

Summary of product characteristics for a biocidal product family

Family name: Iodine based products - CID LINES NV

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

PT04 - Food and feed area (Disinfectants)

Authorisation number: EU-0022265-0000

R4BP 3 asset reference number: IS-0025089-0000

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Part I.- First information level

1. Administrative information

1.1. Family name

Iodine based products - CID LINES NV

1.2. Product type(s)

PT03 - Veterinary hygiene (Disinfectants)
PT04 - Food and feed area (Disinfectants)

1.3. Authorisation holder

**Name and address of the
authorisation holder**

Name	CID LINES NV
Address	Waterpoortstraat 2 8900 Ieper Belgium

Authorisation number

EU-0022265-0000

**R4BP 3 asset reference
number**

IS-0025089-0000

Date of the authorisation

03/09/2020

**Expiry date of the
authorisation**

31/08/2030

1.4. Manufacturer(s) of the biocidal products

Name of the manufacturer

CID LINES NV

Address of the manufacturer

Waterpoortstraat 2 8900 Ieper Belgium

Location of manufacturing sites

Waterpoortstraat 2 8900 Ieper Belgium

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

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

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

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

Active substance	1319 - Iodine
Name of the manufacturer	ISE Chemicals Corporation
Address of the manufacturer	3-1, Kyobashi 1-Chome 104-0031 Tokyo Japan
Location of manufacturing sites	3695 Kitaimaizumi 299-3201 Oamishirasato city Japan
Active substance	1349 - Polyvinylpyrrolidone iodine
Name of the manufacturer	ISP Chemicals LLC, Affiliate of Ashland Inc
Address of the manufacturer	455 N. main st (HWY 95) KY 42029 Calvert City United States
Location of manufacturing sites	455 N. main st (HWY 95) KY 42029 Calvert City United States
Active substance	1349 - Polyvinylpyrrolidone iodine
Name of the manufacturer	Pantheon FZE (DMCC branch)
Address of the manufacturer	403, Reef Tower, Jumeira Lake Tower Shaikh Zayed Road 00 Dubai United Arab Emirates
Location of manufacturing sites	Cala Cala 00 Pozo Almonte Chile

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 - 3
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0 - 10
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active substance	68131-39-5	500-195-7	0 - 21
Phosphoric acid	Phosphoric acid	Non-active substance	7664-38-2	231-633-2	0 - 30
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO	Non-active substance	68439-46-3		0 - 12,5

2.2. Type(s) of formulation

SL - Soluble concentrate

AL - Any other liquid

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

1. Meta SPC administrative information

1.1. Meta SPC identifier

metaSPC 1: PT3 Concentrated teat disinfectants Iodine

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	1,5 - 1,5
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0 - 0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active substance	68131-39-5	500-195-7	12,05 - 12,05
Phosphoric acid	Phosphoric acid	Non-active substance	7664-38-2	231-633-2	0 - 0

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

Causes serious eye damage.

Harmful to aquatic life with long lasting effects.

May cause damage to organs (thyroid) through prolonged or repeated exposure (oral).

Precautionary statements

Wear eye protection.

Wear protective clothing.

Wear protective gloves.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Immediately call a doctor, a poison center.

Avoid release to the environment.

Dispose of contents to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Dispose of container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - PT3- Concentrated Teat disinfectant, post-milking, Iodine

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:

Scientific name:
Common name: Viruses
Development stage:

Field(s) of use

Indoor

Post-milking teat disinfection of milk producing animals

Application method(s)

Manual or automatic spraying on teats
Detailed description:
-

Application rate(s) and frequencies

Application Rate: Dilute the product to a final concentration of 0,3% (w/w) available iodine.
Dilution (%):
Number and timing of application:
Apply 2 times per day with manual sprayer and 3 times per day with a robot.

Category(ies) of users

Professional

Pack sizes and packaging material

1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L
HDPE (High Density Polyethylene)

4.1.1 Use-specific instructions for use

See general directions for use.

4.1.2 Use-specific risk mitigation measures

See general directions for use.

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

See general directions for use.

4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use.

4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use.

5. General directions for use of the meta SPC

5.1. Instructions for use

The product must be diluted before use with clean potable water to allow a final concentration of iodine of 0,3% (200 ml product, add water up to 1L).

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

Assume 5 mL diluted product per cow per treatment. The use of a dosing pump for filling the product into the application equipment is recommended. Use gloves and eye protection during the dilution step. The diluted product can be kept and used during 1 week but do not prepare more fluid than necessary.

Apply the diluted product on the teats with a manual sprayer or with an automatic sprayer.

The product should be used directly after milking 2 times per day by using a manual sprayer and 3 times per day when using a robot (automatic sprayer).

Ensure that the teat is completely covered to three quarters of its length. Let the product dry on teats. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the animal standing for at least 5 minutes). Do not mix with other chemicals.

5.2. Risk mitigation measures

- For mixing and loading of the product: Wear chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) and eye/face protection.
 - For manual spraying application: Wear chemical resistant gloves (glove material to be specified by the authorisation holder within the product information).
 - If 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.

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

After eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain emergency medical attention if pain, blinking, tears or redness persist.
If medical advice is needed, have product container or label at hand.
After ingestion: Rinse mouth. Spit. Do NOT induce vomiting and immediately get medical advice.
Have product container or label at hand.

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

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

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

Keep only in the original container in a cool, well ventilated place. Keep container closed when not in use.
Protect from frost. Do not expose to temperatures >40°C.
The shelf-life of the products is 2 years.

6. Other information

The signal word, hazard- and precautionary statements shall be in Icelandic on the product label.

Signal word:

Hætta

Hazard statements:

H318 Veldur alvarlegum augnskaða.
H412 Skaðlegt lífi í vatni, hefur langvinn áhrif.
H373 Getur skaðað líffæri (skjaldkirtil) við langvinn eða endurtekin váhrif (munn).

Precautionary statements:

P280 Notið augnhlífur.
P280 Notið hlífðarfatnað.
P280 Notið hlífðarhanska.
P305 + P351 + P338 BERIST EFNID Í AUGU: Skolið varlega með vatni í nokkrar mínútur. Fjarlægjið snertilinsur ef það er auðvelt. Skolið áfram.
P310 Hringið umsvifalaust í lækni / EITRUNARMÍÐSTÖÐ s. 112 / 543 2222
P273 Forðist losun út í umhverfi.
P501 Fargið innihaldi hjá viðurkenndum móttökuaðila spilliefna í samræmi við staðbundnar/svæðisbundnar/landsbundnar/alþjóðlegar reglur.
P501 Fargið íláti hjá viðurkenndum móttökuaðila spilliefna í samræmi við staðbundnar/svæðisbundnar/landsbundnar/alþjóðlegar reglur.

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)

Kenodin SD 400	Market area: EU
IodoSD 400	Market area: EU
Velvet Concentrate	Market area: EU
Wynnsan Iodine 3 - 1 conc	Market area: EU
Iodin Teat Spray 400	Market area: EU
Authorisation number <small>(R4BP 3 asset reference number - National Authorisation)</small> IS-0025089-0001 1-1	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	1,5
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active substance	68131-39-5	500-195-7	12,05
Phosphoric acid	Phosphoric acid	Non-active substance	7664-38-2	231-633-2	0
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO	Non-active substance	68439-46-3		0

1. Meta SPC administrative information

1.1. Meta SPC identifier

metaSPC 2: PT3 - Ready to Use (RTU) Teat disinfectants Iodine

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	0,3 - 0,3
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0 - 0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active substance	68131-39-5	500-195-7	2,1 - 2,9
Phosphoric acid	Phosphoric acid	Non-active substance	7664-38-2	231-633-2	0 - 0
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO	Non-active substance	68439-46-3		0 - 0

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

Avoid release to the environment.

Dispose of contents to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Dispose of container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

4. Authorised use(s) of the meta SPC**4.1 Use description****Use 1 - PT3- RTU Teat disinfectant, post-milking, Iodine****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:

Scientific name:
Common name: Viruses
Development stage:

Field(s) of use

Indoor

Post-milking teat disinfection of milk producing animals

Application method(s)

By dipping or spraying on teats
Detailed description:

-

Application rate(s) and frequencies

Application Rate: The product is ready to use.

Dilution (%):

Number and timing of application:

Apply 2 times per day for manual spraying and 3 times per day for manual dipping and spraying with robot

Category(ies) of users

Professional

Pack sizes and packaging material

1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L
HDPE

4.1.1 Use-specific instructions for use

See general directions for use.

4.1.2 Use-specific risk mitigation measures

See general directions for use.

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

See general directions for use.

4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use.

4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use.

5. General directions for use of the meta SPC

5.1. Instructions for use

The product must be brought to a temperature above 20°C before use.
Apply the product by dipping or by spraying:
-By *dipping*: Apply the product with a dip cup. Wash the dip cup with water after use.
-By *spraying*: Apply the product with a manual sprayer or with an automatic sprayer.
Do not prepare more fluid than necessary; assume 5 mL solution per cow per treatment. The use of a dosing pump for filling the product into the application equipment is recommended.
The product should be used immediately after each milking: 2 times per day for manual spraying and 3 times per day for manual dipping and spraying with robot. Ensure that the teat is completely covered to three quarters of its length. Let the product dry on teats. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the animal standing for at least 5 minutes).
Do not mix with other chemicals.

5.2. Risk mitigation measures

- For manual dipping application: No special protection equipment is recommended under normal conditions of use.
- For manual spraying application: Wear chemical resistant gloves (glove material to be specified by the authorisation holder within the product information).
- If a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered for pre-milking disinfection.
- Keep out of reach of children.

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

After eye contact: Rinse immediately with water.

After ingestion: Rinse mouth. Spit.

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

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

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

Keep only in the original container in a cool, well-ventilated place. Keep container closed when not in use.
Protect from frost. Do not expose to temperatures >40°C.
The shelf-life of the products is 2 years.

6. Other information

The hazard- and precautionary statements shall be in Icelandic on the product label.

Hazard statements:

H412 Skaðlegt lífi í vatni, hefur langvinn áhrif.

Precautionary statements:

P273 Forðist losun út í umhverfi.

P501 Fargið innihaldi hjá viðurkenndum móttökuaðila spilliefna í samræmi við staðbundnar/svæðisbundnar/landsbundnar/alþjóðlegar reglur.

P501 Fargið íláti hjá viðurkenndum móttökuaðila spilliefna í samræmi við staðbundnar/svæðisbundnar/landsbundnar/alþjóðlegar reglur.

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)	
IodoDip 3000	Market area: EU
Bio Tec Jodip 3000	Market area: EU
Recoïode	Market area: EU
Stalosan Iø Dip	Market area: EU
Stalosan Super Dip	Market area: EU

Velvet High Visco	Market area: EU
Bühning Joddip 3000	Market area: EU
Kenodin	Market area: EU
Wynnsan trikill RTU	Market area: EU
Wynnsan Iodine RTU teat dip	Market area: EU
Wynnsan Iodine dip RTU	Market area: EU
Iocid	Market area: EU
Iodip+	Market area: EU
Wynngold Iodine Dip	Market area: EU
Pezerk iv plus	Market area: EU
Iod protect 3000 Film	Market area: EU
Seivit® Iode 3000	Market area: EU
Kenostart	Market area: EU
GAHERYOD	Market area: EU
Kenodin 3000	Market area: EU
Iodin Teat Dip 3000	Market area: EU

Iod 3000 dip	Market area: EU
Iodoschutz dip	Market area: EU
Ioschutz dip	Market area: EU
Iodocoop dip	Market area: EU
Iodotech dip	Market area: EU
Iodactiv' dip	Market area: EU
Iododip	Market area: EU
MIROX Dip Jod	Market area: EU
HCP Iodine Dip	Market area: EU
Agib Jodium Dip	Market area: EU
Jod 3000	Market area: EU
Iod dip	Market area: EU
Iode 3000	Market area: EU
Iodoschutz	Market area: EU
Coopjod	Market area: EU
Coopiode	Market area: EU

Coopiode épais	Market area: EU
Semex jod	Market area: EU
Iodotech	Market area: EU
Iododip green	Market area: EU
Iodip bio	Market area: EU
Iododip bio	Market area: EU
Iodactive épais	Market area: EU
Iodactiv	Market area: EU
Iodoactiv'	Market area: EU
Bayley's Premier Iodine Teat Dip	Market area: EU
Pearce Premier Iodine Teat Dip	Market area: EU
Diamond 1:3 Concentrate Iodine Post Dip Spray	Market area: EU
JODOCARE	Market area: EU
KENOSTART DYP	Market area: EU
STREPTOFIT	Market area: EU
Iodall Film	Market area: EU

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

IS-0025089-0002 1-2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,3
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active substance	68131-39-5	500-195-7	2,17
Phosphoric acid	Phosphoric acid	Non-active substance	7664-38-2	231-633-2	0
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO	Non-active substance	68439-46-3		0

Trade name(s)

Kenodin Film	Market area: EU
IodoFilm	Market area: EU
Wynnsan Iofilm teat dip	Market area: EU
Kenodin Film Extra	Market area: EU
Wynngold Film	Market area: EU
Wynnsan trikill film teat dip	Market area: EU
Kenodin Film Soft	Market area: EU

Iocid Film	Market area: EU
TOP Film	Market area: EU
Seivit® Iode Gel	Market area: EU
IOD protect 3000 Film	Market area: EU
Iodin Film Teat Dip 3000	Market area: EU
Iodin Barrier Teat Dip 3000	Market area: EU
Iodin Film Teat Dip	Market area: EU
Iodin Barrier Teat Dip	Market area: EU
Iod 3000 film	Market area: EU
Iodoschutz film	Market area: EU
Ioschutz film	Market area: EU
Iodocoop film	Market area: EU
Iodotech film	Market area: EU
Iodactiv' film	Market area: EU
Iodofilm	Market area: EU
HCP Iodine Film	Market area: EU

Iod 3000 film	Market area: EU
Coopjod film	Market area: EU
Coopiode film	Market area: EU
Iodocoop film	Market area: EU
Semex jod film	Market area: EU
Iodofilm	Market area: EU
Iodofilm bio	Market area: EU
Iofilm bio	Market area: EU
Iodactive film	Market area: EU
Iodactiv film	Market area: EU
Iodactiv' film	Market area: EU
SCUDO 3000	Market area: EU
Authorisation number (R4BP 3 asset reference number - National Authorisation) IS-0025089-0003 1-2	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,3
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active substance	68131-39-5	500-195-7	2,9
Phosphoric acid	Phosphoric acid	Non-active substance	7664-38-2	231-633-2	0
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO	Non-active substance	68439-46-3		0

1. Meta SPC administrative information

1.1. Meta SPC identifier

metaSPC 3: PT3-RTU Udder disinfectant Iodine

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	0,3 - 0,99

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0 - 0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active substance	68131-39-5	500-195-7	2,17 - 2,95
Phosphoric acid	Phosphoric acid	Non-active substance	7664-38-2	231-633-2	0 - 0
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO	Non-active substance	68439-46-3		0 - 0

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

Avoid release to the environment.

Dispose of contents to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Dispose of container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - PT3- RTU Udder disinfectants, Iodine

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 Skin disinfection only for use on intact skin of: - the udder of dairy and beef cattle before calving - the udder of sows before farrowing
Application method(s)	Method: Spraying Detailed description: -
Application rate(s) and frequencies	Application Rate: The product is ready to use. Dilution (%): Number and timing of application: Apply to: <ul style="list-style-type: none"> • the udder of dairy and beef cattle: 1 spray on each teat (equivalent to 4.8 mL per application) • the udder of sows: 15 to 20 mL per animal
Category(ies) of users	Professional
Pack sizes and packaging material	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE

4.1.1 Use-specific instructions for use

See general directions for use.

4.1.2 Use-specific risk mitigation measures

See general directions for use.

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

See general directions for use.

4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use.

4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use.

5. General directions for use of the meta SPC

5.1. Instructions for use

For disinfection of the skin:

The product must be brought to a temperature above 20°C before use. The use of a dosing pump for filling the product into the application equipment is recommended.

Apply by spraying on the animals' intact skin for a topical disinfection:

- on the udder of dairy and beef cattle before calving: 1 spray on each teat (equivalent to 4,8 mL per application). Disinfection takes place once, one day before calving and once, one day after calving. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the animal standing at least 5 minutes).

- on the udder of sows before farrowing: Assume 15 to 20 mL per animal, once one day before farrowing and once every day during 4 days after farrowing. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the animal standing for at least 5 minutes).

Only for use on intact skin.

Do not mix with other chemicals.

5.2. Risk mitigation measures

For manual spraying application on cows and sows: Wear chemical resistant gloves (glove material to be specified by the authorisation holder within the product information).

In case a combination of post-milking disinfection of cows and skin disinfection of cows is necessary, an iodine based product shall not be used by the same person to perform both disinfections.

Keep out of reach of children.

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

After eye contact: Rinse immediately with water.

After ingestion: Rinse mouth. Spit

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

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

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

Keep only in the original container in a cool, well-ventilated place. Keep container closed when not in use.
Protect from frost. Do not expose to temperatures >40°C.
The shelf-life of the products is 2 years.

6. Other information

The hazard- and precautionary statements shall be in Icelandic on the product label.

Hazard statements:

H412 Skaðlegt lífi í vatni, hefur langvinn áhrif.

Precautionary statements:

P273 Forðist losun út í umhverfi.

P501 Fargið innihaldi hjá viðurkenndum móttökuaðila spilliefna í samræmi við staðbundnar/svæðisbundnar/landsbundnar/alþjóðlegar reglur.

P501 Fargið íláti hjá viðurkenndum móttökuaðila spilliefna í samræmi við staðbundnar/svæðisbundnar/landsbundnar/alþjóðlegar reglur.

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)

Animal Skin Disinfectant	Market area: EU
Dermades 3000	Market area: EU

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

Iodin Skin Disinfectant	Market area: EU
IS-0025089-0004 1-3	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,3
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active substance	68131-39-5	500-195-7	2,17
Phosphoric acid	Phosphoric acid	Non-active substance	7664-38-2	231-633-2	0
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO	Non-active substance	68439-46-3		0

Trade name(s)**Authorisation number**

(R4BP 3 asset reference number - National Authorisation)

Dermades	Market area: EU
Animal skin disinfectant 1%	Market area: EU
Dermades Strong	Market area: EU
Iodin Skin Disinfectant Strong	Market area: EU
IS-0025089-0005 1-3	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,99
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active substance	68131-39-5	500-195-7	2,95
Phosphoric acid	Phosphoric acid	Non-active substance	7664-38-2	231-633-2	0
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO	Non-active substance	68439-46-3		0

1. Meta SPC administrative information

1.1. Meta SPC identifier

metaSPC 4: PT3 - RTU Udder and Teat disinfectants Iodine

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	0,3 - 0,3

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0 - 0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active substance	68131-39-5	500-195-7	2,17 - 2,17
Phosphoric acid	Phosphoric acid	Non-active substance	7664-38-2	231-633-2	0 - 0
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO	Non-active substance	68439-46-3		0 - 0

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

Avoid release to the environment.

Dispose of contents to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Dispose of container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - PT3-RTU Teat disinfectant, Post-milking, Iodine

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> <p>Scientific name: Common name: Viruses Development stage:</p>
Field(s) of use	<p>Indoor</p> <p>Ready to use teat disinfectant to be used post milking on milk producing animals.</p>
Application method(s)	<p>Dipping or Spraying Detailed description: -</p>
Application rate(s) and frequencies	<p>Application Rate: The product is ready to use. Dilution (%): Number and timing of application: Apply 2 times per day for manual spraying and 3 times per day for manual dipping and spraying with robot.</p>
Category(ies) of users	<p>Professional</p>
Pack sizes and packaging material	<p>1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE</p>

4.1.1 Use-specific instructions for use

For disinfection of the teats:

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

- By dipping: Apply the product on the teats with a dip cup. Wash the dip cup with water after use.
- By spraying: Apply the product on the teats with a manual sprayer or with an automatic sprayer.

Do not prepare more fluid than necessary. Assume 5 mL solution per cow per treatment. The use of a dosing pump for filling the product into the application equipment is recommended.

The product should be used directly after milking by using a dipping cup or a manual or automatic sprayer. Ensure that the teat is completely covered to three quarters of its length.

The product is applied after milking: 2 times per day for manual spraying and 3 times per day for manual dipping and spraying with robot.

Let the product dry on the teats. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the animal standing for at least 5 minutes).

Do not mix with other chemicals.

4.1.2 Use-specific risk mitigation measures

- For manual spraying application: Wear chemical resistant gloves (glove material to be specified by the authorisation holder within the product information).
- For manual dipping application: no Personal Protection Equipment (PPE) is necessary for safe use.
- If 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

See general directions for use.

4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use.

4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use.

4.2 Use description

Use 2 - PT3- RTU Udder disinfectant, Iodine

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: Yeasts
Development stage:

Scientific name:
Common name: Bacteria
Development stage:

Field(s) of use

Application method(s)	<p>Indoor</p> <p>Ready to use skin disinfectant, only for use on intact skin of:</p> <ul style="list-style-type: none"> - the udder of dairy and beef cattle before calving - the udder of sows before farrowing <p>Application on animal skin: by spraying</p> <p>Detailed description:</p> <p>-</p>
Application rate(s) and frequencies	<p>Application Rate: The product is ready to use.</p> <p>Dilution (%):</p> <p>Number and timing of application:</p> <p>Apply to:</p> <p>-the udder of dairy and beef cattle: 1 spray on each teat (equivalent to 4,8 mL per application)</p> <p>-the udder of sows: 15 to 20 mL per animal</p>
Category(ies) of users	<p>Professional</p>
Pack sizes and packaging material	<p>1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L</p> <p>HDPE</p>

4.2.1 Use-specific instructions for use

For disinfection of the skin:

The product must be brought to a temperature above 20°C before use. The use of a dosing pump for filling the product into the application equipment is recommended.

Apply by spraying on the animals' intact skin for a topical disinfection:

- on the udder of dairy and beef cattle before calving: 1 spray on each teat (equivalent to 4,8 mL per application). Disinfection takes place once, one day before calving and once, one day after calving. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the animal standing for at least 5 minutes).

- on the udder of sows before farrowing: Assume 15 to 20 mL per animal, once one day before farrowing and once every day during 4 days after farrowing. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the animal standing for at least 5 minutes).

Let the product dry on skin.

Only for use on intact skin.

Do not mix with other chemicals.

4.2.2 Use-specific risk mitigation measures

- For manual spraying application on cows and sows: no PPE is necessary for safe use.
- 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

See general directions for use.

4.2.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use.

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 directions for use.

5. General directions for use of the meta SPC

5.1. Instructions for use

See use-specific instructions for use.

5.2. Risk mitigation measures

See use-specific risk mitigation measures

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

After eye contact: Rinse immediately with water.

After ingestion: Rinse mouth. Spit.

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

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

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

Keep only in the original container in a cool, well ventilated place. Keep container closed when not in use. Protect from frost. Do not expose to temperatures >40°C. The shelf-life of the products is 2 years.

6. Other information

The hazard- and precautionary statements shall be in Icelandic on the product label.

Hazard statements:

H412 Skaðlegt lífi í vatni, hefur langvinn áhrif.

Precautionary statements:

P273 Forðist losun út í umhverfi.

P501 Fargið innihaldi hjá viðurkenndum móttökuaðila spilliefna í samræmi við staðbundnar/svæðisbundnar/landsbundnar/alþjóðlegar reglur.

P501 Fargið íláti hjá viðurkenndum móttökuaðila spilliefna í samræmi við staðbundnar/svæðisbundnar/landsbundnar/alþjóðlegar reglur.

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)

Kenodin SD	Market area: EU
IodoSD 3000	Market area: EU
Bio Tec Jodspray 3000	Market area: EU
Q Farm Iodine Des	Market area: EU
ANRO - Euterpflege Dip	Market area: EU

Stalosan Io Spray	Market area: EU
Stalosan Super Spray	Market area: EU
IDip+	Market area: EU
Bühning Jodspray 3000	Market area: EU
Velvet RTU	Market area: EU
Wynnsan trikill spray	Market area: EU
Wynnsan Iodine spray RTU	Market area: EU
Wynngold Iodine Dip and spray	Market area: EU
Pezerk IL	Market area: EU
Iod protect 3000 Sprüh	Market area: EU
Seivit® Iode Spray	Market area: EU
IOD protect 3000 Sprüh	Market area: EU
Kenodin SprayFilm	Market area: EU
Iodo SP	Market area: EU
Kenostart SD	Market area: EU
GAHERYOD SPRAY	Market area: EU

Iodin Teat & Skin 3000	Market area: EU
Iod 3000 sprüh	Market area: EU
Iodoschutz sprüh	Market area: EU
Ioschutz sprüh	Market area: EU
Iodocoop sprüh	Market area: EU
Iodotech sprüh	Market area: EU
Iodactiv' sprüh	Market area: EU
Iodosprüh	Market area: EU
MIROX Spray Jod	Market area: EU
HCP Iodine SD	Market area: EU
Agib Jodium Spray	Market area: EU
Jod 3000 spray	Market area: EU
Iod sprüh	Market area: EU
Coopjod	Market area: EU
Coopiode spray	Market area: EU
Iodocoop spray	Market area: EU

Semex jod spray	Market area: EU
Iododip spray	Market area: EU
Iododip spray green	Market area: EU
Iodospray Bio	Market area: EU
Iospray bio	Market area: EU
Iodactive spray	Market area: EU
Iodactiv spray	Market area: EU
Iodactiv' spray	Market area: EU
Ark Iodine S+D	Market area: EU
Agrihealth Iodine SD	Market area: EU
AGRO LOGIC JODOCARE SPRAY	Market area: EU
IODACTIVE	Market area: EU
Authorisation number <small>(R4BP 3 asset reference number - National Authorisation)</small> IS-0025089-0006 1-4	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,3
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active substance	68131-39-5	500-195-7	2,17
Phosphoric acid	Phosphoric acid	Non-active substance	7664-38-2	231-633-2	0
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO	Non-active substance	68439-46-3		0

1. Meta SPC administrative information

1.1. Meta SPC identifier

metaSPC 5: PT3 - RTU Teat disinfectants PVP-Iodine

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 - 0

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		3 - 3
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active substance	68131-39-5	500-195-7	1,5 - 2,9
Phosphoric acid	Phosphoric acid	Non-active substance	7664-38-2	231-633-2	0 - 0
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO	Non-active substance	68439-46-3		0 - 0

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

Avoid release to the environment.

Dispose of contents to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Dispose of container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - PT3- RTU Teat disinfectant, post milking, PVP-Iodine

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> <p>Scientific name: Common name: Viruses Development stage:</p>
Field(s) of use	<p>Indoor</p> <p>Post-milking disinfection on teats of milk producing animals</p>
Application method(s)	<p>Dipping or spraying Detailed description: -</p>
Application rate(s) and frequencies	<p>Application Rate: The product is ready to use. Dilution (%): Number and timing of application: Apply 2 times per day for manual spraying and 3 times per day for manual dipping and spraying with robot .</p>
Category(ies) of users	<p>Professional</p>
Pack sizes and packaging material	<p>1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE</p>

4.1.1 Use-specific instructions for use

See general directions for use.

4.1.2 Use-specific risk mitigation measures

See general directions for use.

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

See general directions for use.

4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use.

4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use.

5. General directions for use of the meta SPC

5.1. Instructions for use

The product must be brought to a temperature above 20°C before use. The use of a dosing pump for filling the product into the application equipment is recommended.

Apply the product by dipping or by spraying:

-By *dipping*: Apply the product with a dip cup. Wash the dip cup with water after use.

-By *spraying*: Apply the product with a manual sprayer or with an automatic sprayer.

Do not prepare more fluid than necessary. Assume 5 mL solution per cow per treatment.

The product should be used immediately after each milking, two times per day for manual spraying and 3 times per day for manual dipping and spraying with robot. Ensure that the teat is completely covered to three quarters of its length. Let the product dry on teats. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the animal standing for at least 5 minutes).

Do not mix with other chemicals.

5.2. Risk mitigation measures

- For manual spraying application: Wear chemical resistant gloves (glove material to be specified by the authorisation holder within the product information).
- For manual dipping application: no PPE is necessary for safe use.
- If a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered for pre-milking disinfection.
- Keep out of reach of children.

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

After eye contact: Rinse immediately with water.

After ingestion: Rinse mouth. Spit.

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

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

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

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

Keep only in the original container in a cool, well-ventilated place. Keep container closed when not in use.
Protect from frost. Do not expose to temperatures >40°C.
The shelf-life of the products is 18 months.

6. Other information

The hazard- and precautionary statements shall be in Icelandic on the product label.

Hazard statements:

H412 Skaðlegt lífi í vatni, hefur langvinn áhrif.

Precautionary statements:

P273 Forðist losun út í umhverfi.

P501 Fargið innihaldi hjá viðurkenndum móttökuaðila spilliefna í samræmi við staðbundnar/svæðisbundnar/landsbundnar/alþjóðlegar reglur.

P501 Fargið íláti hjá viðurkenndum móttökuaðila spilliefna í samræmi við staðbundnar/svæðisbundnar/landsbundnar/alþjóðlegar reglur.

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)	Iodo PVP	Market area: EU
	Iodin Teat Dip 3000 PVP	Market area: EU
Authorisation number <small>(R4BP 3 asset reference number - National Authorisation)</small>	IS-0025089-0007 1-5	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		3
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active substance	68131-39-5	500-195-7	2,5
Phosphoric acid	Phosphoric acid	Non-active substance	7664-38-2	231-633-2	0
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO	Non-active substance	68439-46-3		0

Trade name(s)

Iodo SD PVP	Market area: EU
Iodin Teat Spray & Dip 3000 PVP	Market area: EU
IS-0025089-0008 1-5	

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		3
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active substance	68131-39-5	500-195-7	2,5
Phosphoric acid	Phosphoric acid	Non-active substance	7664-38-2	231-633-2	0
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO	Non-active substance	68439-46-3		0

1. Meta SPC administrative information

1.1. Meta SPC identifier

metaSPC 6: PT3- RTU Udder disinfectants PVP-Iodine

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 - 0
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		10 - 10
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active substance	68131-39-5	500-195-7	2 - 2
Phosphoric acid	Phosphoric acid	Non-active substance	7664-38-2	231-633-2	0 - 0
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO	Non-active substance	68439-46-3		0 - 0

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.
May cause damage to organs (thyroid) through prolonged or repeated exposure (oral).

Precautionary statements

Avoid release to the environment.
Dispose of contents to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.
Dispose of container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.
Do not breathe spray.

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - PT3- RTU Udder disinfectant PVP-Iodine

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

Ready to use skin disinfectant, only for use on intact skin of:
- the udder of dairy and beef cattle: before calving
- the udder of sows: before farrowing

Application method(s)

Method: Spraying
Detailed description:
-

Application rate(s) and frequencies

Application Rate: The product is ready to use.
Dilution (%):
Number and timing of application:
Apply to:

- The udder of dairy and beef cattle: 1 spray on each teat (equivalent to 4,8 mL per application)
- The udder of sows: 15 to 20 mL per animal

Category(ies) of users

Professional

Pack sizes and packaging material

1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L
HDPE

4.1.1 Use-specific instructions for use

The product must be brought to a temperature above 20°C before use. The use of a dosing pump for filling the product into the application equipment is recommended.

- Dairy and beef cattle: Apply the product by spraying on the udder before calving (1 spray / teat equivalent to 4,8 mL per application). Disinfection takes place once, one day before calving and once, one day after calving. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the animal standing for at least 5 minutes).
- Sows, on the udder before farrowing: Assume 15 to 20 mL per animal. Disinfection takes place once, one day before farrowing and once every day during 4 days after farrowing. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the animal standing for at least 5 minutes).

Only for use on intact skin.
Do not mix with other chemicals.

4.1.2 Use-specific risk mitigation measures

- For manual spraying application on cows and sows: Wear chemical resistant gloves (glove material to be specified by the authorisation holder within the product information).
- In case a combination of post-milking disinfection of cows and skin disinfection of cows is necessary, an iodine based product shall not be used by the same person to perform both disinfections.
- 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

See general directions for use.

4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use.

4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use.

5. General directions for use of the meta SPC

5.1. Instructions for use

See use-specific instructions for use.

5.2. Risk mitigation measures

See use-specific risk mitigation measures.

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

After eye contact: Rinse immediately with water.

After ingestion: Rinse mouth. Spit. Do NOT induce vomiting and immediately get medical advice.

Have product container or label at hand.

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

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

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

Keep only in the original container in a cool, well-ventilated place. Keep container closed when not in use.
Protect from frost. Do not expose to temperatures >40°C.
The shelf-life of the products is 2 years.

6. Other information

The signal word, hazard- and precautionary statements shall be in Icelandic on the product label.

Signal word:

Varúð

Hazard statements:

H412 Skaðlegt lífi í vatni, hefur langvinn áhrif.

H373 Getur skaðað líffæri (skjaldkirtil) við langvinn eða endurtekin váhrif (munn).

Precautionary statements:

P273 Forðist losun út í umhverfi.

P501 Fargið innihaldi hjá viðurkenndum móttökuaðila spilliefna í samræmi við staðbundnar/svæðisbundnar/landsbundnar/alþjóðlegar reglur.

P501 Fargið íláti hjá viðurkenndum móttökuaðila spilliefna í samræmi við staðbundnar/svæðisbundnar/landsbundnar/alþjóðlegar reglur.

P260 Andið ekki að ykkur ýringi.

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)

Dermades PVP	Market area: EU
Wynngold 10% Iodine Solution	Market area: EU
Iodin Skin Disinfectant PVP	Market area: EU
Authorisation number (R4BP 3 asset reference number - National Authorisation)	IS-0025089-0009 1-6

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		10
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active substance	68131-39-5	500-195-7	2
Phosphoric acid	Phosphoric acid	Non-active substance	7664-38-2	231-633-2	0
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO	Non-active substance	68439-46-3		0

1. Meta SPC administrative information

1.1. Meta SPC identifier

metaSPC 7: PT3 and PT4 - Concentrated Surface disinfectants Iodine

1.2. Suffix to the authorisation number

1-7

1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

PT04 - Food and feed area (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	1,8 - 2,49
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0 - 0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active substance	68131-39-5	500-195-7	3,15 - 9,45
Phosphoric acid	Phosphoric acid	Non-active substance	7664-38-2	231-633-2	0 - 0
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO	Non-active substance	68439-46-3		2,5 - 12,5

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

Causes serious eye damage.
 May cause damage to organs (thyroid) through prolonged or repeated exposure (oral).
 May be corrosive to metals.
 Toxic to aquatic life with long lasting effects.

Precautionary statements

Wear protective gloves.
 Wear protective clothing.
 Wear eye protection.
 Wear face protection.
 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 Immediately call a doctor or a POISON CENTER.
 Dispose of contents to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.
 Dispose of container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.
 Collect spillage.
 Avoid release to the environment.

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4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - PT 4 – Concentrated Surface disinfectant in kitchens and in food industry, Iodine

Product type	PT04 - Food and feed area (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 Non-porous surface disinfection in professional kitchens and in food industry
Application method(s)	By spraying with a manual or an automatic sprayer Detailed description: -
Application rate(s) and frequencies	Application Rate: Assume 0,04L solution for every square meter that has to be disinfected. Dilution (%): Bactericidal and yeasticidal activity: 0,015% iodine Number and timing of application: Frequency is once per day.
Category(ies) of users	Professional
Pack sizes and packaging material	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE

4.1.1 Use-specific instructions for use

Use in professional kitchens (PT4) and in food industry (PT4):

The product must be diluted with water before use (according to the table below).
Clean the surfaces thoroughly with a detergent before disinfection. Rinse with clean water and remove surplus water.
The product is used in professional kitchens (surface disinfection): Frequency is once per day.
The product is used in food industry (surface disinfection): Frequency is once per day.
Use at room temperature.

Apply the product by spraying with a manual or an automatic sprayer. Make sure to wet the surface completely. Allow to take effect for at least 15 minutes and rinse the surfaces afterwards with clean water.

Example for a product containing 1% iodine*	Dilution of the product	Contact time
Bactericidal and yeasticidal activity	1,5% (15 ml product, add water up to 1L)	15 min

*Each product label should give information on how the dilution should be made. Since the concentration of iodine in products within this meta SPC can range from 1,8 to 2,49% it is not possible to indicate all product dilutions here.

Do not mix with other chemicals.
Do not prepare more fluid than necessary.

4.1.2 Use-specific risk mitigation measures

- During pouring and pumping of the concentrated product: Wear chemical resistant gloves (material to be specified by the authorisation holder within the product information) and eye/face protection.
- During spraying of the product: Wear chemical resistant gloves and protective coverall (at least type X, EN XXXXX) (glove and coverall material to be specified by the authorisation holder within the product information).
- Keep out of reach of children.
- The general public and animals should be kept away from treated areas until surfaces are dry.

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

See general directions for use.

4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use.

4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use.

4.2 Use description

Use 2 - PT3 - Concentrated Surface disinfectant for veterinary use, Iodine

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: Scientific name: Common name: Viruses Development stage:
Field(s) of use	Indoor Non-porous surface disinfection in veterinary field
Application method(s)	By spraying with a manual or an automatic sprayer Detailed description: /
Application rate(s) and frequencies	Application Rate: Assume 0,04L solution for every square meter that has to be disinfected. Dilution (%): Bactericidal and yeasticidal activity: 0,025% in-use iodine Virucidal activity: 0,035% in-use iodine Number and timing of application: See use-specific risk mitigation measures
Category(ies) of users	Professional
Pack sizes and packaging material	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE

4.2.1 Use-specific instructions for use

4.2.1 Use-specific instructions for use

Use in veterinary field (PT3), surface disinfection:
Product should be diluted with water before use (according to table below).
Clean the surfaces thoroughly with a detergent before disinfection. Rinse with clean water and remove surplus water.
The product is used to disinfect animal housings of pigs, cows and poultry.
Apply the product by spraying with a manual or an automatic sprayer. Make sure to wet the surface completely. Allow to take effect for at least 30 minutes. Animal housing must be empty of animals during application and animals can re-enter 24h after the end of the application.

Example for a product containing 2.49% iodine*	Dilution of the product	Contact time
Bactericidal and yeasticidal activity	1% (10ml product, add water up to 1L)	30 min
Virucidal activity	1,4% (14ml product, add water up to 1L)	30 min

*Each product label should give information on how the dilution should be made. Since the concentration iodine in products within this meta SPC can range from 1,8 to 2,49% it is not possible to indicate all product dilutions here.

Do not mix with other chemicals.
Do not prepare more fluid than necessary.

4.2.2 Use-specific risk mitigation measures

- During pouring and pumping of the concentrated product: Wear chemical resistant gloves, coated coverall (material to be specified by the authorisation holder within the product information) and eye/face protection.
- During spraying of the product: Wear chemical resistant gloves and protective coverall (at least type X, EN XXXXX) which is impermeable for the biocidal product (glove and coverall material to be specified by the authorisation holder within the product information).
- Only use one kind of Iodine-containing product per day.
- Due to potential concern for human health the same professional user shall not carry out animal house disinfection more than 3 times per month and shall not use Iodine products for other purposes during that period.
- Due to potential concern for animal health, disinfection of stables should not be carried out more than once per year or once per lifetime for calves and pigs. Feeding troughs must be covered during application.
- Keep out of reach of children.
- The general public and animals should be kept away from treated areas until surfaces are dry.

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

See general directions for use.

4.2.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use.

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 directions for use.

5. General directions for use of the meta SPC

5.1. Instructions for use

See use-specific instructions for use.

5.2. Risk mitigation measures

See use-specific risk mitigation measures.

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

After eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain emergency medical attention if pain, blinking, tears or redness persist.

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

After ingestion: Rinse mouth. Spit. Do NOT induce vomiting and immediately get medical advice.

Have product container or label at hand.

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

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

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

Keep only in the original container in a cool, well-ventilated place. Keep container closed when not in use.
Protect from frost. Do not expose to temperatures >40°C.
The shelf-life of the products is 2 years.

6. Other information

The signal word, hazard- and precautionary statements shall be in Icelandic on the product label.

Signal word:

Hætta

Hazard statements:

H318 Veldur alvarlegum augnskaða.
H373 Getur skaðað líffæri (skjaldkirtil) við langvinn eða endurtekin váhrif (munn).
H290 Getur verið ætandi fyrir málma.
H411 Eitrað lífi í vatni, hefur langvinn áhrif.

Precautionary statements:

P280 Notið hlífðarhanska.
P280 Notið hlífðarfatnað.
P280 Notið augnhlífur.
P280 Notið andlitshlífur.
P305 + P351 + P338 BERIST EFNID Í AUGU: Skolið varlega með vatni í nokkrar mínútur. Fjarlægjið snertilinsur ef það er auðvelt. Skolið áfram.
P310 Hringið umsvífaust í lækni / EITRUNARMÍÐSTÖÐ s. 112 / 543 2222
P501 Fargið innihaldi hjá viðurkenndum móttökuaðila spilliefna í samræmi við staðbundnar/svæðisbundnar/landsbundnar/alþjóðlegar reglur.
P501 Fargið ílát hjá viðurkenndum móttökuaðila spilliefna í samræmi við staðbundnar/svæðisbundnar/landsbundnar/alþjóðlegar reglur.
P391 Safnið upp því sem hellist niður.
P273 Forðist losun út í umhverfi.

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)

Dodin 20	Market area: EU
Iodo 20	Market area: EU
Bio Tec Joddesinfektion	Market area: EU
Dufa dine 1,8%	Market area: EU
Alfasan super disinfectant	Market area: EU
Iodes	Market area: EU
Streptoclean	Market area: EU
Iodin Surface Disinfectant 1,8%	Market area: EU
IODINE	Market area: EU
IS-0025089-0010 1-7	

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	1,8
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active substance	68131-39-5	500-195-7	5,29
Phosphoric acid	Phosphoric acid	Non-active substance	7664-38-2	231-633-2	0

Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO	Non-active substance	68439-46-3	5
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1. Meta SPC administrative information

1.1. Meta SPC identifier

metaSPC 8: PT3 and PT4 - Concentrated Surface disinfectants Iodine

1.2. Suffix to the authorisation number

1-8

1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

PT04 - Food and feed area (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	2,5 - 3
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0 - 0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active substance	68131-39-5	500-195-7	3,15 - 9,45
Phosphoric acid	Phosphoric acid	Non-active substance	7664-38-2	231-633-2	5 - 12
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO	Non-active substance	68439-46-3		2,5 - 12,5

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 skin irritation.
Causes serious eye damage.
May cause damage to organs (thyroid) through prolonged or repeated exposure (oral).
Toxic to aquatic life with long lasting effects.

Precautionary statements

Wear protective gloves.
Wear protective clothing.
Wear eye protection.
Wear face protection.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
Immediately call a a POISON CENTER or doctor/physician.
If experiencing respiratory symptoms: Call a a POISON CENTER or doctor/physician.
Avoid release to the environment.
Collect spillage.
Dispose of contents to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.
Dispose of container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - PT4 – Concentrated Surface disinfectant in kitchens and in food industry, Iodine

Product type	PT04 - Food and feed area (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 Non-porous surface disinfection in professional kitchens and in food industry
Application method(s)	By spraying with a manual or an automatic sprayer Detailed description: /
Application rate(s) and frequencies	Application Rate: Assume 0,04L solution for every square meter that has to be disinfected. Dilution (%): Bactericidal and yeasticidal activity: 0,015% iodine Number and timing of application: Daily use
Category(ies) of users	Professional
Pack sizes and packaging material	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE

4.1.1 Use-specific instructions for use

<ul style="list-style-type: none">• Use in professional kitchens (PT4) and in food industry (PT4): The product must be diluted with water before use (according to table below). Clean the surfaces thoroughly with a detergent before disinfection. Rinse with clean water and remove surplus water. The product is used in <u>professional kitchens</u> (surface disinfection): Frequency is once per day. The product is used in food industry (surface disinfection): Frequency is once per day. Use at room temperature. The product is applied by spraying with a manual or an automatic sprayer. Make sure to wet the surface completely. Allow to take

effect for at least 15 minutes, and rinse the surfaces afterwards with clean water.

Example for a product containing 3% iodine*

Bactericidal and yeasticidal activity

Dilution of the product

Contact time

0,5% (5 ml product, add water up to 1L)

15 min

*Each product label should give information on how the dilution should be made. Since the concentration of iodine in products within this meta SPC can range from 2,5 to 3% it is not possible to indicate all product dilutions here.

Do not mix with other chemicals.

Do not prepare more fluid than necessary.

4.1.2 Use-specific risk mitigation measures

- During pouring and pumping of the concentrated product: Wear chemical resistant gloves, coverall (material to be specified by the authorisation holder within the product information) and eye/face protection.
- During spraying of the product: Wear chemical resistant gloves and protective coverall (at least type X, EN XXXXX) (glove and coverall material to be specified by the authorisation holder within the product information).
- Keep out of reach of children.
- The general public and animals should be kept away from treated areas until surfaces are dry.

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

See general directions for use.

4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use.

4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use.

4.2 Use description

Use 2 - PT3 – Concentrated Surface disinfectant for veterinary use, Iodine

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> <p>Scientific name: Common name: Viruses Development stage:</p>
Field(s) of use	<p>Indoor</p> <p>Non-porous surface disinfection in veterinary field</p>
Application method(s)	<p>By spraying with a manual or an automatic sprayer Detailed description: /</p>
Application rate(s) and frequencies	<p>Application Rate: Assume 0,04L solution for every square meter that has to be disinfected. Dilution (%): Bactericidal and yeasticidal activity: 0,025% in-use iodine Virucidal activity: 0,035% in-use iodine Number and timing of application: See use-specific risk mitigation measures.</p>
Category(ies) of users	Professional
Pack sizes and packaging material	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE

4.2.1 Use-specific instructions for use

<p><u>Use in veterinary field (PT3), surface disinfection:</u> Product must be diluted with water before use (according to table below). Clean the surfaces thoroughly with a detergent before disinfection. Rinse with clean water and remove surplus water. The product is used to disinfect animal housings of pigs, cows and poultry. Apply the product by spraying with a manual or an automatic sprayer. Make sure to wet the surface completely. Allow to take effect for at least 30 minutes. Animal housing must be empty of animals during application and re-entry of animals can be done 24h after the end of the application.</p>
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Example for a product containing 2.5% iodine*	Dilution of the product	Contact time
Bactericidal and yeasticidal activity	1% (10ml product, add water up to 1L)	30 min
Virucidal activity	1,4% (14ml product, add water up to 1L)	30 min

*Each product label should give information on how the dilution should be made. Since the concentration of iodine in products within this meta SPC can range from 2,5 to 3% it is not possible to indicate all product dilutions here.

Do not mix with other chemicals.
Do not prepare more fluid than necessary.

4.2.2 Use-specific risk mitigation measures

- During pouring and pumping of the concentrated product: Wear chemical resistant gloves, coverall (material to be specified by the authorisation holder within the product information) and eye/face protection.
- During spraying of the product: Wear chemical resistant gloves and protective coverall (at least type X, EN XXXXX) which is impermeable for the biocidal product (glove and coverall material to be specified by the authorisation holder within the product information).
- Only use one kind of Iodine-containing product per day.
- Due to potential concern for human health the same professional user shall not carry out animal house disinfection more than 3 times per month and shall not use Iodine products for other purposes during that period.
- Due to potential concern for animal health, disinfection of stables should not be carried out more than once per year or once per lifetime for calves and pigs. Feeding troughs must be covered during application.
- Keep out of reach of children.
- The general public and animals should be kept away from treated areas until surfaces are dry.

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

See general directions for use.

4.2.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use.

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 directions for use.

5. General directions for use of the meta SPC

5.1. Instructions for use

5.1. Instructions for use

See use-specific instructions for use

5.2. Risk mitigation measures

See use-specific risk mitigation measures.

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

After eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain emergency medical attention if pain, blinking, tears or redness persist.

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

After skin (or hair) contact: Remove contaminated clothing and shoes. Wash the affected area thoroughly with plenty of soap and water. Get medical attention if symptoms occur.

After ingestion: Rinse mouth. Spit. Do NOT induce vomiting and immediately get medical advice.

Have product container or label at hand.

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

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

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

Keep only in the original container in a cool, well ventilated place. Keep container closed when not in use.
Protect from frost. Do not expose to temperatures >40°C.
The shelf-life of the products is 2 years.

6. Other information

The signal word, hazard- and precautionary statements shall be in Icelandic on the product label.

Signal word:

Hætta

Hazard statements:

H318 Veldur alvarlegum augnskaða.
H373 Getur skaðað líffæri (skjaldkirtil) við langvinn eða endurtekin váhrif (munn).
H315 Veldur húðertingu.
H290 Getur verið ætandi fyrir málma.
H411 Eitrað lífi í vatni, hefur langvinn áhrif.

Precautionary statements:

P280 Notið hlífðarhanska.
P280 Notið hlífðarfatnað.
P280 Notið augnhlífur.
P280 Notið andlitshlífur.
P305 + P351 + P338 BERIST EFNID Í AUGU: Skolið varlega með vatni í nokkrar mínútur. Fjarlægjið snertilinsur ef það er auðvelt. Skolið áfram.
P303 + P361 + P353 BERIST EFNID Á HÚÐ (eða í hár): Farið strax úr fötum sem óhreinkast af efninu. Skolið húðina með vatni.
P310 Hringið umsvífalaut í EITRUNARMÍÐSTÖÐ / lækni s. 543 2222 / 112.
P342 + P311 Ef vart verður einkenna frá öndunarvegi: Hringið í EITRUNARMÍÐSTÖÐ / lækni s. 543 2222 / 112.
P501 Fargið innihaldi hjá viðurkenndum móttökuaðila spilliefna í samræmi við staðbundnar/svæðisbundnar/landsbundnar/alþjóðlegar reglur.
P501 Fargið íláti hjá viðurkenndum móttökuaðila spilliefna í samræmi við staðbundnar/svæðisbundnar/landsbundnar/alþjóðlegar reglur.
P391 Safnið upp því sem hellist niður.
P273 Forðist losun út í umhverfi.

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)

locid 30	Market area: EU
Iodo 30	Market area: EU
Dufa dine	Market area: EU
Iodin Surface Disinfectant 2,8%	Market area: EU
Authorisation number (R4BP 3 asset reference number - National Authorisation)	IS-0025089-0011 1-8

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	2,8
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active substance	68131-39-5	500-195-7	7,93
Phosphoric acid	Phosphoric acid	Non-active substance	7664-38-2	231-633-2	11,25
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO	Non-active substance	68439-46-3		12,5

1. Meta SPC administrative information

1.1. Meta SPC identifier

metaSPC 9: PT4 - Concentrated CIP disinfectants Iodine

1.2. Suffix to the authorisation number

1-9

1.3 Product type(s)

PT04 - Food and feed area (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	0,5 - 0,99

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0 - 0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active substance	68131-39-5	500-195-7	0 - 0
Phosphoric acid	Phosphoric acid	Non-active substance	7664-38-2	231-633-2	25 - 30
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO	Non-active substance	68439-46-3		0 - 0

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

Causes severe skin burns and eye damage.
Harmful to aquatic life with long lasting effects.
May be corrosive to metals.

Precautionary statements

Wear protective gloves.
Wear protective clothing.
Wear eye protection.
Wear face protection.
Avoid release to the environment.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
If experiencing respiratory symptoms: Call a doctor.
Dispose of contents to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.
Dispose of container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.
Immediately call a doctor.

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - PT4 – Concentrated Cleaning in place disinfectant, Iodine

Product type	PT04 - Food and feed area (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 Cleaning in place (CIP) disinfection for milking equipment and CIP installations in food industry
Application method(s)	CIP disinfection Detailed description: /
Application rate(s) and frequencies	Application Rate: Apply the product in the automatic system with an end concentration of 0,00125% available iodine Dilution (%): Number and timing of application: The product is used once per day in food industry and up to 2 times per day in milking parlours.
Category(ies) of users	Professional
Pack sizes and packaging material	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE

4.1.1 Use-specific instructions for use

See general directions for use.

4.1.2 Use-specific risk mitigation measures

See general directions for use.

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

See general directions for use.

4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use.

4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use.

5. General directions for use of the meta SPC

5.1. Instructions for use

• Disinfection of milking machines or CIP installations in Food industry
Clean first the CIP installation.
Apply the product in the automatic system with a dilution of the product (according to table below) with water.
Use at room temperature.
Respect a contact time according to the table below.
Rinse the installation with water.

Example for a product containing 0.5% iodine*
Bactericidal and yeasticidal activity

Dilution of the product
0,25% (2,5ml product, add water up to 1L)

Contact time
15 min.

*Each product label should give information on how the dilution should be made. Since the concentration iodine in products within this meta SPC can range from 0,5 to 0,99% it is not possible to indicate all product dilutions here. An example is given for products

with 0,5% iodine.

Do not mix with other chemicals.

5.2. Risk mitigation measures

During pouring and pumping of the concentrated product: Wear chemical resistant gloves and protective coverall (at least type X, EN XXXXX) (glove and coverall material to be specified by the authorisation holder within the product information) and eye/face protection.
Keep out of reach of children.

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

After inhalation: Remove person to fresh air and keep comfortable for breathing. Obtain medical attention if breathing difficulty persists.

After skin (or hair) contact: Remove contaminated clothing and shoes. Wash the affected area thoroughly with plenty of soap and water. Get medical attention if symptoms occur.

After eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain emergency medical attention if pain, blinking, tears or redness persist.

After ingestion: Rinse mouth. Do NOT induce vomiting and immediately get medical advice.

Have product container or label at hand.

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

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

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

Keep only in the original container in a cool, well-ventilated place. Keep container closed when not in use.
Protect from frost. Do not expose to temperatures >40°C.
The shelf-life of the products is 2 years.

6. Other information

The signal word, hazard- and precautionary statements shall be in Icelandic on the product label.

Signal word:
Hætta

Hazard statements:

H314 Veldur alvarlegum bruna á húð og augnskaða.

H412 Skaðlegt lífi í vatni, hefur langvinn áhrif.

H290 Getur verið ætandi fyrir málma.

Precautionary statements:

P280 Notið hlífðarhanska.

P280 Notið hlífðarfatnað.

P280 Notið augnhlífur.

P280 Notið andlitshlífur.

P273 Forðist losun út í umhverfi.

P305 + P351 + P338 BERIST EFNID Í AUGU: Skolið varlega með vatni í nokkrar mínútur. Fjarlægjið snertilinsur ef það er auðvelt. Skolið áfram.

P303 + P361 + P353 BERIST EFNID Á HÚÐ (eða í hár): Farið strax úr fötum sem óhreinkast af efninu. Skolið húðina með vatni.

P342 + P311 Ef vart verður einkenna frá öndunarvegi: Hringið í lækni s. 112.

P501 Fargið innihaldi hjá viðurkenndum móttökuaðila spilliefna í samræmi við staðbundnar/svæðisbundnar/landsbundnar/alþjóðlegar reglur.

P501 Fargið íláti hjá viðurkenndum móttökuaðila spilliefna í samræmi við staðbundnar/svæðisbundnar/landsbundnar/alþjóðlegar reglur.

P310 Hringið umsvífalaust í lækni s. 112.

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)

Iodo CIP	Market area: EU
Iocip	Market area: EU
Bio Tec Jodreiniger	Market area: EU
JODOPHOS SUPER 4001	Market area: EU
Bühning Jodreiniger	Market area: EU
Wynnsan Ice bank Tank Cleaner	Market area: EU
Bulk Tank Sanitizer	Market area: EU

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

Iodin CIP Disinfectant	Market area: EU
IS-0025089-0012 1-9	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,5
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active substance	68131-39-5	500-195-7	0
Phosphoric acid	Phosphoric acid	Non-active substance	7664-38-2	231-633-2	26,3
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO	Non-active substance	68439-46-3		0

1. Meta SPC administrative information**1.1. Meta SPC identifier**

metaSPC 10: PT3 - Concentrated teat disinfectants Iodine

1.2. Suffix to the authorisation number

1-10

1.3 Product type(s)

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	2,8 - 2,8
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0 - 0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active substance	68131-39-5	500-195-7	21 - 21
Phosphoric acid	Phosphoric acid	Non-active substance	7664-38-2	231-633-2	0 - 0
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO	Non-active substance	68439-46-3		0 - 0

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

Causes serious eye damage.
Toxic to aquatic life with long lasting effects.
May cause damage to organs (thyroid) through prolonged or repeated exposure (oral route).

Precautionary statements

Wear protective gloves.
Wear protective clothing.
Wear eye protection.
Wear face protection.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Immediately call a doctor or a poison center.

Avoid release to the environment.

Dispose of contents to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Dispose of container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Collect spillage.

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - PT3 – Concentrated teat disinfectant, Post-milking, Iodine

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> <p>Scientific name: Common name: Viruses Development stage:</p>
Field(s) of use	<p>Indoor</p> <p>Post-milking teat disinfection of milk producing animals</p>
Application method(s)	<p>By spraying with a manual sprayer or with an automatic sprayer on teats. Detailed description:</p> <p>/</p>
Application rate(s) and frequencies	<p>Application Rate: The product must be diluted before use in order to allow a final concentration of iodine of 0,3%</p> <p>Dilution (%):</p> <p>Number and timing of application:</p> <p>Apply 2 times per day by using a manual sprayer and 3 times per day when using a robot (or automatic sprayer).</p>

Category(ies) of users	Professional
Pack sizes and packaging material	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE

4.1.1 Use-specific instructions for use

See general directions for use.

4.1.2 Use-specific risk mitigation measures

See general directions for use.

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

See general directions for use.

4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use.

4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use.

5. General directions for use of the meta SPC

5.1. Instructions for use

The product must be diluted before use in order to allow a final concentration of iodine of 0,3% . The product should be diluted to 11% (110mL product, add water up to 1L).

Do not prepare more fluid than necessary. Assume 5 mL solution per cow per treatment. The use of a dosing pump for filling the product into the application equipment is recommended.

Use gloves and eye protection during the dilution step. The diluted product can be kept and used for 1 week.

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

Apply the diluted product on the teats with a manual sprayer or with an automatic sprayer.

The product should be used directly after milking 2 times per day by using a manual sprayer and 3 times per day by using a robot (automatic sprayer). Ensure that the teat is completely covered to three quarters of its length. Let the product dry on teats. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the animal standing for at least 5 minutes).

Do not mix with other chemicals.

5.2. Risk mitigation measures

- For mixing and loading of the product: Wear chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) and eye/face protection.

- For manual spraying application: Wear chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) and eye/face protection.

- If 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.

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

After eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain emergency medical attention if pain, blinking, tears or redness persist.

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

After ingestion: Rinse mouth. Spit. Do NOT induce vomiting and immediately get medical advice.

Have product container or label at hand.

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

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

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

Keep only in the original container in a cool, well-ventilated place. Keep container closed when not in use.

Protect from frost. Do not expose to temperatures >40°C.

The shelf-life of the products is 2 years.

6. Other information

Dilutions of the product(s) are stable for 1 week.

The signal word, hazard- and precautionary statements shall be in Icelandic on the product label.

Signal word:

Hætta

Hazard statements:

H318 Veldur alvarlegum augnskaða.

H373 Getur skaðað líffæri (skjaldkirtil) við langvinn eða endurtekin váhrif (munn).

H411 Eitrað lífi í vatni, hefur langvinn áhrif.

Precautionary statements:

P280 Notið hlífðarhanska.

P280 Notið hlífðarfatnað.

P280 Notið augnhlíf.

P280 Notið andlitshlíf.

P305 + P351 + P338 BERIST EFNID Í AUGU: Skolið varlega með vatni í nokkrar mínútur. Fjarlægjið snertilinsur ef það er auðvelt. Skolið áfram.

P310 Hringið umsvifalaust í EITRUNARMÍÐSTÖÐ / lækni s. 543 2222 / 112.

P273 Forðist losun út í umhverfi.

P501 Fargið innihaldi hjá viðurkenndum móttökuaðila spilliefna í samræmi við staðbundnar/svæðisbundnar/landsbundnar/alþjóðlegar reglur.

P501 Fargið íláti hjá viðurkenndum móttökuaðila spilliefna í samræmi við staðbundnar/svæðisbundnar/landsbundnar/alþjóðlegar reglur.

P391 Safnið upp því sem hellist niður.

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)

Kenodin SD 900	Market area: EU
IodoSD 900	Market area: EU
IDip+ concentrate	Market area: EU
Jodkonzentrat 1:9	Market area: EU
Bühning Jodkonzentrat 1:9	Market area: EU
Wynnsan Iodine Conc dip 9-1	Market area: EU

Kenodin 900	Market area: EU
Dufa Dip	Market area: EU
Kenostart 900	Market area: EU
Iodin Teat Spray 900	Market area: EU
HCP Iodine Concentrate	Market area: EU
Maxi Subliem CP	Market area: EU
Subliem Konzentrat Plus	Market area: EU
Authorisation number (R4BP 3 asset reference number - National Authorisation) IS-0025089-0013 1-10	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	2,8
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active substance	68131-39-5	500-195-7	21
Phosphoric acid	Phosphoric acid	Non-active substance	7664-38-2	231-633-2	0
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO	Non-active substance	68439-46-3		0

1. Meta SPC administrative information

1.1. Meta SPC identifier

metaSPC 11: PT3 - RTU Teat disinfectants Iodine

1.2. Suffix to the authorisation number

1-11

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 - 0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active substance	68131-39-5	500-195-7	2,1 - 2,1
Phosphoric acid	Phosphoric acid	Non-active substance	7664-38-2	231-633-2	0 - 0
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO	Non-active substance	68439-46-3		0 - 0

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

Avoid release to the environment.

Dispose of contents to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Dispose of container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

4. Authorised use(s) of the meta SPC**4.1 Use description****Use 1 - PT3 – RTU teats disinfectant, Post-milking, Iodine****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

Post-milking teat disinfection of milk producing animals

Application method(s)

By dipping or spraying on teats
Detailed description:

/

Application rate(s) and frequencies

Application Rate: The product is ready to use.

Dilution (%):

Number and timing of application:

Apply 2 times per day when using a manual sprayer and 3 times per day when using a dip cup or a robot (automatic sprayer).

Category(ies) of users

Professional

Pack sizes and packaging material

1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L
HDPE

4.1.1 Use-specific instructions for use

See general directions for use.

4.1.2 Use-specific risk mitigation measures

See general directions for use.

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

See general directions for use.

4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use.

4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use.

5. General directions for use of the meta SPC

5.1. Instructions for use

Apply the product by dipping or by spraying:

- By dipping: Apply the product with a dip cup. Wash the dip cup with water after use.
- By spraying: Apply the product with a manual sprayer or with an automatic sprayer.

Do not prepare more fluid than necessary; assume 5 mL solution per cow per treatment. The product must be brought to a temperature above 20°C before use. The use of a dosing pump for filling the product into the application equipment is recommended.

The product should be used immediately after each milking, two times per day when using a manual sprayer or three times per day when using a dip cup or a robot (automatic sprayer). Ensure that the teat is completely covered to three quarters of its length. Let the product dry on teats. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the animal standing for at least 5 minutes).
Do not mix with other chemicals.

5.2. Risk mitigation measures

- For manual spraying application: Wear chemical resistant gloves (glove material to be specified by the authorisation holder within the product information).
- For manual dipping application: no PPE is necessary for safe use.
- If 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.

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

After eye contact: Rinse immediately with water.

After ingestion: Rinse mouth. Spit.

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

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

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

Keep only in the original container in a cool, well ventilated place. Keep container closed when not in use.
Protect from frost. Do not expose to temperatures >40°C.
The shelf-life of the products is 2 years.

6. Other information

The hazard- and precautionary statements shall be in Icelandic on the product label.

Hazard statements:

H412 Skaðlegt lífi í vatni, hefur langvinn áhrif.

Precautionary statements:

P273 Forðist losun út í umhverfi.

P501 Fargið innihaldi hjá viðurkenndum móttökuaðila spilliefna í samræmi við staðbundnar/svæðisbundnar/landsbundnar/alþjóðlegar reglur.

P501 Fargið íláti hjá viðurkenndum móttökuaðila spilliefna í samræmi við staðbundnar/svæðisbundnar/landsbundnar/alþjóðlegar reglur.

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)

Kenodin 2500	Market area: EU
Iodin Teat Dip 2500	Market area: EU
Jod 2500	Market area: EU
Authorisation number (R4BP 3 asset reference number - National Authorisation) IS-0025089-0014 1-11	

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
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active substance	68131-39-5	500-195-7	2,1

Phosphoric acid	Phosphoric acid	Non-active substance	7664-38-2	231-633-2	0
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO	Non-active substance	68439-46-3		0

1. Meta SPC administrative information

1.1. Meta SPC identifier

meta SPC 12: PT3 – RTU Teat disinfectants Iodine

1.2. Suffix to the authorisation number

1-12

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	0,3 - 0,5
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0 - 0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active substance	68131-39-5	500-195-7	2,1 - 2,9
Phosphoric acid	Phosphoric acid	Non-active substance	7664-38-2	231-633-2	0 - 0
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO	Non-active substance	68439-46-3		0 - 0

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

Avoid release to the environment.

Dispose of contents to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Dispose of container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - PT3- RTU Teat disinfectant, Post-milking, Iodine

Product type

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

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Target organism(s) (including development stage)

Scientific name:
Common name: Bacteria
Development stage:

Scientific name:
Common name: Yeasts
Development stage:

Scientific name:
Common name: Viruses
Development stage:

Field(s) of use

Indoor

Post-milking teat disinfection of milk producing animals

Application method(s)	By dipping or spraying on teats Detailed description: /
Application rate(s) and frequencies	Application Rate: The product is ready to use. Dilution (%): Number and timing of application: Apply 2 times per day for manual spraying and 3 times per day for manual dipping and spraying with robot.
Category(ies) of users	Professional
Pack sizes and packaging material	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE

4.1.1 Use-specific instructions for use

See general directions for use.

4.1.2 Use-specific risk mitigation measures

See general directions for use.

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

See general directions for use.

4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use.

4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use.

5. General directions for use of the meta SPC

5.1. Instructions for use

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

Apply the product by dipping or by spraying:

-By dipping: Apply the product with a dip cup. Wash the dip cup with water after use

-By spraying: Apply the product with a manual sprayer or with an automatic sprayer.

Do not prepare more fluid than necessary; assume 5 mL solution per cow per treatment.

The product should be used immediately after each milking: 2 times per day for manual spraying and 3 times per day for manual dipping and spraying with robot. Ensure that the teat is completely covered to three quarters of its length. Let the product dry on teats. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the animal standing for at least 5 minutes).

Do not mix with other chemicals.

5.2. Risk mitigation measures

- For manual spraying application: Wear chemical resistant gloves (glove material to be specified by the authorisation holder within the product information).

- For manual dipping application: no PPE is necessary for safe use.

- If 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.

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

After eye contact: Rinse immediately with water.

After ingestion: Rinse mouth. Spit.

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

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

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

Keep only in the original container in a cool, well-ventilated place. Keep container closed when not in use.

Protect from frost. Do not expose to temperatures >40°C.

The shelf-life of the products is 2 years.

6. Other information

The hazard- and precautionary statements shall be in Icelandic on the product label.

Hazard statements:

H412 Skaðlegt lífi í vatni, hefur langvinn áhrif.

Precautionary statements:

P273 Forðist losun út í umhverfi.

P501 Fargið innihaldi hjá viðurkenndum móttökuaðila spilliefna í samræmi við staðbundnar/svæðisbundnar/landsbundnar/alþjóðlegar reglur.

P501 Fargið íláti hjá viðurkenndum móttökuaðila spilliefna í samræmi við staðbundnar/svæðisbundnar/landsbundnar/alþjóðlegar reglur.

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)

Kenodin 5000	Market area: EU
IodoDip 5000	Market area: EU
JOD 5000	Market area: EU
Bio Tec Jodip 5000	Market area: EU
Bühning Jodfilmip-Super	Market area: EU
Iocid 5000	Market area: EU
Iod protect 5000 Film	Market area: EU
IOD protect 5000 Film	Market area: EU
Iocid	Market area: EU

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

Iodip+	Market area: EU
Protetos cua	Market area: EU
Iodin Teat Dip 5000	Market area: EU
IS-0025089-0015 1-12	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,5
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active substance	68131-39-5	500-195-7	2,9
Phosphoric acid	Phosphoric acid	Non-active substance	7664-38-2	231-633-2	0
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO	Non-active substance	68439-46-3		0

Trade name(s)

Kenodin SD 5000	Market area: EU
IodoSD 5000	Market area: EU
IODOSPRAY 5000	Market area: EU
Bio Tec Jodspray 5000	Market area: EU

IDip+ 5000	Market area: EU
Bühning Jodspray 5000	Market area: EU
Iod protect 5000 Sprüh	Market area: EU
Kenodin Film Spray	Market area: EU
IOD protect 5000 Sprüh	Market area: EU
Iodin Spray & Dip 5000	Market area: EU
Authorisation number (R4BP 3 asset reference number - National Authorisation) IS-0025089-0016 1-12	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,5
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active substance	68131-39-5	500-195-7	2,9
Phosphoric acid	Phosphoric acid	Non-active substance	7664-38-2	231-633-2	0
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO	Non-active substance	68439-46-3		0