

Commission Implementing Regulation (EU) 2020/1995 of 4 December 2020 amending Implementing Regulation (EU) No 2018/1261 as regards administrative changes of the information related to the Union authorisation of the biocidal product family ‘Hypred’s iodine based products’ (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1995

of 4 December 2020

amending Implementing Regulation (EU) No 2018/1261 as regards administrative changes of the information related to the Union authorisation of the biocidal product family ‘Hypred’s iodine based products’

(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 Article 50(2) thereof,

Whereas:

- (1) On 20 September 2018, a Union authorisation with authorisation number EU-0018397-0000 was granted by Commission Implementing Regulation (EU) 2018/1261⁽²⁾ to HYPRED SAS for the making available on the market and use of the biocidal product family ‘Hypred’s iodine based products’.
- (2) On 04 April 2019, HYPRED SAS submitted a notification to the European Chemicals Agency (‘the Agency’), in accordance with Article 11(1) of Commission Implementing Regulation (EU) No 354/2013⁽³⁾, in respect of administrative changes to the Union authorisation of the biocidal product family ‘Hypred’s iodine based products’ as described in Title 1, Sections 1 and 2 of the Annex to that Regulation.
- (3) HYPRED SAS proposed the following changes to the summary of the product characteristics for the biocidal product family ‘Hypred’s iodine based products’, as set out in the Annex to Implementing Regulation (EU) 2018/1261: (a) the addition of names for the biocidal product family in Section 7.1 of the third information level: individual products in the meta SPCs 1, 2, 3 and 5; (b) the change of the name of the authorisation holder in Section 1.3; (c) the addition of two manufacturers for the active substance and their respective manufacturing sites in Section 1.5; (d) the change of administrative details of the manufacturer in Section 1.4; (e) changes of administrative details of the location of existing manufacturing sites, and addition of location of new manufacturing sites in Section 1.4. The notification was recorded under case number BC-KC049719-36 in the Register for Biocidal Products.

Status: Point in time view as at 31/12/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1995. (See end of Document for details)

- (4) On 19 June 2019, the Agency submitted to the Commission an opinion on the proposed changes, in accordance with Article 11(3) of Implementing Regulation (EU) No 354/2013. The opinion concludes that the amendments to the existing authorisation sought by the authorisation holder falls under the category of change set out in Article 50(3)(a) of Regulation (EU) No 528/2012, and that after the implementation of the changes the conditions of Article 19 to that Regulation are still met.
- (5) On 28 June 2019, the Agency transmitted to the Commission the revised summary of the biocidal product characteristics in all the official languages of the Union in accordance with Article 11(6) of Implementing Regulation (EU) No 354/2013.
- (6) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to amend the Union authorisation of the biocidal product family ‘Hypred’s iodine based products’.
- (7) 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

Implementing Regulation (EU) 2018/1261 is amended as follows:

- (1) in Article 1, ‘HYPRED SAS’ is replaced by ‘HYPRED SAS – KERSIA Group’;
- (2) the Annex is replaced by the Annex to this Regulation.

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, 4 December 2020.

For the Commission

The President

Ursula VON DER LEYEN

Status: Point in time view as at 31/12/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1995. (See end of Document for details)

ANNEX

Summary of product characteristics for a biocidal product family

HYPRED's iodine based products

Product type 3 - Veterinary hygiene (Disinfectants)

Authorisation number: EU-0018397-0000

R4BP asset number: EU-0018397-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. Family name

Name	HYPRED's iodine based products

1.2. Product type(s)

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

1.3. Authorisation holder

Name and address of the authorisation holder	Name	HYPRED SAS – KERSIA Group
	Address	55, Boulevard Jules Verger - BP10180 35803 DINARD Cedex France
Authorisation number	EU-0018397-0000	
<i>R4BP asset number</i>	EU-0018397-0000	
Date of the authorisation	11 October 2018	
Expiry date of the authorisation	30 September 2028	

1.4. Manufacturer(s) of the biocidal products

Name of manufacturer	HYPRED SAS – KERSIA Group
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Status: Point in time view as at 31/12/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1995. (See end of Document for details)

Address of manufacturer	55, Boulevard Jules Verger - BP10180 35803 DINARD France
Location of manufacturing sites	<p>HYPRED SAS – KERSIA Group - 55, Boulevard Jules Verger - BP10180 35803 DINARD France</p> <p>KERSIA POLSKA Sp.z.o.o. - NIEPRUSZEWO, KASZTANOWA 4 64320 Buk Poland</p> <p>KERSIA IBERICA SL - Pol. Miguel Eguía C/Zarapuz s/n 31200 ESTELLA (NAVARRA) Spain</p> <p>KERSIA DEUTSCHLAND GmbH Marie- Curie-Straße 23 53332 Bornheim – Sechtem Germany</p> <p>HYPRED Italia s.r.l. – KERSIA Group Strada Montodine-Gombito Loc. Cà Nova 26010 Ripalta Arpina CR Italy</p> <p>AG France S.A.S – KERSIA Group - Zone Industrielle Le Roineau, 72500 VAAS, FRANCE</p> <p>KERSIA DEUTSCHLAND GmbH - OBERBRÜHLSTRAßE 16-18, 87700 MEMMINGEN, GERMANY</p> <p>KERSIA AUSTRIA GmbH - PFONGAUERSTRAßE 17, 5202 NEUMARKT AM WALLERSEE, AUSTRIA</p> <p>Kilco Holdings Ltd – KERSIA Group - Broomhouses 2 Industrial Estate, Old Glasgow Road, LOCKERBIE - DG11 2SD, UNITED KINGDOM</p> <p>Kilco (International) Ltd – KERSIA Group - 1A Trench Road Mallusk, Newtownabbey, CO ANTRIM BT36 4TY, IRELAND</p> <p>Medentech Ltd – KERSIA Group - Clonard Road, WEXFORD, Y35Y7WY, IRELAND</p>

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

Active substance	Iodine
Name of manufacturer	COSAYACH : SCM Cía. Cosayach Minera Negreiros, Rut. N°96.625.710-5
Address of manufacturer	Terrenos de Elena S/N Terrenos de Elena S/N Huara, Región de Tarapacá Chile
Location of manufacturing sites	<p>Mined at: S.C.M. Cía. Minera Negreiros, S.C.M. Cosayach Soledad.</p> <p>Refined at: S.C.M. Cía. Minera Negreiros. Pozo Almonte Chile</p>

*Status: Point in time view as at 31/12/2020.**Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1995. (See end of Document for details)*

Active substance	Iodine
Name of manufacturer	ACF MINERA SA
Address of manufacturer	San Martín 499 Iquique Chile
Location of manufacturing sites	Faena Lagunas KM. 1.722 Ruta A-5, Pozo Almonte Chile

Active substance	Iodine
Name of manufacturer	SOCIEDAD QUIMICA y MINERA SA
Address of manufacturer	Los Militares 4290 SANTIAGO DE CHILE Chile
Location of manufacturing sites	Pedro de Valdivia (PV) Route B 180 Antofagasta Chile Nueva Victoria (NV) Route 5 North, Km 1925 Pozo Almonte Chile

Active substance	Iodine
Name of manufacturer	ISE Chemicals Corporation
Address of manufacturer	3-1, Kyobashi 1-Chome, Chuo-ku, Tokyo Japan
Location of manufacturing sites	Shirasato Plant (3695 Kitaimaizumi, Oamishirasato City, Chiba, Japan)

Active substance	Iodine
Name of manufacturer	Nihon Tennen Gas Development Co., Ltd
Address of manufacturer	661 Mobara 297-8550 Mobara City, Chiba Japan
Location of manufacturing sites	Chiba Plant, 2508 Minami Hinata, 299-4205 Shirako-Machi, Chosei-Gun, Chiba Japan

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	0,25	2,5
Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), -C12-14- (even numbered)-	Non active substance	68439-50-9		2,697	24,199

Status: Point in time view as at 31/12/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1995. (See end of Document for details)

alkyl--hydroxy					
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2.2. Type(s) of formulation

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

PART II

SECOND INFORMATION LEVEL - META SPC(S)

META SPC 1

1. META SPC 1 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 1 identifier

Identifier	meta SPC 1 : Dipping products - ready to use
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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)

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	0,25	0,49
Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), -C12-14- (even numbered)-alkyl--hydroxy	Non active substance	68439-50-9		2,697	4,993

Status: Point in time view as at 31/12/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1995. (See end of Document for details)

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

Formulation	AL - Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

Hazard statements	Causes serious eye irritation. Harmful to aquatic life with long lasting effects.
Precautionary statements	Keep out of reach of children. Wash hands thoroughly after handling. Wear protective gloves. Wear protective clothing. Wear eye protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

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

4.1. Use description

TABLE 1. USE # 1 – MANUAL OR AUTOMATED DIPPING AFTER MILKING

Product Type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Bacteria Yeasts Algae
Field(s) of use	Indoor Disinfection of teats of milk producing animals by dipping after milking
Application method(s)	Dipping - Manual or automated disinfection of teats by dipping after milking. Dipping cup or automated dipping machine.
Application rate(s) and frequency	— cows and buffaloes (3 to 10ml : 5 ml recommended) — sheep (1.5 to 5 ml : 1.5 ml recommended) — goats (2.5 to 6 ml : 2.5 ml recommended)

Status: Point in time view as at 31/12/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1995. (See end of Document for details)

	Frequency : 2 to 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1000L

4.1.1. *Use-specific instructions for use*

See general directions for use of meta SPC 1

4.1.2. *Use-specific risk mitigation measures*

See general directions for use of meta SPC 1

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 of meta SPC 1

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

None: See general directions for use of meta SPC 1

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 of meta SPC 1

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

5.1. **Instructions for use**

Always read the label or leaflet before use and follow all the instructions provided.

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.

Fill the dipping cup manually or automatically with the ready to use product.

Apply by dipping manually or automatically on animal's teats on the full length of the teat after milking.

- cows and buffaloes (3 to 10ml : 5 ml recommended)
- sheep (1.5 to 5 ml : 1.5 ml recommended)
- goats (2.5 to 6 ml : 2.5 ml recommended)

Leave the product until next milking. Keep the cows standing until the product has dried (at least 5 minutes).

At the next milking, use the teat cleaning and wiping method systematically before attaching the milking cluster.

Where necessary, repeat the application after each milking.

Clean the application equipment regularly with warm water.

5.2. Risk mitigation measures

Wear eye protection.

In case 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.

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

Take the contaminated clothes and shoes off immediately. Wash them before wearing them again.

FIRST AID INSTRUCTIONS

- In the event of inhalation: Bring to fresh air.
- In the event of contact with the skin: Wash with water.
- In the event of contact with the eyes :

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

If eye irritation persists: Get medical advice/attention.

- In the event of ingestion: Rinse mouth. Do NOT induce vomiting. Get medical advice.

Refer to the safety data sheet available for professional user: it contains an emergency phone number.

Large spillage: Mark out, dyke up with an inert absorbant and pump in an emergency tank. Keep in suitable, properly labelled and closed containers for disposal. Never return spills in original containers for re-use.

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.

The paper towels used for removing the product and drying the teats are disposed in the normal and domestic waste.

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

Shelf life : 2 years in HDPE

Do not store at a temperature higher than 30°C.

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

Status: Point in time view as at 31/12/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1995. (See end of Document for details)

Trade name(s)	Dip-io 2500 JOD DIP IODERM PSP DERMINO FR Iododip IODEX EXTRA Iodystrong DERMIODE INO IODE EPAIS INO STAR + IODACTIV 2500 IODIUM BX2500 Usual Iod Post ASiRAL Dip Coat IODOCAN EXTRA UDDER PLUS PRIMADIODE CERTIODE EPAIS IODIPACK GEL HELIO IODE EPAIS VAGEL GELAPIS ACTIV IOSAPIS GEL ZENCARE FLASH REPROGEL DERMADINE + KRONI Jod Dipp 2500 WÜBBELMANN JOD DIP Iodine Cleaner&Sanitizer MUNGIFILM ZEP FS FILMIODINE NIPPLE NP IODOFILM EMPRASAN UDDER SHIELD ANGLIA FARMERS IO-FILM BARRICADE STANTON IODOFILM WYNNSAN IOFILM TEAT DIP				
Authorisation number	EU-0018397-0001 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active substance	7553-56-2	231-442-4	0,25
Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), -C12-14-(even numbered)-alkyl--hydroxy	Non active substance	68439-50-9		2,697

Status: Point in time view as at 31/12/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1995. (See end of Document for details)

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

Trade name(s)	Dip-io YB MAX INO Io Dip MAX JOD DIP YB MAX IodoDip YB MAX Iodium Dip YB MAX JodyDip YB MAX Delta IoDip YB MAX				
Authorisation number	EU-0018397-0002 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active substance	7553-56-2	231-442-4	0,49
Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), -C12-14-(even numbered)-alkyl--hydroxy	Non active substance	68439-50-9		4,993

META SPC 2

1. META SPC 2 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 2 identifier

Identifier	meta SPC 2 : Dipping, foaming, spraying products - Ready to use
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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

Status: Point in time view as at 31/12/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1995. (See end of Document for details)

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active substance	7553-56-2	231-442-4	0,25	0,49
Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), -C12-14- (even numbered)-alkyl--hydroxy	Non active substance	68439-50-9		2,697	4,69

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

Formulation	AL - Any other liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

Hazard statements	Causes serious eye irritation. Harmful to aquatic life with long lasting effects.
Precautionary statements	Keep out of reach of children. Wash hands thoroughly after handling. Wear protective gloves. Wear protective clothing. Wear eye protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

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

4.1. Use description

TABLE 2. USE # 1 – MANUAL OR AUTOMATED DIPPING, FOAMING OR SPRAYING BEFORE MILKING

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

Status: Point in time view as at 31/12/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1995. (See end of Document for details)

	Disinfection of teats of milk producing animals by dipping, foaming or spraying before milking
Application method(s)	Dipping, foaming or spraying before milking - Manual or automated disinfection of teats by dipping, foaming or spraying before milking Dipping cup, foaming cup, teat sprayer, automated dipping machine, automated foaming machine or automated spraying machine
Application rate(s) and frequency	— cows and buffaloes (3 to 10ml : 5 to 8 ml recommended) — sheep (1.5 to 5 ml : 1.5 to 3ml recommended) — goats (2.5 to 6 ml : 2.5 to 4 ml recommended) Frequency : 2 to 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1000L

4.1.1. *Use-specific instructions for use*

Eliminate all visible dirt before applying the product.

Manual or automatic dipping/foaming/spraying on animal's teats on the full length of the teat before milking.

Let the product act at least one minute.

Use the teat cleaning and wiping method systematically before attaching the milking cluster.

See also general instructions for use of meta SPC 2.

4.1.2. *Use-specific risk mitigation measures*

For manual dipping/foaming application: Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information)/ eye protection.

For manual spraying applications wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information)/protective clothing / eye protection.

In case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered for post-milking disinfection.

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 of meta SPC 2

Status: Point in time view as at 31/12/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1995. (See end of Document for details)

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

See general directions for use of meta SPC 2

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 of meta SPC 2

4.2. **Use description**

TABLE 3. USE # 2 – MANUAL OR AUTOMATED DIPPING, FOAMING OR SPRAYING AFTER MILKING

Product Type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Bacteria Yeasts Algae
Field(s) of use	Indoor Disinfection of teats of milk producing animals by dipping, foaming or spraying after milking
Application method(s)	Dipping, foaming, spraying after milking - Manual or automated disinfection of teats by dipping, foaming or spraying after milking Dipping cup, foaming cup, teat sprayer, automated dipping machine, automated foaming machine or automated spraying machine
Application rate(s) and frequency	— cows and buffaloes (3 to 10ml : 5 to 8 ml recommended) — sheep (1,5 to 5 ml : 1,5 to 3ml recommended) — goats (2,5 to 6 ml : 2,5 to 4 ml recommended) Frequency : 2 to 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1000L

4.2.1. *Use-specific instructions for use*

Manual or automatic dipping / foaming / spraying on animal's teats on the full length of the teat after milking.

Leave the product until next milking. Keep the cows standing until the product has dried. (at least 5 minutes)

At the next milking, use the teat cleaning and wiping method systematically before attaching the milking cluster.

See also general instructions for use of meta SPC 2.

4.2.2. *Use-specific risk mitigation measures*

For manual spraying applications wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information)/protective clothing / eye protection.

In case 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.

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 of meta SPC 2

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

See general directions for use of meta SPC 2

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 of meta SPC 2

5. GENERAL DIRECTIONS FOR USE⁽⁶⁾ OF THE META SPC 2

5.1. **Instructions for use**

See use-specific instructions for each use.

Always read the label or leaflet before use and follow all the instructions provided.

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. Fill the dipping/foaming cup/sprayer manually or automatically with the ready to use product.

Where necessary repeat the application at each milking

Clean the application equipment regularly with warm water.

5.2. **Risk mitigation measures**

See use-specific risk mitigation measures for each use.

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

Take the contaminated clothes and shoes off immediately. Wash them before wearing them again.

FIRST AID INSTRUCTIONS

Status: Point in time view as at 31/12/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1995. (See end of Document for details)

- In the event of inhalation: Bring to fresh air.
- In the event of contact with the skin: Wash with water.
- In the event of contact with the eyes :

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

If eye irritation persists: Get medical advice/attention.

- In the event of ingestion: Rinse mouth. Do NOT induce vomiting. Get medical advice.

Refer to the safety data sheet available for professional user: it contains an emergency phone number.

Large spillage: Mark out, dyke up with an inert absorbant and pump in an emergency tank. Keep in suitable, properly labelled and closed containers for disposal. Never return spills in original containers for re-use.

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.

The paper towels used for removing the product and drying the teats are disposed in the normal and domestic waste.

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

Shelf life : 2 years in HDPE

Do not store at a temperature higher than 30°C.

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)	Liq-io 2500 JOD SPRAY IODINE 3000 RTU IODEX 2500 Usual Iod Liquid Iodoliquid Iodospray DESINTEAT IODYSPRAY RBT 2500 IODY'FLASH INO IODE SPRAY IODYPRO 2500 IODYPRO BL2500
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Status: Point in time view as at 31/12/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1995. (See end of Document for details)

	Robot Liq-io 25 ADF iDip+ ASiRAL Dip Spray J IODIPACK HELIO IODE LIQUIDE POLY-IODE CERTIODE LIQUIDE IOSAPIS FLUID GELAPIS ROBOT ZENCARE SPRAY HELIO IODE SPRAY + IODIP + KRONI Jod Spray 2500 WÜBBELMANN JOD LIQUID PRECEPT ANGLIA FARMERS PRECLENZ H&M PREDIP FULLWOOD PRECLEANSE M WILLIAMS PRECEPT STANTON PREDIP RTU WYNN SAN IODINE PREDIP RTU PREMIER GOLD PRE-DIP HODGES & MOSS PREDIP LANODIP PREPOST DAIRYSAN MULTICARE EMPRASAN ADVANCE UDDERWASH IODINE ANGLIA FARMERS PREPOST-IO PREMIER GOLD PRE/POST FULLWOOD PRE/POST IODINE HODGES & MOSS ADVANCE WYNN SAN IODINE PREPOST				
Authorisation number	EU-0018397-0003 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active substance	7553-56-2	231-442-4	0,25
Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), -C12-14-(even numbered)-alkyl--hydroxy	Non active substance	68439-50-9		2,697

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

Status: Point in time view as at 31/12/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1995. (See end of Document for details)

Trade name(s)	Liq-io YB MAX INO Io Liquid Max Iodoliquid YB MAX Iodospray YB MAX Desinteat YB MAX Iodium Spray YB MAX JodySpray YB MAX Delta IoSpray YB MAX				
Authorisation number	EU-0018397-0004 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active substance	7553-56-2	231-442-4	0,49
Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), -C12-14-(even numbered)-alkyl--hydroxy	Non active substance	68439-50-9		4,69

META SPC 3

1. META SPC 3 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 3 identifier

Identifier	meta SPC 3 : Dipping, foaming, spraying concentrated products
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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

Status: Point in time view as at 31/12/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1995. (See end of Document for details)

Iodine		Active substance	7553-56-2	231-442-4	2,5	2,5
Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), -C12-14- (even numbered)-alkyl--hydroxy	Non active substance	68439-50-9		24,199	24,199

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

Formulation	SL - Soluble concentrate
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 3

Hazard statements	Causes serious eye damage. May cause damage to organs (thyroid) through prolonged or repeated exposure oral. Toxic to aquatic life with long lasting effects. May be corrosive to metals.
Precautionary statements	Keep out of reach of children. Do not breathe mist. Do not breathe vapours. Do not breathe spray. Wash hands thoroughly after handling. Wear protective gloves. Wear protective clothing. Wear eye 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 poison center / doctor. Get medical advice/attention if you feel unwell. Dispose of contents to in accordance with local/ regional/ national/ international regulations. Dispose of container to in accordance with local/ regional/ national/ international regulations. Keep only in original container. Absorb spillage to prevent material damage.

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

4.1. Use description

Status: Point in time view as at 31/12/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1995. (See end of Document for details)

TABLE 4. USE # 1 – MANUAL OR AUTOMATED
DIPPING, FOAMING OR SPRAYING BEFORE MILKING

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 Disinfection of teats of milk producing animals by dipping, foaming or spraying before milking
Application method(s)	Dipping, foaming, spraying - Manual or automated disinfection of teats by dipping, foaming or spraying before milking. Dipping cup, foaming cup, teat sprayer, automated dipping machine, automated foaming machine or automated spraying machine
Application rate(s) and frequency	A dilution at 10% (v/v) should be prepared Application rate for the diluted product: — cows and buffaloes (3 to 10ml : 5 to 8 ml recommended) — sheep (1.5 to 5 ml: 1.5 to 3 ml recommended) — goats (2.5 to 6 ml: 2.5 to 4 ml recommended) Frequency: 2 to 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1000L

4.1.1. *Use-specific instructions for use*

Prepare a dilution at 10% (v/v: 10 ml product, add water up to 100ml) for bactericidal and yeasticidal activity.

Fill the dipping / foaming cup / sprayer manually or automatically with the prepared dilution.

Eliminate all visible dirt before applying the product.

Manual or automatic dipping/foaming/spraying on animal's teats on the full length of the teat before milking.

Let the product act at least one minute.

Use the teat cleaning and wiping method systematically before attaching the milking cluster.

See also general directions for use of meta SPC 3.

Status: Point in time view as at 31/12/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1995. (See end of Document for details)

4.1.2. Use-specific risk mitigation measures

For manual spraying applications wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information)/protective clothing / eye protection.

In case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered for post-milking disinfection.

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 of meta SPC 3

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

See general directions for use of meta SPC 3

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 of meta SPC 3

4.2. Use description

TABLE 5. USE # 2 – MANUAL OR AUTOMATED
DIPPING, FOAMING OR SPRAYING AFTER MILKING

Product Type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Bacteria Yeasts Algae Viruses
Field(s) of use	Indoor Disinfection of teats of milk producing animals by dipping, foaming or spraying after milking
Application method(s)	Dipping, foaming, spraying - Manual or automated disinfection of teats by dipping, foaming or spraying after milking. Dipping cup, foaming cup, teat sprayer, automated dipping machine, automated foaming machine or automated spraying machine
Application rate(s) and frequency	For disinfection of bacteria, yeasts and algae a dilution at 10% (v/v: 10 ml product, add water up to 100ml) should be prepared.

Status: Point in time view as at 31/12/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1995. (See end of Document for details)

	For disinfection of viruses a dilution at 20% (v/v: 20 ml product, add water up to 100ml) should be prepared Application rate for the diluted product: — cows and buffaloes (3 to 10ml : 5 to 8 ml recommended) — sheep (1,5 to 5 ml : 1,5 to 3ml recommended) — goats (2,5 to 6 ml : 2,5 to 4 ml recommended) Frequency : 2 to 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1000L

4.2.1. *Use-specific instructions for use*

Prepare a dilution at 10% (v/v: 10 ml product, add water up to 100ml) for bactericidal, yeasticidal and algacidal activity or 20% (v/v: 20 ml product, add water up to 100ml) in case virucidal activity is also needed.

Fill the dipping / foaming cup / sprayer manually or automatically with the prepared dilution.

Manual or automatic dipping / foaming / spraying on animal's teats on the full length of the teat after milking.

Leave the product until next milking. Keep the cows standing until the product has dried (at least 5 minutes).

At the next milking, use the teat cleaning and wiping method systematically before attaching the milking cluster.

See also general directions for use of meta SPC 3

4.2.2. *Use-specific risk mitigation measures*

For manual spraying applications wear chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) /protective clothing/eye protection.

In case 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.

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 of meta SPC 3

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

See general directions for use of meta SPC 3

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 of meta SPC 3

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

5.1. Instructions for use

See use-specific instructions for each use.

Always read the label or leaflet before use and follow all the instructions provided.

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. Fill the dipping / foaming cup / sprayer manually or automatically with the prepared dilution.

Where necessary, repeat the application at each milking

Clean the application equipment regularly with warm water.

5.2. Risk mitigation measures

See use-specific risk mitigation measures for each use.

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

Take the contaminated clothes and shoes off immediately. Wash them before wearing them again.

In case of faintness, get medical advice/attention. Show this safety data sheet to the doctor.

FIRST AID INSTRUCTIONS

- In the event of inhalation: Bring to fresh air.
- In the event of contact with the skin: Wash with water.
- In the event of contact with the eyes: Rinse at once with a soft stream of water for at least 15 minutes, eyes wide open.

Remove contact lenses if present and easy to do. Continue rinsing.

Immediately call a POISON CENTER or doctor/physician.

- In the event of ingestion: Rinse mouth. Do NOT induce vomiting. Get medical advice.

Refer to the safety data sheet available for professional user: it contains an emergency phone number.

Large spillage: Mark out, dyke up with an inert absorbant and pump in an emergency tank. Keep in suitable, properly labelled and closed containers for disposal. Never return spills in original containers for re-use.

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.

The paper towels used for removing the product and drying the teats are disposed in the normal and domestic waste.

Status: Point in time view as at 31/12/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1995. (See end of Document for details)

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

Shelf life : 2 years in HDPE

Do not store at a temperature higher than 30°C.

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)	Liq-io concentrate INO Jod Konzentrat Usual Iod Concent Iodoconcentrat D 10 IODINE D 5 IODINE Liq-io C INO IODE C D 4 IODINE ADF iDip+ concentrate Mammizan Concentré WYNNSAN IODINE CONCENTRATE EMPRASAN OPTIMA ANGLIA FARMERS CONC PROLAC SENTINEL CONC PREMIER GOLD CONCENTRATE FULLWOOD IODINE CONC H&M OPTIMA SENTINAL CONC HARRY TRAVIS SUPER CONC TEAT DIP LANODIP CONC E/SAN SOVEREIGN PROLAC SENTINEL CONC				
Authorisation number	EU-0018397-0005 1-3				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active substance	7553-56-2	231-442-4	2,5
Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), -C12-14-(even numbered)-alkyl--hydroxy	Non active substance	68439-50-9		24,199

Status: Point in time view as at 31/12/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1995. (See end of Document for details)

META SPC 4

1. META SPC 4 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 4 identifier

Identifier	meta SPC 4 : Dipping products reaching virucidal activity – Ready to use
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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	0,5	0,5
Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), -C12-14- (even numbered)-alkyl--hydroxy	Non active substance	68439-50-9		4,993	4,993

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

Formulation	AL - Any other liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 4

Hazard statements	Causes serious eye irritation. Harmful to aquatic life with long lasting effects.
Precautionary statements	Keep out of reach of children.

Status: Point in time view as at 31/12/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1995. (See end of Document for details)

Wash hands thoroughly after handling.
Wear protective gloves.
Wear protective clothing.
Wear eye protection.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.

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

4.1. Use description

TABLE 6. USE # 1 – MANUAL OR AUTOMATED DIPPING AFTER MILKING

Product Type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Bacteria Yeasts Algae Viruses
Field(s) of use	Indoor Disinfection of teats of milk producing animals by dipping after milking
Application method(s)	Dipping - Manual or automated disinfection of teats by dipping after milking. Dipping cup or automated dipping machine.
Application rate(s) and frequency	— cows and buffaloes (3 to 10ml : 5 ml recommended) — sheep (1,5 to 5 ml : 1,5 ml recommended) — goats (2,5 to 6 ml : 2,5 ml recommended) Frequency : 2 to 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1000L

4.1.1. Use-specific instructions for use

See general directions for use of meta SPC 4

4.1.2. Use-specific risk mitigation measures

See general directions for use of meta SPC 4

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 of meta SPC 4

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

See general directions for use of meta SPC 4

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 of meta SPC 4

5. GENERAL DIRECTIONS FOR USE⁽⁷⁾ OF THE META SPC 4

5.1. Instructions for use

Always read the label or leaflet before use and follow all the instructions provided.

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. Fill the dipping cup manually or automatically with the ready to use product.

Apply by dipping manually or automatically on animal's teats on the full length of the teat after milking.

- cows and buffaloes (3 to 10ml : 5 ml recommended)
- sheep (1,5 to 5 ml : 1,5 ml recommended)
- goats (2,5 to 6 ml : 2,5 ml recommended)

Leave the product until next milking. Keep the cows standing until the product has dried (at least 5 minutes).

At the next milking, use the teat cleaning and wiping method systematically before attaching the milking cluster.

Where necessary, repeat the application after each milking.

Clean the application equipment regularly with warm water.

5.2. Risk mitigation measures

Wear eye protection.

In case 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.

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

Take the contaminated clothes and shoes off immediately. Wash them before wearing them again.

FIRST AID INSTRUCTIONS

- In the event of inhalation: Bring to fresh air.

Status: Point in time view as at 31/12/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1995. (See end of Document for details)

- In the event of contact with the skin: Wash with water.
- In the event of contact with the eyes :

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

If eye irritation persists: Get medical advice/attention.

- In the event of ingestion: Rinse mouth. Do NOT induce vomiting. Get medical advice.

Refer to the safety data sheet available for professional user: it contains an emergency phone number.

Large spillage: Mark out, dyke up with an inert absorbant and pump in an emergency tank. Keep in suitable, properly labelled and closed containers for disposal. Never return spills in original containers for re-use.

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.

The paper towels used for removing the product and drying the teats are disposed in the normal and domestic waste.

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

Shelf life : 2 years in HDPE

Do not store at a temperature higher than 30°C.

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)	Dip-io 5000 IODIUM TX INO JOD 50 DIP Usual Iod Post + IODIUM PRO DIP IODERM PSP + IODEX EXTRA + Iododip + IODYSTRONG PLUS INO TREMP INO STAR IODACTIV 5000 DERMINO IODERM 5000 IODIUM BX5000 HOEVE-PLUS DIP
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*Status: Point in time view as at 31/12/2020.**Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1995. (See end of Document for details)*

	TREMPASEPT IODE DERMADINE MAMMO-DERM KRONI Jod Dipp 5000				
Authorisation number	EU-0018397-0006 1-4				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active substance	7553-56-2	231-442-4	0,5
Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), -C12-14-(even numbered)-alkyl--hydroxy	Non active substance	68439-50-9		4,993

META SPC 5

1. META SPC 5 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 5 identifier

Identifier	meta SPC 5 : Dipping, foaming, spraying products 5500 ppm – Ready to use
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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	0,55	0,55
Alcohols, C12-14, ethoxylated	Poly(oxy-1,2-ethanediyl), -C12-14-	Non active substance	68439-50-9		4,69	4,69

Status: Point in time view as at 31/12/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1995. (See end of Document for details)

(11 mol EO average molar ratio)	(even numbered)-alkyl--hydroxy					
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2.2. Type(s) of formulation of the meta SPC 5

Formulation	AL - Any other liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 5

Hazard statements	Causes serious eye irritation. Harmful to aquatic life with long lasting effects.
Precautionary statements	Keep out of reach of children. Wash hands thoroughly after handling. Wear protective gloves. Wear protective clothing. Wear eye protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

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

4.1. Use description

TABLE 7. USE # 1 – MANUAL OR AUTOMATED DIPPING, FOAMING OR SPRAYING BEFORE MILKING

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 Disinfection of teats of milk producing animals by dipping, foaming or spraying before milking
Application method(s)	Dipping, foaming, spraying - Manual or automated disinfection of teats by dipping, foaming or spraying before milking

Status: Point in time view as at 31/12/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1995. (See end of Document for details)

	Dipping cup, foaming cup, teat sprayer, automated dipping machine, automated foaming machine or automated spraying machine
Application rate(s) and frequency	<ul style="list-style-type: none"> — cows and buffaloes (3 to 10ml : 5 to 8 ml recommended) — sheep (1,5 to 5 ml : 1,5 to 3ml recommended) — goats (2,5 to 6 ml : 2,5 to 4 ml recommended) Frequency : 2 to 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1000L

4.1.1. *Use-specific instructions for use*

Fill the dipping / foaming cup / sprayer manually or automatically with the ready to use product.

Eliminate all visible dirt before applying the product.

Manual or automatic dipping / foaming / spraying on animal's teats on the full length of the teat before milking.

Let the product act at least one minute.

Use the teat cleaning and wiping method systematically before attaching the milking cluster.

See also general instructions for use of meta SPC5.

4.1.2. *Use-specific risk mitigation measures*

For manual dipping/foaming application : Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information)/ eye protection.

For manual spraying applications wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information)/protective clothing / eye protection.

In case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered for post-milking disinfection.

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 of meta SPC 5

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

See general directions for use of meta SPC 5

Status: Point in time view as at 31/12/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1995. (See end of Document for details)

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 of meta SPC 5

4.2. **Use description**

TABLE 8. USE # 2 – MANUAL OR AUTOMATED
DIPPING, FOAMING OR SPRAYING AFTER MILKING

Product Type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Bacteria Yeasts Algae Viruses
Field(s) of use	Indoor Disinfection of teats of milk producing animals by dipping, foaming or spraying after milking
Application method(s)	Dipping, foaming, spraying - Manual or automated disinfection of teats by dipping, foaming or spraying after milking. Dipping cup, foaming cup, teat sprayer, automated dipping machine, automated foaming machine or automated spraying machine.
Application rate(s) and frequency	— cows and buffaloes (3 to 10ml : 5 to 8 ml recommended) — sheep (1,5 to 5 ml : 1,5 to 3ml recommended) — goats (2,5 to 6 ml : 2,5 to 4 ml recommended) Frequency : 2 to 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1000L

4.2.1. *Use-specific instructions for use*

Fill the dipping / foaming cup / sprayer manually or automatically with the ready to use product.

Manual or automatic dipping / foaming / spraying on animal's teats on the full length of the teat after milking.

Leave the product until next milking. Keep the cows standing until the product has dried. (at least 5 minutes)

At the next milking, use the teat cleaning and wiping method systematically before attaching the milking cluster.

See also general instructions for use of meta SPC 5.

4.2.2. *Use-specific risk mitigation measures*

For manual spraying applications wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information)/protective clothing/eye protection.

In case 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.

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 of meta SPC 5

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

See general directions for use of meta SPC 5

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 of meta SPC 5

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

5.1. **Instructions for use**

See use-specific instructions for each use.

Always read the label or leaflet before use and follow all the instructions provided.

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.

Where necessary repeat the application at each milking

Clean the application equipment regularly with warm water.

5.2. **Risk mitigation measures**

See use-specific risk mitigation measures for each use.

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

Take the contaminated clothes and shoes off immediately. Wash them before wearing them again.

FIRST AID INSTRUCTIONS

- In the event of inhalation: Bring to fresh air.
- In the event of contact with the skin: Wash with water.
- In the event of contact with the eyes :

Status: Point in time view as at 31/12/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1995. (See end of Document for details)

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

If eye irritation persists: Get medical advice/attention.

— In the event of ingestion: Rinse mouth. Do NOT induce vomiting. Get medical advice.

Refer to the safety data sheet available for professional user: it contains an emergency phone number.

Large spillage: Mark out, dyke up with an inert absorbant and pump in an emergency tank. Keep in suitable, properly labelled and closed containers for disposal. Never return spills in original containers for re-use.

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.

The paper towels used for removing the product and drying the teats are disposed in the normal and domestic waste.

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

Shelf life : 2 years in HDPE

Do not store at a temperature higher than 30°C.

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)	
	Liq-io 5500
	IODYPRO
	INO JOD 50 Liquid
	Usual Iod Liquid +
	IODIUM PRO SPRAY
	IODEX
	Iodoliquid +
	Iodospray Plus
	DESINTEAT PLUS
	ROBOSPRAY IODE
	INOTRAYON
	IODYPRO 5500
	Robot Liq-io 55
	IODYPRO BL5500
	ADF iDip+ 5500
	HOEVE-JODIUM SPRAY
	GRUPAIODE
	IODOCAN

Status: Point in time view as at 31/12/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1995. (See end of Document for details)

	JOFO JODI PLUS K-AGRO PRODIP ID IODIP HELIO IODE SPRAY MAMMO-JOD KRONI Jod Spray 5500 MUNGI-IOD LELY QUARESS-Iodine GOLD GLYCODIP EMPRASAN EXTRA CARE H&M RTU IODINE ANGLIA FARMERS SUPPLEDIP-IO PROLAC RTU IODINE TEAT DIP PREMIER GOLD POST DIP FULLWOOD IODINE EXTRA H&M EXTRACARE M WILLIAMS TEAT DIP PLATINUM WDH GOLD DIP RTU WYNNSAN IODINE HE RTU				
Authorisation number	EU-0018397-0007 1-5				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active substance	7553-56-2	231-442-4	0,55
Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), -C12-14-(even numbered)-alkyl--hydroxy	Non active substance	68439-50-9		4,69

Status: Point in time view as at 31/12/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1995. (See end of Document for details)

- (1) [OJ L 167, 27.6.2012, p. 1.](#)
- (2) Commission Implementing Regulation (EU) 2018/1261 of 20 September 2018 granting a Union authorisation for the biocidal product family Hypred's iodine based products ([OJ L 238, 21.9.2018, p. 33](#)).
- (3) Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council ([OJ L 109, 19.4.2013, p. 4](#)).
- (4) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC1.
- (5) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC2.
- (6) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC3.
- (7) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC4.
- (8) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC5.

Status:

Point in time view as at 31/12/2020.

Changes to legislation:

There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1995.