

Summary of product characteristics for a biocidal product

Product name: Dip es lo-film

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

PT03 - Veterinary hygiene (Disinfectants)

Authorisation number: EU-0018724-0000

R4BP 3 asset reference number: EU-0018724-0002

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Administrative information

1.1. Trade names of the product

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|--------------------|
| Dip es lo-film |
| Dip es lo-film 3.0 |
| Iod-Dip lo-film 30 |

1.2. Authorisation holder

| | | |
|---|---------------------|--|
| Name and address of the authorisation holder | Name | CVAS Development GmbH |
| | Address | Dr. Albert Reimann Str. 16 a 68526 Ladenburg Germany |
| Authorisation number | EU-0018724-0000 1-2 | |

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|---|-----------------|
| R4BP 3 asset reference number | EU-0018724-0002 |
| Date of the authorisation | 18/12/2018 |
| Expiry date of the authorisation | 30/11/2028 |

1.3. Manufacturer(s) of the biocidal products

| | |
|--|--|
| Name of the manufacturer | Arthur Schopf Hygiene GmbH & Co. KG |
| Address of the manufacturer | Pfaffensteinstr. 1 83115 Neubeuern Germany |
| Location of manufacturing sites | Pfaffensteinstr. 1 83115 Neubeuern Germany |

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

| | |
|--|---|
| Active substance | 1319 - Iodine |
| Name of the manufacturer | Cosayach Nitratos S.A. |
| Address of the manufacturer | Amunategui 178 not applicable Santiago Chile |
| Location of manufacturing sites | S.C.M. Cosayach Cala Cala not applicable Pozo Almonte Chile |

| | |
|--|--|
| Active substance | 1319 - Iodine |
| Name of the manufacturer | ACF Minera S.A. |
| Address of the manufacturer | San Martin No 499 not applicable Iquique Chile |
| Location of manufacturing sites | Lagunas mine not applicable Pozo Almonte Chile |

| | |
|--|---|
| Active substance | 1319 - Iodine |
| Name of the manufacturer | SQM S.A. |
| Address of the manufacturer | Los Militares 4290, Piso 4 not applicable Las Condes Chile |
| Location of manufacturing sites | Nueva Victoria plant not applicable Pedro de Valdivia plant Chile |

| | |
|--|--|
| Active substance | 1319 - Iodine |
| Name of the manufacturer | Nihon Tennen Gas Co., Ltd / Kanto Natural Gas Development Co., Ltd |
| Address of the manufacturer | 661 Mobara 297-8550 Mobara City, Chiba Japan |
| Location of manufacturing sites | 2508 Minami-Hinata 299-4205 Shirako-Machi, Chosei-Gun, Chiba Japan |

| | |
|--|--|
| Active substance | 1349 - Polyvinylpyrrolidone iodine |
| Name of the manufacturer | Norkem Limited |
| Address of the manufacturer | Norkem House, Bexton Lane WA 16 9FB Knutsford, Cheshire United Kingdom |
| Location of manufacturing sites | Norkem House, Bexton Lane WA 16 9FB Knutsford, Cheshire United Kingdom |

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 |
| Polyvinylpyrrolidone iodine | | Active Substance | 25655-41-8 | | 2,5 |
| Acetic acid | Acetic acid | | 64-19-7 | 200-580-7 | 0 |

2.2. Type of formulation

| |
|-----------------------|
| AL - Any other liquid |
|-----------------------|

3. Hazard and precautionary statements

| | |
|---------------------------------|--|
| Hazard statements | Harmful to aquatic life with long lasting effects. |
| Precautionary statements | <p>If medical advice is needed, have product container or label at hand.</p> <p>Keep out of reach of children.</p> <p>Avoid release to the environment.</p> <p>Dispose of contents to local/regional/national/international regulation.</p> <p>Dispose of container to local/regional/national/international regulation.</p> |

4. Authorised use(s)

4.1 Use description

Use 1 - Use # 2.1 - 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: Bacteria Common name: Bacteria Development stage: vegetative cells Scientific name: Yeasts Common name: Yeasts Development stage: vegetative cells |
| Field(s) of use | Indoor Teat disinfection for milkable animals (dairy cows) for use after milking |
| Application method(s) | Manual dipping using a dip cup - see use instructions |
| Application rate(s) and frequencies | Cows: 5 mL per treatment - 0% - Post-milking application: 2-3x/day (after each milking) |
| Category(ies) of users | Professional |
| Pack sizes and packaging material | Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 - 1000 kg |

4.1.1 Use-specific instructions for use

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 reservoir with the RTU product assuming 5 mL product per cow and screw the dip cup on top. Avoid discharge of surplus fluids.
Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking.
After milking, squeeze the reservoir and put the dip cup over each teat from below making sure that about 3 cm of the teat are immersed into the disinfectant.

Refill the cup of the dipping unit with fresh disinfectant by squeezing the reservoir as needed. Refill the reservoir with fresh disinfectant as needed.
Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.
After disinfection, empty the reservoir and clean reservoir and dip cup by rinsing with water.

4.1.2 Use-specific risk mitigation measures

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

4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use.

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

See general directions for use.

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

See general directions for use.

4.2 Use description

Use 2 - Use #2.2 - Teat disinfection of milkable animals: Post-milking teat disinfection by automated 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: Bacteria
Common name: Bacteria
Development stage: vegetative cells

Scientific name: Yeasts
Common name: Yeasts
Development stage: vegetative cells

Field(s) of use

Indoor

Teat disinfection for milkable animals (dairy cows) for use after milking

| | |
|--|--|
| Application method(s) | Automated dipping - see instructions for use |
| Application rate(s) and frequencies | cows: 5 mL per treatment - 0% - Post-milking application: 2 - 3x/day (after each milking) |
| Category(ies) of users | Professional |
| Pack sizes and packaging material | Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 - 1000 kg |

4.2.1 Use-specific instructions for use

The product must be brought to a temperature above 20°C before use.
 Open a can containing the RTU product and insert a suction tube of the automated dipping-system. Avoid discharge of surplus fluids.
 After milking, the vacuum is shut off and the teat dip is injected into a manifold on the clawpiece. The teats are coated with ca. 5 mL of dip when the teat cup is withdrawn by the Automatic Cluster Removal (ACR). After the removal of the ACR, every liner of the automated dipping-system is thoroughly rinsed with water and blown out with compressed air.
 In a final cleaning step after each milking session of the herd, the liners are disinfected (e.g. with a chlorine-based product) and blown out again with compressed air.
 Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.
 Afterwards, the milking system is ready for the next milking event.
 The whole process is automated.

4.2.2 Use-specific risk mitigation measures

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

4.2.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use.

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

See general directions for use.

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

See general directions for use.

5. General directions for use

5.1. Instructions for use

See use specific instructions for use.

5.2. Risk mitigation measures

See use specific risk mitigation measures.

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

Mentioned in the MSDS

Description of first aid measures

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

After skin contact: Instantly wash with water and soap and rinse thoroughly.

After eye contact: Rinse opened eye for several minutes under running water (at least 15 minutes).

After swallowing: Rinse out mouth and then drink plenty of water. Instantly call for doctor.

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

Stability and reactivity

Reactivity: No dangerous reactions known.

Chemical stability: The product is chemically stable under normal surroundings terms (ambient temperature).

Possibility of hazardous reactions: By designated use no dangerous reactions are to be expected.

Conditions to avoid: Not determined.

Incompatible materials: Not determined.

Hazardous decomposition products: No dangerous decomposition products known.

Accidental release measures

Personal precautions, protective equipment and emergency procedures: Wear protective clothing.

Ensure adequate ventilation.

Keep ignition sources away - Do not smoke.

Environmental precautions: Do not allow to enter drainage system, surface or ground water.

Methods and material for containment and cleaning up: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose of the material collected according to regulations.

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

Mentioned in the MSDS

Waste treatment methods: Hazardous waste (AVV). Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Must be specially treated under adherence to official regulations.

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.

Recommended cleaning agent: Water, if needed detergent.

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

Shelf-life: 18 months

Products need to be protected from frost, stored at temperatures not exceeding 30°C and away from direct sunlight.

6. Other information

Not provided