

Summary of product characteristics for a biocidal product

Product name: ALGOFILM

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

Authorisation number: FR-2022-0005

R4BP 3 asset reference number: FR-0027784-0000

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Administrative information

1.1. Trade names of the product

ALGOFILM
TEAT FILM by CTH
IODIFILM by CTH
EPRO

1.2. Authorisation holder

Name and address of the authorisation holder	Name	centre technique d'hygiene
	Address	128 avenue chateau fleury 26104 romans sur isere France
Authorisation number		FR-2022-0005
R4BP 3 asset reference number		FR-0027784-0000
Date of the authorisation		04/02/2022
Expiry date of the authorisation		03/02/2032

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	Laboratoire Solutio
Address of the manufacturer	Parc d'activités des Chasses BP147 26100 Romans sur isere France
Location of manufacturing sites	Parc d'activités des Chasses BP147 26100 Romans sur isere France

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

Active substance	1349 - Polyvinylpyrrolidone iodine
Name of the manufacturer	Alcoholes Montplet, S.A
Address of the manufacturer	American Iodine Company Inc., 3120 Golden Springs Drive TX 75025 Plano United States
Location of manufacturing sites	Cosayach S.A. Compania de Salitre y Yodo - Amunategui 178 - Santiago Chile

Active substance	1349 - Polyvinylpyrrolidone iodine
Name of the manufacturer	Alcoholes Montplet, S.A
Address of the manufacturer	Norkem Limited Bexton Lane, Knutsford WA 16 9FB Cheshire United Kingdom
Location of manufacturing sites	Cosayach S.A. Compania de Salitre y Yodo – Amunategui 178 - Santiago Chile

Active substance	1349 - Polyvinylpyrrolidone iodine
Name of the manufacturer	Alcoholes Montplet, S.A
Address of the manufacturer	Pantheon European Office, Norkem Limited, Julianalaan 11 3708 BA Zeist Netherlands
Location of manufacturing sites	Cosayach S.A. Compania de Salitre y Yodo – Amunategui 178 - Santiago Chile

Active substance	1349 - Polyvinylpyrrolidone iodine
Name of the manufacturer	Alcoholes Montplet, S.A
Address of the manufacturer	Independent Iodine Company NV, Hortensiadreef 40 2920 Kalmthout Belgium
Location of manufacturing sites	Cosayach S.A. Compania de Salitre y Yodo – Amunategui 178 - Santiago Chile

Active substance	1322 - L-(+)-lactic acid
Name of the manufacturer	Jungbunzlauer S.A.
Address of the manufacturer	Z.I et Portuaire, B.P. 32 67390 Marckolsheim France
Location of manufacturing sites	Z.I et Portuaire, B.P. 32 67390 Marckolsheim France

Active substance	1322 - L-(+)-lactic acid
Name of the manufacturer	Purac Bioquimica sa
Address of the manufacturer	Gran Vial 19-25 E-08160 Montmeló Spain
Location of manufacturing sites	Gran Vial 19-25 E-08160 MONTMELÓ Spain

Active substance	1322 - L-(+)-lactic acid
Name of the manufacturer	PURAC Biochem
Address of the manufacturer	Arkelsedijk 46 NL-4206 GORINCHEM Netherlands
Location of manufacturing sites	Arkelsedijk 46 NL-4206 GORINCHEM Netherlands

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		0,9
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	0,08

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 disinfection after milking – Professional

Product type

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

Non-medical teat disinfection post-milking

Target organism(s) (including development stage)

Scientific name: bacteria
Common name: Bacteria
Development stage: not relevant

Scientific name: yeast
Common name: yeast
Development stage: not relevant

Field(s) of use

Other

The ready to use product is applied after milking on dairy animals (cows, ewes or goats)

Application method(s)

Method: Manual or automatic application by dipping the teats

Detailed description:

The ready to use product is applied after milking on dairy animals (cows, ewes or goats)

Application rate(s) and frequencies

Application Rate: 2 mL product/teat (4 teats/animals equal to 8 mL product by animal or 2 teats/animal equal to 4 ml of product by animal)

Dilution (%): -

Number and timing of application:

Ready-to-use

	<p>2 mL product/teat (4 teats/animals equal to 8 mL product by animal or 2 teats/animal equal to 4 ml of product by animal)</p> <p>Twice a day after each milking Contact time: 5 minutes Ambient temperature</p>
Category(ies) of users	Professional
Pack sizes and packaging material	Can – 20 L, opaque HDPE, hermetically closed. Barrels – 60, 220 L, opaque HDPE, hermetically closed.

4.1.1 Use-specific instructions for use

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4.1.2 Use-specific risk mitigation measures

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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

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

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

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5. General directions for use

5.1. Instructions for use

- Comply with the instructions for use.
- Respect the conditions of use of the product (concentration, contact time, temperature, pH, etc.).
- Inform the registration holder if the treatment is ineffective.
- The product must be brought to a temperature above 20°C before use.
- Leave the product until next milking. Keep the cows standing until the product has dried (at least 5 minutes).

5.2. Risk mitigation measures

- In case a combination of pre- and post-milking disinfection is necessary, using another 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

- IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.
- IF ON SKIN: If symptoms occur call a POISON CENTRE or a doctor.
- IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.

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

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains.
- Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

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

- Protect from frost.
- Do not store at a temperature above 25°C.
- Shelf life: 12 months
- Protect from direct sunlight.

6. Other information

- The product contains pyrrolidones derivatives. Do not use in case of known hypersensitivity.