

Commission Implementing Regulation (EU) 2020/1187 of 7 August 2020 granting a Union authorisation for the biocidal product family ‘Iodine based products – CID LINES NV’ (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1187
of 7 August 2020

granting a Union authorisation for the biocidal product
family ‘Iodine based products – CID LINES NV’

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products⁽¹⁾, and in particular the first subparagraph of Article 44(5) thereof,

Whereas:

- (1) On 13 August 2015, CID LINES NV submitted an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for authorisation of a biocidal product family named ‘Iodine based products – CID LINES NV’ of product-types 3 and 4, as described in Annex V to that Regulation, providing written confirmation that the competent authority of the Netherlands had agreed to evaluate the application. The application was recorded under case number BC-BY019142-30 in the Register for Biocidal Products.
- (2) ‘Iodine based products – CID LINES NV’ contains iodine including polyvinylpyrrolidone iodine, as the active substance, which is included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012. Taking into account the intrinsic properties of the active substance, and the scientific criteria for the determination of endocrine-disrupting properties set out in Commission Delegated Regulation (EU) 2017/2100⁽²⁾, the Commission is carrying out a review of the approval of iodine, including polyvinylpyrrolidone iodine, in accordance with Article 15 of Regulation (EU) No 528/2012. Depending on the outcome of that review, the Commission will consider whether the Union authorisations for products containing the active substance have to be cancelled or amended in accordance with Article 48 of Regulation (EU) No 528/2012.
- (3) On 28 May 2019, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, an assessment report and the conclusions of its evaluation to the European Chemicals Agency (‘the Agency’).
- (4) On 17 January 2020, the Agency submitted to the Commission an opinion⁽³⁾, including the draft summary of the biocidal product characteristics (‘SPC’) of ‘Iodine based

- products – CID LINES NV’ and the final assessment report on the biocidal product family in accordance with Article 44(3) of Regulation (EU) No 528/2012.
- (5) The opinion concludes that ‘Iodine based products – CID LINES NV’ is a biocidal product family within the meaning of Article 3(1)(s) of Regulation (EU) No 528/2012, that it is eligible for Union authorisation in accordance with Article 42(1) of that Regulation and that subject to compliance with the draft SPC, it meets the conditions laid down in Article 19(1) and (6) of that Regulation.
- (6) On 4 February 2020 the Agency transmitted to the Commission the draft SPC in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.
- (7) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for ‘Iodine based products – CID LINES NV’.
- (8) According to the opinion of the Agency, as regards the non-active substances sodium iodide and sodium iodate contained in ‘Iodine based products – CID LINES NV’, it was not possible to conclude whether they meet the scientific criteria for the determination of endocrine-disrupting properties set out in Delegated Regulation (EU) 2017/2100 within the period for the evaluation of the application. Further examination of sodium iodide and sodium iodate should therefore take place. If it is concluded that sodium iodide or sodium iodate or both are considered as having endocrine-disrupting properties, the Commission will consider whether to cancel or amend the Union authorisation for ‘Iodine based products – CID LINES NV’ in accordance with Article 48 of Regulation (EU) No 528/2012.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0022265-0000 is granted to CID LINES NV for the making available on the market and use of the biocidal product family ‘Iodine based products – CID LINES NV’ in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 3 September 2020 until 31 August 2030.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 7 August 2020.

For the Commission

The President

Ursula VON DER LEYEN

Status: This is the original version (as it was originally adopted).

ANNEX

Summary of product characteristics for a biocidal product family

Iodine based products – CID LINES NV

Product type 3 – Veterinary hygiene (Disinfectants)

Product type 4 – Food and feed area (Disinfectants)

Authorisation number: EU-0022265-0000

R4BP asset number: EU-0022265-0000

PART I

FIRST INFORMATION LEVEL**1. ADMINISTRATIVE INFORMATION****1.1. Family name**

Name	Iodine based products – CID LINES NV
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1.2. Product type(s)

Product type(s)	PT03 – Veterinary hygiene (Disinfectants) PT04 – Food and feed area (Disinfectants)
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1.3. Authorisation holder

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

1.4. Manufacturer(s) of the biocidal products

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

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

Active substance	Iodine
Name of manufacturer	SQM S.A.
Address of manufacturer	Los Militares, Piso 4, 4290 Santiago Chile
Location of manufacturing sites	Nueva Victoria plant, 00 Pedro de Valdivia Chile
Active substance	Iodine
Name of manufacturer	Cosayach Nitratos S.A.
Address of manufacturer	Amunategui 178, 00 Santiago Chile
Location of manufacturing sites	Cala Cala, 00 Pozo Almonte Chile
Active substance	Iodine
Name of manufacturer	ACF Minera S.A.
Address of manufacturer	San Martin No 499, 00 Iquique Chile
Location of manufacturing sites	Lagunas mine, 00 Pozo Almonte Chile
Active substance	Iodine
Name of manufacturer	ISE Chemicals Corporation
Address of manufacturer	3-1, Kyobashi 1-Chome, 104-0031 Tokyo Japan
Location of manufacturing sites	3695 Kitaimaizumi, 299-3201 Oamishirasato city Japan
Active substance	Polyvinylpyrrolidone iodine
Name of manufacturer	ISP Chemicals LLC, Afiliate of Ashland Inc
Address of manufacturer	455 N. main st (HWY 95), KY 42029 Calvert City United States
Location of manufacturing sites	455 N. main st (HWY 95), KY 42029 Calvert City United States
Active substance	Polyvinylpyrrolidone iodine
Name of manufacturer	Pantheon FZE (DMCC branch)
Address of manufacturer	403, Reef Tower, Jumeira Lake Tower Shaikh Zayed Road, 00 Dubai United Arab Emirates
Location of manufacturing sites	Cala Cala, 00 Pozo Almonte Chile

Status: This is the original version (as it was originally adopted).

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

2.2. Type(s) of formulation

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

SECOND INFORMATION LEVEL – META SPC(S)

META SPC 1

1. META SPC 1 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 1 identifier

Identifier	metaSPC 1: PT3 Concentrated teat disinfectants Iodine
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1.2. Suffix to the authorisation number

Number	1-1
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1.3. Product type(s)

Product type(s)	PT03 – Veterinary hygiene (Disinfectants)
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2. META SPC 1 COMPOSITION

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

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

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

Formulation(s)	SL – Soluble concentrate
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

Hazard statements	Causes serious eye damage. Harmful to aquatic life with long lasting effects. May cause damage to organs (thyroid) through prolonged or repeated exposure (oral).
Precautionary statements	Wear eye protection. Wear protective clothing. Wear protective gloves. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a doctor or a poison center. Avoid release to the environment. Dispose of contents to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation. Dispose of container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Status: This is the original version (as it was originally adopted).

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

4.1. Use description

TABLE 1. USE # 1 – PT3– CONCENTRATED
TEAT DISINFECTANT, POST-MILKING, IODINE

Product type	PT03 – Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts Viruses
Field(s) of use	Indoor Post-milking teat disinfection of milk producing animals
Application method(s)	Manual or automatic spraying on teats
Application rate(s) and frequency	Dilute the product to a final concentration of 0,3 % (w/w) available iodine. Apply 2 times per day with manual sprayer and 3 times per day with a robot.
Category(ies) of users	Professional
Pack sizes and packaging material	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 600 L, 1000 L HDPE (High Density Polyethylene)

4.1.1. *Use-specific instructions for use*

See general directions for use.

4.1.2. *Use-specific risk mitigation measures*

See general directions for use.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

5. GENERAL DIRECTIONS FOR USE⁽⁴⁾ OF THE META SPC 1

5.1. **Instructions for use**

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

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

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

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

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

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

Do not mix with other chemicals.

5.2. **Risk mitigation measures**

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

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

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

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

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

Have product container or label at hand.

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

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

Status: This is the original version (as it was originally adopted).

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

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

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

The shelf-life of the products is 2 years.

6. OTHER INFORMATION

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

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

Trade name(s)	Kenodin SD 400 IodoSD 400 Velvet Concentrate Wynnsan Iodine 3 – 1 conc Iodin Teat Spray 400				
Authorisation number	EU-0022265-0001 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	1,5
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0,0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active Substance	68131-39-5	500-195-7	12,05

META SPC 2

1. META SPC 2 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 2 identifier

Identifier	metaSPC 2: PT3 – Ready to Use (RTU) Teat disinfectants Iodine
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1.2. Suffix to the authorisation number

Number	1-2
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1.3. Product type(s)

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

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

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

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

Formulation(s)	AL – Any other liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

Hazard statements	Harmful to aquatic life with long lasting effects.
Precautionary statements	Avoid release to the environment. Dispose of contents to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation. Dispose of container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

4. AUTHORISED USE(S) OF THE META SPC 2

4.1. Use description

Status: This is the original version (as it was originally adopted).

TABLE 2. USE # 1 – PT3– RTU TEAT DISINFECTANT, POST-MILKING, IODINE

Product type	PT03 – Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts Viruses
Field(s) of use	Indoor Post-milking teat disinfection of milk producing animals
Application method(s)	By dipping or spraying on teats
Application rate(s) and frequency	The product is ready to use. Apply 2 times per day for manual spraying and 3 times per day for manual dipping and spraying with robot
Category(ies) of users	Professional
Pack sizes and packaging material	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 600 L, 1000 L HDPE

4.1.1. *Use-specific instructions for use*

See general directions for use.

4.1.2. *Use-specific risk mitigation measures*

See general directions for use.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

5. **GENERAL DIRECTIONS FOR USE⁽⁵⁾ OF THE META SPC 2**

5.1. **Instructions for use**

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

Apply the product by dipping or by spraying:

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

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

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

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

Do not mix with other chemicals.

5.2. **Risk mitigation measures**

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

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

After eye contact: Rinse immediately with water.

After ingestion: Rinse mouth. Spit.

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

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

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

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

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

The shelf-life of the products is 2 years.

6. **OTHER INFORMATION**

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

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

Status: This is the original version (as it was originally adopted).

Trade name(s)	
	IodoDip 3000 Bio Tec Jodip 3000 Recoïode Stalosan Io Dip Stalosan Super Dip Velvet High Visco Bühning Joddip 3000 Kenodin Wynnsan trikill RTU Wynnsan Iodine RTU teat dip Wynnsan Iodine dip RTU Iocid Iodip+ Wynngold Iodine Dip Pezerk iv plus Iod protect 3000 Film Seivit® Iode 3000 Kenostart GAHERYOD Kenodin 3000 Iodin Teat Dip 3000 Iod 3000 dip Iodoschutz dip Ioschutz dip Iodocoop dip Iodotech dip Iodactiv' dip Iododip MIROX Dip Jod HCP Iodine Dip Agib Jodium Dip Jod 3000 Iod dip Iode 3000 Iodoschutz Coopjod Coopiode Coopiode épais Semex jod Iodotech Iododip green Iodip bio Iododip bio Iodactive épais Iodactiv Iodoactiv' Bayley's Premier Iodine Teat Dip Pearce Premier Iodine Teat Dip Diamond 1:3 Concentrate Iodine Post Dip Spray JODOCARE KENOSTART DYP STREPTOFIT

	Iodall Film				
Authorisation number	EU-0022265-0002 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,3
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0,0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active Substance	68131-39-5	500-195-7	2,17

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

Trade name(s)	Kenodin Film IodoFilm Wynnsan Iofilm teat dip Kenodin Film Extra Wynngold Film Wynnsan trikill film teat dip Kenodin Film Soft Iocid Film TOP Film Seivit® Iode Gel IOD protect 3000 Film Iodin Film Teat Dip 3000 Iodin Barrier Teat Dip 3000 Iodin Film Teat Dip Iodin Barrier Teat Dip Iod 3000 film Iodoschutz film Ioschutz film Iodocoop film Iodotech film Iodactiv' film Iodofilm HCP Iodine Film Iod 3000 film Coopjod film Coopiode film Iodocoop film Semex jod film Iodofilm Iodofilm bio Iofilm bio Iodactive film Iodactiv film
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Status: This is the original version (as it was originally adopted).

	Iodactiv' film SCUDO 3000				
Authorisation number	EU-0022265-0003 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,3
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0,0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active Substance	68131-39-5	500-195-7	2,9

META SPC 3

1. META SPC 3 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 3 identifier

Identifier	metaSPC 3: PT3-RTU Udder disinfectants Iodine
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1.2. Suffix to the authorisation number

Number	1-3
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1.3. Product type(s)

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

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

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

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

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

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

Hazard statements	Harmful to aquatic life with long lasting effects.
Precautionary statements	Avoid release to the environment. Dispose of contents to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation. Dispose of container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

4. AUTHORISED USE(S) OF THE META SPC 3

4.1. Use description

TABLE 3. USE # 1 – PT3- RTU UDDER DISINFECTANT, IODINE

Product type	PT03 – Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Skin disinfection only for use on intact skin of: — the udder of dairy and beef cattle before calving — the udder of sows before farrowing
Application method(s)	Spraying
Application rate(s) and frequency	The product is ready to use. Apply to:

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	<ul style="list-style-type: none"> — the udder of dairy and beef cattle: 1 spray on each teat (equivalent to 4,8 mL per application) — the udder of sows: 15 to 20 mL per animal
Category(ies) of users	Professional
Pack sizes and packaging material	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 600 L, 1000 L HDPE

4.1.1. *Use-specific instructions for use*

See general directions for use.

4.1.2. *Use-specific risk mitigation measures*

See general directions for use.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

5. **GENERAL DIRECTIONS FOR USE⁽⁶⁾ OF THE META SPC 3**

5.1. **Instructions for use**

For disinfection of the skin:

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

The use of a dosing pump for filling the product into the application equipment is recommended.

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

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

Only for use on intact skin.

Do not mix with other chemicals.

5.2. Risk mitigation measures

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

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

Keep out of reach of children.

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

After eye contact: Rinse immediately with water.

After ingestion: Rinse mouth. Spit

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

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

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

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

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

The shelf-life of the products is 2 years.

6. OTHER INFORMATION

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

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

Trade name(s)	Animal Skin Disinfectant Dermades 3000 Iodin Skin Disinfectant				
Authorisation number	EU-0022265-0004 1-3				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,3

Status: This is the original version (as it was originally adopted).

Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0,0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active Substance	68131-39-5	500-195-7	2,17

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

Trade name(s)	Dermades Animal skin disinfectant 1 % Dermades Strong Iodin Skin Disinfectant Strong				
Authorisation number	EU-0022265-0005 1-3				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,99
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0,0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active Substance	68131-39-5	500-195-7	2,95

META SPC 4

1. META SPC 4 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 4 identifier

Identifier	metaSPC 4: PT3 – RTU Udder and Teat disinfectants Iodine
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1.2. Suffix to the authorisation number

Number	1-4
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1.3. Product type(s)

Product type(s)	PT03 – Veterinary hygiene (Disinfectants)
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2. META SPC 4 COMPOSITION

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

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

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

Formulation(s)	AL – Any other liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 4

Hazard statements	Harmful to aquatic life with long lasting effects.
Precautionary statements	Avoid release to the environment. Dispose of contents to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation. Dispose of container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

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

4.1. Use description

TABLE 4. USE # 1 – PT3– RTU TEAT DISINFECTANT, POST-MILKING, IODINE

Product type	PT03 – Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts Viruses

Status: This is the original version (as it was originally adopted).

Field(s) of use	Indoor Ready to use teat disinfectant to be used post milking on milk producing animals.
Application method(s)	Dipping or spraying
Application rate(s) and frequency	The product is ready to use. Apply 2 times per day for manual spraying and 3 times per day for manual dipping and spraying with robot.
Category(ies) of users	Professional
Pack sizes and packaging material	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 600 L, 1000 L HDPE

4.1.1. *Use-specific instructions for use*

For disinfection of the teats:

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

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

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

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

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

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

Do not mix with other chemicals.

4.1.2. *Use-specific risk mitigation measures*

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

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

4.2. **Use description**

TABLE 5. USE # 2 – PT3- RTU UDDER DISINFECTANT, IODINE

Product type	PT03 – Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Yeasts Bacteria
Field(s) of use	Indoor Ready to use skin disinfectant, only for use on intact skin of: — the udder of dairy and beef cattle before calving — the udder of sows before farrowing
Application method(s)	Application on animal skin: by spraying
Application rate(s) and frequency	The product is ready to use. Apply to: — the udder of dairy and beef cattle: 1 spray on each teat (equivalent to 4,8 mL per application) — the udder of sows: 15 to 20 mL per animal
Category(ies) of users	Professional
Pack sizes and packaging material	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 600 L, 1000 L HDPE

4.2.1. *Use-specific instructions for use*

For disinfection of the skin:

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

The use of a dosing pump for filling the product into the application equipment is recommended.

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

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

Status: This is the original version (as it was originally adopted).

- 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⁽⁷⁾ OF THE META SPC 4**

5.1. **Instructions for use**

See use-specific instructions for use.

5.2. **Risk mitigation measures**

See use-specific risk mitigation measures

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

After eye contact: Rinse immediately with water.

After ingestion: Rinse mouth. Spit.

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

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

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

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

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

The shelf-life of the products is 2 years.

6. **OTHER INFORMATION**

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

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

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

	Iododip spray green Iodospray Bio Iospray bio Iodactive spray Iodactiv spray Iodactiv' spray Ark Iodine S+D Agrihealth Iodine SD AGRO LOGIC JODOCARE SPRAY IODACTIVE				
Authorisation number	EU-0022265-0006 1-4				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,3
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0,0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active Substance	68131-39-5	500-195-7	2,17

META SPC 5

1. META SPC 5 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 5 identifier

Identifier	metaSPC 5: PT3 – RTU Teat disinfectants PVP-Iodine
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1.2. Suffix to the authorisation number

Number	1-5
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1.3. Product type(s)

Product type(s)	PT03 – Veterinary hygiene (Disinfectants)
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2. META SPC 5 COMPOSITION

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

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

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

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

Formulation(s)	AL – Any other liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 5

Hazard statements	Harmful to aquatic life with long lasting effects.
Precautionary statements	Avoid release to the environment. Dispose of contents to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation. Dispose of container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

4. AUTHORISED USE(S) OF THE META SPC 5

4.1. Use description

TABLE 6. USE # 1 – PT3 – RTU TEAT DISINFECTANT, POST MILKING, PVP-IODINE

Product type	PT03 – Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts Viruses
Field(s) of use	Indoor Post-milking disinfection on teats of milk producing animals
Application method(s)	Dipping or spraying

Status: This is the original version (as it was originally adopted).

Application rate(s) and frequency	The product is ready to use. Apply 2 times per day for manual spraying and 3 times per day for manual dipping and spraying with robot.
Category(ies) of users	Professional
Pack sizes and packaging material	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 600 L, 1000 L HDPE

4.1.1. *Use-specific instructions for use*

See general directions for use.

4.1.2. *Use-specific risk mitigation measures*

See general directions for use.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

5. **GENERAL DIRECTIONS FOR USE⁽⁸⁾ OF THE META SPC 5**

5.1. **Instructions for use**

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

The use of a dosing pump for filling the product into the application equipment is recommended.

Apply the product by dipping or by spraying:

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

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

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

Do not mix with other chemicals.

5.2. **Risk mitigation measures**

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

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

After eye contact: Rinse immediately with water.

After ingestion: Rinse mouth. Spit.

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

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

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

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

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

The shelf-life of the products is 18 months.

6. OTHER INFORMATION

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

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

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

Status: This is the original version (as it was originally adopted).

Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active Substance	68131-39-5	500-195-7	2,5
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7.2. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	Iodo SD PVP Iodin Teat Spray & Dip 3000 PVP				
Authorisation number	EU-0022265-0008 1-5				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,0
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		3,0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active Substance	68131-39-5	500-195-7	2,5

META SPC 6

1. META SPC 6 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 6 identifier

Identifier	metaSPC 6: PT3- RTU Udder disinfectants PVP-Iodine
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1.2. Suffix to the authorisation number

Number	1-6
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1.3. Product type(s)

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

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max

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

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

Formulation(s)	AL – Any other liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 6

Hazard statements	Harmful to aquatic life with long lasting effects. May cause damage to organs (thyroid) through prolonged or repeated exposure (oral).
Precautionary statements	Avoid release to the environment. Dispose of contents to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation. Dispose of container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation. Do not breathe spray.

4. AUTHORISED USE(S) OF THE META SPC 6

4.1. Use description

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

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

Status: This is the original version (as it was originally adopted).

Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Ready to use skin disinfectant, only for use on intact skin of: — the udder of dairy and beef cattle: before calving — the udder of sows: before farrowing
Application method(s)	Spraying
Application rate(s) and frequency	The product is ready to use. Apply to: — The udder of dairy and beef cattle: 1 spray on each teat (equivalent to 4,8 mL per application) — The udder of sows: 15 to 20 mL per animal
Category(ies) of users	Professional
Pack sizes and packaging material	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 600 L, 1000 L HDPE

4.1.1. *Use-specific instructions for use*

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

The use of a dosing pump for filling the product into the application equipment is recommended.

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

Only for use on intact skin.

Do not mix with other chemicals.

4.1.2. *Use-specific risk mitigation measures*

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

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

5. GENERAL DIRECTIONS FOR USE⁽⁹⁾ OF THE META SPC 6

5.1. Instructions for use

See use-specific instructions for use.

5.2. Risk mitigation measures

See use-specific risk mitigation measures.

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

After eye contact: Rinse immediately with water.

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

Have product container or label at hand.

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

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

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

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

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

The shelf-life of the products is 2 years.

6. OTHER INFORMATION

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

Status: This is the original version (as it was originally adopted).

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

Trade name(s)	Dermades PVP Wynngold 10 % Iodine Solution Iodin Skin Disinfectant PVP				
Authorisation number	EU-0022265-0009 1-6				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,0
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		10,0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active Substance	68131-39-5	500-195-7	2,0

META SPC 7

1. META SPC 7 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 7 identifier

Identifier	metaSPC 7: PT3 and PT4 – Concentrated Surface disinfectants Iodine
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1.2. Suffix to the authorisation number

Number	1-7
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1.3. Product type(s)

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

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

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

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

2.2. Type(s) of formulation of the meta SPC 7

Formulation(s)	SL – Soluble concentrate
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 7

Hazard statements	Causes serious eye damage. May cause damage to organs (thyroid) through prolonged or repeated exposure (oral). May be corrosive to metals. Toxic to aquatic life with long lasting effects.
Precautionary statements	Wear protective gloves. Wear protective clothing. Wear eye protection. Wear face protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a doctor or a POISON CENTER. Dispose of contents to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation. Dispose of container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation. Collect spillage. Avoid release to the environment.

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

4.1. Use description

Status: This is the original version (as it was originally adopted).

TABLE 8. USE # 1 – PT 4 – CONCENTRATED SURFACE DISINFECTANT IN KITCHENS AND IN FOOD INDUSTRY, IODINE

Product type	PT04 – Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Non-porous surface disinfection in professional kitchens and in food industry
Application method(s)	By spraying with a manual or an automatic sprayer
Application rate(s) and frequency	Assume 0,04 L solution for every square meter that has to be disinfected. Bactericidal and yeasticidal activity: 0,015 % iodine Frequency is once per day.
Category(ies) of users	Professional
Pack sizes and packaging material	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 600 L, 1000 L HDPE

4.1.1. Use-specific instructions for use

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

The product must be diluted with water before use (according to the table below).

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

The product is used in professional kitchens (surface disinfection): Frequency is once per day.

The product is used in food industry (surface disinfection): Frequency is once per day.

Use at room temperature.

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

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

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

Do not mix with other chemicals.

Do not prepare more fluid than necessary.

4.1.2. *Use-specific risk mitigation measures*

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

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

4.2. **Use description**

TABLE 9. USE # 2 – PT3 – CONCENTRATED SURFACE DISINFECTANT FOR VETERINARY USE, IODINE

Product type	PT03 – Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts Viruses
Field(s) of use	Indoor Non-porous surface disinfection in veterinary field
Application method(s)	By spraying with a manual or an automatic sprayer
Application rate(s) and frequency	Assume 0,04 L solution for every square meter that has to be disinfected. Bactericidal and yeasticidal activity: 0,025 % in-use iodine Virucidal activity: 0,035 % in-use iodine
Category(ies) of users	Professional

Status: This is the original version (as it was originally adopted).

Pack sizes and packaging material	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 600 L, 1000 L HDPE
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4.2.1. Use-specific instructions for use

Use in veterinary field (PT3), surface disinfection:

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

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

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

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

Example for a product containing 2,49 % iodine ^a	Dilution of the product	Contact time
Bactericidal and yeasticidal activity	1 % (10ml product, add water up to 1 L)	30 min
Virucidal activity	1,4 % (14ml product, add water up to 1 L)	30 min

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

Do not mix with other chemicals.

Do not prepare more fluid than necessary.

4.2.2. Use-specific risk mitigation measures

- During pouring and pumping of the concentrated product: Wear chemical resistant gloves, coated coverall (material to be specified by the authorisation holder within the product information) and eye/face protection.
- During spraying of the product: Wear chemical resistant gloves and protective coverall (at least type X, EN XXXXX) which is impermeable for the biocidal product (glove and coverall material to be specified by the authorisation holder within the product information).
- Only use one kind of Iodine-containing product per day.
- Due to potential concern for human health the same professional user shall not carry out animal house disinfection more than 3 times per month and 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⁽¹⁰⁾ OF THE META SPC 7**

5.1. **Instructions for use**

See use-specific instructions for use.

5.2. **Risk mitigation measures**

See use-specific risk mitigation measures.

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

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

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

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

Have product container or label at hand.

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

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

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

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

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

The shelf-life of the products is 2 years.

Status: This is the original version (as it was originally adopted).

6. OTHER INFORMATION

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

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

Trade name(s)	Dodin 20 Iodo 20 Bio Tec Joddesinfektion Dufa dine 1,8 % Alfasan super disinfectant Iodes Streptoclean Iodin Surface Disinfectant 1,8 % IODINE				
Authorisation number	EU-0022265-0010 1-7				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	1,8
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0,0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active Substance	68131-39-5	500-195-7	5,29
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO	Non-active Substance	68439-46-3		5,0

META SPC 8

1. META SPC 8 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 8 identifier

Identifier	metaSPC 8: PT3 and PT4 – Concentrated Surface disinfectants Iodine
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1.2. Suffix to the authorisation number

Number	1-8
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1.3. Product type(s)

Product type(s)	PT03 – Veterinary hygiene (Disinfectants) PT04 – Food and feed area (Disinfectants)
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2. META SPC 8 COMPOSITION

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

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

2.2. Type(s) of formulation of the meta SPC 8

Formulation(s)	SL – Soluble concentrate
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 8

Hazard statements	May be corrosive to metals. Causes skin irritation. Causes serious eye damage. May cause damage to organs (thyroid) through prolonged or repeated exposure (oral). Toxic to aquatic life with long lasting effects.
Precautionary statements	Wear protective gloves. Wear protective clothing. Wear eye protection. Wear face protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.

Status: This is the original version (as it was originally adopted).

Immediately call a a POISON CENTER or doctor/physician.
 If experiencing respiratory symptoms: Call a a POISON CENTER or doctor/physician.
 Avoid release to the environment.
 Collect spillage.
 Dispose of contents to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.
 Dispose of container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

4. AUTHORISED USE(S) OF THE META SPC 8

4.1. Use description

TABLE 10. USE # 1 – PT4 – CONCENTRATED SURFACE DISINFECTANT IN KITCHENS AND IN FOOD INDUSTRY, IODINE

Product type	PT04 – Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Non-porous surface disinfection in professional kitchens and in food industry
Application method(s)	By spraying with a manual or an automatic sprayer
Application rate(s) and frequency	Assume 0,04 L solution for every square meter that has to be disinfected. Bactericidal and yeasticidal activity: 0,015 % iodine Daily use
Category(ies) of users	Professional
Pack sizes and packaging material	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 600 L, 1000 L HDPE

4.1.1. Use-specific instructions for use

- Use in professional kitchens (PT4) and in food industry (PT4):
- The product must be diluted with water before use (according to table below).
- Clean the surfaces thoroughly with a detergent before disinfection. Rinse with clean water and remove surplus water.

- The product is used in professional kitchens (surface disinfection): Frequency is once per day.
- The product is used in food industry (surface disinfection): Frequency is once per day.
- Use at room temperature.
- The product is applied by spraying with a manual or an automatic sprayer. Make sure to wet the surface completely. Allow to take effect for at least 15 minutes, and rinse the surfaces afterwards with clean water.

Example for a product containing 3 % iodine^a	Dilution of the product	Contact time
Bactericidal and yeasticidal activity	0,5 % (5 ml product, add water up to 1 L)	15 min

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

Do not mix with other chemicals.

Do not prepare more fluid than necessary.

4.1.2. *Use-specific risk mitigation measures*

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

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

4.2. **Use description**

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

Product type	PT03 – Veterinary hygiene (Disinfectants)
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Status: This is the original version (as it was originally adopted).

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

4.2.1. Use-specific instructions for use

Use in veterinary field (PT3), surface disinfection:

The product must be diluted with water before use (according to table below).

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

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

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

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

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

Do not mix with other chemicals.

Do not prepare more fluid than necessary.

4.2.2. *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⁽¹⁾ OF THE META SPC 8**

5.1. **Instructions for use**

See use-specific instructions for use

5.2. **Risk mitigation measures**

See use-specific risk mitigation measures.

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

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

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

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

Status: This is the original version (as it was originally adopted).

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

Have product container or label at hand.

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

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

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

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

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

The shelf-life of the products is 2 years.

6. **OTHER INFORMATION**

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

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

Trade name(s)	Iocid 30 Iodo 30 Dufa dine Iodin Surface Disinfectant 2,8 %				
Authorisation number	EU-0022265-0011 1-8				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	2,8
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0,0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active Substance	68131-39-5	500-195-7	7,93
Phosphoric acid	Phosphoric acid	Non-active Substance	7664-38-2	231-633-2	11,25

Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO	Non-active Substance	68439-46-3		12,5
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META SPC 9**1. META SPC 9 ADMINISTRATIVE INFORMATION****1.1. Meta SPC 9 identifier**

Identifier	metaSPC 9: PT4 – Concentrated CIP disinfectants Iodine
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1.2. Suffix to the authorisation number

Number	1-9
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1.3. Product type(s)

Product type(s)	PT04 – Food and feed area (Disinfectants)
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2. META SPC 9 COMPOSITION**2.1. Qualitative and quantitative information on the composition of the meta SPC 9**

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

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

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

Status: This is the original version (as it was originally adopted).

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

4. AUTHORISED USE(S) OF THE META SPC 9

4.1. Use description

TABLE 12. USE # 1 – PT4 – CONCENTRATED CLEANING IN PLACE DISINFECTANT, IODINE

Product type	PT04 – Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Cleaning in place (CIP) disinfection for milking equipment and CIP installations in food industry
Application method(s)	CIP disinfection
Application rate(s) and frequency	Apply the product in the automatic system with an end concentration of 0,00125 % available iodine

	The product is used once per day in food industry and up to 2 times per day in milking parlours.
Category(ies) of users	Professional
Pack sizes and packaging material	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 600 L, 1000 L HDPE

4.1.1. *Use-specific instructions for use*

See general instructions.

4.1.2. *Use-specific risk mitigation measures*

See general directions for use.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

5. **GENERAL DIRECTIONS FOR USE⁽¹²⁾ OF THE META SPC 9**

5.1. **Instructions for use**

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

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

^a Each product label should give information on how the dilution should be made. Since the concentration of iodine in products within this meta SPC can range from 0,5 to 0,99 % it is not possible to 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 9

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

Trade name(s)	Iodo CIP Iocip Bio Tec Jodreiniger JODOPHOS SUPER 4001 Bühning Jodreiniger Wynnsan Ice bank Tank Cleaner Bulk Tank Sanitizer
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	Iodin CIP Disinfectant				
Authorisation number	EU-0022265-0012 1-9				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,5
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0,0
Phosphoric acid	Phosphoric acid	Non-active Substance	7664-38-2	231-633-2	26,3

META SPC 10**1. META SPC 10 ADMINISTRATIVE INFORMATION****1.1. Meta SPC 10 identifier**

Identifier	metaSPC 10: PT3 – Concentrated teat disinfectants Iodine
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1.2. Suffix to the authorisation number

Number	1-10
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1.3. Product type(s)

Product type(s)	PT03 – Veterinary hygiene (Disinfectants)
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2. META SPC 10 COMPOSITION**2.1. Qualitative and quantitative information on the composition of the meta SPC 10**

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

Status: This is the original version (as it was originally adopted).

Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO	Non-active Substance	68439-46-3		0,0	0,0
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2.2. Type(s) of formulation of the meta SPC 10

Formulation(s)	SL – Soluble concentrate
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 10

Hazard statements	Causes serious eye damage. Toxic to aquatic life with long lasting effects. May cause damage to organs (thyroid) through prolonged or repeated exposure (oral route).
Precautionary statements	Wear protective gloves. Wear protective clothing. Wear eye protection. Wear face protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a doctor or a poison center. Avoid release to the environment. Dispose of contents to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation. Dispose of container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation. Collect spillage.

4. AUTHORISED USE(S) OF THE META SPC 10

4.1. Use description

TABLE 13. USE # 1 – PT3 – CONCENTRATED
TEAT DISINFECTANT, POST-MILKING, IODINE

Product type	PT03 – Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts Viruses

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

4.1.1. *Use-specific instructions for use*

See general directions for use.

4.1.2. *Use-specific risk mitigation measures*

See general directions for use.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

5. **GENERAL DIRECTIONS FOR USE⁽¹³⁾ OF THE META SPC 10**

5.1. **Instructions for use**

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

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

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

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

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

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 10

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

Trade name(s)	Kenodin SD 900 IodoSD 900 IDip+ concentrate Jodkonzentrat 1:9 Bühning Jodkonzentrat 1:9 Wynnsan Iodine Conc dip 9-1 Kenodin 900 Dufa Dip Kenostart 900 Iodin Teat Spray 900 HCP Iodine Concentrate Maxi Subliem CP Subliem Konzentrat Plus				
Authorisation number	EU-0022265-0013 1-10				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	2,8
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0,0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active Substance	68131-39-5	500-195-7	21,0

META SPC 11

1. META SPC 11 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 11 identifier

Identifier	metaSPC 11: PT3 – RTU Teat disinfectants Iodine
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1.2. Suffix to the authorisation number

Number	1-11
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1.3. Product type(s)

Product type(s)	PT03 – Veterinary hygiene (Disinfectants)
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Status: This is the original version (as it was originally adopted).

2. META SPC 11 COMPOSITION

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

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

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

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

Hazard statements	Harmful to aquatic life with long lasting effects.
Precautionary statements	Avoid release to the environment. Dispose of contents to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation. Dispose of container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

4. AUTHORISED USE(S) OF THE META SPC 11

4.1. Use description

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

Product type	PT03 – Veterinary hygiene (Disinfectants)
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Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Post-milking teat disinfection of milk producing animals
Application method(s)	By dipping or spraying on teats
Application rate(s) and frequency	The product is ready to use. Apply 2 times per day when using a manual sprayer and 3 times per day when using a dip cup or a robot (automatic sprayer).
Category(ies) of users	Professional
Pack sizes and packaging material	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 600 L, 1000 L HDPE

4.1.1. *Use-specific instructions for use*

See general instructions.

4.1.2. *Use-specific risk mitigation measures*

See general instructions.

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

See general instructions.

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

See general instructions.

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

See general instructions.

5. **GENERAL DIRECTIONS FOR USE⁽¹⁴⁾ OF THE META SPC 11**

5.1. **Instructions for use**

Apply the product by dipping or by spraying:

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

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

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

Do not mix with other chemicals.

5.2. **Risk mitigation measures**

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

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

After eye contact: Rinse immediately with water.

After ingestion: Rinse mouth. Spit.

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

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

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

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

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

The shelf-life of the products is 2 years.

6. **OTHER INFORMATION**

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

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

Trade name(s)	Kenodin 2500 Iodin Teat Dip 2500 Jod 2500	
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Authorisation number	EU-0022265-0014 1-11				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,25
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0,0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active Substance	68131-39-5	500-195-7	2,1

META SPC 12**1. META SPC 12 ADMINISTRATIVE INFORMATION****1.1. Meta SPC 12 identifier**

Identifier	meta SPC 12: PT3 – RTU Teat disinfectants Iodine
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1.2. Suffix to the authorisation number

Number	1-12
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1.3. Product type(s)

Product type(s)	PT03 – Veterinary hygiene (Disinfectants)
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2. META SPC 12 COMPOSITION**2.1. Qualitative and quantitative information on the composition of the meta SPC 12**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0,3	0,5
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0,0	0,0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active Substance	68131-39-5	500-195-7	2,1	2,9
Phosphoric acid	Phosphoric acid	Non-active Substance	7664-38-2	231-633-2	0,0	0,0

Status: This is the original version (as it was originally adopted).

Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO	Non-active Substance	68439-46-3		0,0	0,0
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2.2. Type(s) of formulation of the meta SPC 12

Formulation(s)	AL – Any other liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 12

Hazard statements	Harmful to aquatic life with long lasting effects.
Precautionary statements	Avoid release to the environment. Dispose of contents to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation. Dispose of container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

4. AUTHORISED USE(S) OF THE META SPC 12

4.1. Use description

TABLE 15. USE # 1 – PT3– RTU TEAT DISINFECTANT, POST-MILKING, IODINE

Product type	PT03 – Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts Viruses
Field(s) of use	Indoor Post-milking teat disinfection of milk producing animals
Application method(s)	By dipping or spraying on teats
Application rate(s) and frequency	The product is ready to use. Apply 2 times per day for manual spraying and 3 times per day for manual dipping and spraying with robot.
Category(ies) of users	Professional
Pack sizes and packaging material	1 L, 5 L, 10 L, 20 L, 25 L, 30 L, 60 L, 200 L, 600 L, 1000 L

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⁽¹⁵⁾ OF THE META SPC 12**

5.1. **Instructions for use**

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

Apply the product by dipping or by spraying:

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

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

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

Do not mix with other chemicals.

5.2. **Risk mitigation measures**

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

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

After eye contact: Rinse immediately with water.

Status: This is the original version (as it was originally adopted).

After ingestion: Rinse mouth. Spit.

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

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

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

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

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

The shelf-life of the products is 2 years.

6. OTHER INFORMATION

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

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

Trade name(s)	Kenodin 5000 IodoDip 5000 JOD 5000 Bio Tec Jodip 5000 Bühning Jodfilmdip-Super Iocid 5000 Iod protect 5000 Film IOD protect 5000 Film Iocid Iodip+ Protetos cua Iodin Teat Dip 5000				
Authorisation number	EU-0022265-0015 1-12				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,5
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0,0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active Substance	68131-39-5	500-195-7	2,9

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

Trade name(s)	Kenodin SD 5000 IodoSD 5000 IODOSPRAY 5000 Bio Tec Jodspray 5000 IDip+ 5000 Bühning Jodspray 5000 Iod protect 5000 Sprüh Kenodin Film Spray IOD protect 5000 Sprüh Iodin Spray & Dip 5000				
Authorisation number	EU-0022265-0016 1-12				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,5
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0,0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active Substance	68131-39-5	500-195-7	2,9

- (1) [OJ L 167, 27.6.2012, p. 1.](#)
- (2) Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council ([OJ L 301, 17.11.2017, p. 1](#)).
- (3) ECHA opinion of 11 December 2019 on the Union authorisation of ‘Iodine based products – CID LINES NV’ (ECHA/BPC/237/2019).
- (4) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 1.
- (5) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 2.
- (6) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 3.
- (7) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 4.
- (8) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 5.
- (9) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 6.
- (10) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 7.
- (11) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 8.
- (12) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 9.
- (13) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 10.
- (14) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 11.
- (15) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 12.