

Summary of product characteristics for a biocidal product

Product name: Io-Shield D

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

Authorisation number: EU-0018398-0000

R4BP 3 asset reference number: IS-0019667-0003

Table Of Contents

| | |
|---|---|
| Administrative information | 1 |
| 1.1. Trade names of the product | 1 |
| 1.2. Authorisation holder | 1 |
| 1.3. Manufacturer(s) of the biocidal products | 1 |
| 1.4. Manufacturer(s) of the active substance(s) | 2 |
| 2. Product composition and formulation | 4 |
| 2.1. Qualitative and quantitative information on the composition of the biocidal product | 4 |
| 2.2. Type of formulation | 4 |
| 3. Hazard and precautionary statements | 4 |
| 4. Authorised use(s) | 4 |
| 5. General directions for use | 6 |
| 5.1. Instructions for use | 6 |
| 5.2. Risk mitigation measures | 6 |
| 5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment | 6 |
| 5.4. Instructions for safe disposal of the product and its packaging | 7 |
| 5.5. Conditions of storage and shelf-life of the product under normal conditions of storage | 7 |
| 6. Other information | 7 |

Administrative information

1.1. Trade names of the product

| |
|--------------------|
| Io-Shield D |
| IoShield |
| MEPA Barrier D |
| BARIOPROTECT |
| MS Cow Udder BLOCK |
| Iodocop EXTRA |

1.2. Authorisation holder

| | | |
|---|---------------------|---|
| Name and address of the authorisation holder | Name | Ecolab Deutschland GmbH |
| | Address | Ecolab Allee 1 40789 Monheim am Rhein Germany |
| Authorisation number | EU-0018398-0000 1-2 | |
| R4BP 3 asset reference number | IS-0019667-0003 | |
| Date of the authorisation | 07/11/2018 | |
| Expiry date of the authorisation | 30/09/2028 | |

1.3. Manufacturer(s) of the biocidal products

| | |
|--|--|
| Name of the manufacturer | Ecolab Europe GmbH |
| Address of the manufacturer | Richtstrasse 7, 8304 Wallisellen Switzerland |
| Location of manufacturing sites | Ecolab Baglan, ECOLAB CONTAMINATION CONTROL BRUNEL WAY, BAGLAN ENERGY PARK, NEATH, SA11 2GA South Wales European Union |
| | Ecolab Leeds, LOTHERTON WAY, GARFORTH, LEEDS LS25 2JY Leeds United Kingdom |
| | Ecolab Rovigo, Viale del Lavoro 10 , 45100 Rovigo Italy |
| | Ecolab Biebesheim Nalco Deutschland Manufacturing GmbH und Co.KG, Justus-von-Liebig-Str. 11 D-64584 Biebesheim Germany |
| | Ecolab NETHERLANDS BV, NL01ECOLAB, BRUGWAL 11 3432NZ NIEUWEGEIN Netherlands |
| | Ecolab Weavergate, ECOLAB WEAVERGATE PLANT WINNINGTON AVENUE, NORTHWICH CHESHIRE CW8 3AA NORTHWICH United Kingdom |
| | Ecolab Mullingar, Forest Park, Mullingar Ind. Estate, Mullingar, Co. Zone C Westmeath Ireland |
| | Ecolab Maribor, Ecolab d.o.o., Vajngerlova 4 2000 Maribor Slovenia |
| | Ecolab Rozzano, VIA GRANDI 9/11 20089 ROZZANO Italy |
| | Ecolab B.V.B.A, Havenlaan: 4 3980 Tessenderlo Belgium |
| Ecolab CELRA, Nalco Española Manufacturing, SLU C/Tramuntana s/n, Polígono Industrial de Celrà 17460 CELRÀ Spain | |
| Ecolab Chalons Ecolab production France SAS, BP509 Avenue de Général Patton 51006 Châlons-en-Champagne France | |
| Ecolab Mandra, 25km Old National Road Athens Mandra, oo Attica Greece | |
| NALCO FINLAND MANUFACTURING OY, Kivikumuntie 1 FIN-07955 Tesjoki Finland | |

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

| | |
|--|--|
| Active substance | 1349 - Polyvinylpyrrolidone iodine |
| Name of the manufacturer | ISP Chemicals LLC, Affiliate of Ashland Inc. |
| Address of the manufacturer | 455 N. MAIN ST. (HWY 95) KY 42029 CALVERT CITY United States |
| Location of manufacturing sites | 455 N. MAIN ST. (HWY 95) KY 42029 CALVERT CITY United States |

| | |
|--|------------------------------------|
| Active substance | 1319 - Iodine |
| Name of the manufacturer | ACF Minera S.A. |
| Address of the manufacturer | San Martín No 499 00 Iquique Chile |
| Location of manufacturing sites | Lagunas mine 00 Pozo Almonte Chile |

| | |
|--|---|
| Active substance | 1319 - Iodine |
| Name of the manufacturer | SQM S.A. |
| Address of the manufacturer | Los Militares 4290 Piso 4 Santiago Chile |
| Location of manufacturing sites | Nueva Victoria plant 00 Pedro de Valdivia Chile |

| | |
|--|---|
| Active substance | 1319 - Iodine |
| Name of the manufacturer | Cosayach Nitratos S.A. |
| Address of the manufacturer | Amunategui 178 00 Santiago Chile |
| Location of manufacturing sites | S.C.M. Cosayach Cala Cala 00 Pozo Almonte Chile |

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

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 (%) |
|-----------------------------|------------|------------------|------------|-----------|-------------|
| Polyvinylpyrrolidone iodine | | Active Substance | 25655-41-8 | | 1,35 |
| Iodine | | Active Substance | 7553-56-2 | 231-442-4 | 0,15 |

2.2. Type of formulation

AL - Any other liquid

3. Hazard and precautionary statements

Hazard statements

Precautionary statements

4. Authorised use(s)

4.1 Use description

Use 1 - Teat dips for post-milking disinfection

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> <p>Scientific name: Enveloped viruses Common name: Enveloped viruses Development stage:</p> |
| Field(s) of use | <p>Indoor</p> <p>Post-milking disinfection of teats of milk producing animals (cows, buffaloes, goats, sheep)</p> |
| Application method(s) | <p>Dipping - Manual dipping using a dip cup</p> |
| Application rate(s) and frequencies | <p>Post-milking application 1x -3x per day (apply after every milking). - - Per milking event 3 - 10 mL of product are needed (animals with four teats).</p> |
| Category(ies) of users | <p>Professional</p> |
| Pack sizes and packaging material | <p>0.5 L – 1000 L HDPE container</p> |

4.1.1 Use-specific instructions for use

See general directions for use of meta SPC 2

4.1.2 Use-specific risk mitigation measures

See general directions for use of meta SPC 2

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

5. General directions for use

5.1. Instructions for use

Always read the label or leaflet before use and follow all the instructions provided.
The products must be brought to temperatures above 20°C before use.
Product to be applied post-milking by use of a dipping cup.
Apply product on the whole teat and do not wipe it. Keep the animals standing for 5 min. Before the next milking, carefully clean the teats.

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

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.

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

Potential Health Effects

Eyes: Health injuries are not known or expected under normal use.

Skin: Health injuries are not known or expected under normal use.

Ingestion: Health injuries are not known or expected under normal use.

Inhalation: Health injuries are not known or expected under normal use.

Chronic Exposure: Health injuries are not known or expected under normal use.

First Aid Measures:

Eye contact: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.

Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. In case of inhalation of decomposition products in a fire, symptoms may be delayed. Get medical attention if symptoms occur.

Skin contact: Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.

Ingestion: Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Environmental emergency measures: Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer if legally allowed.

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.

European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29.

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

Store between 5° C and 25° C and away from direct sunlight. Keep out of reach of children. Keep container tightly closed. Store in the original containers.

Shelf life: 24 months

6. Other information