

Summary of product characteristics for a biocidal product

Product name: 0233.00

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

Authorisation number: 801-1

R4BP 3 asset reference number: DK-0016289-0007

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Administrative information

1.1. Trade names of the product

| |
|--------------------|
| Eimü MultiCare Dip |
|--------------------|

1.2. Authorisation holder

Name and address of the authorisation holder

| | |
|----------------------|-------------------------------------|
| Name | Ferdinand Eimermacher GmbH & Co. KG |
| Address | Westring 24 48356 Nordwalde Germany |
| Authorisation number | 801-1 1-5 |

R4BP 3 asset reference number

DK-0016289-0007

Date of the authorisation

09/08/2022

Expiry date of the authorisation

05/08/2032

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer

F. Eimermacher GmbH & Co. KG

Address of the manufacturer

Westring 24 48356 Nordwalde Germany

Location of manufacturing sites

Westring 24 48356 Nordwalde Germany

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

| | |
|--|---|
| Active substance | 1319 - Iodine |
| Name of the manufacturer | Independent Iodine Europe N.V |
| Address of the manufacturer | Hoogeind 43 2940 Stabroek Belgium |
| Location of manufacturing sites | Acf Minera SA, Chile no data Santiago Chile |

| | |
|--|---|
| Active substance | 1319 - Iodine |
| Name of the manufacturer | SQM Europe N.V. |
| Address of the manufacturer | St Pietersvliet 7, bus 8 2000 Antwerpen Belgium |
| Location of manufacturing sites | Sociedad Quimica y Minera SA no data Santiago Chile |

| | |
|--|---|
| Active substance | 1319 - Iodine |
| Name of the manufacturer | Norkem Limited |
| Address of the manufacturer | Bexton lane WA 16 9FB Knutsford, Cheshire United Kingdom |
| Location of manufacturing sites | Cosayach S.A. Compania de Salitre y Yodo no data Santiago Chile |

| | |
|--|--|
| Active substance | 1349 - Polyvinylpyrrolidone iodine |
| Name of the manufacturer | ISP Europe |
| Address of the manufacturer | Waterfield KT20 5HQ Tadworth United Kingdom |
| Location of manufacturing sites | ISP Chemicals inc., Highway 95 Industrial Complex P.O. Box 37 Calvert City, Kentucky United States |

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 | 0,000001 |
| Polyvinylpyrrolidone iodine | | Active Substance | 25655-41-8 | | 2,7 |
| 2-(2-butoxyethoxy)ethanol | 2-(2-butoxyethoxy)ethanol | Non-active substance | 112-34-5 | 203-961-6 | 0 |
| Phosphoric acid | orthophosphoric acid | Non-active substance | 7664-38-2 | 231-633-2 | 0 |
| Methanol | Methan-1-ol | Non-active substance | 67-56-1 | 200-659-6 | 0 |
| Alcohols C9-C11, ethoylated | AlcoholsC9-C11, ethoylated | Non-active substance | 68439-46-3 | 500-446-0 | 0 |
| Fatty alcohol alkoxylate 4 | Fattyalcohol alkoxylate 4 | Non-active substance | 111905-53-4 | | 0 |

2.2. Type of formulation

AL - Any other liquid

3. Hazard and precautionary statements

Hazard statements

Safety data sheet available on request.

Precautionary statements

4. Authorised use(s)

4.1 Use description

Use 1 - Teat disinfection (post-milking), Foam dipping, RTU

Product type

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

-

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

The product is RTU, used for teat disinfection (post-milking) of cows, sheep, goats.

Application method(s)

Method: dipping
Detailed description:

-

Application rate(s) and frequencies

Application Rate: Dipping (per teat): 15 mL/cow; 5 mL/goat; 5 mL/sheep
Dilution (%): 0
Number and timing of application:

Application frequency: 2x/day (post-milking)
Contact time: 5 min.

Category(ies) of users

Professional

Pack sizes and packaging material

Plastic bottle of HDPE: 500 mL, 1000 mL
Jerry can of HDPE : 5 L, 20 L, 25 L
Drum of HDPE: 200 L
IBC container of HDPE: 1000 L

4.1.1 Use-specific instructions for use

Fill the foam beaker with the ready to use foam product.
Dipping on animal's teats on the full length of the teat after milking (max. twice a day).

Use : 15 ml per cow 5 ml per goat 5 ml per sheep

Keep the animals standing until the product has dried (at least 5 minutes). Leave the product until next milking. The product creates a film on the skin.

At the next milking, wipe the teat systematically with a dry or wet cloth to remove product residues before attaching the milking cluster for the next milking event.
The product must be brought to a temperature above 20°C before use.

4.1.2 Use-specific risk mitigation measures

Keep container tightly closed. Protect against UV-radiation/sunlight and heat.
Wash hands thoroughly after handling.
It is recommended to design all work processes always so that the following is excluded: Inhalation of vapours or spray/mists Use only in well-ventilated areas.
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.

Keep out of reach of children.

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

Particulars of likely direct or indirect effects:

Not known if the product is used properly according to the product label.

First aid instructions:

In case of skin contact: After contact with skin, wash immediately with plenty of water.

In case of eye contact: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.

If swallowed: if swallowed, seek medical advice immediately (call a POISON CENTER/doctor) and show this container or label.

4.1.4 Where specific to the use, the 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.

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 conditions of storage and shelf life of the product

5. General directions for use

5.1. Instructions for use

See use-specific instructions for use of Meta SPC 6.
Always read the label or leaflet before use and follow all the instructions provided

5.2. Risk mitigation measures

See use-specific risk mitigation measures for use of Meta SPC 6.

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

See specific Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment of meta SPC 6.

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

See specific Instructions for safe disposal of the product and its packaging of meta SPC 6.

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

Requirements for storage areas and containers:

Keep container tightly closed in a cool place. Protect against UV-radiation/sunlight. Do not store at temperatures exceeding 40°C.

Further information on storage conditions:

Do not store near food, drink and feed.

The products have a shelf life of 2 years.

Protect from frost

6. Other information

Bilag 1

Oplysninger til etiket og brugsanvisning for Eimermacher Iodine Compounds, MetaSPC 6, BPR-reg. nr. 801-1-6-x

[1]

I. Etiketten skal udformes i overensstemmelse med det godkendte resumé af det biocidholdige produkts egenskaber, jf. artikel 69, stk. 1, i biocidforordningen (Forordning (EU) nr. 528/2012), og CLP-Forordningen [2].

II. Det er udelukkende ansøgers/godkendelsesindehaverens ansvar, at etiket, mærkning og pakning lever op til lovens krav, jf. biocidforordningen artikel 69. Etiket og mærkning skal være på dansk.

Nedenstående tekst i afsnit III er bidrag til overholdelsen af reglerne og således kun en del af de krav, som stilles til blandt andet etiketten.

III. Etiketten skal indeholde nedenstående oplysninger. Oplysninger i citationstegn skal angives ordret:

1) I hovedfeltet:

"Veterinærhygiejne

Må kun anvendes erhvervsmæssigt til pattedesinfektion af køer, får og geder ved dypning i skum mod bakterier og gær efter malkning."

2) I advarselsfeltet:

"**FORSIGTIG**

Sikkerhedsdatablad kan på anmodning rekvireres (EUH210).

Vask huden grundigt efter brug

Overtrædelse af nedenstående særligt fremhævede forskrifter kan medføre straf:

Må kun anvendes erhvervsmæssigt til pattedesinfektion af køer, får og geder ved dypning i skum mod bakterier og gær efter malkning.

Må ikke anvendes mod andre skadevoldere og ikke i højere doseringer end de i brugsanvisningen nævnte.

Opbevares utilgængeligt for børn.

Må ikke opbevares sammen med fødevarer, drikkevarer og foderstoffer."

Evt. oplysninger om førstehjælp.

3) I deklaraionsfeltet:

a) Teksten " Veterinærhygiejne BPR-reg. nr. 801-1-6-x. Aktivstof og biocidholdigt produkt er godkendt efter biocidforordningen (Forordning (EU) nr. 528/2012)".

b) Oplysning om præparattype: "væske" for dette præparat.

c) Indholdet af aktivstof i vægtprocent (% w/w) og g/L ved 20 °C.

d) Sætningen: "Indeholder methanol."

e) Udløbsdatoen skal anføres. Denne dato må højst være 2 år efter produktionsdatoen. Etikettens dato kan udformes som en henvisning til en produktionsdato andetsteds på emballagen.

f) Batchnummer eller – betegnelse skal anføres.

g) Pakningsstørrelse i L.

h) Godkendelsesindehavers navn og adresse.

4) Brugsanvisningen:

Oplysninger om skadevoldere, anvendelsesområde og doseringer.

Følgende retningslinjer gælder i forhold til bortskaffelse.

Der skal mærkes med sikkerhedssætning P501: "Rester og emballage bortskaffes som farligt affald."

Følgende sætning skal anføres under sikkerhedssætning P501: "Ovenstående sætning er Miljøstyrelsens vejledning om affaldshåndtering af dette produkt. Følg altid kommunens affaldsregulativ og forhør dig hos kommunen, hvis du er i tvivl."