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ANNEX

Summary of product characteristics for a biocidal product family

Iodine based products - CID LINES NV

Product type 3 – Veterinary hygiene (Disinfectants)

Product type 4 – Food and feed area (Disinfectants)

Authorisation number: EU-0022265-0000

R4BP asset number: EU-0022265-0000

PART I

FIRST INFORMATION LEVEL

1. **ADMINISTRATIVE INFORMATION**

1.1. Family name

Name		Iodine based products – CID LINES NV
1.2.	Product type(s)	
Produc	ct type(s)	PT03 – Veterinary hygiene (Disinfectants) PT04 – Food and feed area (Disinfectants)

1.3. **Authorisation holder**

Name and address of the	Name	CID LINES NV
authorisation holder	Address	Waterpoortstraat 2, 8900, Ieper, Belgium
Authorisation number	EU-0022265-0000	
R4BP asset number	EU-0022265-0000	
Date of the authorisation	3 September 2020	
Expiry date of the authorisation	31 August 2030	

1.4. Manufacturer(s) of the biocidal products

Name of manufacturer	CID LINES NV	
Address of manufacturer	Waterpoortstraat 2, 8900 Ieper Belgium	
Location of manufacturing sites	Waterpoortstraat 2, 8900 Ieper Belgium	

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

Active substance	Iodine		
Name of manufacturer	SQM S.A.		
Address of manufacturer	Los Militares, Piso 4, 4290 Santiago Chile		
Location of manufacturing sites	Nueva Victoria plant, 00 Pedro de Valdivia Chile		
Active substance	Iodine		
Name of manufacturer	Cosayach Nitratos S.A.		
Address of manufacturer	Amunategui 178, 00 Santiago Chile		
Location of manufacturing sites	Cala Cala, 00 Pozo Almonte Chile		
Active substance	Iodine		
Name of manufacturer	ACF Minera S.A.		
Address of manufacturer	San Martin No 499, 00 Iquique Chile		
Location of manufacturing sites	Lagunas mine, 00 Pozo Almonte Chile		
Active substance	Iodine		
Name of manufacturer	ISE Chemicals Corporation		
Address of manufacturer	3-1, Kyobashi 1-Chome, 104-0031 Tokyo Japan		
Location of manufacturing sites	3695 Kitaimaizumi, 299-3201 Oamishirasato city Japan		
Active substance	Polyvinylpyrrolidone iodine		
Name of manufacturer	ISP Chemicals LLC, Afiliate of Ashland Inc		
Address of 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	Polyvinylpyrrolidone iodine		
Name of manufacturer	Pantheon FZE (DMCC branch)		
Address of 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		

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2. PRODUCT FAMILY COMPOSITION AND FORMULATION

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

Common	IUPAC	Function	CAS	EC	Content (%	6)
name	name		number	number	Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0,0	3,0
Polyvinylpy iodine	rrolidone	Active Substance	25655-41-8		0,0	10,0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active Substance	68131-39-5	500-195-7	0,0	21,0
Phosphoric acid	Phosphoric acid	Non-active Substance	7664-38-2	231-633-2	0,0	30,0
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO	Non-active Substance	68439-46-3		0,0	12,5

2.2. Type(s) of formulation

Formulation(s)	SL – Soluble concentrate
	AL – Any other liquid

PART II

SECOND INFORMATION LEVEL - META SPC(S)

META SPC 1

1. META SPC 1 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 1 identifier

Identifier	metaSPC 1: PT3 Concentrated teat disinfectants Iodine

1.2. Suffix to the authorisation number

Number	1-1
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1.3. **Product type(s)**

Product type(s)	PT03 – Veterinary hygiene (Disinfectants)
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Status: Point in time view as at 07/08/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

2. META SPC 1 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 1

Common	IUPAC	Function	CAS	EC	Content (%	/o)
name	name		number	number	Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	1,5	1,5
Polyvinylpyi iodine	rolidone	Active Substance	25655-41-8		0,0	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	0,0
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO	Non-active Substance	68439-46-3		0,0	0,0

2.2. Type(s) of formulation of the meta SPC 1

Formulation(s)	SL – Soluble concentrate

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

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 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.

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4. **AUTHORISED USE(S) OF THE META SPC 1**

4.1. Use description

TABLE 1. 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)	Bacteria Yeasts Viruses
Field(s) of use	Indoor Post-milking teat disinfection of milk producing animals
Application method(s)	Manual or automatic spraying on teats
Application rate(s) and frequency	Dilute the product to a final concentration of 0,3 % (w/w) available iodine. 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	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 600 L, 1000 L 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⁽¹⁾OF THE META SPC 1

Status: Point in time view as at 07/08/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

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 1 L).

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.

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Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

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**

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1

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

Trade name(s)	Kenodin SD 400 IodoSD 400	-
	Velvet Concentrate	
	Wynnsan Iodine 3 – 1 conc Iodin Teat Spray 400	

AuthorisationEU-0022265-0001 1-1

number

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	1,5
Polyvinylpyr iodine	rolidone	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

META SPC 2

1. META SPC 2 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 2 identifier

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

1.2. Suffix to the authorisation number

1.3. **Product type(s)**

Status: Point in time view as at 07/08/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

Product type(s)	PT03 – Veterinary hygiene (Disinfectants)

2. META SPC 2 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 2

Common	IUPAC	Function	CAS	EC	Content ((%)
name	name		number	number	Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0,3	0,3
Polyvinylpy iodine	rolidone	Active Substance	25655-41-8		0,0	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	0,0
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO	Non-active Substance	68439-46-3		0,0	0,0

2.2. Type(s) of formulation of the meta SPC 2

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

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 2

4.1. Use description

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TABLE 2. 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)	Bacteria Yeasts Viruses
Field(s) of use	Indoor Post-milking teat disinfection of milk producing animals
Application method(s)	By dipping or spraying on teats
Application rate(s) and frequency	The product is ready to use. 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	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 600 L, 1000 L 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⁽²⁾OF THE META SPC 2

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.

Status: Point in time view as at 07/08/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

— 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**

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 2

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

Status: Point in time view as at 07/08/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

Trade name(s)

IodoDip 3000

Bio Tec Jodip 3000

Recoïode

Stalosan Io Dip

Stalosan Super Dip

Velvet High Visco

Bühning Joddip 3000

Kenodin

Wynnsan trikill RTU

Wynnsan Iodine RTU teat dip

Wynnsan Iodine dip RTU

Iocid

Iodip+

Wynngold Iodine Dip

Pezerk iv plus

Iod protect 3000 Film

Seivit® Iode 3000

Kenostart

GAHERYOD

Kenodin 3000

Iodin Teat Dip 3000

Iod 3000 dip

Iodoschutz dip

Ioschutz dip

Iodocoop dip

Iodotech dip

Iodactiv' dip

Iododip

MIROX Dip Jod

HCP Iodine Dip

Agib Jodium Dip

Jod 3000

Iod dip

Iode 3000

Iodoschutz

Coopjod

Coopiode

Coopiode épais

Semex jod

Iodotech

Iododip green

Iodip bio

Iododip bio

Iodactive épais

Iodactiv

Iodoactiv'

Bayley's Premier Iodine Teat Dip

Pearce Premier Iodine Teat Dip

Diamond 1:3 Concentrate Iodine Post

Dip Spray

JODOCARE

KENOSTART DYP

STREPTOFIT

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Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

Iodall Film

AuthorisationEU-0022265-0002 1-2

number

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,3
Polyvinylpyr iodine	rolidone	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

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

•		
Trade	Kenodin Film	
name(s)	IodoFilm	
. ,	Wynnsan Iofilm teat dip	
	Kenodin Film Extra	
	Wynngold Film	
	Wynnsan trikill film teat dip	
	Kenodin Film Soft	
	Iocid Film	
	TOP Film	
	Seivit® Iode Gel	
	IOD protect 3000 Film	
	Iodin Film Teat Dip 3000	
	Iodin Barrier Teat Dip 3000	
	Iodin Film Teat Dip	
	Iodin Barrier Teat Dip	
	Iod 3000 film	
	Iodoschutz film	
	Ioschutz film	
	Iodocoop film	
	Iodotech film	
	Iodactiv' film	
	Iodofilm	
	HCP Iodine Film	
	Iod 3000 film	
	Coopjod film	
	Coopiode film	
	Iodocoop film	
	Semex jod film	
	Iodofilm	
	Iodofilm bio	
	Iofilm bio	
	Iodactive film	
	Iodactiv film	

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Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

Iodactiv'	film
SCUDO	

AuthorisationEU-0022265-0003 1-2

number

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,3
Polyvinylpyi iodine	rolidone	Active Substance	25655-41-8		0,0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active Substance	68131-39-5	500-195-7	2,9

META SPC 3

1. META SPC 3 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 3 identifier

Identifier	metaSPC 3: PT3-RTU Udder disinfectants	
	Iodine	

1.2. Suffix to the authorisation number

Number	1-3

1.3. **Product type(s)**

Product type(s)	PT03 – Veterinary hygiene (Disinfectants)
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2. META SPC 3 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 3

Common	IUPAC	Function	CAS	EC	Content (%	(o)
name	name		number	number	Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0,3	0,99
Polyvinylpyi iodine	rolidone	Active Substance	25655-41-8		0,0	0,0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active Substance	68131-39-5	500-195-7	2,17	2,95

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Status: Point in time view as at 07/08/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

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

2.2. Type(s) of formulation of the meta SPC 3

Formulation(s)	AL – Any other liquid
· /	1

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 3

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 3

4.1. Use description

TABLE 3. USE # 1 – 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)	Bacteria Yeasts
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)	Spraying
Application rate(s) and frequency	The product is ready to use. Apply to:

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	 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	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 600 L, 1000 L 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⁽³⁾OF THE META SPC 3

5.1. **Instructions for use** *For disinfection of the skin:*

· ·

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:

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

- 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.

Status: Point in time view as at 07/08/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

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**

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 3

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

Trade	Animal Skin Disinfectant	
name(s)	Dermades 3000	
	Iodin Skin Disinfectant	

AuthorisationEU-0022265-0004 1-3 number

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,3

Document Generated: 2024-08-15

Status: Point in time view as at 07/08/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

Polyvinylpyr iodine	rolidone	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

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

Trade name(s)	Dermades Animal skin disinfectant 1 %	
name(s)	Dermades Strong	
	Iodin Skin Disinfectant Strong	

AuthorisationEU-0022265-0005 1-3

number

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,99
Polyvinylpyr iodine	rolidone	Active Substance	25655-41-8		0,0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active Substance	68131-39-5	500-195-7	2,95

META SPC 4

1. META SPC 4 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 4 identifier

Identifier	metaSPC 4: PT3 – RTU Udder and Teat
	disinfectants Iodine

1.2. Suffix to the authorisation number

Number	1-4
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1.3. **Product type(s)**

Product type(s) PT03 – Veterinary hygiene (Disinfectants)

2. META SPC 4 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 4

Status: Point in time view as at 07/08/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

Common	IUPAC	Function	CAS	EC	Content (0%)
name	name		number	number	Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0,3	0,3
Polyvinylpy iodine	rrolidone	Active Substance	25655-41-8		0,0	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	0,0
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO	Non-active Substance	68439-46-3		0,0	0,0

2.2. Type(s) of formulation of the meta SPC 4

Formulation(s)	AL – Any other liquid
	1

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 4

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

4.1. Use description

TABLE 4. 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)	Bacteria Yeasts Viruses

Document Generated: 2024-08-15

	Status: Point in time view as at 07/08/2020.
Changes to legislation:	There are currently no known outstanding effects for the Commission
Implementing Page	ation (FII) 2020/1197 ANNEY (See and of Dogument for details)

Field(s) of use	Indoor Ready to use teat disinfectant to be used post milking on milk producing animals.
Application method(s)	Dipping or spraying
Application rate(s) and frequency	The product is ready to use. 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	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 600 L, 1000 L HDPE

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

ANNEX PART II
Document Generated: 2024-08-15

Status: Point in time view as at 07/08/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

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

TABLE 5. 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)	Yeasts Bacteria		
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)	Application on animal skin: by spraying		
Application rate(s) and frequency	The product is ready to use. 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	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 600 L, 1000 L HDPE		

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).

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Status: Point in time view as at 07/08/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

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⁽⁴⁾OF THE META SPC 4

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

Status: Point in time view as at 07/08/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

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**

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 4

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

F	
Trade	Kenodin SD
name(s)	IodoSD 3000
. ,	Bio Tec Jodspray 3000
	Q Farm Iodine Des
	ANRO – Euterpflege Dip
	Stalosan Io Spray
	Stalosan Super Spray
	IDip+
	Bühning Jodspray 3000
	Velvet RTU
	Wynnsan trikill spray
	Wynnsan Iodine spray RTU
	Wynngold Iodine Dip and spray
	Pezerk IL
	Iod protect 3000 Sprüh
	Seivit® Iode Spray
	IOD protect 3000 Sprüh
	Kenodin SprayFilm
	Iodo SP
	Kenostart SD
	GAHERYOD SPRAY
	Iodin Teat & Skin 3000
	Iod 3000 sprüh
	Iodoschutz sprüh
	Ioschutz sprüh
	Iodocoop sprüh
	Iodotech sprüh
	Iodactiv' sprüh
	Iodosprüh
	MIROX Spray Jod
	HCP Iodine SD
	Agib Jodium Spray
	Jod 3000 spray
	Iod sprüh
	Coopjod
	Coopiode spray
	Iodocoop spray
	Semex jod spray
	Iododip spray

Document Generated: 2024-08-15

Status: Point in time view as at 07/08/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

Iododip spray green
Iodospray Bio
Iospray bio
Iodactive spray
Iodactiv spray
Iodactiv' spray
Ark Iodine S+D
Agrihealth Iodine SD
AGRO LOGIC JODOCARE SPRAY
IODACTIVE

AuthorisationEU-0022265-0006 1-4

number

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,3
Polyvinylpy iodine	rolidone	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

META SPC 5

1. META SPC 5 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 5 identifier

Identifier	metaSPC 5: PT3 – RTU Teat disinfectants PVP-Iodine
	1 / 1 100,1110

1.2. Suffix to the authorisation number

Number	1-5
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1.3. **Product type(s)**

2. META SPC 5 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 5

Common	IUPAC	Function	CAS	EC	Content	(%)
name	name		number	number	Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0,0	0,0

Document Generated: 2024-08-15

Status: Point in time view as at 07/08/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

Polyvinylpyn iodine	rolidone	Active Substance	25655-41-8		3,0	3,0
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	0,0
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO	Non-active Substance	68439-46-3		0,0	0,0

2.2. Type(s) of formulation of the meta SPC 5

Formulation(s)	AI Any other liquid
romination(s)	AL – Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 5

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 5

4.1. Use description

TABLE 6. 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)	Bacteria Yeasts Viruses
Field(s) of use	Indoor Post-milking disinfection on teats of milk producing animals
Application method(s)	Dipping or spraying

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Status: Point in time view as at 07/08/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

Application rate(s) and frequency	The product is ready to use. 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	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 600 L, 1000 L 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⁽⁵⁾OF THE META SPC 5

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

Status: Point in time view as at 07/08/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

- 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

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**

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 5

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

Trade name(s)	Iodo PVP Iodin Teat D	ip 3000 PVP				
Authorisation number	nEU-0022265	5-0007 1-5				
Common name	IUPAC name	Function	CAS numb	er	EC number	Content (%)
Iodine		Active Substance	7553-56-2		231-442-4	0,0
Polyvinylpyi iodine	rolidone	Active Substance	25655-41-8			3,0

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Status: Point in time view as at 07/08/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

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

Trade name(s), authorisation number and specific composition of each individual 7.2. product

Trade name(s)	Iodo SD PVP Iodin Teat Spray & Dip 3000 PVP		
AuthorisationEU-0022265-0008 1-5			

number

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,0
Polyvinylpyr iodine	rolidone	Active Substance	25655-41-8		3,0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active Substance	68131-39-5	500-195-7	2,5

META SPC 6

1. META SPC 6 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 6 identifier

Identifier	metaSPC 6: PT3- RTU Udder disinfectants
	PVP-Iodine

Suffix to the authorisation number 1.2.

Number	1-6
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1.3. **Product type(s)**

Product type(s)	PT03 – Veterinary hygiene (Disinfectants)
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2. **META SPC 6 COMPOSITION**

2.1. Qualitative and quantitative information on the composition of the meta SPC 6

Common	IUPAC	Function	CAS	EC	Content (%	<u>(o)</u>
name	name		number	number	Min	Max

Document Generated: 2024-08-15

Status: Point in time view as at 07/08/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

Iodine		Active Substance	7553-56-2	231-442-4	0,0	0,0
Polyvinylpy iodine	rolidone	Active Substance	25655-41-8		10,0	10,0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active Substance	68131-39-5	500-195-7	2,0	2,0
Phosphoric acid	Phosphoric acid	Non-active Substance	7664-38-2	231-633-2	0,0	0,0
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO	Non-active Substance	68439-46-3		0,0	0,0

2.2. Type(s) of formulation of the meta SPC 6

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 6

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 6

4.1. Use description

TABLE 7. USE # 1 – PT3- RTU UDDER DISINFECTANT PVP-IODINE

Product type	PT03 – Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	

ANNEX PART II Document Generated: 2024-08-15

Status: Point in time view as at 07/08/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

Target organism(s) (including development stage)	Bacteria Yeasts
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)	Spraying
Application rate(s) and frequency	The product is ready to use. 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	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 600 L, 1000 L 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.

Status: Point in time view as at 07/08/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

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⁽⁶⁾OF THE META SPC 6

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**

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 6

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Status: Point in time view as at 07/08/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

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

Trade name(s)	Dermades PVP Wynngold 10 % Iodine Solution	
	Iodin Skin Disinfectant PVP	

AuthorisationEU-0022265-0009 1-6

number

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,0
Polyvinylpyr iodine	rolidone	Active Substance	25655-41-8		10,0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active Substance	68131-39-5	500-195-7	2,0

META SPC 7

1. META SPC 7 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 7 identifier

metaSPC 7: PT3 and PT4 – Concentrated
Surface disinfectants Iodine

1.2. Suffix to the authorisation number

Number	1-7

1.3. **Product type(s)**

Product type(s)	PT03 – Veterinary hygiene (Disinfectants) PT04 – Food and feed area (Disinfectants)
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2. META SPC 7 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 7

Common	IUPAC	Function	CAS	EC	Content (%	6)
name	name		number	number	Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	1,8	2,49

Document Generated: 2024-08-15

Status: Point in time view as at 07/08/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

Polyvinylpyi iodine	rolidone	Active Substance	25655-41-8		0,0	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	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 7

Formulation(s)	SL – Soluble concentrate

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 7

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.

4. **AUTHORISED USE(S) OF THE META SPC 7**

4.1. Use description

Document Generated: 2024-08-15

Status: Point in time view as at 07/08/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

TABLE 8. 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)	Bacteria Yeasts
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
Application rate(s) and frequency	Assume 0,04 L solution for every square meter that has to be disinfected. Bactericidal and yeasticidal activity: 0,015 % iodine Frequency is once per day.
Category(ies) of users	Professional
Pack sizes and packaging material	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 600 L, 1000 L 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 ^a	Dilution of the product	Contact time
Bactericidal and yeasticidal activity	1,5 % (15 ml product, add water up to 1 L)	15 min

a 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.

Status: Point in time view as at 07/08/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

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

TABLE 9. 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)	Bacteria Yeasts Viruses	
Field(s) of use	Indoor Non-porous surface disinfection in veterinary field	
Application method(s)	By spraying with a manual or an automatic sprayer	
Application rate(s) and frequency	Assume 0,04 L solution for every square meter that has to be disinfected. Bactericidal and yeasticidal activity: 0,025 % in-use iodine Virucidal activity: 0,035 % in-use iodine	
Category(ies) of users	Professional	

Document Generated: 2024-08-15

Status: Point in time view as at 07/08/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

600	L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 600 L, 1000 L HDPE
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4.2.1. Use-specific instructions for use

Use in veterinary field (PT3), surface disinfection:

The 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 ^a	Dilution of the product	Contact time
Bactericidal and yeasticidal activity	1 % (10ml product, add water up to 1 L)	30 min
Virucidal activity	1,4% (14ml product, add water up to 1 L)	30 min

a 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.

4.2.2. *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 shll 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.

ANNEX PART II Document Generated: 2024-08-15

Status: Point in time view as at 07/08/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

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⁽⁷⁾OF THE META SPC 7

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.

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Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

6. **OTHER INFORMATION**

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 7

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

Trade	Dodin 20	
name(s)	Iodo 20	
	Bio Tec Joddesinfektion	
	Dufa dine 1,8 %	
	Alfasan super disinfectant	
	Iodes	
	Streptoclean	
	Iodin Surface Disinfectant 1,8 %	
	IODINE	

AuthorisationEU-0022265-0010 1-7

number

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	1,8
Polyvinylpyi iodine	rolidone	Active Substance	25655-41-8		0,0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active Substance	68131-39-5	500-195-7	5,29
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO	Non-active Substance	68439-46-3		5,0

META SPC 8

1. META SPC 8 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 8 identifier

Identifier	metaSPC 8: PT3 and PT4 – Concentrated
	Surface disinfectants Iodine

1.2. Suffix to the authorisation number

Number	1-8
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1.3. **Product type(s)**

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Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

Product type(s)	PT03 – Veterinary hygiene (Disinfectants)
	PT04 – Food and feed area (Disinfectants)

2. META SPC 8 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 8

Common	IUPAC	Function	CAS	EC	Content (%	(o)
name	name		number	number	Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	2,5	3,0
Polyvinylpyr iodine	rolidone	Active Substance	25655-41-8		0,0	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	5,0	12,0
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 8

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 8

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.

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Status: Point in time view as at 07/08/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

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 8

4.1. Use description

TABLE 10. 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)	Bacteria Yeasts
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
Application rate(s) and frequency	Assume 0,04 L solution for every square meter that has to be disinfected. Bactericidal and yeasticidal activity: 0,015 % iodine Daily use
Category(ies) of users	Professional
Pack sizes and packaging material	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 600 L, 1000 L 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 table below).
- Clean the surfaces thoroughly with a detergent before disinfection. Rinse with clean water and remove surplus water.

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Status: Point in time view as at 07/08/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

- 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.
- 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 ^a	Dilution of the product	Contact time
Bactericidal and yeasticidal activity	0,5 % (5 ml product, add water up to 1 L)	15 min

a 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

TABLE 11. USE # 2 – PT3 – CONCENTRATED SURFACE DISINFECTANT FOR VETERINARY USE, IODINE

Product type	PT03 – Veterinary hygiene (Disinfectants)

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Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

Where relevant, an exact description of the authorised use	_
Target organism(s) (including development stage)	Bacteria Yeasts Viruses
Field(s) of use	Indoor Non-porous surface disinfection in veterinary field
Application method(s)	By spraying with a manual or an automatic sprayer
Application rate(s) and frequency	Assume 0,04 L solution for every square meter that has to be disinfected. Bactericidal and yeasticidal activity: 0,025 % in-use iodine Virucidal activity: 0,035 % in-use iodine
Category(ies) of users	Professional
Pack sizes and packaging material	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 600 L, 1000 L HDPE

4.2.1. Use-specific instructions for use

Use in veterinary field (PT3), surface disinfection:

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 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.

Example for a product containing 2,5 % iodine ^a	Dilution of the product	Contact time
Bactericidal and yeasticidal activity	1 % (10ml product, add water up to 1 L)	30 min
Virucidal activity	1,4 % (14ml product, add water up to 1 L)	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.

ANNEX PART II Document Generated: 2024-08-15

Status: Point in time view as at 07/08/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

- 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⁽⁸⁾OF THE META SPC 8

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.

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Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

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**

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 8

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

Trade	Iocid 30	
name(s)	Iodo 30	
	Dufa dine	
	Iodin Surface Disinfectant 2,8 %	

AuthorisationEU-0022265-0011 1-8

number

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

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Status: Point in time view as at 07/08/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

Alcohol	Alcohol	Non-active	68439-46-3	12,5
C9-11+6	C9-11+6	Substance		
EO	EO			

META SPC 9

1. META SPC 9 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 9 identifier

T.1	CDC O DTA C
Identifier	metaSPC 9: PT4 – Concentrated CIP
	disinfectants Iodine

1.2. Suffix to the authorisation number

Number	1-9
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1.3. **Product type(s)**

Product type(s)	PT04 – Food and feed area (Disinfectants)

2. META SPC 9 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 9

Common	IUPAC	Function	CAS	EC	Content ((%)
name	name		number	number	Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0,5	0,99
Polyvinylpyriodine	rolidone	Active Substance	25655-41-8		0,0	0,0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active Substance	68131-39-5	500-195-7	0,0	0,0
Phosphoric acid	Phosphoric acid	Non-active Substance	7664-38-2	231-633-2	25,0	30,0
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO	Non-active Substance	68439-46-3		0,0	0,0

2.2. Type(s) of formulation of the meta SPC 9

Formulation(s)	SL – Soluble concentrate
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 9

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Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

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 9

4.1. Use description

TABLE 12. 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)	Bacteria Yeasts
Field(s) of use	Indoor Cleaning in place (CIP) disinfection for milking equipment and CIP installations in food industry
Application method(s)	CIP disinfection
Application rate(s) and frequency	Apply the product in the automatic system with an end concentration of 0,00125 % available iodine

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to legislation: There are currently no known outstanding effects for the Co

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

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

4.1.1. *Use-specific instructions for use*

See general instructions.

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⁽⁹⁾OF THE META SPC 9

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 ^a	Dilution of the product	Contact time
Bactericidal and yeasticidal activity	0,25 % (2,5 ml product, add water up to 1 L)	15 min

a 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 0,5 to 0,99 % it is not possible to indicte 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

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Status: Point in time view as at 07/08/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

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**

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 9

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

Trade	Iodo CIP	
name(s)	Iocip	
	Bio Tec Jodreiniger	
	JODOPHOS SUPER 4001	
	Bühning Jodreiniger	
	Wynnsan Ice bank Tank Cleaner	
	Bulk Tank Sanitizer	

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Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

Iodin	CIP	Disinfectant
IUUIII	\sim 11	Disiniculant

AuthorisationEU-0022265-0012 1-9

number

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,5
Polyvinylpyi iodine	rolidone	Active Substance	25655-41-8		0,0
Phosphoric acid	Phosphoric acid	Non-active Substance	7664-38-2	231-633-2	26,3

META SPC 10

1. META SPC 10 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 10 identifier

Identifier	metaSPC 10: PT3 – Concentrated teat
	disinfectants Iodine

1.2. Suffix to the authorisation number

Number	1-10

1.3. **Product type(s)**

Product type(s)	PT03 – Veterinary hygiene (Disinfectants)
110 date () p • (5)	1 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0

2. META SPC 10 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 10

Common	IUPAC	Function	CAS	EC	Content (%	6)
name	name		number	number	Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	2,8	2,8
Polyvinylpyi iodine	rolidone	Active Substance	25655-41-8		0,0	0,0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active Substance	68131-39-5	500-195-7	21,0	21,0
Phosphoric acid	Phosphoric acid	Non-active Substance	7664-38-2	231-633-2	0,0	0,0

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Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

Alcohol	Alcohol	Non-active	68439-46-3	0,0	0,0
C9-11+6	C9-11+6	Substance			
EO	EO				

2.2. Type(s) of formulation of the meta SPC 10

Formulation(s)	SL – Soluble concentrate

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 10

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 10

4.1. Use description

TABLE 13. 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)	Bacteria Yeasts Viruses

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Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

Field(s) of use	Indoor Post-milking teat disinfection of milk producing animals
Application method(s)	By spraying with a manual sprayer or with an automatic sprayer on teats.
Application rate(s) and frequency	The product must be diluted before use in order to allow a final concentration of iodine of 0,3 %. Apply 2 times per day by using a manual sprayer and 3 times per day when using a robot (or automatic sprayer).
Category(ies) of users	Professional
Pack sizes and packaging material	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 600 L, 1000 L 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⁽¹⁰⁾OF THE META SPC 10

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 1 L).

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.

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Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

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.

Status: Point in time view as at 07/08/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META **SPC 10**

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

Trade name(s)	Kenodin SD 900 IodoSD 900 IDip+ concentrate Jodkonzentrat 1:9 Bühning Jodkonzentrat 1:9
	Wynnsan Iodine Conc dip 9-1
	Kenodin 900
	Dufa Dip
	Kenostart 900
	Iodin Teat Spray 900
	HCP Iodine Concentrate
	Maxi Subliem CP
	Subliem Koncentrat Plus

AuthorisationEU-0022265-0013 1-10 number

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	2,8
Polyvinylpyr iodine	rolidone	Active Substance	25655-41-8		0,0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active Substance	68131-39-5	500-195-7	21,0

META SPC 11

1. META SPC 11 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 11 identifier

Identifier	metaSPC 11: PT3 – RTU Teat disinfectants Iodine

1.2. Suffix to the authorisation number

Number	1-11

1.3. Product type(s)

Product type(s)	PT03 – Veterinary hygiene (Disinfectants)
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Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

2. META SPC 11 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 11

Common IUPAC		Function CAS		EC	Content (%)	
name	name		number	number	Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0,25	0,25
Polyvinylpy iodine	rolidone	Active Substance	25655-41-8		0,0	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	0,0
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO	Non-active Substance	68439-46-3		0,0	0,0

2.2. Type(s) of formulation of the meta SPC 11

Formulation(s)	AL – Any other liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 11

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 11

4.1. Use description

TABLE 14. USE # 1 – PT3 – RTU TEATS DISINFECTANT, POST-MILKING, IODINE

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Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Post-milking teat disinfection of milk producing animals
Application method(s)	By dipping or spraying on teats
Application rate(s) and frequency	The product is ready to use. 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	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 600 L, 1000 L HDPE

4.1.1. *Use-specific instructions for use*

See general instructions.

4.1.2. Use-specific risk mitigation measures

See general instructions.

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 instructions.

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

See general instructions.

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 instructions.

5. GENERAL DIRECTIONS FOR USE⁽¹¹⁾OF THE META SPC 11

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.

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Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

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**

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 11

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

Trade	Kenodin 2500		
name(s)	Iodin Teat Dip 2500		
	Jod 2500		

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Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

AuthorisationEU-0022265-0014 1-11

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Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,25
Polyvinylpyr iodine	rolidone	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

META SPC 12

1. META SPC 12 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 12 identifier

Identifier	meta SPC 12: PT3 – RTU Teat disinfectants Iodine

1.2. Suffix to the authorisation number

Number	1-12
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1.3. **Product type(s)**

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Product type(s)	PT03 – Veterinary hygiene (Disinfectants)

2. META SPC 12 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 12

Common	IUPAC	Function	CAS	EC	Content (%	(6)
name	name		number	number	Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0,3	0,5
Polyvinylpyi iodine	rolidone	Active Substance	25655-41-8		0,0	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	0,0

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Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

Alcohol	Alcohol	Non-active	68439-46-3	0,0	0,0
C9-11+6	C9-11+6	Substance			
EO	EO				

2.2. Type(s) of formulation of the meta SPC 12

AL – Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 12

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 12

4.1. Use description

TABLE 15. 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)	Bacteria Yeasts Viruses
Field(s) of use	Indoor Post-milking teat disinfection of milk producing animals
Application method(s)	By dipping or spraying on teats
Application rate(s) and frequency	The product is ready to use. 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	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 600 L, 1000 L

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Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

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⁽¹²⁾OF THE META SPC 12

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.

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Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

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**

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 12

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

Trade name(s)	Kenodin 5000 IodoDip 5000 JOD 5000 Bio Tec Jodip 5000 Bühning Jodfilmdip-Super Iocid 5000 Iod protect 5000 Film IOD protect 5000 Film

AuthorisationEU-0022265-0015 1-12 number

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,5
Polyvinylpyi iodine	rolidone	Active Substance	25655-41-8		0,0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active Substance	68131-39-5	500-195-7	2,9

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Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX. (See end of Document for details)

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

Trade	Kenodin SD 5000
name(s)	IodoSD 5000 IODOSPRAY 5000
	Bio Tec Jodspray 5000 IDip+ 5000
	Bühning Jodspray 5000 Iod protect 5000 Sprüh
	Kenodin Film Spray IOD protect 5000 Sprüh Iodin Spray & Dip 5000

AuthorisationEU-0022265-0016 1-12

number

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,5
Polyvinylpyr iodine	rolidone	Active Substance	25655-41-8		0,0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active Substance	68131-39-5	500-195-7	2,9

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- (1) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 1.
- (2) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 2.
- (3) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 3.
- (4) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 4.
- (5) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 5.
- (6) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 6.
- (7) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 7.
- (8) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 8.
- (9) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 9.
- (10) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 10.
- (11) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 11.
- (12) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 12.

Status:

Point in time view as at 07/08/2020.

Changes to legislation:

There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, ANNEX.