

## ANNEX

## Summary of product characteristics for a biocidal product family

## PART II

## SECOND INFORMATION LEVEL – META SPC(S)

## 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

**Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, META SPC 2. (See end of Document for details)

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

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<sup>(1)</sup> 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

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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**

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
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**Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, META SPC 2. (See end of Document for details)

	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				
<b>Common name</b>	<b>IUPAC name</b>	<b>Function</b>	<b>CAS number</b>	<b>EC number</b>	<b>Content (%)</b>
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
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	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 Iodactiv' film SCUDO 3000				
Authorisation number	EU-0022265-0003 1-2				
<b>Common name</b>	<b>IUPAC name</b>	<b>Function</b>	<b>CAS number</b>	<b>EC number</b>	<b>Content (%)</b>
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

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- (1) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 2.

**Changes to legislation:**

There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1187, META SPC 2.