6.10.2023

COMMISSION IMPLEMENTING REGULATION (EU) 2023/2384

2023/2384

of 29 September 2023

amending Implementing Regulation (EU) 2018/1287 to make an administrative change to the Union authorisation of the biocidal product family 'Quat-Chem'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:

- On 24 September 2018, Commission Implementing Regulation (EU) 2018/1287 (2) granted a Union authorisation (1)with authorisation number EU-0018496-0000 to Quatchem Ltd for the making available on the market and use of the biocidal product family 'Quat-Chem's iodine based products'.
- On 14 December 2020, Quatchem Ltd submitted a notification to the European Chemicals Agency ('the Agency'), in (2)accordance with Article 11(1) of Commission Implementing Regulation (EU) No 354/2013 (3), regarding an administrative change to the Union authorisation for the biocidal product family 'Quat-Chem's iodine based products' referred to in Title 1, Section 1, of the Annex to that Regulation.
- (3)Quatchem Ltd proposed to transfer the authorisation to a new holder established in the European Economic Area as set out in Title 1, Section 1, point 3, of the Annex to Implementing Regulation (EU) No 354/2013. The notification was recorded under case number BC-VP063434-15 in the Register for Biocidal Products.
- On 29 April 2022, the Agency submitted an opinion (4) to the Commission on the proposed change, in accordance with Article 11(3) of Implementing Regulation (EU) No 354/2013. The opinion concludes that the amendment to the existing authorisation sought by the authorisation holder falls under Article 50(3), point (a), of Regulation (EU) No 528/2012, that the parties have agreed to the transfer of the authorisation, that the prospective new authorisation holder is established in the Union, and that after the implementation of the changes, the conditions of Article 19 of that Regulation are still met. On the same date, 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.
- (5) The Commission concurs with the opinion of the Agency and therefore considers it appropriate to amend the Union authorisation of the biocidal product family 'Quat-Chem's iodine based products'.
- Save for the amendment regarding the transfer of the authorisation to a new holder, all other information included (6) in the summary of the biocidal product characteristics of 'Quat-Chem's iodine based products' as set out in the Annex to Implementing Regulation (EU) 2018/1287 remains unchanged,

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ 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 (OJ L 240, 25.9.2018, p. 10).

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).

ECHA opinion on an administrative change of the Union authorisation of QUAT-CHEM's iodine based products of 13 August 2021, Opinion No UTR-C-1527940-77-00/F, https://echa.europa.eu/opinions-on-union-authorisation

HAS ADOPTED THIS REGULATION:

Article 1

Implementing Regulation (EU) 2018/1287 is amended as follows:

- (1) in Article 1, first paragraph, the name 'Quatchem Ltd' is replaced by the name 'Neogen Italia S.r.l.';
- (2) the Annex is replaced by the text set out in 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, 29 September 2023.

For the Commission
The President
Ursula VON DER LEYEN

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

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		
R4BP asset number	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 Cía. Cosayach Minera Negreiros, Rut. No 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	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 nam	HIDA C	Function	CAS number	EC number	Content (%)	
	TOPAC flame				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-ethane- diyl), -C12-14-(even numbered)- alkyl-hydroxy	Non-active substance	68439-50-9		2,697	24,199

2.2. Type(s) of formulation

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

1.2. Suffix to the authorisation number

Number	1-1

1.3. **Product type(s)**

2. META SPC 1 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC ${\bf 1}$

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-ethane- diyl), -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.

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

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)	Scientific name: Bacteria Common name: Bacteria Development stage: Scientific name: Yeasts
	Common name: Yeasts Development stage:
	Scientific name: Algae Common name: Algae Development stage:
Field(s) of use	Indoor Disinfection of teats of milk producing animals by dipping after milking
Application method(s)	Method: Dipping
	Detailed description:
	Manual or automated disinfection of teats by dipping after milking.
	Dipping cup or automated dipping machine.
Application rate(s) and frequency	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)
	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
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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.

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.

⁽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.

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

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-ethane- diyl), -C12-14-(even numbered)- alkyl-hydroxy	Non-active substance	68439-50-9		2,697

META SPC 2

1. META SPC 2 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 2 identifier

1.2. Suffix to the authorisation number

Number	1-2

1.3. **Product type(s)**

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

2. META SPC 2 COMPOSITION

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

C	H IDAC mama	Function	CAS number	EC number	Content (%)	
Common name	IUPAC name				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-ethane- diyl), -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(s)	AL – Any other liquid

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.
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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
	Detailed description:
	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	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

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

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)	Scientific name: Bacteria Common name: Bacteria Development stage: Scientific name: Yeasts Common name: Yeasts Development stage: Scientific name: Algae Common name: Algae Development stage:
Field(s) of use	Indoor Disinfection of teats of milk producing animals by dipping, foaming or spraying after milking

Application method(s)	Method: Dipping, foaming, spraying after milking
	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: – 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

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 (2) 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

- 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.

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

6. **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-ethane- diyl), -C12-14-(even numbered)- alkyl–hydroxy	Non-active substance	68439-50-9		2,697

META SPC 3

1. META SPC 3 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 3 identifier

1.2. Suffix to the authorisation number

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1.3. Product type(s)

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-ethane- diyl), -C12-14-(even numbered)-	Non-active substance	68439-50-9	24,199	24,199
	alkyl–hydroxy				

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

Formulation(s)	SL – Soluble concentrate

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 if you feel unwell. Get medical attention if you feel unwell. Dispose of contents to in accordance with local/regional/international regulations. Dispose of container to in accordance with local/regional/national/international regulations. Keep only in original packaging. Absorb spillage to prevent material damage.

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	

Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria
Suige	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.
	Dipping cup, foaming cup, teat sprayer, automated dipping machine, automated foaming machine or automated spraying machine
Application rate(s) and frequency	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)
	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

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.

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

Use # 2 – Use # 3.2 – Manual or automated dipping, foaming or spraying after milking

Table 5

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: Scientific name: Algae Common name: Algae Development stage: Scientific name: Viruses Common name: Viruses Development stage:
Field(s) of use	Indoor Disinfection of teats of milk producing animals by dipping, foaming or spraying after milking
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.

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 (3) 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.

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.

⁽³⁾ 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

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-ethane- diyl), -C12-14-(even numbered)- alkyl–hydroxy	Non-active substance	68439-50-9		24,199

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
	10 450

1.2. Suffix to the authorisation number

Number	1-4
rumber	

1.3. **Product type(s)**

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

2. META SPC 4 COMPOSITION

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

Common name IUPAC name	HIDAC nama	Function	CAS number	EC number	Content (%)	
	runction	CAS number	EC Humber	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-ethane- diyl), -C12-14-(even numbered)- alkyl-hydroxy	Non-active substance	68439-50-9	4,993	4,993
	aikyi–iiyuioxy				

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

Formulation(s)	AL – Any other liquid

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. If eye irritation persists: Get medical advice. Get medical advice.

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)	Scientific name: Bacteria Common name: Bacteria Development stage: Scientific name: Yeasts Common name: Yeasts Development stage: Scientific name: Algae Common name: Algae Development stage: Scientific name: Viruses Common name: Viruses Development stage:

Field(s) of use	Indoor Disinfection of teats of milk producing animals by dipping after milking
Application method(s)	Method: Dipping
	Detailed description:
	Manual or automated disinfection of teats by dipping after milking.
	Dipping cup or automated dipping machine.
Application rate(s) and frequency	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)
	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

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 (4) 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.

⁽⁴⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 4.

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.

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 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 50	IODO GUARD 5000		Market area: EU		
Authorisation number	EU-0018496-0004	4 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-ethane- diyl), -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

1.2. Suffix to the authorisation number

Number	1-5

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

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
	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

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

Use # 2 – Use # 5.2 – Manual or automated dipping, foaming or spraying after milking

Table 8

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: Scientific name: Algae Common name: Algae Development stage: Scientific name: Viruses Common name: Viruses Development stage:		
Field(s) of use	Indoor Disinfection of teats of milk producing animals by dipping, foaming or spraying after milking		
Application method(s) Application rate(s) and frequency	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: – cows and buffaloes (3 to 10 ml: 5 to 8 ml		
rippieuton face(s) and frequency	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 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 (5) 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⁾ 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.

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 5

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

Trade name(s)	Teat Guard 5500		Market area: EU			
	IODO 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-ethane- diyl), -C12-14-(even numbered)- alkyl–hydroxy	Non-active substance	68439-50-9		4,69	