

Summary of product characteristics for a biocidal product

Product name: IoDark

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

Authorisation number: EU-0018398-0000

R4BP 3 asset reference number: EU-0018398-0004

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Administrative information

1.1. Trade names of the product

IoDark
Iodocop EXTRA GREEN
Mammizan Protect
MS Cow Udder BLACK

1.2. Authorisation holder

Name and address of the authorisation holder	Name	Ecolab Deutschland GmbH
	Address	Ecolab Allee 1 40789 Monheim am Rhein Germany
Authorisation number	EU-0018398-0000 1-2	

R4BP 3 asset reference number	EU-0018398-0004
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	Ecolab Europe GmbH
Address of the manufacturer	Richtstrasse 7, 8304 Wallisellen Switzerland
Location of manufacturing sites	Ecolab Baglan, ECOLAB CONTAMINATION CONTROL BRUNEL WAY, BAGLAN ENERGY PARK, NEATH, SA11 2GA South Wales European Union
	Ecolab Leeds, LOTHERTON WAY, GARFORTH, LEEDS LS25 2JY Leeds United Kingdom
	Ecolab Rovigo, Viale del Lavoro 10 , 45100 Rovigo Italy
	Ecolab Biebesheim Nalco Deutschland Manufacturing GmbH und Co.KG, Justus-von-Liebig-Str. 11 D-64584 Biebesheim Germany
	Ecolab NETHERLANDS BV, NL01ECOLAB, BRUGWAL 11 3432NZ NIEUWEGEIN Netherlands
	Ecolab Weavergate, ECOLAB WEAVERGATE PLANT WINNINGTON AVENUE, NORTHWICH CHESHIRE CW8 3AA NORTHWICH United Kingdom
	Ecolab Mullingar, Forest Park, Mullingar Ind. Estate, Mullingar, Co. Zone C Westmeath Ireland
	Ecolab Maribor, Ecolab d.o.o., Vajngerlova 4 2000 Maribor Slovenia
	Ecolab Rozzano, VIA GRANDI 9/11 20089 ROZZANO Italy
	Ecolab B.V.B.A, Havenlaan: 4 3980 Tessenderlo Belgium
Ecolab CELRA, Nalco Española Manufacturing, SLU C/Tramuntana s/n, Polígono Industrial de Celrà 17460 CELRÀ Spain	
Ecolab Chalons Ecolab production France SAS, BP509 Avenue de Général Patton 51006 Châlons-en-Champagne France	
Ecolab Mandra, 25km Old National Road Athens Mandra, oo Attica Greece	
NALCO FINLAND MANUFACTURING OY, Kivikumuntie 1 FIN-07955 Tesjoki Finland	

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

Active substance	1349 - Polyvinylpyrrolidone iodine
Name of the manufacturer	ISP Chemicals LLC, Affiliate of Ashland Inc.
Address of the manufacturer	455 N. MAIN ST. (HWY 95) KY 42029 CALVERT CITY United States
Location of manufacturing sites	455 N. MAIN ST. (HWY 95) KY 42029 CALVERT CITY United States

Active substance	1319 - Iodine
Name of the manufacturer	ACF Minera S.A.
Address of the manufacturer	San Martín No 499 00 Iquique Chile
Location of manufacturing sites	Lagunas mine 00 Pozo Almonte Chile

Active substance	1319 - Iodine
Name of the manufacturer	SQM S.A.
Address of the manufacturer	Los Militares 4290 Piso 4 Santiago Chile
Location of manufacturing sites	Nueva Victoria plant 00 Pedro de Valdivia Chile

Active substance	1319 - Iodine
Name of the manufacturer	Cosayach Nitratos S.A.
Address of the manufacturer	Amunategui 178 00 Santiago Chile
Location of manufacturing sites	S.C.M. Cosayach Cala Cala 00 Pozo Almonte Chile

Active substance	1319 - Iodine
Name of the manufacturer	Nihon Tennen Gas Development Co., Ltd/ Kanto Natural Gas Development Co., Ltd
Address of the manufacturer	661 Mobara Chiba 297-8550 Mobara City Japan
Location of manufacturing sites	Chiba Plant, 2508 Minami-Hinata, Shirako-Machi, Chosei-Gun 299-4205 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 (%)
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		1,35
Iodine		Active Substance	7553-56-2	231-442-4	0,15

2.2. Type of formulation

AL - Any other liquid

3. Hazard and precautionary statements

Hazard statements

Precautionary statements

4. Authorised use(s)

4.1 Use description

Use 1 - Teat dips for post-milking disinfection

Product type

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

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Target organism(s) (including development stage)

Scientific name: Bacteria
Common name: Bacteria
Development stage:

	<p>Scientific name: Yeasts Common name: Yeasts Development stage:</p> <p>Scientific name: Enveloped viruses Common name: Enveloped viruses Development stage:</p>
Field(s) of use	<p>Indoor</p> <p>Post-milking disinfection of teats of milk producing animals (cows, buffaloes, goats, sheep)</p>
Application method(s)	<p>Dipping - Manual dipping using a dip cup</p>
Application rate(s) and frequencies	<p>Post-milking application 1x -3x per day (apply after every milking). - - Per milking event 3 - 10 mL of product are needed (animals with four teats).</p>
Category(ies) of users	<p>Professional</p>
Pack sizes and packaging material	<p>0.5 L – 1000 L HDPE container</p>

4.1.1 Use-specific instructions for use

See general directions for use of meta SPC 2

4.1.2 Use-specific risk mitigation measures

See general directions for use of meta SPC 2

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

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 products must be brought to temperatures above 20°C before use.
Product to be applied post-milking by use of a dipping cup.
Apply product on the whole teat and do not wipe it. Keep the animals standing for 5 min. Before the next milking, carefully clean the teats.

The use of a dosing pump for filling the product into the application equipment is recommended.

5.2. Risk mitigation measures

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

Potential Health Effects

Eyes: Health injuries are not known or expected under normal use.

Skin: Health injuries are not known or expected under normal use.

Ingestion: Health injuries are not known or expected under normal use.

Inhalation: Health injuries are not known or expected under normal use.

Chronic Exposure: Health injuries are not known or expected under normal use.

First Aid Measures:

Eye contact: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.

Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. In case of inhalation of decomposition products in a fire, symptoms may be delayed. Get medical attention if symptoms occur.

Skin contact: Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.

Ingestion: Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Environmental emergency measures: Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer if legally allowed.

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.

European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29.

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

Store between 5° C and 25° C and away from direct sunlight. Keep out of reach of children. Keep container tightly closed. Store in the original containers.

Shelf life: 24 months

6. Other information