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► **B** **COMMISSION IMPLEMENTING REGULATION (EU) 2018/1287**
 of 24 September 2018
 granting a Union authorisation for the biocidal product family Quat-Chem's iodine based products
 (Text with EEA relevance)
 (OJ L 240, 25.9.2018, p. 10)

Amended by:

		Official Journal		
		No	page	date
► M1	Commission Implementing Regulation (EU) 2023/2384 of 29 September 2023	L 2384	1	6.10.2023

▼B

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1287
of 24 September 2018
granting a Union authorisation for the biocidal product family
Quat-Chem's iodine based products
(Text with EEA relevance)

Article 1

A Union authorisation is granted to ►**M1** Neogen Italia S.r.l. ◀ for the same biocidal product family Quat-chem's iodine based products with authorisation number EU-0018496-0000.

The Union authorisation is valid from 15 October 2018 until 30 September 2028.

The Union authorisation is subject to compliance with the SPC set out in the Annex.

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.

▼ **M1**

ANNEX

Summary of product characteristics for a biocidal product family**QUAT-CHEM's iodine based products****Product type 3 – Veterinary hygiene (Disinfectants)****Authorisation number: EU-0018496-0000****R4BP asset number: EU-0018496-0000**

PART I

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

Name	QUAT-CHEM's iodine based products
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1.2. Product type(s)

Product type(s)	PT03 – Veterinary hygiene (Disinfectants)
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1.3. Authorisation holder

Name and address of the authorisation holder	Name	Neogen Italia S.r.l.
	Address	Via Agnello 8, 20121 Milano, Italy
Authorisation number	EU-0018496-0000	
<i>R4BP asset number</i>	EU-0018496-0000	
Date of the authorisation	15 October 2018	
Expiry date of the authorisation	30 September 2028	

1.4. Manufacturer(s) of the biocidal products

Name of manufacturer	QUAT-CHEM LTD
Address of manufacturer	Charter House 33 – Greek Street, SK3 8AX Stockport United Kingdom
Location of manufacturing sites	QUAT-CHEM LTD – Charter House 33 – Greek Street, SK3 8AX Stockport United Kingdom

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

Active substance	Iodine
Name of manufacturer	COSAYACH: SCM Cia. Cosayach Minera Negreiros, Rut. No 96.625.710-5

▼ **M1**

Address of manufacturer	Terrenos de Elena S/N, Terrenos de Elena S/ N Huara, Región de Tarapacá Chile
Location of manufacturing sites	Mined at: S.C.M. Cía. Minera Negreiros, S.C.M. Cosayach Soledad., Refined at: S.C.M. Cía. Minera Negreiros. Pozo Almonte Chile

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

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)-alkyl-hydroxy	Non-active substance	68439-50-9		2,697	24,199

2.2. Type(s) of formulation

Formulation(s)	AL – Any other liquid SL – Soluble concentrate
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▼ **M1**

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)
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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	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

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

Formulation(s)	AL – Any other liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

Hazard statements	Causes serious eye irritation. Harmful to aquatic life with long lasting effects.
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▼ **M1**

Precautionary statements	<p>Keep out of reach of children.</p> <p>Wash hands thoroughly after handling.</p> <p>Wear protective gloves.</p> <p>Wear protective clothing.</p> <p>Wear eye protection.</p> <p>IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>If eye irritation persists: Get medical advice.</p> <p>Get medical advice.</p>
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4. **AUTHORISED USE(S) OF THE META SPC 1**4.1. **Use description**

Table 1

Use # 1 – Use # 1.1 – 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)	<p>Scientific name: Bacteria Common name: Bacteria Development stage:</p> <p>Scientific name: Yeasts Common name: Yeasts Development stage:</p> <p>Scientific name: Algae Common name: Algae Development stage:</p>
Field(s) of use	<p>Indoor</p> <p>Disinfection of teats of milk producing animals by dipping after milking</p>
Application method(s)	<p>Method: Dipping</p> <p>Detailed description:</p> <p>Manual or automated disinfection of teats by dipping after milking.</p> <p>Dipping cup or automated dipping machine.</p>
Application rate(s) and frequency	<p>Application Rate: – cows and buffaloes (3 to 10 ml: 5 ml recommended) – sheep (1,5 to 5 ml: 1,5 ml recommended) – goats (2,5 to 6 ml: 2,5 ml recommended)</p> <p>Dilution (%):</p> <p>Number and timing of application: Frequency: 2 to 3 times per day</p>

▼ M1

Category(ies) of users	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1 000 L

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 directions for use 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 ⁽¹⁾ 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 10 ml: 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.

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

▼ M1

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.

▼ **M1**

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)	Teatsan 2500	Market area: EU			
	iodo GUARD 2500	Market area: EU			
Authorisation number	EU-0018496-0001 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

META SPC 21. **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**

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

▼ M1**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	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. Get medical advice.

4. AUTHORISED USE(S) OF THE META SPC 2**4.1. Use description***Table 2***Use # 1 – Use # 2.1 – 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)	Scientific name: Bacteria Common name: Bacteria Development stage: Scientific name: Yeasts Common name: Yeasts Development stage:
Field(s) of use	Indoor Disinfection of teats of milk producing animals by dipping, foaming or spraying before milking
Application method(s)	Method: Dipping, foaming or spraying before milking

▼ **M1**

	<p>Detailed description:</p> <p>Manual or automated disinfection of teats by dipping, foaming or spraying before milking</p> <p>Dipping cup, foaming cup, teat sprayer, automated dipping machine, automated foaming machine or automated spraying machine</p>
Application rate(s) and frequency	<p>Application Rate: – cows and buffaloes (3 to 10 ml: 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)</p> <p>Dilution (%):</p> <p>Number and timing of application:</p> <p>Frequency: 2 to 3 times per day</p>
Category(ies) of users	Professional
Pack sizes and packaging material	<p>HDPE JERRYCAN 5, 10, 22 L</p> <p>HDPE DRUM 60, 120, 220 L</p> <p>HDPE CONTAINER 1 000 L</p>

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

▼ M1

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 – Use # 2.2 – 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)	<p>Scientific name: Bacteria Common name: Bacteria Development stage:</p> <p>Scientific name: Yeasts Common name: Yeasts Development stage:</p> <p>Scientific name: Algae Common name: Algae Development stage:</p>
Field(s) of use	<p>Indoor</p> <p>Disinfection of teats of milk producing animals by dipping, foaming or spraying after milking</p>
Application method(s)	<p>Method: Dipping, foaming, spraying after milking</p> <p>Detailed description:</p> <p>Manual or automated disinfection of teats by dipping, foaming or spraying after milking</p> <p>Dipping cup, foaming cup, teat sprayer, automated dipping machine, automated foaming machine or automated spraying machine</p>
Application rate(s) and frequency	<p>Application Rate: – cows and buffaloes (3 to 10 ml: 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)</p> <p>Dilution (%):</p> <p>Number and timing of application: Frequency: 2 to 3 times per day</p>
Category(ies) of users	Professional
Pack sizes and packaging material	<p>HDPE JERRYCAN 5, 10, 22 L</p> <p>HDPE DRUM 60, 120, 220 L</p> <p>HDPE CONTAINER 1 000 L</p>

▼ M1**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 ⁽¹⁾ 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.

⁽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.

▼ M1

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:

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.

▼ **M1**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)	Teat Guard 2500	Market area: EU			
	iodo spray 2500	Market area: EU			
Authorisation number	EU-0018496-0002 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

META SPC 31. **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
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

▼ M1**2.2. Type(s) of formulation of the meta SPC 3**

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

Hazard statements	<p>Causes serious eye damage.</p> <p>May cause damage to organs (thyroid) through prolonged or repeated exposure oral.</p> <p>Toxic to aquatic life with long lasting effects.</p> <p>May be corrosive to metals.</p>
Precautionary statements	<p>Keep out of reach of children.</p> <p>Do not breathe mist.</p> <p>Do not breathe vapours.</p> <p>Do not breathe spray.</p> <p>Wash hands thoroughly after handling.</p> <p>Wear protective gloves.</p> <p>Wear protective clothing.</p> <p>Wear eye protection.</p> <p>IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>Immediately call a poison center / doctor.</p> <p>Get medical advice if you feel unwell.</p> <p>Get medical attention if you feel unwell.</p> <p>Dispose of contents to in accordance with local/regional/national/international regulations.</p> <p>Dispose of container to in accordance with local/regional/national/international regulations.</p> <p>Keep only in original packaging.</p> <p>Absorb spillage to prevent material damage.</p>

4. AUTHORISED USE(S) OF THE META SPC 3**4.1. Use description***Table 4***Use # 1 – Use # 3.1 – Manual or automated dipping, foaming or spraying before milking**

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

▼ **M1**

Target organism(s) (including development stage)	<p>Scientific name: Bacteria Common name: Bacteria Development stage:</p> <p>Scientific name: Yeasts Common name: Yeasts Development stage:</p>
Field(s) of use	<p>Indoor</p> <p>Disinfection of teats of milk producing animals by dipping, foaming or spraying before milking</p>
Application method(s)	<p>Method: Dipping, foaming, spraying</p> <p>Detailed description:</p> <p>Manual or automated disinfection of teats by dipping, foaming or spraying before milking.</p> <p>Dipping cup, foaming cup, teat sprayer, automated dipping machine, automated foaming machine or automated spraying machine</p>
Application rate(s) and frequency	<p>Application Rate: A dilution at 10 % (v/v) should be prepared Application rate for the diluted product:- cows and buffaloes (3 to 10 ml: 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)</p> <p>Dilution (%):</p> <p>Number and timing of application: Frequency: 2 to 3 times per day</p>
Category(ies) of users	Professional
Pack sizes and packaging material	<p>HDPE JERRYCAN 5, 10, 22 L</p> <p>HDPE DRUM 60, 120, 220 L</p> <p>HDPE CONTAINER 1 000 L</p>

4.1.1. *Use-specific instructions for use*

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

▼ M14.1.2. *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 – Use # 3.2 – 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)	<p>Scientific name: Bacteria Common name: Bacteria Development stage:</p> <p>Scientific name: Yeasts Common name: Yeasts Development stage:</p> <p>Scientific name: Algae Common name: Algae Development stage:</p> <p>Scientific name: Viruses Common name: Viruses Development stage:</p>
Field(s) of use	<p>Indoor</p> <p>Disinfection of teats of milk producing animals by dipping, foaming or spraying after milking</p>

▼ **M1**

Application method(s)	Method: Dipping, foaming, spraying Detailed description: 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	Application Rate: For disinfection of bacteria, yeasts and algae a dilution at 10 % (v/v: 10 ml product, add water up to 100 ml) should be prepared. For disinfection of viruses a dilution at 20 % (v/v: 20 ml product, add water up to 100 ml) should be prepared Application rate for the diluted product:- cows and buffaloes (3 to 10 ml: 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) Dilution (%): Number and timing of application: 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 1 000 L

4.2.1. *Use-specific instructions for use*

Prepare a dilution at 10 % (v/v: 10 ml product, add water up to 100 ml) for bactericidal, yeasticidal and algaecidal activity or 20 % (v/v: 20 ml product, add water up to 100 ml) 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.

▼ M1**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 ⁽¹⁾ 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.

⁽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 3.

▼ M1

- 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.

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)	Teat Guard Concentrate 1:4	Market area: EU			
	iodo guard concentrate 1:4	Market area: EU			
Authorisation number	EU-0018496-0003 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

▼ M1**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(s)	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. 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.

▼ **M1**

	If eye irritation persists: Get medical advice. Get medical advice.
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4. **AUTHORISED USE(S) OF THE META SPC 4**4.1. **Use description**

Table 6

Use # 1 – Use # 4.1 – 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)	<p>Scientific name: Bacteria Common name: Bacteria Development stage:</p> <p>Scientific name: Yeasts Common name: Yeasts Development stage:</p> <p>Scientific name: Algae Common name: Algae Development stage:</p> <p>Scientific name: Viruses Common name: Viruses Development stage:</p>
Field(s) of use	<p>Indoor</p> <p>Disinfection of teats of milk producing animals by dipping after milking</p>
Application method(s)	<p>Method: Dipping</p> <p>Detailed description:</p> <p>Manual or automated disinfection of teats by dipping after milking.</p> <p>Dipping cup or automated dipping machine.</p>
Application rate(s) and frequency	<p>Application Rate: – cows and buffaloes (3 to 10 ml: 5 ml recommended) – sheep (1,5 to 5 ml: 1,5 ml recommended) – goats (2,5 to 6 ml: 2,5 ml recommended)</p> <p>Dilution (%):</p> <p>Number and timing of application: Frequency: 2 to 3 times per day</p>

▼ M1

Category(ies) of users	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1 000 L

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 ⁽¹⁾ 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 10 ml: 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.

⁽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 4.

▼ M1**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.

▼ M1

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)	Teatsan 5000	Market area: EU			
	IODO GUARD 5000	Market area: EU			
Authorisation number	EU-0018496-0004 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 5 500 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 (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	4,69

▼ M1**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	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. Get medical advice.

4. AUTHORISED USE(S) OF THE META SPC 5**4.1. Use description***Table 7***Use # 1 – Use # 5.1 – 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)	Scientific name: Bacteria Common name: Bacteria Development stage: Scientific name: Yeasts Common name: Yeasts Development stage:
Field(s) of use	Indoor Disinfection of teats of milk producing animals by dipping, foaming or spraying before milking
Application method(s)	Method: Dipping, foaming, spraying Detailed description: Manual or automated disinfection of teats by dipping, foaming or spraying before milking

▼ **M1**

	Dipping cup, foaming cup, teat sprayer, automated dipping machine, automated foaming machine or automated spraying machine
Application rate(s) and frequency	Application Rate: – cows and buffaloes (3 to 10 ml: 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) Dilution (%): Number and timing of application: 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 1 000 L

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

▼ M1

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 – Use # 5.2 – 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)	<p>Scientific name: Bacteria Common name: Bacteria Development stage:</p> <p>Scientific name: Yeasts Common name: Yeasts Development stage:</p> <p>Scientific name: Algae Common name: Algae Development stage:</p> <p>Scientific name: Viruses Common name: Viruses Development stage:</p>
Field(s) of use	<p>Indoor</p> <p>Disinfection of teats of milk producing animals by dipping, foaming or spraying after milking</p>
Application method(s)	<p>Method: Dipping, foaming, spraying</p> <p>Detailed description:</p> <p>Manual or automated disinfection of teats by dipping, foaming or spraying after milking.</p> <p>Dipping cup, foaming cup, teat sprayer, automated dipping machine, automated foaming machine or automated spraying machine.</p>
Application rate(s) and frequency	<p>Application Rate: – cows and buffaloes (3 to 10 ml: 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)</p> <p>Dilution (%):</p> <p>Number and timing of application: Frequency: 2 to 3 times per day</p>

▼ M1

Category(ies) of users	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1 000L

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 ⁽¹⁾ OF THE META SPC 5**5.1. Instructions for use**

See use-specific instructions for each use.

⁽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 5.

▼ M1

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:

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.

▼ M1**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)	Teat Guard 5500	Market area: EU			
	IDO SPRAY 5500	Market area: EU			
Authorisation number	EU-0018496-0005 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