

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Synodex

Product type(s)

PT03: Veterinary hygiene

Authorisation number: EU-0030143-0000 1-1

R4BP asset number: EU-0030143-0001

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	Synodex Lactopost Lactopost Y Lactopost Plus Lactopost Extra Synodex Y Synodex Extra Synodex Plus Udder X Teat Care Lacto Gold Lacto Extra Lactogold Lacto Spray
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	Neogen Italia S.r.l.
	Address	Via Agnello 8 20121 Milano (MI) Italy
Authorisation number	EU-0030143-0000 1-1	
<i>R4BP asset number</i>	EU-0030143-0001	
Date of the authorisation	03/10/2023	
Expiry date of the authorisation	30/09/2033	

1.3. Manufacturer(s) of the product

Name of manufacturer	Quat-Chem Ltd. A Neogen Company
Address of manufacturer	1-4 Sandfield Industrial Park, Dodgson Street, Rochdale OL16 5SJ Lancashire United Kingdom of Great Britain and Northern Ireland (the)
Location of manufacturing sites	Quat-Chem Ltd. A Neogen Company site 1 1-4 Sandfield Industrial Park, Dodgson Street, Rochdale OL16 5SJ Lancashire United Kingdom of Great Britain and Northern Ireland (the)

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

Active substance	L-(+)-lactic acid
Name of manufacturer	Purac Biochem bv
Address of manufacturer	Arkelsedijk 46 4206 AC Gorinchem Netherlands (the)
Location of manufacturing sites	Purac Biochem bv site 1 Arkelsedijk 46 4206 AC Gorinchem Netherlands (the)

Active substance	L-(+)-lactic acid
Name of manufacturer	Jungbunzlauer S. A

Address of manufacturer	Z.I. et Portuaire, B.P. 32 FR-67390 Marckolsheim France
Location of manufacturing sites	Jungbunzlauer S. A site 1 Z.I. et Portuaire, B.P. 32 FR-67390 Marckolsheim France

2. PRODUCT COMPOSITION AND FORMULATION

2.1. Qualitative and quantitative information on the composition of the product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		active substance	79-33-4	201-196-2	4 % (w/w)

2.2. Type(s) of formulation

AL Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H315: Causes skin irritation. H318: Causes serious eye damage.
Precautionary statements	P280: Wear protective gloves. P280: Wear eye protection. P264: Wash hands thoroughly after handling. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a doctor. P302+P352: IF ON SKIN: Wash with plenty of water. P332+P313: If skin irritation occurs: Get medical advice. P332+P313: If skin irritation occurs: Get medical attention. P362+P364: Take off contaminated clothing and wash it before reuse. P501: Dispose of contents to hazardous or special waste collection point in accordance with national regulations. P501: Dispose of container to hazardous or special waste collection point in accordance with national regulations.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Use # 1.1 – Post milking teat disinfection – manual dipping

Product type	PT03: Veterinary hygiene
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: - Scientific name: Yeasts Common name: Yeasts Development stage: -
Field(s) of use	indoor use Teat disinfection post-milking by manual dipping using a dip cup
Application method(s)	Method: Manual dipping using a dip cup Detailed description: Contact time for dipping at 30 °C in dirty conditions: - 5 minutes for bacteria and yeasts.
Application rate(s) and frequency	Application rate: 5 to 10 ml per teat Dilution (%): RTU (Ready-to-use) product Number and timing of application: up to twice per day
Category(ies) of users	professional
Pack sizes and packaging material	1000 litre high density polyethylene (HDPE) container with HDPE closure; 200 litre plastic drum with HDPE closure; 25 litre HDPE keg with DIN 61 or equivalent HDPE screw cap; 5 litre HDPE keg with DIN 51 or equivalent HDPE screw cap.

4.1.1. Use-specific instructions

See general directions for use.

Product to be applied post-milking by use of a dipping cup.

Pre-clean teat with dry wipe, pour the product into the reservoir of the dip cup. When using a dip cup, the cup is applied to each teat in turn and the operator squeezes the product from the reservoir into the cup. The cup has a non-return valve so any residual product cannot go back into the reservoir.

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.

4.2. Use description

Table 2. Use # 1.2 – Post milking teat disinfection - spraying

Product type	PT03: Veterinary hygiene
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: - Scientific name: Yeasts Common name: Yeasts Development stage: -
Field(s) of use	indoor use Teat disinfection post-milking by using hand-held sprayer
Application method(s)	Method: Manual spraying using hand-held sprayer Detailed description: Contact time for spraying at 30 °C in dirty conditions: - 5 minutes for bacteria and yeasts.
Application rate(s) and frequency	Application rate: 5 to 10 ml per teat Dilution (%): RTU product Number and timing of application: up to twice per day

Category(ies) of users	professional
Pack sizes and packaging material	1000 litre HDPE container with HDPE closure; 200 litre plastic drum with HDPE closure; 25 litre HDPE keg with DIN 61 or equivalent HDPE screw cap; 5 litre HDPE keg with DIN 51 or equivalent HDPE screw cap.

4.2.1. Use-specific instructions

See general directions for use.

Product to be applied post-milking by use of a hand-held sprayer.

Pre-clean teat with dry wipe, pour the product into the reservoir of the sprayer. The operator will spray each animal once after milking.

4.2.2. Use-specific risk mitigation measures

See general directions for use.

Professional users have to ensure that professional bystanders are not present in the treatment area during disinfection process by spraying. If it is necessary for professional bystanders to be present, professional users have to ensure that those bystanders wear the same type of PPE as the operator.

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

See general directions for use.

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

See general directions for use.

4.2.5. 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 USE¹

5.1. Instructions for use

See use-specific instruction for use of meta SPC 1.

Always read the label or leaflet before use.

The product must be brought to room temperature before use. The amount of product applied per teat is dependent upon the animal being treated. For large mammals (cows, camels) – up to 10 ml per teat, and for small mammals (sheep, goats) – up to 5 ml per teat. Make sure that the teats are fully covered with disinfectant. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing for at least 5 minutes).

5.2. Risk mitigation measures

The use of eye protection consistent with European standard EN ISO 16321 or equivalent during handling of the product is mandatory.

Avoid hand to eye transfer.

Wear protective chemical resistant gloves during product handling phase (nitrile gloves – classified under European standards EN ISO 374 or EN 455 or equivalent).

The full titles of the European standards indicated here are available under section 6.

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

IF ON SKIN: Immediately wash 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.

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: 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.

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

At the end of the treatment, dispose of 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 out of reach of children.

Store in original container tightly closed.

Store between 0 °C and + 30 °C.

¹Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.

Shelf life: 24 months

6. OTHER INFORMATION

The full titles of the European standards referenced in section 5.2 'Risk mitigation measures' are :

EN ISO 16321 - Eye and face protection for occupational use

EN ISO 374 – Protective gloves against dangerous chemicals and microorganisms

EN 455 - Medical gloves for single use