Summary of product characteristics for a biocidal product

Product name: 3.2 Dermades

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

Authorisation number: EU-0022265-0000

R4BP 3 asset reference number: IS-0025089-0005

Table Of Contents

Administrative information	1
1.1. Trade names of the product	1
1.2. Authorisation holder	1
1.3. Manufacturer(s) of the biocidal products	1
1.4. Manufacturer(s) of the active substance(s)	2
2. Product composition and formulation	3
2.1. Qualitative and quantitative information on the composition of the biocidal product	3
2.2. Type of formulation	3
3. Hazard and precautionary statements	4
4. Authorised use(s)	4
5. General directions for use	5
5.1. Instructions for use	5
5.2. Risk mitigation measures	6
5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment	6
5.4. Instructions for safe disposal of the product and its packaging	6
5.5. Conditions of storage and shelf-life of the product under normal conditions of storage	6
6. Other information	6

Administrative information

1.1. Trade names of the product

Dermades	
Animal skin disinfectant 1%	
Dermades Strong	
Iodin Skin Disinfectant Strong	

1.2. Authorisation holder

Name and address of the authorisation holder

Name	CID LINES NV		
Address	Waterpoortstraat 2 8900 leper Belgium		

Authorisation number

EU-0022265-0000 1-3

R4BP 3 asset reference number

Date of the authorisation

Expiry date of the authorisation

IS-0025089-0005
03/09/2020
31/08/2030

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer

Address of the manufacturer

Waterpoortstraat 2 8900 leper Belgium

Waterpoortstraat 2 8900 leper Belgium

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

Active substance	1319 - Iodine	
Name of the manufacturer	SQM S.A.	
Address of the manufacturer	Los Militares, Piso 4 4290 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	Cala Cala 00 Pozo Almonte Chile	
Active substance	1319 - Iodine	
Active substance Name of the manufacturer	1319 - Iodine ACF Minera S.A.	
Name of the manufacturer	ACF Minera S.A.	
Name of the manufacturer Address of the manufacturer	ACF Minera S.A. San Martin No 499 00 Iquique Chile	
Name of the manufacturer Address of the manufacturer	ACF Minera S.A. San Martin No 499 00 Iquique Chile	
Name of the manufacturer Address of the manufacturer Location of manufacturing sites	ACF Minera S.A. San Martin No 499 00 Iquique Chile Lagunas mine 00 Pozo Almonte Chile	
Name of the manufacturer Address of the manufacturer Location of manufacturing sites Active substance	ACF Minera S.A. San Martin No 499 00 Iquique Chile Lagunas mine 00 Pozo Almonte Chile 1319 - Iodine	

Active substance	1349 - Polyvinylpyrrolidone iodine		
Name of the manufacturer	ISP Chemicals LLC, Afiliate 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	1349 - Polyvinylpyrrolidone iodine		
Name of the manufacturer	Pantheon FZE (DMCC branch)		
Address of the manufacturer	403, Reef Tower, Jumeira Lake Tower Shaikh Zayed Road 00 Dubai United Arab Emirates		
Location of manufacturing sites	Cala Cala 00 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 (%)
lodine		Active Substance	7553-56-2	231-442-4	0,99
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active substance	68131-39-5	500-195-7	2,95
Phosphoric acid	Phosphoric acid	Non-active substance	7664-38-2	231-633-2	0
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO	Non-active substance	68439-46-3		0

2.2. Type of formulation

AL - Any other liquid

3. Hazard and precautionary statements

Hazard statements

Harmful to aquatic life with long lasting effects.

Precautionary statements

Avoid release to the environment.

Dispose of contents to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Dispose of container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

4. Authorised use(s)

4.1 Use description

Use 1 - PT3- RTU Udder disinfectants, Iodine

Product type

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

_

Target organism(s) (including development stage)

Scientific name: Common name: Bacteria Development stage:

Scientific name: Common name: Yeasts Development stage:

Field(s) of use

Indoor

Skin disinfection only for use on intact skin of:

- the udder of dairy and beef cattle before calving
- the udder of sows before farrowing

Application method(s)

Method: Spraying Detailed description:

-

Application rate(s) and frequencies

Application Rate: The product is ready to use.

Dilution (%):

Number and timing of application:

Apply to:

- the udder of dairy and beef cattle: 1 spray on each teat (equivalent to 4.8 mL per application)
 - the udder of sows: 15 to 20 mL per animal $\,$

Category(ies) of users	tegory(ies) of users Professional		
Pack sizes and packaging material			
4.1.1 Use-specific instruction	ns for use		
See general directions for use.			
4.1.2 Use-specific risk mitiga	ation measures		
See general directions for use.			
<u>-</u>	se, the particulars of likely direct or indirect effects, first aid measures to protect the environment		
See general directions for use.			
4.1.4 Where specific to the us packaging	se, the instructions for safe disposal of the product and its		
See general directions for use.			
4.1.5 Where specific to the us under normal conditions of s	se, the conditions of storage and shelf-life of the product storage		
See general directions for use.			
5. General directions for u	50		

5.1. Instructions for use

For disinfection of the skin:

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.

Apply by spraying on the animals' intact skin for a topical disinfection:

- on the udder of dairy and beef cattle before calving: 1 spray on each teat (equivalent to 4,8 mL per application). Disinfection takes place once, one day before calving and once, one day after calving. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the animal standing at least 5 minutes).
- on the udder of sows before farrowing: Assume 15 to 20 mL per animal, once one day before farrowing and once every day during 4 days after farrowing. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the animal standing for at least 5 minutes).

Only for use on intact skin.

Do not mix with other chemicals.

5.2. Risk mitigation measures

For manual spraying application on cows and sows: Wear chemical resistant gloves (glove material to be specified by the authorisation holder within the product information).

In case a combination of post-milking disinfection of cows and skin disinfection of cows is necessary, an iodine based product shall not be used by the same person to perform both disinfections.

Keep out of reach of children.

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

After eye contact: Rinse immediately with water.

After ingestion: Rinse mouth. Spit

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.

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

Keep only in the original container in a cool, well-ventilated place. Keep container closed when not in use.

Protect from frost. Do not expose to temperatures >40°C.

The shelf-life of the products is 2 years.

6. Other information

The hazard- and precautionary statements shall be in Icelandic on the product label.

Hazard statements:

H412 Skaðlegt lífi í vatni, hefur langvinn áhrif.

Precautionary statements:

P273 Forðist losun út í umhverfi. P501 Fargið innihaldi hjá viðurkenndum móttökuaðila spilliefna í samræmi við staðbundnar/svæðisbundnar/landsbundnar/alþjóðlegar

P501 Fargið íláti hjá viðurkenndum móttökuaðila spilliefna í samræmi við staðbundnar/svæðisbundnar/landsbundnar/alþjóðlegar reglur.