

Summary of product characteristics for a biocidal product

Product name: Dip-io 5000

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

Authorisation number: EU-0018397-0000

R4BP 3 asset reference number: EU-0018397-0006

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Administrative information

1.1. Trade names of the product

Dip-io 5000
IODIUM TX
INO JOD 50 DIP
Usual Iod Post +
IODIUM PRO DIP
IODERM PSP +
IODEX EXTRA +
Iododip +
IODYSTRONG PLUS
INO TREMP
INO STAR
IODACTIV 5000
DERMINO
IODERM 5000
IODIUM BX5000
HOEVE-PLUS DIP
TREMPASEPT IODE
DERMADINE
MAMMO-DERM
KRONI Jod Dipp 5000

1.2. Authorisation holder

**Name and address of the
authorisation holder**

Name	HYPRED SAS
Address	55, boulevard Jules Verger 35803 DINARD France
Authorisation number	EU-0018397-0000 1-4

R4BP 3 asset reference number

EU-0018397-0006

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

HYPRED SAS - KERSIA Group

Address of the manufacturer

55, Boulevard Jules Verger - BP10180 35803 DINARD France

Location of manufacturing sites

HYPRED SAS - KERSIA Group - 55, Boulevard Jules Verger - BP10180 35803 DINARD France

KERSIA POLSKA SP. Z O.O. NIEPRUSZEWO, KASZTANOWA 4 64320 Buk Poland

KERSIA IBERICA S.L Pol. Miguel Eguía C/Zarapuz s/n 31200 ESTELLA – NAVARRA Spain

KERSIA DEUTSCHLAND GmbH Marie-Curie-Straße 23 53332 Bornheim – Sechtem Germany

HYPRED Italia s.r.l. - KERSIA Group - Strada Montodine-Gombito Loc. Cà Nova 26010 Ripalta Arpina CR Italy

AG France S.A.S – KERSIA Group - Zone Industrielle Le Roineau 72500 VAAS France

KERSIA DEUTSCHLAND GmbH - OBERBRÜHLSTRAßE 16-18 87700 MEMMINGEN Germany

KERSIA AUSTRIA GmbH - PFONGAUERSTRAßE 17 5202 NEUMARKT AM WALLERSEE Austria

Kilco Holdings Ltd – KERSIA Group - Broomhouses 2 Industrial Estate, Old Glasgow Road DG11 2SD LOCKERBIE United Kingdom

Kilco (International) Ltd – KERSIA Group - 1A Trench Road Mallusk, Newtownabbey BT36 4TY CO ANTRIM Ireland

Medentech Ltd – KERSIA Group - Clonard Road Y35Y7WY WEXFORD Ireland

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 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

Active substance	1319 - Iodine
Name of the manufacturer	ISE Chemicals Corporation
Address of the manufacturer	3-1, Kyobashi 1-Chome Chuo-ku Tokyo Japan
Location of manufacturing sites	Shirasato Plant 3695 Kitaimaizumi, Oamishirasato City, Chiba Japan

Active substance	1319 - Iodine
Name of the manufacturer	Nihon Tennen Gas Development Co., Ltd
Address of the manufacturer	661 Mobara 297-8550 Mobara City, Chiba Japan
Location of manufacturing sites	Chiba Plant, 2508 Minami Hinata 299-4205 Shirako-Machi, Chosei-Gun, Chiba Japan

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	0,5
Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), -C12-14-(even numbered)-alkyl--hydroxy	Non-active substance	68439-50-9		4,993

2.2. Type of formulation

AL - Any other liquid

3. Hazard and precautionary statements

Hazard statements	<p>Causes serious eye irritation.</p> <p>Harmful to aquatic life with long lasting effects.</p>
Precautionary statements	<p>Keep out of reach of children.</p> <p>Wash hands thoroughly after handling.</p> <p>Wear protective gloves.</p> <p>Wear protective clothing.</p> <p>Wear eye protection.</p> <p>IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p>

If eye irritation persists: Get medical advice.

Get medical .

4. Authorised use(s)

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)	Method: Dipping Detailed description: Manual or automated disinfection of teats by dipping after milking. Dipping cup or automated dipping machine.
Application rate(s) and frequencies	Application Rate: - 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) 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 1000L

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

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