

Summary of product characteristics for a biocidal product

Product name: PRMX

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

PT03 - Veterinary hygiene (Disinfectants)

Authorisation number: EU-0018497-0000

R4BP 3 asset reference number: EU-0018497-0003

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Administrative information

1.1. Trade names of the product

PRMX
IODOSE

1.2. Authorisation holder

Name and address of the authorisation holder	Name	PRODHYNET SA
	Address	11 avenue des châtelets 22440 PLOUFRAGAN France
Authorisation number	EU-0018497-0000 1-3	
R4BP 3 asset reference number	EU-0018497-0003	
Date of the authorisation	11/10/2018	
Expiry date of the authorisation	30/09/2028	

1.3. 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

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

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 composition and formulation

2.1. Qualitative and quantitative information on the composition of the biocidal product

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		68439-50-9		24,199

2.2. Type of formulation

SL - Soluble concentrate

3. Hazard and precautionary statements

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/ 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)

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 - 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

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

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