

Summary of product characteristics for a biocidal product

Product name: ANTI-GERM IO-SPRAY

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

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Authorisation number: IE/BPA 70450

R4BP 3 asset reference number: IE-0021581-0001

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Administrative information

1.1. Trade names of the product

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|--------------------|
| ANTI-GERM IO-SPRAY |
|--------------------|

1.2. Authorisation holder

Name and address of the authorisation holder

| | |
|----------------------|--|
| Name | HYPRED SAS |
| Address | 55, boulevard Jules Verger 35803 DINARD France |
| Authorisation number | IE/BPA 70450 1-1 |

R4BP 3 asset reference number

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|-----------------|
| IE-0021581-0001 |
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Date of the authorisation

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|------------|
| 11/10/2019 |
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Expiry date of the authorisation

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|------------|
| 28/03/2029 |
|------------|

1.3. Manufacturer(s) of the biocidal products

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

| | |
|--|--|
| Active substance | 1319 - Iodine |
| Name of the manufacturer | ANTI-GERM INTERNATIONAL GmbH |
| Address of the manufacturer | Oberbrühlstr. 16-18 87700 MEMMINGEN Germany |
| Location of manufacturing sites | S.C.M. Cosayach Cala Cala unknown Pozo Almonte Chile |

| | |
|--|---|
| Active substance | 1319 - Iodine |
| Name of the manufacturer | ANTI-GERM INTERNATIONAL GmbH |
| Address of the manufacturer | Oberbrühlstr. 16-18 87700 MEMMINGEN Germany |
| Location of manufacturing sites | Lagunas mine unknown Pozo Almonte Chile |

| | |
|--|---|
| Active substance | 1319 - Iodine |
| Name of the manufacturer | ANTI-GERM INTERNATIONAL GmbH |
| Address of the manufacturer | Oberbrühlstr. 16-18 87700 MEMMINGEN Germany |
| Location of manufacturing sites | Nueva Victoria plant unknown unknown Chile |
| | Pedro de Valdivia plant unknown unknown Chile |

| | |
|--|--|
| Active substance | 1319 - Iodine |
| Name of the manufacturer | Ise Chemicals Corporation |
| Address of the manufacturer | 3-1, Kyobashi 1-Chome, Chuo-Ku unknown Tokyo Japan |
| Location of manufacturing sites | Shirasato Plant, 3695 Kitaimaizumi unknown Oamishirasato City, Chiba Japan |

| | |
|--|--|
| Active substance | 1319 - Iodine |
| Name of the manufacturer | Atacama Minerals SCM |
| Address of the manufacturer | Coronel Pereira No 72 Of. 701, Las Condes unknown Santiago Chile |
| Location of manufacturing sites | Agua Blancas Facility unknown Antofagasta Chile |

2. Product composition and formulation

2.1. Qualitative and quantitative information on the composition of the biocidal product

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|--|--|----------------------|-------------|-----------|-------------|
| Iodine | | Active Substance | 7553-56-2 | 231-442-4 | 0,27 |
| Phosphoric acid | orthophosphoric acid | Non-active substance | 7664-38-2 | 231-633-2 | 0 |
| Laureth-11 carboxylic acid | Polyethylene glycol carboxymethyl dodecyl ether | Non-active substance | 27306-90-7 | | 0 |
| Butyl diglycol | 2-(2-Butoxyethoxy)ethanol | Non-active substance | 112-34-5 | 203-961-6 | 0 |
| Alcohols, C12-15-branched and linear, ethoxylated propoxylated | - | Non-active substance | 120313-48-6 | | 0 |
| Isotridecanol, ethoxylated | Poly(oxy-1,2-ethanediyl), α -tridecyl- ω -hydroxy-, branched | Non-active substance | 69011-36-5 | | 0 |
| 1-Decanol, ethoxylated (8 EO) | 1-Decanol, ethoxylated | Non-active substance | 26183-52-8 | | 0 |

2.2. Type of formulation

Any other liquid (ready-to-use)

3. Hazard and precautionary statements

Hazard statements

Harmful to aquatic life with long lasting effects.

Precautionary statements

Avoid release to the environment.

4. Authorised use(s)**4.1 Use description****Use 1 - Use 1.1: Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping****Product type**

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

not relevant

Target organism(s) (including development stage)

Scientific name: --
Common name: Bacteria
Development stage: -

Scientific name: --
Common name: Yeasts
Development stage: -

Field(s) of use

Indoor

Outdoor

Disinfection for veterinary hygiene: teat disinfection for milkable animals (dairy cows, buffaloes, sheep and goats) for use after milking

Application method(s)

Method: Manual dipping using a dip cup
Detailed description:
-

Application rate(s) and frequencies

Application Rate: Application rates: Cows and buffaloes: 8 - 10 mL/treatment Sheep: 4 – 5 mL/treatment Goats: 5 – 6 mL/treatment
Dilution (%): 0
Number and timing of application:
Application frequency:
Post-milking application: 1 – 3x/day (after each milking)

Category(ies) of users

Professional

Pack sizes and packaging material

Jerrycan (HDPE): 1-35 kg
Drum (HDPE): 35-240 kg
IBC (HDPE): 1000 kg

4.1.1 Use-specific instructions for use

- 1) A no-spill dip cup should be used for manual teat dipping.
- 2) Fill the reservoir with the RTU product and screw the dip cup on top.
- 3) The product must be brought to a temperature above 20 °C before use.
- 4) Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking.
- 5) After milking, squeeze the reservoir and put the dip cup over each teat from below making sure that the full length of the teat (3-5 cm) is immersed into the disinfectant.
- 6) Top up with fresh disinfectant as needed.
- 7) Keep the animals standing for at least five minutes after treatment. Leave the product on the teats until next milking.
- 8) After disinfection, empty the reservoir and clean reservoir and dip cup by rinsing with water.

4.1.2 Use-specific risk mitigation measures

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

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

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

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

-

4.2 Use description

Use 2 - Use 1.2 – Teat disinfection of milkable animals: Post-milking teat disinfection by manual foaming

Product type

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

not relevant

Target organism(s) (including development stage)

Scientific name: --
Common name: Bacteria
Development stage: -

Scientific name: --
Common name: Yeasts
Development stage: -

| | |
|--|--|
| Field(s) of use | Indoor Outdoor Disinfection for veterinary hygiene: teat disinfection for milkable animals (dairy cows, buffaloes, sheep and goats) for use after milking |
| Application method(s) | Method: Manual foaming using a foam cup Detailed description: - |
| Application rate(s) and frequencies | Application Rate: Application rates: Cows and buffaloes: 4 - 5 mL/treatment Sheep: 2 – 2.5 mL/treatment Goats: 2.5 – 3 mL/treatment Dilution (%): 0 Number and timing of application: Application frequency: Post-milking application: 1 – 3x/day (after each milking) |
| Category(ies) of users | Professional |
| Pack sizes and packaging material | Jerrycan (HDPE): 1-35 kg Drum (HDPE): 35-240 kg IBC (HDPE): 1000 kg |

4.2.1 Use-specific instructions for use

- 1) Fill the reservoir with the RTU product and screw the foam cup on top.
- 2) The product must be brought to a temperature above 20 °C before use.
- 3) Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking.
- 4) After milking, squeeze the reservoir and put the foam cup over each teat from below making sure that the full length of the teat (3-5 cm) is immersed into the disinfectant.
- 5) Top up with fresh disinfectant as needed.
- 6) Keep the animals standing for at least five minutes after treatment. Leave the product on the teats until next milking.
- 7) After disinfection, empty the reservoir and clean reservoir and foam cup by rinsing with water.

4.2.2 Use-specific risk mitigation measures

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

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

-

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

-

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

-

4.3 Use description

Use 3 - Use 1.3 - Teat disinfection of milkable animals: Post-milking teat disinfection by manual spraying using a trigger sprayer

| | |
|---|--|
| Product type | PT03 - Veterinary hygiene (Disinfectants) |
| Where relevant, an exact description of the authorised use | not relevant |
| Target organism(s) (including development stage) | Scientific name: -- Common name: Bacteria Development stage: - Scientific name: -- Common name: Yeasts Development stage: - |
| Field(s) of use | Indoor Outdoor Disinfection for veterinary hygiene: teat disinfection for milkable animals (dairy cows, buffaloes, sheep and goats) for use after milking |
| Application method(s) | Method: Manual spraying using a trigger sprayer Detailed description: - |
| Application rate(s) and frequencies | Application Rate: Application rates: Cows and buffaloes: 12 – 15 mL/treatment Sheep: 6 – 7.5 mL/treatment Goats: 7 – 9 mL/treatment Dilution (%): 0 Number and timing of application: Application frequency: Post-milking application: 1 – 3x/day (after each milking) |
| Category(ies) of users | Professional |

Pack sizes and packaging material

Jerrycan (HDPE): 1-35 kg
Drum (HDPE): 35-240 kg
IBC (HDPE): 1000 kg

4.3.1 Use-specific instructions for use

- 1) Fill the reservoir with the RTU product and screw the top of the trigger sprayer on it.
- 2) The product must be brought to a temperature above 20 °C before use.
- 3) Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking.
- 4) After milking, spray the disinfectant on the teats using the trigger sprayer making sure that the full length of the teat (3-5 cm) is covered with the disinfectant.
- 5) Top up with fresh disinfectant as needed.
- 6) Keep the animals standing for at least five minutes after treatment. Leave the product on the teats until next milking.
- 7) After disinfection, empty the reservoir and clean reservoir and trigger sprayer by rinsing with water.

4.3.2 Use-specific risk mitigation measures

- 1) The following personal risk mitigation measures shall be applied unless they can be replaced by technical and / or organisational measures:
Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).
- 2) The use of a dosing pump for filling the product into the application equipment is recommended.

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

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

-

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

-

4.4 Use description

Use 4 - Use 1.4 – Teat disinfection of milkable animals: Post-milking teat disinfection by manual spraying using an electronic sprayer

| | |
|---|--|
| Product type | PT03 - Veterinary hygiene (Disinfectants) |
| Where relevant, an exact description of the authorised use | not relevant |
| Target organism(s) (including development stage) | Scientific name: -- Common name: Bacteria Development stage: - Scientific name: -- Common name: Yeasts Development stage: - |
| Field(s) of use | Indoor Outdoor Disinfection for veterinary hygiene: teat disinfection for milkable animals (dairy cows, buffaloes, sheep and goats) for use after milking |
| Application method(s) | Method: Manual spraying using an electronic sprayer Detailed description: - |
| Application rate(s) and frequencies | Application Rate: Application rates: Cows and buffaloes: 12 – 15 mL/treatment Sheep: 6 – 7.5 mL/treatment Goats: 7 – 9 mL/treatment Dilution (%): 0 Number and timing of application: Application frequency: Post-milking application: 1 – 3x/day (after each milking) |
| Category(ies) of users | Professional |
| Pack sizes and packaging material | Jerrycan (HDPE): 1-35 kg Drum (HDPE): 35-240 kg IBC (HDPE): 1000 kg |

4.4.1 Use-specific instructions for use

- 1) Open a can containing the RTU product and insert a sucking lance of the electronic sprayer.
- 2) The product must be brought to a temperature above 20 °C before use.
- 3) Clean carefully the teats by wiping with a single service paper towel/cloth before milking.
- 4) After milking, spray the disinfectant on the teats using the electronic sprayer making sure that the full length of the teat (3-5 cm) is covered with the disinfectant.

- 5) Replace the empty can by a new can containing the RTU product as needed.
- 6) Keep the animals standing for at least five minutes after treatment. Leave the product on the teats until next milking.
- 6) After disinfection, put the sucking lance system into a bucket of water and rinse the sprayer by pumping the water through the sprayer.

4.4.2 Use-specific risk mitigation measures

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

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

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

-

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

-

4.5 Use description

Use 5 - Use 1.5 – Teat disinfection of milkable animals: Post-milking teat disinfection by automated spraying by robot

Product type

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

not relevant

Target organism(s) (including development stage)

Scientific name: --
Common name: Bacteria
Development stage: -

Scientific name: --
Common name: Yeasts
Development stage: -

Field(s) of use

Indoor

Outdoor

Disinfection for veterinary hygiene: teat disinfection for milkable animals (dairy cows, buffaloes, sheep and goats) for use after milking

| | |
|--|--|
| Application method(s) | Method: Automated spraying by robot Detailed description: - |
| Application rate(s) and frequencies | Application Rate: Application rates: Cows and buffaloes: 12 – 15 mL/treatment Sheep: 6 – 7.5 mL/treatment Goats: 7 – 9 mL/treatment Dilution (%): 0 Number and timing of application: Application frequency: Post-milking application: 1 – 3x/day (after each milking) |
| Category(ies) of users | Professional |
| Pack sizes and packaging material | Jerrycan (HDPE): 1-35 kg Drum (HDPE): 35-240 kg IBC (HDPE): 1000 kg |

4.5.1 Use-specific instructions for use

| |
|--|
| <ol style="list-style-type: none"> 1) Open a can containing the RTU product and insert a sucking lance of the robotic milking device. 2) The product must be brought to a temperature above 20 °C before use. 3) The teats are cleaned by robot with automatic brushes. 4) After robotic milking, the disinfectant is sprayed automatically onto the teats from a cluster arm. 5) Keep the animals standing for at least five minutes after treatment. Leave the product on the teats until next milking. 6) Rinsing of the automatic sprayer is done fully automated. |
|--|

4.5.2 Use-specific risk mitigation measures

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|--|
| The use of a dosing pump for filling the product into the application equipment is required. |
|--|

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

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| - |
|---|

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

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|---|
| - |
|---|

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

-

5. General directions for use

5.1. Instructions for use

see use specific instructions for use

5.2. Risk mitigation measures

- 1) Keep out of reach of children.
- 2) When pre-milking disinfection is also performed, then disinfection should be done with a product based on another active substance (not iodine).

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

- 1) In case of spillage or leakage contain and collect product for disposal.
- 2) Disposal must comply with local requirements.

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

- 1) At the end of the treatment, dispose unused product, used paper towels and the packaging in accordance with local requirements.
- 2) Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements.
- 3) 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

- 1) Do not store at temperatures above 30°C.
- 2) Shelf-life of 18 months.

6. Other information

Due to technical deficits of the SPC editor I have to list the following points currently at this point of the SPC:
Precautionary statements:

P501 Dispose of contents/containers in accordance with local/regional/national/international regulation.