

Summary of product characteristics for a biocidal product

Product name: Product 3-2 - Hydrachim

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

PT03 - Veterinary hygiene (Disinfectants)

Authorisation number: FR-2023-0054

R4BP 3 asset reference number: FR-0030922-0016

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Administrative information

1.1. Trade names of the product

VITAFILM PLUS
FILMOLAC

1.2. Authorisation holder

Name and address of the authorisation holder	Name	Hydrachim
	Address	ZA du piquet 35370 Etreilles France
Authorisation number	FR-2023-0054 1-3	

R4BP 3 asset reference number

FR-0030922-0016

Date of the authorisation

20/09/2023

Expiry date of the authorisation

19/09/2033

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	HYDRACHIM
Address of the manufacturer	ZA DU PIQUET F-35370 ETRELLES France
Location of manufacturing sites	ZA DE LA POINTE F-35380 PLELAN LE GRAND France
	ROUTE DE SAINTE POIX F-35370 LE PERTRE France

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

Active substance	1322 - L-(+)-lactic acid
Name of the manufacturer	Jungbunzlauer S.A
Address of the manufacturer	ZI Portuaire - BP 32 F-67390 Marcklosheim France
Location of manufacturing sites	Jungbunzlauer S.A - ZI Portuaire - BP 32 F-67390 Marcklosheim France

Active substance	1322 - L-(+)-lactic acid
Name of the manufacturer	Purac Bioquimica sa
Address of the manufacturer	Gran Vial 19-25 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 Bioquimica sa
Address of the manufacturer	Gran Arkelsedijk 46 4206 AC Gorinchem Netherlands
Location of manufacturing sites	Arkelsedijk 46 NL-4200 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 (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	10,26

2.2. Type of formulation

AL - Any other liquid

3. Hazard and precautionary statements

Hazard statements

Causes serious eye damage.
Contains Carvone and d-limonene. May produce an allergic reaction.

Precautionary statements

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/....

4. Authorised use(s)

4.1 Use description

Use 1 - Use # 11 Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping with a film-forming property thick liquid

Product type

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

Non-medical teat disinfection.

Target organism(s) (including development stage)

Scientific name:
Common name: Bacteria
Development stage:

Scientific name:
Common name: Yeasts
Development stage:

Scientific name:
Common name: Enveloped viruses
Development stage:

Field(s) of use

Indoor
Disinfection of teats of milk producing animals

Application method(s)

Method: Open system: dip treatment
Detailed description:
Manual film-forming property thick liquid dipping after milking

Application rate(s) and frequencies

Application Rate: Cows and buffaloes: 3 to 10ml - sheep:1.5 to 5 ml - goats: 2.5 to 6 ml
Dilution (%): No dilution. Ready-to-use product
Number and timing of application:
- cows and buffaloes: 2 to 3 times per day for post-milking disinfection
- sheep and goats: 1 to 2 times per day for post-milking disinfection
Contact time: 5 minutes
Ambient temperature

Category(ies) of users

Professional

Pack sizes and packaging material

1L HDPE Bottle
5L HDPE Jerrican
10L HDPE Jerrican
20L HDPE Jerrican
22L HDPE Jerrican
60L HDPE Drum
220L HDPE Drum
1000L HDPE Container

4.1.1 Use-specific instructions for use

- Fill manually the clean and dry 300 ml dipping cup with the 225ml of the ready to use product.
- Squeeze three to six times the dip cup reservoir to make the film-forming thick liquid product rise into the 2/3 of the dipping cup reservoir.
- Apply by dipping manually on animal's teats on the full length of the teat after milking.
- For post-milking application, leave the product until next milking. Keep the cows standing until the product has dried (at least 5 minutes). At the next milking, clean the teats with a a single use paper or a towel.
- Clean the application equipment regularly with water.

4.1.2 Use-specific risk mitigation measures

The professional user has to wear chemical goggles and gloves during loading, application by dipping and cleaning of the equipment.

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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4.2 Use description

Use 2 - Use # 12 - Teat disinfection of milkable animals: Post-milking teat disinfection by semi-automated dipping with a film-forming property thick liquid

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Non-medical teat disinfection
Target organism(s) (including development stage)	Scientific name: Common name: Bacteria Development stage: Scientific name: Common name: Yeasts Development stage: Scientific name: Common name: Enveloped viruses Development stage:
Field(s) of use	Indoor Disinfection of teats of milk producing animals
Application method(s)	Method: Open system: dip treatment Detailed description: Semi-automated film-forming property thick liquid dipping after milking
Application rate(s) and frequencies	Application Rate: Cows and buffaloes: 3 to 10ml - sheep:1.5 to 5 ml - goats: 2.5 to 6 ml Dilution (%): No dilution. Ready-to-use product Number and timing of application: - cows and buffaloes: 2 to 3 times per day for post-milking disinfection - sheep and goats: 1 to 2 times per day for post-milking disinfection Contact time: 5 minutes Ambient temperature
Category(ies) of users	Professional
Pack sizes and packaging material	1L HDPE Bottle 5L HDPE Jerrican 10L HDPE Jerrican

20L HDPE Jerrican
22L HDPE Jerrican
60L HDPE Drum
220L HDPE Drum
1000L HDPE Container

4.2.1 Use-specific instructions for use

- Connect the container to the semi-automated dipping equipment.
- Press the trigger to fill the dipping cup reservoir with the film-forming thick liquid product.
- Apply by dipping manually on animal's teats on the full length of the teat after milking.
- For post-milking application, leave the product until next milking. Keep the animals standing for five minutes. At the next milking, clean the teats with a single use paper or a towel.
- Clean the application equipment regularly with water.

4.2.2 Use-specific risk mitigation measures

The professional user has to wear chemical goggles and gloves during loading, application by dipping and cleaning of the equipment.

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

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

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4.2.5 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° before use

5.2. Risk mitigation measures

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

- IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.
- IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.
- IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.
- IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance. Information to Healthcare personnel/doctor:
 - The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH>11), amines and acids like acetic acid, formic acid or propionic acid

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

- Do no store above 40°C.
- Protect from frost.
- Shelf-life : 2 years

6. Other information

