Summary of product characteristics for a biocidal product family

Family name: Iodine based products - CID LINES NV

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

PT04 - Food and feed area (Disinfectants)

Authorisation number: EU-0022265-0000

R4BP 3 asset reference number: EU-0022265-0000

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Part I.- First information level

1. Administrative information

1.1. Family name

Iodine based products - CID LINES NV

1.2. Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

PT04 - Food and feed area (Disinfectants)

1.3. Authorisation holder

Name and address of the authorisation holder

Name	CID LINES NV
Address	Waterpoortstraat 2 8900 leper Belgium
EU-0022265-0000	

Authorisation number

R4BP 3 asset reference number

Date of the authorisation

Expiry date of the authorisation

EU-	0022	2265	5-00	00

03/09/2020

31/08/2030

1.4. Manufacturer(s) of the biocidal products

Name of the manufacturer

CID LINES NV

Address of the manufacturer

Waterpoortstraat 2 8900 leper Belgium

Location of manufacturing sites

Waterpoortstraat 2 8900 leper Belgium

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

Active substance	1319 - Iodine		
Name of the manufacturer	SQM S.A.		
Address of the manufacturer	Los Militares, Piso 4 4290 Santiago Chile		
Location of manufacturing sites	lueva Victoria plant 00 Pedro de Valdivia Chile		
Active substance	1319 - Iodine		
Name of the manufacturer	Cosayach Nitratos S.A.		
Address of the manufacturer	Amunategui 178 00 Santiago Chile		
Location of manufacturing sites	Cala Cala 00 Pozo Almonte Chile		
Active substance	1319 - Iodine		
Name of the manufacturer	ACF Minera S.A.		
Address of the manufacturer	San Martin No 499 00 Iquique Chile		
Location of manufacturing sites	Lagunas mine 00 Pozo Almonte Chile		

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

2. Product family composition and formulation

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

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

2.2. Type(s) of formulation

SL - Soluble concentrate

AL - Any other liquid

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

1. Meta SPC administrative information

1.1. Meta SPC identifier

metaSPC 1: PT3 Concentrated teat disinfectants Iodine

1.2. Suffix to the authorisation number

1-1

1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

2. Meta SPC composition

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		Active Substance	7553-56-2	231-442-4	1,5 - 1,5
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0 - 0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated		68131-39-5	500-195-7	12,05 - 12,05
Phosphoric acid	Phosphoric acid		7664-38-2	231-633-2	0 - 0

Alcohol C9-11 + 6 EO Alcohol C9-11 + 6 EO 68439-46-3 0 - 0

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

Formulation(s)

SL - Soluble concentrate

3. Hazard and precautionary statements of the meta SPC

Hazard statements

Causes serious eye damage.

Harmful to aquatic life with long lasting effects.

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

Precautionary statements

Wear eye protection.

Wear protective clothing.

Wear protective gloves.

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

Immediately call a doctor, a poison center.

Avoid release to the environment.

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

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

4. Authorised use(s) of the meta SPC

4.1 Use description

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

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

Target organism(s) (including development stage)	Scientific name: Common name: Bacteria Development stage: Scientific name: Common name: Yeasts Development stage: Scientific name: Common name: Viruses Development stage:			
Field(s) of use	Indoor Post-milking teat disinfection of milk producing animals			
Application method(s)	Manual or automatic spraying on teats - -			
Application rate(s) and frequencies	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	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE (High Density Polyethylene)			
4.1.1 Use-specific instructions for use				
See general directions for use.				
4.1.2 Use-specific risk mitigation measures				
See general directions for use.				

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

See general directions for use.			

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

See general	directions	for	use.
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4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

	See genera	directions	for	use
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5. General directions for use of the meta SPC

5.1. Instructions for use

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

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

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

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

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

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

5.2. Risk mitigation measures

- For mixing and loading of the product: Wear chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) and eye/face protection.
- For manual spraying application: Wear chemical resistant gloves (glove material to be specified by the authorisation holder within the product information).
- If a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.
 - · Keep out of reach of children.

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

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

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

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

Have product container or label at hand.

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

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

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

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

6. Other information		

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

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

Trade name(s)

Kenodin SD 400	Market area: EU
lodoSD 400	Market area: EU
Velvet Concentrate	Market area: EU

Wynnsan Iodine 3 - 1 conc	Market area: EU
Iodin Teat Spray 400	Market area: EU
EU-0022265-0001 1-1	

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

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

1. Meta SPC administrative information

1.1. Meta SPC identifier

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

1.2. Suffix to the authorisation number

1-2

1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

2. Meta SPC composition

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		Active Substance	7553-56-2	231-442-4	0,3 - 0,3
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0 - 0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated		68131-39-5	500-195-7	2,1 - 2,9
Phosphoric acid	Phosphoric acid		7664-38-2	231-633-2	0 - 0
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO		68439-46-3		0 - 0

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

Formulation(s)

AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

Hazard statements

Harmful to aquatic life with long lasting effects.

Precautionary statements

Avoid release to the environment.

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

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

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - PT3- RTU Teat disinfectant, post-milking, lodine

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Common name: Bacteria Development stage:
	Scientific name: Common name: Yeasts Development stage:
	Scientific name: Common name: Viruses Development stage:
Field(s) of use	Indoor
	Post-milking teat disinfection of milk producing animals
Application method(s)	By dipping or spraying on teats -
Application rate(s) and frequencies	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	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE

4.1.1 Use-specific instructions for use
See general directions for use.
4.1.2 Use-specific risk mitigation measures
See general directions for use.
4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment
See general directions for use.
4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging
See general directions for use.
4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage
See general directions for use.
5. General directions for use of the meta SPC
5.1. Instructions for use

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

Apply the product by dipping or by spraying:

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

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

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

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

Do not mix with other chemicals.

5.2. Risk mitigation measures

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

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

After eye contact: Rinse immediately with water.

After ingestion: Rinse mouth. Spit.

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

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

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

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

6. Other information

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

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

Trade name(s)

lodoDip 3000	Market area: EU
Bio Tec Jodip 3000	Market area: EU
Recoïode	Market area: EU
Stalosan Io Dip	Market area: EU
Stalosan Super Dip	Market area: EU
Velvet High Visco	Market area: EU
Bühning Joddip 3000	Market area: EU
Kenodin	Market area: EU
Wynnsan trikill RTU	Market area: EU
Wynnsan Iodine RTU teat dip	Market area: EU
Wynnsan Iodine dip RTU	Market area: EU
locid	Market area: EU
lodip+	Market area: EU
Wynngold lodine Dip	Market area: EU

Pezerk iv plus	Market area: EU
lod protect 3000 Film	Market area: EU
Seivit® lode 3000	Market area: EU
Kenostart	Market area: EU
GAHERYOD	Market area: EU
Kenodin 3000	Market area: EU
Iodin Teat Dip 3000	Market area: EU
lod 3000 dip	Market area: EU
lodoschutz dip	Market area: EU
loschutz dip	Market area: EU
lodocoop dip	Market area: EU
lodotech dip	Market area: EU
lodactiv' dip	Market area: EU
lododip	Market area: EU
MIROX Dip Jod	Market area: EU
HCP lodine Dip	Market area: EU

Agib Jodium Dip	Market area: EU
Jod 3000	Market area: EU
lod dip	Market area: EU
lode 3000	Market area: EU
lodoschutz	Market area: EU
Coopjod	Market area: EU
Coopiode	Market area: EU
Coopiode épais	Market area: EU
Semex jod	Market area: EU
lodotech	Market area: EU
lododip green	Market area: EU
lodip bio	Market area: EU
lododip bio	Market area: EU
lodactive épais	Market area: EU
Iodactiv	Market area: EU
Iodoactiv'	Market area: EU

Bayley's Premier Iodine Teat Dip	Market area: EU
Pearce Premier Iodine Teat Dip	Market area: EU
Diamond 1:3 Concentrate Iodine Post Dip Spray	Market area: EU
JODOCARE	Market area: EU
KENOSTART DYP	Market area: EU
STREPTOFIT	Market area: EU
Iodall Film	Market area: EU

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

EU-0022265-0002 1-2

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

Trade name(s)

Kenodin Film	Market area: EU
lodoFilm	Market area: EU
Wynnsan Iofilm teat dip	Market area: EU
Kenodin Film Extra	Market area: EU
Wynngold Film	Market area: EU
Wynnsan trikill film teat dip	Market area: EU
Kenodin Film Soft	Market area: EU
locid Film	Market area: EU
TOP Film	Market area: EU
Seivit® lode Gel	Market area: EU
IOD protect 3000 Film	Market area: EU
Iodin Film Teat Dip 3000	Market area: EU
Iodin Barrier Teat Dip 3000	Market area: EU
Iodin Film Teat Dip	Market area: EU
Iodin Barrier Teat Dip	Market area: EU
lod 3000 film	Market area: EU

lodoschutz film	Market area: EU
loschutz film	Market area: EU
lodocoop film	Market area: EU
lodotech film	Market area: EU
lodactiv' film	Market area: EU
Iodofilm	Market area: EU
HCP lodine Film	Market area: EU
lod 3000 film	Market area: EU
Coopjod film	Market area: EU
Coopiode film	Market area: EU
lodocoop film	Market area: EU
Semex jod film	Market area: EU
lodofilm	Market area: EU
lodofilm bio	Market area: EU
lofilm bio	Market area: EU
lodactive film	Market area: EU

lodactiv film	Market area: EU
lodactiv' film	Market area: EU
SCUDO 3000	Market area: EU

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

EU-0022265-0003 1-2

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

1. Meta SPC administrative information

1.1. Meta SPC identifier

metaSPC 3: PT3-RTU Udder disinfectant Iodine

1.2. Suffix to the authorisation number

1-3

1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

2. Meta SPC composition

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		Active Substance	7553-56-2	231-442-4	0,3 - 0,99
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0 - 0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated		68131-39-5	500-195-7	2,17 - 2,95
Phosphoric acid	Phosphoric acid		7664-38-2	231-633-2	0 - 0
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO		68439-46-3		0 - 0

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

Formulation(s)

AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

Hazard statements

Harmful to aquatic life with long lasting effects.

Precautionary statements

Avoid release to the environment.

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

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

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - PT3- RTU Udder disinfectants, lodine

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Common name: Bacteria Development stage:
	Scientific name: Common name: Yeasts Development stage:
Field(s) of use	Indoor
	Skin disinfection only for use on intact skin of: - the udder of dairy and beef cattle before calving - the udder of sows before farrowing
Application method(s)	Spraying - -
Application rate(s) and frequencies	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	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE
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4.1.1 Use-specific instruction	ns for use

See general directions for use.

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product into the cation). Disinfection are should be taken and once every day moved after
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5.2. RISK IIIIUYAUOII IIIEASUIES

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 direc	t or indirect effects, first aid inst	ructions and emergency		
measures to protect the envil After eye contact: Rinse immediately with				
After ingestion: Rinse mouth. Spit	water.			
Arter ingestion. Ninse mouth. Spit				
5.4. Instructions for safe disp	osal of the product and its pack	aging		
	ed product and the packaging in accordance wit d to the manure deposit depending on local req			
5.5. Conditions of storage and	d shelf-life of the product under i	normal conditions of storage		
Keep only in the original container in a co Protect from frost. Do not expose to temp The shelf-life of the products is 2 years.	ol, well-ventilated place. Keep container closed eratures >40°C.	when not in use.		
The short me of the products to 2 years.				
6. Other information				
o. Other information				
1				
7. Third information level:	individual products in the me	ta SPC		
7.1 Trade name(s), authorisation number and specific composition of each individual product				
Trade name(s)	Animal Skin Disinfectant	Market area: EU		
	Dermades 3000	Market area: EU		
ļ				

Iodin Skin Disinfectant

Market area: EU

EU-0022265-0004 1-3

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

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

Trade name(s)

Dermades	Market area: EU
Animal skin disinfectant 1%	Market area: EU
Dermades Strong	Market area: EU
lodin Skin Disinfectant Strong	Market area: EU

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

EU-0022265-0005 1-3

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

1. Meta SPC administrative information

1.1. Meta SPC identifier

metaSPC 4: PT3 - RTU Udder and Teat disinfectants Iodine

1.2. Suffix to the authorisation number

1-4

1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

2. Meta SPC composition

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

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

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

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

Formulation(s)

AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

Hazard statements

Harmful to aquatic life with long lasting effects.

Precautionary statements

Avoid release to the environment.

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

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

4. Authorised use(s) of the meta SPC

4.1 Use description

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

Proc	luct	type
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PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised

Target organism(s) (including development stage)

Scientific name: Common name: Bacteria Development stage:

Scientific name: Common name: Yeasts Development stage:

Scientific name: Common name: Viruses Development stage:

Field(s) of use

Indoor

Ready to use teat disinfectant to be used post milking on milk producing animals.

Application method(s)

Dipping or Spraying -

Application rate(s) and frequencies

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

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

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

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

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

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

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

Do not mix with other chemicals.

4.1.2 Use-specific risk mitigation measures

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

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

4.2 Use description

Use 2 - PT3- RTU Udder disinfectant, Iodine

Where relevant, an exact
description of the authorised

use

Product type

Target organism(s) (including development stage)

PT03 - Veterinary hygiene (Disinfectants)

Scientific name: Common name: Yeasts Development stage:

Scientific name: Common name: Bacteria Development stage:

Field(s) of use

Indoor

Ready to use skin disinfectant, only for use on intact skin of:

- the udder of dairy and beef cattle before calving
- the udder of sows before farrowing

Application method(s)

Application on animal skin: by spraying -

-

Application rate(s) and frequencies

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

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

4.2.1 Use-specific instructions for use

For disinfection of the skin:

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

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

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

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

Only for use on intact skin.

Do not mix with other chemicals.

4.2.2 Use-specific risk mitigation measures

- For manual spraying application on cows and sows: no PPE is necessary for safe use.
- Keep out of reach of children.

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

See general directions for use.
4.2.4 Where specific to the use, the instructions for safe disposal of the product and its packaging
See general directions for use.
4.2.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage
See general directions for use.
5. General directions for use of the meta SPC 5.1. Instructions for use
See use-specific instructions for use.
5.2. Risk mitigation measures
See use-specific risk mitigation measures
5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment
After eye contact: Rinse immediately with water.
After ingestion: Rinse mouth. Spit.
5.4. Instructions for safe disposal of the product and its packaging
At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

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

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

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6	Other	inform	ation
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7. Third information level: individual products in the meta SPC

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

Trade name(s)

Kenodin SD	Market area: EU
lodoSD 3000	Market area: EU
Bio Tec Jodspray 3000	Market area: EU
Q Farm Iodine Des	Market area: EU
ANRO - Euterpflege Dip	Market area: EU
Stalosan Io Spray	Market area: EU
Stalosan Super Spray	Market area: EU
IDip+	Market area: EU
Bühning Jodspray 3000	Market area: EU
Velvet RTU	Market area: EU
Wynnsan trikill spray	Market area: EU

Wynnsan Iodine spray RTU	Market area: EU
Wynngold Iodine Dip and spray	Market area: EU
Pezerk IL	Market area: EU
lod protect 3000 Sprüh	Market area: EU
Seivit® lode Spray	Market area: EU
IOD protect 3000 Sprüh	Market area: EU
Kenodin SprayFilm	Market area: EU
lodo SP	Market area: EU
Kenostart SD	Market area: EU
GAHERYOD SPRAY	Market area: EU
Iodin Teat & Skin 3000	Market area: EU
lod 3000 sprüh	Market area: EU
lodoschutz sprüh	Market area: EU
loschutz sprüh	Market area: EU
lodocoop sprüh	Market area: EU
lodotech sprüh	Market area: EU

Market area: EU
Market area: EU

Iodactiv spray	Market area: EU
Iodactiv' spray	Market area: EU
Ark lodine S+D	Market area: EU
Agrihealth Iodine SD	Market area: EU
AGRO LOGIC JODOCARE SPRAY	Market area: EU
IODACTIVE	Market area: EU
EU-0022265-0006 1-4	

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

EU-0022265-0006 1-4

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

1. Meta SPC administrative information

1.1. Meta SPC identifier

metaSPC 5: PT3 - RTU Teat disinfectants PVP-lodine

1.2. Suffix to the authorisation number

1-5

1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

2. Meta SPC composition

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		Active Substance	7553-56-2	231-442-4	0 - 0
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		3 - 3
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated		68131-39-5	500-195-7	1,5 - 2,9
Phosphoric acid	Phosphoric acid		7664-38-2	231-633-2	0 - 0
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO		68439-46-3		0 - 0

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

Formulation(s)

AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

Hazard statements

Harmful to aquatic life with long lasting effects.

Precautionary statements

Avoid release to the environment.

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

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

4. Authorised use(s) of the meta SPC

4.1 Use description

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

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Common name: Bacteria Development stage:
	Scientific name: Common name: Yeasts Development stage:
	Scientific name: Common name: Viruses Development stage:
Field(s) of use	Indoor
	Post-milking disinfection on teats of milk producing animals
Application method(s)	Dipping or spraying -
Application rate(s) and frequencies	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	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE

4.1.1 Use-specific instructions for use

See general directions for use.

4.1.2 Use-specific risk mitigation measures

See general directions for use.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

5. General directions for use of the meta SPC

5.1. Instructions for use

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

Apply the product by dipping or by spraying:

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

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

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

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

Do not mix with other chemicals.

5.2. Risk mitigation measures

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

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

After eye contact: Rinse immediately with water.

After ingestion: Rinse mouth. Spit.

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

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.

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

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

Trade name(s)

Iodo PVP	Market area: EU
lodin Teat Dip 3000 PVP	Market area: EU

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

EU-0022265-0007 1-5

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

Trade name(s)	Iodo SD PVP	Market area: EU
	Iodin Teat Spray & Dip 3000 PVP	Market area: EU
Authorisation number (R4BP 3 asset reference number - National Authorisation)	EU-0022265-0008 1-5	

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

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

1. Meta SPC administrative information

1.1. Meta SPC identifier

metaSPC 6: PT3- RTU Udder disinfectants PVP-lodine

1.2. Suffix to the authorisation number

1-6

1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

2. Meta SPC composition

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		Active Substance	7553-56-2	231-442-4	0 - 0
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		10 - 10

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

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

Formulation(s)

AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

Hazard statements

Harmful to aquatic life with long lasting effects.

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

Precautionary statements

Avoid release to the environment.

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

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

Do not breathe spray.

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - PT3- RTU Udder disinfectant PVP-lodine

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

Target organism(s) (including development stage)

Scientific name: Common name: Bacteria Development stage:

Scientific name:

Common name: Yeasts Development stage:

Field(s) of use

Indoor

Ready to use skin disinfectant, only for use on intact skin of:

the udder of dairy and beef cattle: before calving
the udder of sows: before farrowing

Application method(s)

Spraying -

Application rate(s) and frequencies

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

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

4.1.1 Use-specific instructions for use

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

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

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

4.1.2 Use-specific risk mitigation measures

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

4.1.3 Where specific to the u	se, the particul	ars of likely dire	ect or indirect	effects, first aid
instructions and emergency	measures to p	rotect the environ	onment	

See general directions for use.

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

See general directions for use.

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

See general directions for use.

5. General directions for use of the meta SPC

5.1. Instructions for use

See use-specific instructions for use.

5.2. Risk mitigation measures

See use-specific risk mitigation measures.

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

After eye contact: Rinse immediately with water.

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

Have product container or label at hand.

5.4. Instructions for safe disposal of the product and its packaging					
At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.					
		der normal conditions of storage			
Keep only in the original container in a Protect from frost. Do not expose to te The shelf-life of the products is 2 years		losed when not in use.			
6. Other information 7. Third information level: individual products in the meta SPC 7.1 Trade name(s), authorisation number and specific composition of each individual					
.1 Trade name(s), authoris	·				
	·				
.1 Trade name(s), authoris	·				
.1 Trade name(s), authoris roduct	sation number and specific cor	nposition of each individual			
1 Trade name(s), authoris roduct	Dermades PVP	mposition of each individual Market area: EU			

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

1. Meta SPC administrative information

1.1. Meta SPC identifier

metaSPC 7: PT3 and PT4 - Concentrated Surface disinfectants Iodine

1.2. Suffix to the authorisation number

1-7

1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

PT04 - Food and feed area (Disinfectants)

2. Meta SPC composition

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		Active Substance	7553-56-2	231-442-4	1,8 - 2,49
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0 - 0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated		68131-39-5	500-195-7	3,15 - 9,45
Phosphoric acid	Phosphoric acid		7664-38-2	231-633-2	0 - 0
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO		68439-46-3		2,5 - 12,5

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

Formulation(s)

SL - Soluble concentrate

3. Hazard and precautionary statements of the meta SPC

L	ard	statem	onto

Causes serious eye damage.

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

May be corrosive to metals.

Toxic to aquatic life with long lasting effects.

Precautionary statements

Wear protective gloves.

Wear protective clothing.

Wear eye protection.

Wear face protection.

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

Immediately call a doctor or a POISON CENTER.

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

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

Collect spillage.

Avoid release to the environment.

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4. Authorised use(s) of the meta SPC

4.1 Use description

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

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Common name: Bacteria Development stage:
	Scientific name: Common name: Yeasts Development stage:
Field(s) of use	Indoor
	Non-porous surface disinfection in professional kitchens and in food industry
Application method(s)	By spraying with a manual or an automatic sprayer -
Application rate(s) and frequencies	Assume 0,04L 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	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE

4.1.1 Use-specific instructions for use

Use in professional kitchens (PT4) and in food industry (PT4): The product must be diluted with water before use (according to the table below). Clean the surfaces thoroughly with a detergent before disinfection. Rinse with clean water and remove surplus water. The product is used in professional kitchens (surface disinfection): Frequency is once per day. The product is used in food industry (surface disinfection): Frequency is once per day. Use at room temperature. Apply the product by spraying with a manual or an automatic sprayer. Make sure to wet the surface completely. Allow to take effect for at least 15 minutes and rinse the surfaces afterwards with clean water. Example for a product containing 1% iodine* Dilution of the product Contact time Bactericidal and yeasticidal activity 1,5% (15 ml product, add water up to 1L) 15 min *Each product label should give information on how the dilution should be made. Since the concentration of iodine in products within this meta SPC can range from 1,8 to 2,49% it is not possible to indicate all product dilutions here. Do not mix with other chemicals. Do not prepare more fluid than necessary. 4.1.2 Use-specific risk mitigation measures During pouring and pumping of the concentrated product: Wear chemical resistant gloves (material to be specified by the authorisation holder within the product information) and eye/face protection. During spraying of the product: Wear chemical resistant gloves and protective coverall (at least type X, EN XXXXX) (glove and coverall material to be specified by the authorisation holder within the product information). Keep out of reach of children. The general public and animals should be kept away from treated areas until surfaces are dry. 4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment See general directions for use. 4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging See general directions for use.

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

See general directions for use.

4.2 Use description

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

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Common name: Bacteria Development stage:
	Scientific name: Common name: Yeasts Development stage:
	Scientific name: Common name: Viruses Development stage:
Field(s) of use	Indoor
	Non-porous surface disinfection in veterinary field
Application method(s)	By spraying with a manual or an automatic sprayer -
Application method (c)	
Application rate(s) and frequencies	Assume 0,04L 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 - See use-specific risk mitigation measures
Category(ies) of users	Professional
Pack sizes and packaging material	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE

4.2.1 Use-specific instructions for use

Use in veterinary field (PT3), surface disinfection:

Product should be diluted with water before use (according to table below).

Clean the surfaces thoroughly with a detergent before disinfection. Rinse with clean water and remove surplus water.

The product is used to disinfect animal housings of pigs, cows and poultry.

Apply the product by spraying with a manual or an automatic sprayer. Make sure to wet the surface completely. Allow to take effect for at least 30 minutes. Animal housing must be empty of animals during application and animals can re-enter 24h after the end of the application.

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

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

Do not mix with other chemicals.

Do not prepare more fluid than necessary.

4.2.2 Use-specific risk mitigation measures

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

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

5. General directions for use of the meta SPC

5.1. Instructions for use
See use-specific instructions for use.
5.2. Risk mitigation measures
See use-specific risk mitigation measures.
5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment
After eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain emergency medical attention if pain, blinking, tears or redness persist.
If medical advice is needed, have product container or label at hand.
After ingestion: Rinse mouth. Spit. Do NOT induce vomiting and immediately get medical advice.
Have product container or label at hand.
5.4. Instructions for safe disposal of the product and its packaging
At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.
5.5. Conditions of storage and shelf-life of the product under normal conditions of storage
Keep only in the original container in a cool, well-ventilated place. Keep container closed when not in use. Protect from frost. Do not expose to temperatures >40°C. The shelf-life of the products is 2 years.

6. Other information	
1	

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

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

Trade name(s)

Dodin 20	Market area: EU
lodo 20	Market area: EU
Bio Tec Joddesinfektion	Market area: EU
Dufa dine 1,8%	Market area: EU
Alfasan super disinfectant	Market area: EU
lodes	Market area: EU
Streptoclean	Market area: EU
lodin Surface Disinfectant 1,8%	Market area: EU
IODINE	Market area: EU

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

EU-0022265-0010 1-7

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		Active Substance	7553-56-2	231-442-4	1,8
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated		68131-39-5	500-195-7	5,29
Phosphoric acid	Phosphoric acid		7664-38-2	231-633-2	0
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO		68439-46-3		5

1. Meta SPC administrative information

1.1. Meta SPC identifier

metaSPC 8: PT3 and PT4 - Concentrated Surface disinfectants Iodine

1.2. Suffix to the authorisation number

1-8

1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

PT04 - Food and feed area (Disinfectants)

2. Meta SPC composition

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		Active Substance	7553-56-2	231-442-4	2,5 - 3
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0 - 0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated		68131-39-5	500-195-7	3,15 - 9,45
Phosphoric acid	Phosphoric acid		7664-38-2	231-633-2	5 - 12
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO		68439-46-3		2,5 - 12,5

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

Formulation(s)

SL - Soluble concentrate

3. Hazard and precautionary statements of the meta SPC

Hazard	statements	

May be corrosive to metals.

Causes skin irritation.

Causes serious eye damage.

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

Toxic to aquatic life with long lasting effects.

Precautionary statements

Wear protective gloves.

Wear protective clothing.

Wear eye protection.

Wear face protection.

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

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.

Immediately call a a POISON CENTER or doctor/physician.

If experiencing respiratory symptoms: Call a a POISON CENTER or doctor/physician.

Avoid release to the environment.

Collect spillage.

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

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

4. Authorised use(s) of the meta SPC

4.1 Use description

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

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Common name: Bacteria Development stage:
	Scientific name: Common name: Yeasts Development stage:
	Indoor
Field(s) of use	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 frequencies	Assume 0,04L 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	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE

4.1.1 Use-specific instructions for use

• Use in professional kitchens (PT4) and in food industry (PT4): The product must be diluted with water before use (according to 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. 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* Dilution of the product Contact time Bactericidal and yeasticidal activity 0,5% (5 ml product, add water up to 1L) 15 min *Each product label should give information on how the dilution should be made. Since the concentration of iodine in products within this meta SPC can range from 2,5 to 3% it is not possible to indicate all product dilutions here.
Do not mix with other chemicals. Do not prepare more fluid than necessary.
4.1.2 Use-specific risk mitigation measures
 During pouring and pumping of the concentrated product: Wear chemical resistant gloves, coverall (material to be specified by the authorisation holder within the product information) and eye/face protection. During spraying of the product: Wear chemical resistant gloves and protective coverall (at least type X, EN XXXXX) (glove and coverall material to be specified by the authorisation holder within the product information).
 Keep out of reach of children. The general public and animals should be kept away from treated areas until surfaces are dry.
4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment
See general directions for use.
4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging
See general directions for use.
1.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage
See general directions for use.

4.2 Use description

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

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Common name: Bacteria Development stage:
	Scientific name: Common name: Yeasts Development stage:
	Scientific name: Common name: Viruses Development stage:
Field(s) of use	Indoor
	Non-porous surface disinfection in veterinary field
Application method(s)	By spraying with a manual or an automatic sprayer - /
Application rate(s) and frequencies	Assume 0,04L 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 - See use-specific risk mitigation measures.
Category(ies) of users	Professional
Pack sizes and packaging material	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE

4.2.1 Use-specific instructions for use

Use in veterinary field (PT3), surface disinfection:

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

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

Do not mix with other chemicals.

Do not prepare more fluid than necessary.

4.2.2 Use-specific risk mitigation measures

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

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

5. General directions for use of the meta SPC

5.1. Instructions for use

See use-specific instructions for use

5.2. Risk mitigation measures

See use-specific risk mitigation measures.

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

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

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

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

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

Have product container or label at hand.

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

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

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

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

6. Other information

1		

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

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

Trade name(s)

locid 30	Market area: EU
lodo 30	Market area: EU
Dufa dine	Market area: EU
Iodin Surface Disinfectant 2,8%	Market area: EU

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

EU-0022265-0011 1-8

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

1. Meta SPC administrative information

1.1. Meta SPC identifier

metaSPC 9: PT4 - Concentrated CIP disinfectants Iodine

1.2. Suffix to the authorisation number

1-9

1.3 Product type(s)

PT04 - Food and feed area (Disinfectants)

2. Meta SPC composition

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

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

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

Formulation(s)

SL - Soluble concentrate

3. Hazard and precautionary statements of the meta SPC

Hazard statements

Causes severe skin burns and eye damage.

Harmful to aquatic life with long lasting effects.

May be corrosive to metals.

Precautionary statements

Wear protective gloves.

Wear protective clothing.

Wear eye protection.

Wear face protection.

Avoid release to the environment.

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

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.

If experiencing respiratory symptoms: Call a doctor.

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

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

Immediately call a doctor.

4. Authorised use(s) of the meta SPC

4.1 Use description

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

PT04 - Food and feed area (Disinfectants)

Where relevant, an exact description of the authorised use

-	

Target organism(s) (including development stage)	Scientific name: Common name: Bacteria Development stage:
	Scientific name: Common name: Yeasts Development stage:
Field(s) of use	Indoor Cleaning in place (CIP) disinfection for milking equipment and CIP installations in food
Application method(s)	industry CIP disinfection -
Application rate(a) and	Apply the product in the automatic system with an end concentration of 0,00125%
Application rate(s) and frequencies	available iodine The product is used once per day in food industry and up to 2 times per day in milking parlours.
Category(ies) of users	Professional
Pack sizes and packaging material	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE
4.1.1 Use-specific instruction	ns for use
See general directions for use	

4.1.2 Use-specific risk mitigation measures

See general directions for use.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

5. General directions for use of the meta SPC

5.1. Instructions for use

· Disinfection of milking machines or CIP installations in Food industry

Clean first the CIP installation.

Apply the product in the automatic system with a dilution of the product (according to table below) with water.

Use at room temperature.

Respect a contact time according to the table below.

Rinse the installation with water.

Example for a product containing 0.5% iodine*

Bactericidal and yeasticidal activity

Dilution of the product 0,25% (2,5ml product, add water up to 1L) Contact time 15 min.

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

Do not mix with other chemicals.

5.2. Risk mitigation measures

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

Keep out of reach of children.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment
After inhalation: Remove person to fresh air and keep comfortable for breathing. Obtain medical attention if breathing difficulty persists.
After skin (or hair) contact: Remove contaminated clothing and shoes. Wash the affected area thoroughly with plenty of soap and water. Get medical attention if symptoms occur.
After eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain emergency medical attention if pain, blinking, tears or redness persist.
After ingestion: Rinse mouth. Do NOT induce vomiting and immediately get medical advice.
Have product container or label at hand.
5.4. Instructions for safe disposal of the product and its packaging At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.
5.5. Conditions of storage and shelf-life of the product under normal conditions of storage
Keep only in the original container in a cool, well-ventilated place. Keep container closed when not in use. Protect from frost. Do not expose to temperatures >40°C. The shelf-life of the products is 2 years.
6. Other information

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

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

Trade name(s)

lodo CIP	Market area: EU		
locip	Market area: EU		
Bio Tec Jodreiniger	Market area: EU		
JODOPHOS SUPER 4001	Market area: EU		
Bühning Jodreiniger	Market area: EU		
Wynnsan Ice bank Tank Cleaner	Market area: EU		
Bulk Tank Sanitizer	Market area: EU		
Iodin CIP Disinfectant	Market area: EU		

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

EU-0022265-0012 1-9

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

1. Meta SPC administrative information

1.1. Meta SPC identifier

metaSPC 10: PT3 - Concentrated teat disinfectants Iodine

1.2. Suffix to the authorisation number

1-10

1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

2. Meta SPC composition

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

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

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

Formulation(s)

SL - Soluble concentrate

3. Hazard and precautionary statements of the meta SPC

Hazard statements

Causes serious eye damage.

Toxic to aquatic life with long lasting effects.

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

Precautionary statements

Wear protective gloves.

Wear protective clothing.

Wear eye protection.

Wear face protection.

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

Immediately call a doctor or a poison center.

Avoid release to the environment.

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

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

Collect spillage.

4. Authorised use(s) of the meta SPC

4.1 Use description

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

Product type

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

Target organism(s) (including development stage)

Scientific name: Common name: Bacteria Development stage: Scientific name:
Common name: Yeasts
Development stage:

Scientific name:
Common name: Viruses
Development stage:

Field(s) of use

Indoor

Post-milking teat disinfection of milk producing animals

Application method(s)

By spraying with a manual sprayer or with an automatic sprayer on teats. -

1

Application rate(s) and frequencies

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

 $1\mathsf{L},\, 5\mathsf{L},\, 10\mathsf{L},\, 20\mathsf{L},\, 25\mathsf{L},\, 30\mathsf{L},\, 60\mathsf{L},\, 200\mathsf{L},\, 600\mathsf{L},\, 1000\mathsf{L}$ 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 of the meta SPC

5.1. Instructions for use

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

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

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

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

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

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

Do not mix with other chemicals.

5.2. Risk mitigation measures

- For mixing and loading of the product: Wear chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) and eye/face protection.
- For manual spraying application: Wear chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) and eye/face protection.
- If a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.
 - · Keep out of reach of children.

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

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

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

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

Have product container or label at hand.

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

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

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

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

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

The shelf-life of the products is 2 years.

6. Other information

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

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

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

Trade name(s)

Kenodin SD 900	Market area: EU
IodoSD 900	Market area: EU
IDip+ concentrate	Market area: EU

Jodkonzentrat 1:9	Market area: EU
Bühning Jodkonzentrat 1:9	Market area: EU
Wynnsan Iodine Conc dip 9-1	Market area: EU
Kenodin 900	Market area: EU
Dufa Dip	Market area: EU
Kenostart 900	Market area: EU
Iodin Teat Spray 900	Market area: EU
HCP lodine Concentrate	Market area: EU
Maxi Subliem CP	Market area: EU
Subliem Koncentrat Plus	Market area: EU
ELL 0000005 0040 4 40	

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

EU-0022265-0013 1-10

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

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

1. Meta SPC administrative information

1.1. Meta SPC identifier

metaSPC 11: PT3 - RTU Teat disinfectants Iodine

1.2. Suffix to the authorisation number

1-11

1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

2. Meta SPC composition

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		Active Substance	7553-56-2	231-442-4	0,25 - 0,25
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0 - 0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated		68131-39-5	500-195-7	2,1 - 2,1
Phosphoric acid	Phosphoric acid		7664-38-2	231-633-2	0 - 0
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO		68439-46-3		0 - 0

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

Formulation(s)

AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

Hazard statements

Harmful to aquatic life with long lasting effects.

Precautionary statements

Avoid release to the environment.

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

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

4. Authorised use(s) of the meta SPC

4.1 Use description

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

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Common name: Bacteria Development stage: Scientific name: Common name: Yeasts Development stage:
	Indoor
Field(s) of use	Post-milking teat disinfection of milk producing animals
Application method(s)	By dipping or spraying on teats -

4.1.1 Use-specific instructions for use				
See general directions for use.				
4.1.2 Use-specific risk mitig	ation 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 upackaging	use, the instructions for safe disposal of the product and its			

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

See general directions for use.

5. General directions for use of the meta SPC

5.1. Instructions for use

Apply the product by dipping or by spraying:

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

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

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

Do not mix with other chemicals.

5.2. Risk mitigation measures

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

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

After eye contact: Rinse immediately with water.

After ingestion: Rinse mouth. Spit.

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

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

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

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

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-	Other	Intorn	nation
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7. Third information level: individual products in the meta SPC

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

Trade name(s)

Kenodin 2500	Market area: EU
Iodin Teat Dip 2500	Market area: EU
Jod 2500	Market area: EU

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

EU-0022265-0014 1-11

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		Active Substance	7553-56-2	231-442-4	0,25
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated		68131-39-5	500-195-7	2,1

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

1. Meta SPC administrative information

1.1. Meta SPC identifier

meta SPC 12: PT3 - RTU Teat disinfectants Iodine

1.2. Suffix to the authorisation number

1-12

1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

2. Meta SPC composition

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		Active Substance	7553-56-2	231-442-4	0,3 - 0,5
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0 - 0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated		68131-39-5	500-195-7	2,1 - 2,9
Phosphoric acid	Phosphoric acid		7664-38-2	231-633-2	0 - 0
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO		68439-46-3		0 - 0

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

Formulation(s)

AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

Hazard statements

Harmful to aquatic life with long lasting effects.

Precautionary statements

Avoid release to the environment.

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

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

4. Authorised use(s) of the meta SPC

4.1 Use description

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

Prod	uct	ty	ре
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PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised

Target organism(s) (including development stage)

Scientific name: Common name: Bacteria Development stage:

Scientific name: Common name: Yeasts Development stage:

Scientific name: Common name: Viruses Development stage:

Field(s) of use

Indoor

Post-milking teat disinfection of milk producing animals

Application method(s)	By dipping or spraying on teats - /
Application rate(s) and frequencies	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	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE
4.1.1 Use-specific instructio	ons for use
See general directions for use.	
4.1.2 Use-specific risk mitig	ation measures
See general directions for use.	
-	use, the particulars of likely direct or indirect effects, first aid measures to protect the environment
See general directions for use.	
4.1.4 Where specific to the upackaging	use, the instructions for safe disposal of the product and its
See general directions for use.	
4.1.5 Where specific to the ບ under normal conditions of	use, the conditions of storage and shelf-life of the product storage
See general directions for use.	

5. General directions for use of the meta SPC

5.1. Instructions for use

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

Apply the product by dipping or by spraying:

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

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

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

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

Do not mix with other chemicals.

5.2. Risk mitigation measures

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

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

After eye contact: Rinse immediately with water.

After ingestion: Rinse mouth. Spit.

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

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

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

Keep only in the original container in a cool, well-ventilated place. Keep container closed when not in use. Protect from frost. Do not expose to temperatures $>40^{\circ}$ C.

The shelf-life of the products is 2 years.

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

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

Trade name(s)

Kenodin 5000	Market area: EU
lodoDip 5000	Market area: EU
JOD 5000	Market area: EU
Bio Tec Jodip 5000	Market area: EU
Bühning Jodfilmdip-Super	Market area: EU
locid 5000	Market area: EU
lod protect 5000 Film	Market area: EU
IOD protect 5000 Film	Market area: EU
locid	Market area: EU
lodip+	Market area: EU
Protetos cua	Market area: EU
Iodin Teat Dip 5000	Market area: EU

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

EU-0022265-0015 1-12

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

Trade name(s)

Kenodin SD 5000	Market area: EU
lodoSD 5000	Market area: EU
IODOSPRAY 5000	Market area: EU
Bio Tec Jodspray 5000	Market area: EU
IDip+ 5000	Market area: EU
Bühning Jodspray 5000	Market area: EU
lod protect 5000 Sprüh	Market area: EU
Kenodin Film Spray	Market area: EU
IOD protect 5000 Sprüh	Market area: EU
lodin Spray & Dip 5000	Market area: EU

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

EU-0022265-0016 1-12

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