# Summary of product characteristics for a biocidal product family

Family name: PRODHYNET's iodine based products

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

Authorisation number: EU-0018497-0000

R4BP 3 asset reference number: EU-0018497-0000

#### **Table Of Contents**

Part I First information level	
	1
1. Administrative information	1
2. Product family composition and formulation	2
Part II Second information level - meta SPC(s)	3
1. Meta SPC administrative information - meta SPC 1 : Dipping products - ready to use	3
2. Meta SPC composition	3
3. Hazard and precautionary statements of the meta SPC	4
4. Authorised use(s) of the meta SPC	4
5. General directions for use of the meta SPC	6
6. Other information	7
7. Third information level: individual products in the meta SPC	7
1. Meta SPC administrative information - <b>meta SPC 2 : Dipping, foaming, spraying products - Ready</b> to use	8
2. Meta SPC composition	8
3. Hazard and precautionary statements of the meta SPC	9
4. Authorised use(s) of the meta SPC	9
5. General directions for use of the meta SPC	14
6. Other information	15
7. Third information level: individual products in the meta SPC	15
1. Meta SPC administrative information - <b>meta SPC 3 : Dipping, foaming, spraying concentrated</b> products	16
2. Meta SPC composition	16
3. Hazard and precautionary statements of the meta SPC	17
4. Authorised use(s) of the meta SPC	17
5. General directions for use of the meta SPC	22
6. Other information	23
7. Third information level: individual products in the meta SPC	23
1. Meta SPC administrative information - meta SPC 4 : Dipping products reaching virucidal activity –	24
Ready to use         2. Meta SPC composition	24

3. Hazard and precautionary statements of the meta SPC	25
4. Authorised use(s) of the meta SPC	25
5. General directions for use of the meta SPC	27
6. Other information	29
7. Third information level: individual products in the meta SPC	29
<ol> <li>Meta SPC administrative information - meta SPC 5 : Dipping, foaming, spraying products 5500 ppm - Ready to use</li> </ol>	30
2. Meta SPC composition	31
3. Hazard and precautionary statements of the meta SPC	31
4. Authorised use(s) of the meta SPC	32
5. General directions for use of the meta SPC	36
6. Other information	37
7. Third information level: individual products in the meta SPC	37

## 1. Administrative information

#### 1.1. Family name

PRODHYNET's iodine based products

#### 1.2. Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

#### **1.3.** Authorisation holder

Name and address of the	Name	PRODHYNET SA	
authorisation holder	Address	11 avenue des châtelets 22440 PLOUFRAGAN France	
Authorisation number	EU-0018497-0000		
R4BP 3 asset reference number	EU-0018497-0000		
Date of the authorisation	11/10/2018		
Expiry date of the authorisation	30/09/2028		

#### **1.4. Manufacturer(s) of the biocidal products**

Name of the manufacturer	PRODHYNET SA
Address of the manufacturer	11, Avenue des Châtelets 22440 PLOUFRAGAN France
Location of manufacturing sites	PRODHYNET SA - 11, Avenue des Châtelets 22440 PLOUFRAGAN France

Active substance	1319 - Iodine	
Name of the manufacturer	COSAYACH : SCM Cía. Cosayach Minera Negreiros, Rut. N°96.625.710-5	
Address of the 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	1319 - Iodine	
Name of the manufacturer	ACF MINERA SA	
Address of the manufacturer	San Martín 499 Iquique Chile	
Location of manufacturing sites	Faena Lagunas KM. 1.722 Ruta A-5, Pozo Almonte Chile	
Active substance	1319 - Iodine	
Name of the manufacturer	SOCIEDAD QUIMICA Y MINERA SA	
Address of the 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 (%)
lodine		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)-alkylhydroxy		68439-50-9		2,697 - 24,199

#### 2.2. Type(s) of formulation

AL - Any other liquid

SL - Soluble concentrate

### Part II.- Second information level - meta SPC(s)

#### 1. Meta SPC administrative information

#### 1.1. Meta SPC identifier

meta SPC 1 : Dipping products - ready to use

#### 1.2. Suffix to the authorisation number

1-1

#### 1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

#### 2. Meta SPC composition

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		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)-alkylhydroxy		68439-50-9		2,697 - 4,993

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

Formulation(s)

AL - Any other liquid

## 3. Hazard and precautionary statements of the meta SPC

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

## 4. Authorised use(s) of the meta SPC

#### 4.1 Use description

Use 1 - Use # 1.1 - Manual or automated dipping after milking

PT03 - Veterinary hygiene (Disinfectants)
_
Scientific name: Bacteria Common name: Bacteria Development stage:
Scientific name: Yeasts Common name: Yeasts Development stage:
Scientific name: Algae Common name: Algae Development stage:
Indoor Disinfection of teats of milk producing animals by dipping after milking

Application method(s)	Dipping - Manual or automated disinfection of teats by dipping after milking. Dipping cup or automated dipping machine.
Application rate(s) and frequencies	- cows and buffaloes (3 to 10ml : 5 ml recommended) - sheep (1.5 to 5 ml : 1.5 ml recommended) - goats (2.5 to 6 ml : 2.5 ml recommended) Frequency : 2 to 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1000L

#### 4.1.1 Use-specific instructions for use

See general directions for use of meta SPC 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

## 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 of the meta SPC

#### 5.1. Instructions for use

Always read the label or leaflet before use and follow all the instructions provided. The product must be brought to a temperature above 20°C before use. The use of a dosing pump for filling the product into the application equipment is recommended. Fill the dipping cup manually or automatically with the ready to use product. Apply by dipping manually or automatically on animal's teats on the full length of the teat after milking. - cows and buffaloes (3 to 10ml : 5 ml recommended) - sheep (1.5 to 5 ml : 1.5 ml recommended) - goats (2.5 to 6 ml : 2.5 ml recommended) Leave the product until next milking. Keep the cows standing until the product has dried (at least 5 minutes). At the next milking, use the teat cleaning and wiping method systematically before attaching the milking cluster. Where necessary, repeat the application after each milking. Clean the application equipment regularly with warm water.

#### 5.2. Risk mitigation measures

Wear eye protection.

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

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

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

FIRST AID INSTRUCTIONS

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

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

- In the event of contact with the eyes :

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

If eye irritation persists: Get medical advice/attention.
- In the event of ingestion : Rinse mouth. Do NOT induce vomiting. Get medical advice.
Refer to the safety data sheet available for professional user : it contains an emergency phone number.
Large spillage : Mark out, dyke up with an inert absorbant and pump in an emergency tank. Keep in suitable, properly labelled and
closed containers for disposal. Never return spills in original containers for re-use.

#### 5.4. Instructions for safe disposal of the product and its packaging

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

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

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

Shelf life : 2 years in HDPE Do not store at a temperature higher than 30°C.

### 6. Other information

### 7. Third information level: individual products in the meta SPC

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

Trade name(s)

IODO EP25	Market area: EU
IODOGEL	Market area: EU

	PRO TI-N	Market area: EU
Authorisation number (R4BP 3 asset reference number - National Authorisation)	EU-0018497-0001 1-1	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		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)-alkylhydroxy		68439-50-9		2,697

## **1. Meta SPC administrative information**

#### 1.1. Meta SPC identifier

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

#### **1.2.** Suffix to the authorisation number

1-2

#### 1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

### 2. Meta SPC composition

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		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)-alkylhydroxy		68439-50-9		2,697 - 4,69

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

Formulation(s)

AL - Any other liquid

### 3. Hazard and precautionary statements of the meta SPC

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

### 4. Authorised use(s) of the meta SPC

#### 4.1 Use description

#### 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 mathed(c)	Dipping, foaming or spraying before milking -		
Application method(s)	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 frequencies	- 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

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

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)	Dipping, foaming, spraying after milking -
	Manual or automated disinfection of teats by dipping, foaming or spraying after milking Dipping cup, foaming cup, teat sprayer, automated dipping machine, automated foaming machine or automated spraying machine
Application rate(s) and frequencies	- 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

#### 4.2.1 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 of the meta SPC

#### 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.

## 6. Other information

## 7. Third information level: individual products in the meta SPC

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

Trade name(s)	IODO FL25	Market area: EU
	PRO ROBO I-N	Market area: EU
Authorisation number (R4BP 3 asset reference number - National Authorisation)	EU-0018497-0002 1-2	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		Active Substance	7553-56-2	231-442-4	0,25

#### **1. Meta SPC administrative information**

#### 1.1. Meta SPC identifier

meta SPC 3 : Dipping, foaming, spraying concentrated products

#### 1.2. Suffix to the authorisation number

1-3

#### 1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

### 2. Meta SPC composition

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		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)-alkylhydroxy		68439-50-9		24,199 - 24,199

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

Formulation(s)

SL - Soluble concentrate

## 3. Hazard and precautionary statements of the meta SPC

	Causes serious eye damage.
Hazard statements	, ,
	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/ national/ 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

4.1 Use description

#### 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 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)	Dipping, foaming, spraying -
Application method(s)	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 frequencies	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
Category(ies) of users Pack sizes and packaging	recommended) - goats (2.5 to 6 ml : 2.5 to 4 ml recommended) Frequency : 2 to 3 times per day Professional HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L

### 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

## 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

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)	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 frequencies	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 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

#### 4.2.1 Use-specific instructions for use

Prepare a dilution at 10% (v/v: 10 ml product, add water up to 100ml) for bactericidal, yeasticidal and algaecidal 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 of the meta SPC

#### 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.

- 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

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

#### Trade name(s)

Trade name(s)	PRMX	Market area: EU
	IODOSE	Market area: EU
Authorisation number (R4BP 3 asset reference number - National Authorisation)	EU-0018497-0003 1-3	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		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)-alkylhydroxy		68439-50-9		24,199

### 1. Meta SPC administrative information

#### 1.1. Meta SPC identifier

meta SPC 4 : Dipping products reaching virucidal activity - Ready to use

#### 1.2. Suffix to the authorisation number

1-4

#### 1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

#### 2. Meta SPC composition

#### **IUPAC** name Common name Function **CAS** number **EC** number Content (%) lodine Active Substance 7553-56-2 231-442-4 0,5 - 0,5 Alcohols, C12-14, Poly(oxy-1,2-ethanediyl), ethoxylated (11 mol EO 68439-50-9 4.993 - 4.993

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

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

-C12-14-(even

numbered)-alkyl--hydroxy

Formulation(s)

average molar ratio)

AL - Any other liquid

### 3. Hazard and precautionary statements of the meta SPC

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

## 4. Authorised use(s) of the meta SPC

#### 4.1 Use description

#### 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)	Dipping -
Application method(s)	Manual or automated disinfection of teats by dipping after milking. Dipping cup or automated dipping machine.
Application rate(s) and frequencies	- cows and buffaloes (3 to 10ml : 5 ml recommended) - sheep (1.5 to 5 ml : 1.5 ml recommended) - goats (2.5 to 6 ml : 2.5 ml recommended) Frequency : 2 to 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L
	HDPE CONTAINER 1000L

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 of the meta SPC

#### 5.1. Instructions for use

Always read the label or leaflet before use and follow all the instructions provided. The product must be brought to a temperature above 20°C before use. The use of a dosing pump for filling the product into the application equipment is recommended. Fill the dipping cup manually or automatically with the ready to use product.

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

- cows and buffaloes (3 to 10ml : 5 ml recommended)

- sheep (1.5 to 5 ml : 1.5 ml recommended)

- goats (2.5 to 6 ml : 2.5 ml recommended)

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

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.

## 7. Third information level: individual products in the meta SPC

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

#### Trade name(s)

AGRI IODE EPAIS S	Market area: EU
HYGIA IODE EPAIS S	Market area: EU
IODE EPAIS	Market area: EU
NETAIODE EPAIS S	Market area: EU
TREMPAGE EPAIS IODE S	Market area: EU
IODO EP50	Market area: EU
ADIEL IODE EPAIS	Market area: EU
LATI IODE	Market area: EU
PRO TI	Market area: EU
PROXA IODE EPAIS S	Market area: EU
BREIZH-IODE EPAIS S	Market area: EU

BRETAIODE EPAIS	Market area: EU
DR16	Market area: EU
PLUSAIOD EPAIS	Market area: EU
HELIO FIRST EP	Market area: EU
TECNO FIRST	Market area: EU
LACTOIODE EPAIS	Market area: EU
MAG IODE EPAIS S	Market area: EU
EU-0018497-0004 1-4	

#### Authorisation number

(R4BP 3 asset reference number - National Authorisation)

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		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)-alkylhydroxy		68439-50-9		4,993

### 1. Meta SPC administrative information

#### 1.1. Meta SPC identifier

meta SPC 5 : Dipping, foaming, spraying products 5500 ppm – Ready to use

1-5

#### 1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

### 2. Meta SPC composition

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		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)-alkylhydroxy		68439-50-9		4,69 - 4,69

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

Formulation(s)

AL - Any other liquid

## **3.** Hazard and precautionary statements of the meta SPC

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 ....

## 4. Authorised use(s) of the meta SPC

#### 4.1 Use description

#### 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)	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 frequencies	- 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

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

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)	Dipping, foaming, spraying -	
Application method(5)	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 frequencies	- 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) - 0 - Frequency : 2 to 3 times per day	

Category(ies) of users

Pack sizes and packaging material

Professional

HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L

HDPE CONTAINER 1000L

#### 4.2.1 Use-specific instructions for use

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

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

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

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

See also general instructions for use of meta SPC 5.

#### 4.2.2 Use-specific risk mitigation measures

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

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

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

See general directions for use of meta SPC 5

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

See general directions for use of meta SPC 5

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

See general directions for use of meta SPC 5

### 5. General directions for use of the meta SPC

#### 5.1. Instructions for use

See use-specific instructions for each use.

Always read the label or leaflet before use and follow all the instructions provided. The product must be brought to a temperature above 20°C before use. The use of a dosing pump for filling the product into the application equipment is recommended. Where necessary repeat the application at each milking Clean the application equipment regularly with warm water.

#### 5.2. Risk mitigation measures

See use-specific risk mitigation measures for each use.

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

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

FIRST AID INSTRUCTIONS

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

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

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

#### Trade name(s)

AGRI IODE FLUIDE	Market area: EU
HYGIA IODE FLUIDE	Market area: EU
IODE FLUIDE	Market area: EU
IOSPRAY FLUIDE	Market area: EU
PULVE IODE	Market area: EU
IODO FL55	Market area: EU
IODOLIN	Market area: EU
ADIEL IODE FLUIDE	Market area: EU
BOVI IODE SPRAY	Market area: EU
PRO ROBO I	Market area: EU
PROXA IODE FLUIDE	Market area: EU
HELIODE FLUIDE	Market area: EU
TECNO FLUIDE	Market area: EU
DR15	Market area: EU
GANAIODE FLUIDE	Market area: EU
PLUSAIOD	Market area: EU

PROTECTION FLUIDE IODE	Market area: EU			
BREIZH-IODE FLUIDE	Market area: EU			
BRETAIODE LQ	Market area: EU			
IODE NET FLUIDE	Market area: EU			
LACTOIODE FLUIDE	Market area: EU			
MAG IODE FLUIDE	Market area: EU			
NETAIODE FLUIDE	Market area: EU			
NETAIODE	Market area: EU			
EU-0018497-0005 1-5				

#### Authorisation number

(R4BP 3 asset reference number - National Authorisation)

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		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)-alkylhydroxy		68439-50-9		4,69