

Summary of product characteristics for a biocidal product family

Family name: Eimermacher Iodine Compounds

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

Authorisation number: 801-1

R4BP 3 asset reference number: DK-0016289-0000

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Part I.- First information level

1. Administrative information

1.1. Family name

Eimermacher Iodine Compounds

1.2. Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

1.3. 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

R4BP 3 asset reference number

DK-0016289-0000

Date of the authorisation

09/08/2022

Expiry date of the authorisation

05/08/2032

1.4. 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

1.5. 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 family composition and formulation

2.1. Qualitative and quantitative information on the composition of the family

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|-----------------------------|----------------------------|----------------------|-------------|-----------|------------------|
| Iodine | | Active Substance | 7553-56-2 | 231-442-4 | 0,000001 - 1,625 |
| Polyvinylpyrrolidone iodine | | Active Substance | 25655-41-8 | | 0,000001 - 2,7 |
| 2-(2-butoxyethoxy)ethanol | 2-(2-butoxyethoxy)ethanol | Non-active substance | 112-34-5 | 203-961-6 | 0 - 6 |
| Phosphoric acid | orthophosphoric acid | Non-active substance | 7664-38-2 | 231-633-2 | 0 - 3,75 |
| Methanol | Methan-1-ol | Non-active substance | 67-56-1 | 200-659-6 | 0 - 0,15 |
| Alcohols C9-C11, ethoylated | AlcoholsC9-C11, ethoylated | Non-active substance | 68439-46-3 | 500-446-0 | 0 - 4,875 |
| Fatty alcohol alkoxylate 4 | Fattyalcohol alkoxylate 4 | Non-active substance | 111905-53-4 | | 0 - 1,8 |

2.2. Type(s) of formulation

AL - Any other liquid

SL - Soluble concentrate

Part II.- Second information level - meta SPC(s)

1. Meta SPC administrative information

1.1. Meta SPC identifier

meta SPC 1: Milking cluster disinfection, ready to use

1.2. Suffix to the authorisation number

1-1

1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

2. Meta SPC composition

2.1. Qualitative and quantitative information on the composition of the meta SPC

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|-----------------------------|----------------------------|----------------------|-------------|-----------|---------------------|
| Iodine | | Active Substance | 7553-56-2 | 231-442-4 | 0,25 - 0,25 |
| Polyvinylpyrrolidone iodine | | Active Substance | 25655-41-8 | | 0,000001 - 0,000001 |
| 2-(2-butoxyethoxy)ethanol | 2-(2-butoxyethoxy)ethanol | Non-active substance | 112-34-5 | 203-961-6 | 0 - 6 |
| Phosphoric acid | orthophosphoric acid | Non-active substance | 7664-38-2 | 231-633-2 | 3,75 - 3,75 |
| Alcohols C9-C11, ethoylated | AlcoholsC9-C11, ethoylated | Non-active substance | 68439-46-3 | 500-446-0 | 0,75 - 0,75 |
| Fatty alcohol alkoxylate 4 | Fattyalcohol alkoxylate 4 | Non-active substance | 111905-53-4 | | 1,8 - 1,8 |

2.2. Type(s) of formulation of the meta SPC

Formulation(s)

AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

Hazard statements

May be corrosive to metals.
Causes serious eye irritation.
Harmful to aquatic life with long lasting effects.

Precautionary statements

If medical advice is needed, have product container or label at hand.
Keep only in original packaging.
Wash hands thoroughly after handling.
Avoid release to the environment.
Wear eye protection.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice.

Absorb spillage to prevent material damage.

Dispose of container to relevant legislation.

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - External milking cluster disinfection

| | |
|---|--|
| 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 ready to use and applied for surface disinfection of milking cluster |
| Application method(s) | Method: Spraying Detailed description: 1) Low to medium pressure spraying with Knapsack type sprayers. 2) Triggered sprays |
| Application rate(s) and frequencies | Application Rate: Application rate: 400 mL product/m ² Dilution (%): 0 Number and timing of application: application frequency: twice daily, contact time is minimal 30 minutes |

Category(ies) of users

Professional

Pack sizes and packaging material

Plastic bottle of HDPE: 500 mL (trigger), 1000 mL
Jerry can of HDPE : 5 L, 20 L, 25 L
Drum of HDPE: 200 L
IBC container of HDPE: 1000 L
Spraying equipment is available at the farms.

4.1.1 Use-specific instructions for use

The biocidal product is used for surface disinfection of external surface of milking clusters. It is applied twice daily by professional users. The surfaces should be cleaned before disinfection: gross dirt thoroughly removed from clusters, followed by cleaning with a lukewarm, water diluted detergent and a final rinse with water. Allow the surfaces to dry completely after which this product is used as a ready to use spray. The RTU product is directly sprayed on the surface. The product is allowed to react for minimal 30 min. Post-rinsing with potable water afterwards. The approximate application rate is 0.4 L/m².

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), a coated coverall and eye/face protection and respiratory protection (protection factor 10).
Avoid eye exposure.
In case a combination of pre- or post-milking disinfection or disinfection of milking clusters is necessary, an iodine based product can only be used for one of these uses.
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.

Keep out of reach of children.

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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 of the meta SPC

5.1. Instructions for use

See use-specific instructions for use of meta SPC 1.
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 1.

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 1.

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 1.

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 1, BPR-reg. nr. 801-1-1-x

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 desinfektion af malkemaskinens pattekopper ved spray mod bakterier og gær."

2) I advarselsfeltet:
"ADVARSEL

Kan ætse metaller (H290).

Forårsager alvorlig øjenirritation (H319).

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/øjenskytelse/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 desinfektion af malkemaskinens pattekopper ved spray 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."

Farepiktogrammet GHS05.

Miljøstyrelsen henleder opmærksomheden på, at godkendelsesindehaver skal anføre oplysninger om førstehjælp, herunder:

Hvis der er brug for lægehjælp, medbring da beholderen eller etiketten
VED KONTAKT MED ØJNENE: Skyl forsigtigt med vand i flere minutter. Fjern eventuelle kontaktlinser, hvis dette kan gøres let.
Fortsæt skylning. Ring omgående til en læge.

3) I deklaraionsfeltet:

a) Teksten "Veterinærhygiejne BPR-reg. nr. 801-1-1-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 phosphorsyre, 2-(2-butoxyethoxy)ethanol, alkohols C9-C11 ethoxylated, og fatty alcohol alkoxyate 4."

d) 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.

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."

7. Third information level: individual products in the meta SPC

7.1 Trade name(s), authorisation number and specific composition of each individual product

| | | |
|--|---------------------|-----------------|
| Trade name(s) | Ferdei Rox | Market area: DK |
| Authorisation number <small>(R4BP 3 asset reference number - National Authorisation)</small> | DK-0016289-0001 1-1 | |

| 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 | 6 |
| Phosphoric acid | orthophosphoric acid | Non-active substance | 7664-38-2 | 231-633-2 | 3,75 |

| | | | | | |
|-----------------------------|----------------------------|----------------------|-------------|-----------|------|
| Alcohols C9-C11, ethoylated | AlcoholsC9-C11, ethoylated | Non-active substance | 68439-46-3 | 500-446-0 | 0,75 |
| Fatty alcohol alkoxyate 4 | Fattyalcohol alkoxyate 4 | Non-active substance | 111905-53-4 | | 1,8 |

1. Meta SPC administrative information

1.1. Meta SPC identifier

meta SPC 3: Teat disinfection (pre-/post-milking), ready to use

1.2. Suffix to the authorisation number

1-2

1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

2. Meta SPC composition

2.1. Qualitative and quantitative information on the composition of the meta SPC

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|-----------------------------|------------|------------------|------------|-----------|---------------------|
| Iodine | | Active Substance | 7553-56-2 | 231-442-4 | 0,25 - 0,4125 |
| Polyvinylpyrrolidone iodine | | Active Substance | 25655-41-8 | | 0,000001 - 0,000001 |

2.2. Type(s) of formulation of the meta SPC

Formulation(s)

AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

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) of the meta SPC

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 | - |
| 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.

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

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

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:

Application frequency: max.2x/day.
Contact time 60sec.

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 of the meta SPC

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
particulars 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. Oplysninger 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:

- Teksten "Veterinærhygiejne BPR-reg. nr. 801-1-3-x. Aktivstof og biocidholdigt produkt er godkendt efter biocidforordningen (Forordning (EU) nr. 528/2012)".
- Oplysning om præparattype: "væske" for dette præparat.
- Indholdet af aktivstof i vægtprocent (% w/w) og g/L ved 20 °C.
- 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.
- Batchnummer eller – betegnelse skal anføres.
- Pakningsstørrelse i L.
- Godkendelsesindehavers navn og adresse.

4) Brugsanvisningen:

Oplysninger om skadevoldere, anvendelsesområde og doseringer.

Følgende retningslinjer gælder i forhold til bortskaffelse.

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

Følgende sætning skal anføres under sikkerhedsætning 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."

7. Third information level: individual products in the meta SPC

7.1 Trade name(s), authorisation number and specific composition of each individual product

| | | |
|--|-----------------------|-----------------|
| Trade name(s) | Eimü Doppeldip Iodine | Market area: DK |
| Authorisation number <small>(R4BP 3 asset reference number - National Authorisation)</small> | DK-0016289-0002 1-2 | |

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|-----------------------------|------------|------------------|------------|-----------|-------------|
| Iodine | | Active Substance | 7553-56-2 | 231-442-4 | 0,4 |
| Polyvinylpyrrolidone iodine | | Active Substance | 25655-41-8 | | 0,000001 |

Trade name(s)

Eimü PremaFoam Iodine

Market area: DK

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

DK-0016289-0003 1-2

| 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 |

Trade name(s)

Eimü Doppel-Film-Dip

Market area: DK

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

DK-0016289-0004 1-2

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|-----------------------------|------------|------------------|------------|-----------|-------------|
| Iodine | | Active Substance | 7553-56-2 | 231-442-4 | 0,4125 |
| Polyvinylpyrrolidone iodine | | Active Substance | 25655-41-8 | | 0,000001 |

1. Meta SPC administrative information

1.1. Meta SPC identifier

meta SPC 4: Teat disinfection (pre-milking), concentrates

1.2. Suffix to the authorisation number

1-3

1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

2. Meta SPC composition

2.1. Qualitative and quantitative information on the composition of the meta SPC

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|-----------------------------|-------------|----------------------|------------|-----------|---------------------|
| Iodine | | Active Substance | 7553-56-2 | 231-442-4 | 1,625 - 1,625 |
| Polyvinylpyrrolidone iodine | | Active Substance | 25655-41-8 | | 0,000001 - 0,000001 |
| Methanol | Methan-1-ol | Non-active substance | 67-56-1 | 200-659-6 | 0 - 0,15 |

2.2. Type(s) of formulation of the meta SPC

Formulation(s)

SL - Soluble concentrate

3. Hazard and precautionary statements of the meta SPC

Hazard statements

May be corrosive to metals.
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.
Get medical advice if you feel unwell.
Absorb spillage to prevent material damage.
Dispose of container to in accordance to national legislation.

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - Udder disinfection (pre-milking), Foam beaker or use of soaked tissue, concentrates

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 concentrated, used for udder/teat disinfection (pre-milking) of cows, sheep, goats. |
| Application method(s) | Method: Soaked tissue and dipping Detailed description: Wiping of clean udders/teats with a cloth or tissue soaked with disinfection solution for udder and teats or using foam beaker on teats. |
| Application rate(s) and frequencies | Application Rate: Amount of diluted product (per teat): 5-15 mL on tissue per udder and teats 4-6 mL product foam / cow teat 1-2 mL product foam / goat and sheep teat Dilution (%): 2 20mL product is diluted in 1000mL water. Number and timing of application: Application frequency: max. 2x/day. Contact time: 60 sec. |
| 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

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. The product needs to be diluted in lukewarm water (20 mL product with 1000mL water). 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.

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.

4.1.2 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 post-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 of the meta SPC

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 frost.

6. Other information

Bilag 1

Oplysninger til etiket og brugsanvisning for Eimermacher Iodine Compounds, MetaSPC 4, BPR-reg. nr. 801-1-4-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.
Nedstående 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 yver- og pattedesinfektion af køer, får og geder ved dypning i skum eller ved aftørring før malkning mod bakterier og gær."

2) I advarselsfeltet:
"ADVARSEL

Kan ætse metaller (H290).

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 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 dykning i skum eller ved aftørring før 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."

Farepiktogrammerne GHS 05 og GHS08.

Miljøstyrelsen henleder opmærksomheden på, at godkendelsesindehaver skal anføre oplysninger om førstehjælp, herunder Hvis der er brug for lægehjælp, medbring da beholderen eller etiketten Søg lægehjælp ved ubehag.

3) I deklaraionsfeltet:

- Teksten "Veterinærhygiejne BPR-reg. nr. 801-1-4-x. Aktivstof og biocidholdigt produkt er godkendt efter biocidforordningen (Forordning (EU) nr. 528/2012)".
- Oplysning om præparattype: "væske" for dette præparat.
- Indholdet af aktivstof i vægtprocent (% w/w) og g/L ved 20 °C.
- Sætningen: "Indeholder methanol."
- 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.
- Batchnummer eller – betegnelse skal anføres.
- Pakningsstørrelse i L.
- 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."

7. Third information level: individual products in the meta SPC

7.1 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)

Eimü Euterwasch

Market area: DK

Authorisation number

(R4BP 3 asset reference number - National
Authorisation)

DK-0016289-0005 1-3

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|--------------------------------|------------|------------------|------------|-----------|-------------|
| Iodine | | Active Substance | 7553-56-2 | 231-442-4 | 1,625 |
| Polyvinylpyrrolidone iodine | | Active Substance | 25655-41-8 | | 0,000001 |

1. Meta SPC administrative information

1.1. Meta SPC identifier

meta SPC 5: Teat disinfection (post-milking), ready to use with PVP-I

1.2. Suffix to the authorisation number

1-4

1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

2. Meta SPC composition

2.1. Qualitative and quantitative information on the composition of the meta SPC

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|-----------------------------|------------|------------------|------------|-----------|---------------------|
| Iodine | | Active Substance | 7553-56-2 | 231-442-4 | 0,000001 - 0,000001 |
| Polyvinylpyrrolidone iodine | | Active Substance | 25655-41-8 | | 2,7 - 2,7 |

2.2. Type(s) of formulation of the meta SPC

Formulation(s)

AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

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) of the meta SPC

4.1 Use description

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

| | |
|--|---|
| | <p>Scientific name: Common name: Yeasts Development stage:</p> |
| Field(s) of use | <p>Indoor</p> <p>The product is RTU, used for teat disinfection (post-milking) of cows, sheep, goats.</p> |
| Application method(s) | <p>Method: Spraying Detailed description: (triggered) spraying</p> |
| Application rate(s) and frequencies | <p>Application Rate: Spraying (per teat): 5-15 mL/cow 3-5 mL/goat 3-5 mL/sheep Dilution (%): 0 Number and timing of application:</p> <p>Application frequency: 2x/day (post-milking) Contact time: 5 min.</p> |
| Category(ies) of users | <p>Professional</p> |
| Pack sizes and packaging material | <p>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</p> |

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), a coated coverall and chemical resistant boots.
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, 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): 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.

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 of the meta SPC

5.1. Instructions for use

See use-specific instructions for use of meta SPC 5.
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 5.

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 5.

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 5.

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 5, BPR-reg. nr. 801-1-5-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 og spray mod bakterier og gær efter malkning."

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 pattedesinfektion af køer, får og geder ved dypning og spray mod bakterier og gær efter malkning.

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."

Evt. oplysninger om førstehjælp.

3) I deklaraionsfeltet:

a) Teksten " Veterinærhygiejne BPR-reg. nr. 801-1-5-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 henvisning 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."

7. Third information level: individual products in the meta SPC

7.1 Trade name(s), authorisation number and specific composition of each individual product

| | | |
|--|--------------------------|-----------------|
| Trade name(s) | eimü Hygiēna Dip & Spray | Market area: DK |
| Authorisation number <small>(R4BP 3 asset reference number - National Authorisation)</small> | DK-0016289-0006 1-4 | |

| 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 |

1. Meta SPC administrative information

1.1. Meta SPC identifier

meta SPC 6: Teat disinfection (post-milking), ready to use with PVP-I

1.2. Suffix to the authorisation number

1-5

1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

2. Meta SPC composition

2.1. Qualitative and quantitative information on the composition of the meta SPC

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|-----------------------------|-------------|----------------------|------------|-----------|---------------------|
| Iodine | | Active Substance | 7553-56-2 | 231-442-4 | 0,000001 - 0,000001 |
| Polyvinylpyrrolidone iodine | | Active Substance | 25655-41-8 | | 2,7 - 2,7 |
| Methanol | Methan-1-ol | Non-active substance | 67-56-1 | 200-659-6 | 0 - 0,12 |

2.2. Type(s) of formulation of the meta SPC

Formulation(s)

AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

Hazard statements

Safety data sheet available on request.

Precautionary statements

4. Authorised use(s) of the meta SPC

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 of the meta SPC

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 erhvervmæssigt 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 erhvervmæssigt 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 deklarationsfeltet:

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."

7. Third information level: individual products in the meta SPC

7.1 Trade name(s), authorisation number and specific composition of each individual product

| | | |
|---|---------------------|-----------------|
| Trade name(s) | Eimü MultiCare Dip | Market area: DK |
| Authorisation number (R4BP 3 asset reference number - National Authorisation) | DK-0016289-0007 1-5 | |

| 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 |

| | | |
|-----------------------------|--------------------|-----------------|
| Trade name(s) | Eimü DoppelProtect | Market area: DK |
| Authorisation number | | |

(R4BP 3 asset reference number - National Authorisation)

DK-0016289-0008 1-5

| 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 |
| Methanol | Methan-1-ol | Non-active substance | 67-56-1 | 200-659-6 | 0,12 |

1. Meta SPC administrative information

1.1. Meta SPC identifier

meta SPC 7: Teat disinfection (pre-/post-milking), ready to use

1.2. Suffix to the authorisation number

1-6

1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

2. Meta SPC composition

2.1. Qualitative and quantitative information on the composition of the meta SPC

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|-----------------------------|------------|------------------|------------|-----------|---------------------|
| Iodine | | Active Substance | 7553-56-2 | 231-442-4 | 0,6675 - 0,6675 |
| Polyvinylpyrrolidone iodine | | Active Substance | 25655-41-8 | | 0,000001 - 0,000001 |

2.2. Type(s) of formulation of the meta SPC

Formulation(s)

AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

Hazard statements

May be corrosive to metals.
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.
Keep only in original packaging.
Avoid release to the environment.
Absorb spillage to prevent material damage.
Dispose of container to in accordance to national legislation.

4. Authorised use(s) of the meta SPC

4.1 Use description

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

Product type

PT03 - Veterinary hygiene (Disinfectants)

| | |
|---|---|
| Where relevant, an exact description of the authorised use | - |
| Target organism(s) (including development stage) | <p>Scientific name: Common name: Bacteria Development stage:</p> <p>Scientific name: Common name: Yeasts Development stage:</p> |
| Field(s) of use | <p>Indoor</p> <p>The product is a RTU, used for teat disinfection (post-milking) of cows, sheep, goats.</p> |
| Application method(s) | <p>Method: Spraying Detailed description: (triggered) spraying</p> |
| Application rate(s) and frequencies | <p>Application Rate: spraying (per teat): 5-15 mL/cow; 3-5 mL/goat; 3-5 mL/sheep Dilution (%): 0 Number and timing of application:</p> <p>Application frequency: 2x/day (post-milking) Contact time: 5 min.</p> |
| Category(ies) of users | Professional |
| Pack sizes and packaging material | <p>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</p> |

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), coveralls and chemical resistant boots.
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, 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 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.
Wear protective gloves/protective clothing/eye protection.
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

| |
|--|
| |
|--|

4.3 Use description

Use 3 - Udder disinfection (pre-milking),disinfection by wiping/ dipping with foam, 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 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 | 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: Application frequency: max. 2x/day. Contact time: 60 sec. |
| 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 of the meta SPC**5.1. Instructions for use**

See use-specific instructions for use of Meta SPC 7.

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 7.

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 7.

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 7.

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 7, BPR-reg. nr. 801-1-7-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 yver- og pattedesinfektion af køer, får og geder ved aftørring eller dypning af yver/patter i skum før malkning og ved dypning eller spray af patter efter malkning mod bakterier og gær."

2) I advarselsfeltet:

"ADVARSEL

Kan ætse metaller (H290).

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

Opbevares kun i den originale beholder.

Undgå udledning til miljøet.

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

"Bær coveralls og kemisk resistente støvler ved påføring med spray.

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 eller 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 kloakfløb.

Opbevares utilgængeligt for børn.

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

Farepiktogrammet GHS0 5

Evt. oplysninger om førstehjælp.

Hvis der er brug for lægehjælp, medbring da beholderen eller etiketten

3) I deklarationsfeltet:

a) Teksten "Veterinærhygiejne BPR-reg. nr. 801-1-7-x. Aktivstofog 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."

7. Third information level: individual products in the meta SPC

7.1 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)

Eimü Defender Dip

Market area: DK

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

DK-0016289-0009 1-6

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|-----------------------------|------------|------------------|------------|-----------|-------------|
| Iodine | | Active Substance | 7553-56-2 | 231-442-4 | 0,6675 |
| Polyvinylpyrrolidone iodine | | Active Substance | 25655-41-8 | | 0,000001 |

1. Meta SPC administrative information

1.1. Meta SPC identifier

Meta SPC 8: Teat disinfection (post-milking), concentrates

1.2. Suffix to the authorisation number

1-7

1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

2. Meta SPC composition

2.1. Qualitative and quantitative information on the composition of the meta SPC

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|-----------------------------|-------------|----------------------|------------|-----------|---------------------|
| Iodine | | Active Substance | 7553-56-2 | 231-442-4 | 1,562 - 1,5625 |
| Polyvinylpyrrolidone iodine | | Active Substance | 25655-41-8 | | 0,000001 - 0,000001 |
| Methanol | Methan-1-ol | Non-active substance | 67-56-1 | 200-659-6 | 0 - 0,15 |

2.2. Type(s) of formulation of the meta SPC

Formulation(s)

SL - Soluble concentrate

3. Hazard and precautionary statements of the meta SPC

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) of the meta SPC

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) | <p>Scientific name: Common name: Bacteria Development stage:</p> <p>Scientific name: Common name: Yeasts Development stage:</p> |
| Field(s) of use | <p>Indoor</p> <p>The product is a concentrate, used for teat disinfection (post-milking) of cows, sheep, goats</p> |
| Application method(s) | <p>Method: Spraying Detailed description: (triggered) spraying;</p> |
| Application rate(s) and frequencies | <p>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.</p> |
| Category(ies) of users | Professional |
| Pack sizes and packaging material | <p>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</p> |



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: Dipping (per teat): 4-6 mL/cow 1-2 mL/goat 1-2 mL/sheep |

Application rate(s) and frequencies

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 of the meta SPC

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. Oplysninger 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/øjensbeskyttelse/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 deklarationsfeltet:

- Teksten "Veterinærhygiejne BPR-reg. nr. 801-1-8-x. Aktivstof og biocidholdigt produkt er godkendt efter biocidforordningen (Forordning (EU) nr. 528/2012)".
- Oplysning om præparattype: "væske, flydende koncentrat" for dette præparat.
- Indholdet af aktivstof i vægtprocent (% w/w) og g/L ved 20 °C.
- Sætningen: "Indeholder methanol."
- 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.
- Batchnummer eller – betegnelse skal anføres.
- Pakningsstørrelse i L.
- 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."

7. Third information level: individual products in the meta SPC

7.1 Trade name(s), authorisation number and specific composition of each individual product

| | | |
|---|------------------------------------|-----------------|
| Trade name(s) | Eimü Iodine-DES-Concentrate (Film) | Market area: DK |
| Authorisation number (R4BP 3 asset reference number - National Authorisation) | DK-0016289-0010 1-7 | |

| 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 |
| Methanol | Methan-1-ol | Non-active substance | 67-56-1 | 200-659-6 | 0,15 |

| | | |
|---|------------------------------|-----------------|
| Trade name(s) | Eimü Film-Dip-Konzentrat | Market area: DK |
| | Stafilex-Dipspray-Konzentrat | Market area: DK |
| Authorisation number (R4BP 3 asset reference number - National Authorisation) | DK-0016289-0011 1-7 | |

| 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 |
