection.
For manual spraying applications wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information)/protective clothing /eye protection.

In case a combination of pre- and post-milking disinfection is necessary, using another biocidal 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 of meta SPC 5

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 meta SPC 5

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 meta SPC 5

4.2 Use description

Use 2 - Use # 5.2 – Manual or automated dipping, foaming or spraying after milking

| | |
|---|---|
| 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: Yeasts Common name: Yeasts Development stage:</p> <p>Scientific name: Algae Common name: Algae Development stage:</p> <p>Scientific name: Viruses Common name: Viruses Development stage:</p> |
| Field(s) of use | <p>Indoor</p> <p>Disinfection of teats of milk producing animals by dipping, foaming or spraying after milking</p> |
| Application method(s) | <p>Method: Dipping, foaming, spraying Detailed description:</p> <p>Manual or automated disinfection of teats by dipping, foaming or spraying after milking. Dipping cup, foaming cup, teat sprayer, automated dipping machine, automated foaming machine or automated spraying machine.</p> |

Application rate(s) and frequencies

Application Rate: - cows and buffaloes (3 to 10ml : 5 to 8 ml recommended) - sheep (1.5 to 5 ml : 1.5 to 3 ml recommended) - goats (2.5 to 6 ml : 2.5 to 4 ml recommended)
Dilution (%):
Number and timing of application:
Frequency : 2 to 3 times per day

Category(ies) of users

Professional

Pack sizes and packaging material

HDPE JERRYCAN 5, 10, 22 L
HDPE DRUM 60, 120, 220 L

HDPE CONTAINER 1000L

4.2.1 Use-specific instructions for use

Fill the dipping / foaming cup / sprayer manually or automatically with the ready to use product.

Manual or automatic dipping / foaming / spraying on animal's teats on the full length of the teat after milking.

Leave the product until next milking. Keep the cows standing until the product has dried. (at least 5 minutes)

At the next milking, use the teat cleaning and wiping method systematically before attaching the milking cluster.

See also general instructions for use of meta SPC 5.

4.2.2 Use-specific risk mitigation measures

For manual spraying applications wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information)/protective clothing/eye protection.

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.

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 meta SPC 5

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 meta SPC 5

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 meta SPC 5

5. General directions for use of the meta SPC

5.1. Instructions for use

See use-specific instructions for each use.

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.
The use of a dosing pump for filling the product into the application equipment is recommended.
Where necessary repeat the application at each milking
Clean the application equipment regularly with warm water.

5.2. Risk mitigation measures

See use-specific risk mitigation measures for each use.

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

Take the contaminated clothes and shoes off immediately. Wash them before wearing them again.

FIRST AID INSTRUCTIONS

- In the event of inhalation : Bring to fresh air.

- In the event of contact with the skin : Wash with water.

- In the event of contact with the eyes :

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/attention.

- In the event of ingestion : Rinse mouth. Do NOT induce vomiting. Get medical advice.

Refer to the safety data sheet available for professional user : it contains an emergency phone number.

Large spillage : Mark out, dyke up with an inert absorbant and pump in an emergency tank. Keep in suitable, properly labelled and closed containers for disposal. Never return spills in original containers for re-use.

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.

The paper towels used for removing the product and drying the teats are disposed in the normal and domestic waste.

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

Shelf life : 2 years in HDPE

Do not store at a temperature higher than 30°C.

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)

| | |
|---------------------|-----------------|
| Teat Guard 5500 | Market area: EU |
| IODO SPRAY 5500 | Market area: EU |
| EU-0018496-0005 1-5 | |

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 | 0,55 |
| Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio) | Poly(oxy-1,2-ethanediyl), -C12-14-(even numbered)-alkyl--hydroxy | Non-active substance | 68439-50-9 | | 4,69 |
