

Summary of product characteristics for a biocidal product

Product name: 1351.0

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

PT03 - Veterinary hygiene (Disinfectants)

Authorisation number: 801-1

R4BP 3 asset reference number: DK-0016289-0011

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)	1
2. Product composition and formulation	2
2.1. Qualitative and quantitative information on the composition of the biocidal product	2
2.2. Type of formulation	3
3. Hazard and precautionary statements	3
4. Authorised use(s)	4
5. General directions for use	8
5.1. Instructions for use	8
5.2. Risk mitigation measures	8
5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment	8
5.4. Instructions for safe disposal of the product and its packaging	8
5.5. Conditions of storage and shelf-life of the product under normal conditions of storage	9
6. Other information	9

Administrative information

1.1. Trade names of the product

Eimü Film-Dip-Konzentrat
Stafilex-Dipspray-Konzentrat

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 1-7	
R4BP 3 asset reference number	DK-0016289-0011	
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	1,5625
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

SL - Soluble concentrate

3. Hazard and precautionary statements

Hazard statements

May be corrosive to metals.
 Causes severe skin burns and eye damage.
 May cause damage to organs thyroid through prolonged or repeated exposure oral.
 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.
 Wear protective gloves/protective clothing/eye protection/face protection..
 IF ON SKIN (or hair):Take off immediately all contaminated clothing.Rinse skin with water.
 IF ON SKIN (or hair):Take off immediately all contaminated clothing.Rinse skin with shower.
 Immediately call a POISON CENTER/doctor.
 IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing.

Immediately call a POISON CENTER/doctor.

Absorb spillage to prevent material damage.

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 concentrate, 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 (%): 20
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).
The product needs to be diluted with water (100mL product with 400mL with potable water = 20% dilution). A measuring beaker is used for weighing the amount of concentrated product. The needed amount is poured in a 10 L bucket and diluted with a calculated amount of water according to the label instructions. The resulting blend is stirred with a stirring rod and filled in the application equipment.
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	-
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 concentrate, 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 (%): 20 100 mL product is diluted in 400 mL water Number and timing of application: Application frequency: 2x/day (post-milking) 5 minutes contact time

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).

The product needs to be diluted with water (100mL product with 400mL lukewarm potable water = 20% dilution). A measuring beaker is used for weighing the amount of concentrated product. The needed amount is poured in a 10 L bucket and diluted with a calculated amount of water according to the label instructions. The resulting blend is stirred with a stirring rod and filled in the application equipment.

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.

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.

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

5. General directions for use

5.1. Instructions for use

See use-specific instructions for use of meta SPC 4.
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 4.

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 4.

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 4.

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 from frost.

6. Other information

Bilag 1

Oplysninger til etiket og brugsanvisning for Eimermacher Iodine Compounds, MetaSPC 8, BPR-reg. nr. 801-1-8-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 pattedesinfektion hos køer, får og geder ved dypning og spray efter malkning mod bakterier og gær ."

2) I advarselsfeltet:
"FARE

Kan ætse metaller (H290).

Forårsager svære ætsninger af huden og øjenskader (H314).

Kan forårsage skader på skjoldbruskkirtlen ved længerevarende eller gentagen indtagelse (H373).

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

Opbevares kun i den originale beholder.

Undgå udledning til miljøet.

Absorber udslip for at undgå materielskade.

Bær Beskyttelsestøj/øjenskyttelse/ansigtsbeskyttelse. 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 pattedesinfektion hos køer, får og geder ved dypning og spray efter malkning mod bakterier og gær .

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

Må ikke tømmes i kloak afløb.

Opbevares utilgængeligt for børn.

Må ikke opbevares sammen med fødevarer, drikkevarer og foderstoffer.

Farepiktogrammet GHS 05 og GHS 08.

Miljøstyrelsen henleder opmærksomheden på, at godkendelsesindehaver skal anføre oplysninger om førstehjælp, herunder:
VED KONTAKT MED ØJNENE: Skyl forsigtigt med vand i flere minutter. Fjern eventuelle kontaktlinser, hvis dette kan gøres let.
Fortsæt skylning. Ring omgående til GIFTLINJEN/en læge/...

VED KONTAKT MED HUDEN (eller håret): Tilsmudset tøj tages straks af/fjernes. Skyl [eller brus] huden med vand. Ring omgående til GIFTLINJEN/en læge/...

3) I deklaraionsfeltet:

- a) Teksten "Veterinærhygiejne BPR-reg. nr. 801-1-8-x. Aktivstof og biocidholdigt produkt er godkendt efter biocidforordningen (Forordning (EU) nr. 528/2012)".
- b) Oplysning om præparattype: "væske, flydende koncentrat" 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."