

Summary of product characteristics for a biocidal product

Product name: 0347.00

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

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Authorisation number: 801-1

R4BP 3 asset reference number: DK-0016289-0003

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Administrative information

1.1. Trade names of the product

Eimü PremaFoam Iodine

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 1-2

R4BP 3 asset reference number

DK-0016289-0003

Date of the authorisation

09/08/2022

Expiry date of the authorisation

05/08/2032

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	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	0,25
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0,000001
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

Harmful to aquatic life with long lasting effects.

Precautionary statements

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

Keep out of reach of children.

Read carefully and follow all instructions.

Avoid release to the environment.

Dispose of container to in accordance to national legislation.

4. Authorised use(s)

4.1 Use description

Use 1 - Teat disinfection (post-milking), spraying

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 a RTU, used for teat disinfection (post-milking) of cows, sheep, goats.
Application method(s)	Method: Spraying Detailed description: (triggered) spraying
Application rate(s) and frequencies	Application Rate: spraying (per teat) 5-15 mL/cow 3-5 mL/goat 3-5 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 spraying cup with the ready to use product.
Spray on animal's teats on the full length of the teat after milking (max. twice a day).
Use : 5-15ml per cow / 3-5 ml per goat / 3-5 ml per sheep
Keep the animals standing until the product has dried (at least 5 minutes). Leave the product until next milking.
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.
During use wear chemical resistant gloves (glove material to be specified by the authorisation holder within the product information).
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

4.2 Use description

Use 2 - Teat disinfection (post-milking), dipping

Product type

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

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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 a 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) 4-6 mL/cow 1-2 mL/goat 1-2 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

4.2.1 Use-specific instructions for use

Fill the dipping cup with the ready to use product.
Dipping on animal's teats on the full length of the teat after milking (max. twice a day).
Use : 4-6 ml per cow / 1-2 ml per goat / 1-2 ml per sheep
Keep the animals standing until the product has dried (at least 5 minutes). Leave the product until next milking.
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.

4.2.2 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.

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

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.

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4.2.4 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.
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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 conditions of storage and shelf life of the product

4.3 Use description

Use 3 - Udder disinfection (pre-milking), wiping or dipping in foam

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 udder/teat disinfection (pre-milking) of cows, sheep, goats.
Application method(s)	Method: wiping and dipping Detailed description:

	Wiping of clean udders/teats with a cloth or tissue soaked with disinfection solution or using a foam applicator on teats.
Application rate(s) and frequencies	<p>Application Rate: Amount of product (per teat): 5–15 mL with soaked tissue/udder and teats 4-6 mL product foam / cow teat 1-2 mL product foam / goat and sheep teat Dilution (%): 0 Number and timing of application:</p> <p>Application frequency: max.2x/day. Contact time 60sec.</p>
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

4.3.1 Use-specific instructions for use

The product is used occasionally before milking with a soaked wet tissue on udder and teats or a foam beaker for teats. Clean the udder with a cloth, rinse with water and dry before application of the product.

Wiping method: For the disinfection the product is applied using a cloth which has been soaked in the application solution (5-15 ml/tissue).The product is allowed to remain on the teats and udders for 60 seconds then wiped off using a clean moist cloth before the milking equipment is attached. Residual product not completely used up for udder washing is disposed of.

Foam application: The teat foam product is applied via a foam beaker and pushed to form foam in the applicator. The foam is applied to every teat (4-6 ml per cow, 1-2 ml per goat and sheep teats) by dipping and allowed to remain for 60 seconds before it is removed using a water drenched towel.

The product must be brought to a temperature above 20°C before use.

4.3.2 Use-specific risk mitigation measures

Keep container tightly closed. Protect against UV-radiation/sunlight and heat.
During use wear chemical resistant gloves (glove material to be specified by the authorisation holder within the product information).
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 post-milking disinfection.

Keep out of reach of children.

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

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.

4.3.4 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.

4.3.5 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 3.
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 3.

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

See specific P
articulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment of meta SPC 3.

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 3.

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 3, BPR-reg. nr. 801-1-3-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. Op-lys-ninger i citationstegn skal angives ordret:

1) I hovedfeltet:
"Veterinærhygiejne

Må kun anvendes erhvervsmæssigt til yver- og pattedesinfektion af køer, får og geder ved aftørring og dypning af yver/patter i skum før malkning og ved dypning eller spray af patter efter malkning mod bakterier og gær. "

2) I advarselsfeltet:
"FORSIGTIG

Skadelig for vandlevende organismer, med langvarige virkninger (H412).

Undgå udledning til miljøet.

Bær kemisk resistente beskyttelseshandsker ved brug af produktet." Handskematerialet skal angives af godkendelsesindehaveren i produktdatabladet

"Vask huden grundigt efter brug.

Overtrædelse af nedenstående særligt fremhævede forskrifter kan medføre straf:

**Må kun anvendes erhvervsmæssigt til yver- og pattedesinfektion af køer, får og geder ved aftørring og dypning af yver/patter i skum før malkning og ved dypning eller spray af patter efter malkning mod bakterier og gær.
Må ikke anvendes mod andre skadevoldere og ikke i højere doseringer end de i brugsanvisningen nævnte.**

Ved desinfektion både før og efter malkning må der kun anvendes et jobbaseret produkt den ene gang.

Må ikke tømmes i kloak afløb.

Opbevares utilgængeligt for børn.

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

Evt. oplysninger om førstehjælp.

3) I deklarationsfeltet:

- a) Teksten ” Veterinærhygiejne BPR-reg. nr. 801-1-3-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) Udløbsdatoen skal anføres. Denne dato må højst være 2 år efter produktionsdatoen. Etikettens dato kan udformes som en hen-visning til en produktionsdato andetsteds på emballagen.
- e) Batchnummer eller – betegnelse skal anføres.
- f) Pakningsstørrelse i L.
- g) 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.”