

ANNEX

Summary of product characteristics for a biocidal product family

PART II

SECOND INFORMATION LEVEL - META SPC(S)**META SPC 3**

1. META SPC 3 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 3 identifier**

Identifier	meta SPC 3 : Dipping, foaming, spraying concentrated products
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1.2. **Suffix to the authorisation number**

Number	1-3
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1.3. **Product type(s)**

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

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active substance	7553-56-2	231-442-4	2,5	2,5
Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), -C12-14- (even numbered)-alkyl--hydroxy	Non active substance	68439-50-9		24,199	24,199

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

Formulation	SL - Soluble concentrate
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Status: This is the original version (as it was originally adopted).

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 3

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

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

4.1. Use description

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

Product Type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Disinfection of teats of milk producing animals by dipping, foaming or spraying before milking
Application method(s)	Dipping, foaming, spraying - Manual or automated disinfection of teats by dipping, foaming or spraying before milking.

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

4.1.1. *Use-specific instructions for use*

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

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

Eliminate all visible dirt before applying the product.

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

Let the product act at least one minute.

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

See also general directions for use of meta SPC 3.

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

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

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

See general directions for use of meta SPC 3

4.2. Use description

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

Product Type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Bacteria Yeasts Algae Viruses
Field(s) of use	Indoor Disinfection of teats of milk producing animals by dipping, foaming or spraying after milking
Application method(s)	Dipping, foaming, spraying - Manual or automated disinfection of teats by dipping, foaming or spraying after milking. Dipping cup, foaming cup, teat sprayer, automated dipping machine, automated foaming machine or automated spraying machine
Application rate(s) and frequency	For disinfection of bacteria, yeasts and algae a dilution at 10% (v/v: 10 ml product, add water up to 100ml) should be prepared. For disinfection of viruses a dilution at 20% (v/v: 20 ml product, add water up to 100ml) should be prepared Application rate for the diluted product: — cows and buffaloes (3 to 10ml : 5 to 8 ml recommended) — sheep (1,5 to 5 ml : 1,5 to 3ml recommended) — goats (2,5 to 6 ml : 2,5 to 4 ml recommended) Frequency : 2 to 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1000L

4.2.1. *Use-specific instructions for use*

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

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

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

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

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

See also general directions for use of meta SPC 3

4.2.2. *Use-specific risk mitigation measures*

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

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

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

See general directions for use of meta SPC 3

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

See general directions for use of meta SPC 3

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

See general directions for use of meta SPC 3

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

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

- (1) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC3.