

Summary of product characteristics for a biocidal product

Product name: calgodip Amadine forte Film

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

Authorisation number: EU-0028957-00000

R4BP 3 asset reference number: EU-0028957-0005

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Administrative information

1.1. Trade names of the product

calgodip Amadine forte Film

1.2. Authorisation holder

Name and address of the authorisation holder

Name	CVAS Development GmbH
Address	Am Hafen 16 68526 Ladenburg Germany
Authorisation number	EU-0028957-00000 1-2

R4BP 3 asset reference number

EU-0028957-0005

Date of the authorisation

18/07/2023

Expiry date of the authorisation

30/06/2033

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer

Calvatis GmbH

Address of the manufacturer

Am Hafen 16 68526 Ladenburg Germany

Location of manufacturing sites

Am Hafen 16 68526 Ladenburg Germany

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

Active substance	1322 - L-(+)-lactic acid
Name of the manufacturer	Purac Biochem bv
Address of the manufacturer	Arkelsedijk 46 4206AC Gorinchem Netherlands
Location of manufacturing sites	Arkelsedijk 46 4206AC 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	6,8
Methanesulphonic acid	Methanesulphonic acid	Non-active substance	75-75-2	200-898-6	0
Phosphoric acid	Phosphoric acid	Non-active substance	7664-38-2	231-633-2	0
Sulphuric acid	Sulphuric acid	Non-active substance	7664-93-9	231-639-5	0
Isononanoic acid	Isononanoic acid	Non-active substance	3302-10-1	221-975-0	0

2.2. Type of formulation

AL - Any other liquid

3. Hazard and precautionary statements

Hazard statements	Causes skin irritation. Causes serious eye damage.
Precautionary statements	Wash hands thoroughly after handling. Wear protective gloves.

Wear eye protection.

IF ON SKIN:Wash with plenty of water.

If skin irritation occurs:Get medical advice.

If skin irritation occurs:Get medical attention.

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.

Immediately call a doctor.

Dispose of contents to in accordance with local regulations.

Dispose of container to in accordance with local regulations.

4. Authorised use(s)

4.1 Use description

Use 1 - Use # 2.1 - Teat-disinfection post-milking by manual or automated dipping

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	<p>Scientific name: Common name: Bacteria Development stage:</p> <p>Scientific name: Common name: Yeasts Development stage:</p>
Field(s) of use	<p>Indoor</p> <p>Teat-disinfection post-milking</p>
Application method(s)	<p>Method: Dipping Detailed description: Teat-disinfection post-milking Manual dipping using a dip cup Automated dipping by robot</p>
Application rate(s) and frequencies	<p>Application Rate: RTU product, 6,80% L-(-)-lactic acid Dilution (%): -</p>

	Number and timing of application: 2-3 times a day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE jerrycan: 5-60 kg HDPE drum: 60-200 kg HDPE IBC: 600-1000 kg

4.1.1 Use-specific instructions for use

See general directions for use.

4.1.2 Use-specific risk mitigation measures

See general directions for use.

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.

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

See general directions for use.

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.

5. General directions for use

5.1. Instructions for use

The product must be brought to a temperature between 20°C and 30°C before use.
The use of a dosing pump for filling the product into the application equipment is recommended.
Fill in the dosing pump reservoir with the RTU product. Avoid discharge of surplus fluids.
Apply the product by manual or automated dipping. Make sure that the teats are fully covered with disinfectant. Application volumes for cows and buffaloes - 5 ml/treatment and for sheep and goats - 3 ml/treatment.
Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.
After disinfection clean the application equipment by rinsing with water.
Keep out of reach of children.

5.2. Risk mitigation measures

Wear chemical goggles consistent with the European Standard EN ISO 16321 or equivalent, protective clothing chemically resistant to the biocidal product, chemical resistant gloves classified under the European Standard EN ISO 374 or equivalent. See section 6 for the full titles of the EN standards.
Goggles, gloves and coverall material to be specified by the authorisation holder within the product information.
This is without prejudice to the application of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work. See section 6 for the full reference to this act.

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

First aid instructions

IF INHALED: if symptoms occur call a POISON CENTRE or a doctor.
IF ON SKIN: take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation occurs: Get medical advice.
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 or an ambulance for medical assistance.
IF SWALLOWED: immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112 or an ambulance for medical assistance.

Emergency measure to protect the environment

Environmental precautions: do not allow product to reach sewage systems or water bodies.
Methods and material for containment and cleaning up: absorb with liquid-binding material (sand, diatomite, universal binder). Do not use combustible material like sawdust. Dispose of the material collected in accordance with local regulations.

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 municipal sewer or disposed to the manure deposit depending on local requirements.

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

Shelf life: 24 months
Do not store at temperatures above 40°C.
Keep away from heat and direct sunlight.
Protect from frost.
Keep container tightly closed.

6. Other information

The full titles of EN standards mentioned in the section 5.2 'Risk mitigation measures' are:

EN ISO 16321– Eye and face protection for occupational users.

EN ISO 374 – Protective gloves against dangerous chemicals and micro-organisms.

The full reference of the legal act mentioned in the section 5.2 'Risk mitigation measures' is:

Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).