



2024/1990

23.7.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/1990

of 22 July 2024

amending Implementing Regulation (EU) 2023/1763 as regards an administrative change to the Union authorisation of the biocidal product family 'Lactic acid Family – Quatchem'

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular Article 50(2) thereof,

Whereas:

- (1) On 12 September 2023, Commission Implementing Regulation (EU) 2023/1763 ⁽²⁾ granted a Union authorisation with authorisation number EU-0030143-0000 to Arrow Regulatory (Ireland) Limited for the making available on the market and use of the biocidal product family 'Lactic acid Family – Quatchem'.
- (2) On 25 January 2024, Arrow Regulatory (Ireland) Limited submitted a notification to the European Chemicals Agency ('the Agency'), in accordance with Article 11(1) of Commission Implementing Regulation (EU) No 354/2013 ⁽³⁾ regarding an administrative change to the Union authorisation for the biocidal product family 'Lactic acid Family – Quatchem' as referred to in Title 1, Section 1, of the Annex to that Regulation.
- (3) Arrow Regulatory (Ireland) Limited proposed to transfer the authorisation to a new holder established in the European Economic Area as set out in Title 1, Section 1, point 3, of the Annex to Implementing Regulation (EU) No 354/2013. The notification was recorded in the Register for Biocidal Products under the case number BC-PG091934-25.
- (4) On 12 March 2024, the Agency submitted an opinion ⁽⁴⁾ to the Commission on the proposed change, in accordance with Article 11(3) of Implementing Regulation (EU) No 354/2013. The opinion concludes that the amendment to the existing authorisation sought by the authorisation holder falls under Article 50(3), point (a), of Regulation (EU) No 528/2012, that the parties have agreed to the transfer of the authorisation, that the prospective new authorisation holder is established in the Union, and that after the implementation of the changes, the conditions of Article 19 of Regulation (EU) No 528/2012 are still met.
- (5) On 3 April 2024, the Agency transmitted to the Commission the revised summary of the biocidal product characteristics in all the official languages of the Union in accordance with Article 11(6) of Implementing Regulation (EU) No 354/2013.
- (6) The Commission concurs with the opinion of the Agency and therefore considers it appropriate to amend the Union authorisation of the biocidal product family 'Lactic acid Family – Quatchem'.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1, ELI: <http://data.europa.eu/eli/reg/2012/528/oj>.

⁽²⁾ Commission Implementing Regulation (EU) 2023/1763 of 12 September 2023 granting a Union authorisation for the biocidal product family 'Lactic acid Family – Quatchem' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 225, 13.9.2023, p. 5, ELI: http://data.europa.eu/eli/reg_impl/2023/1763/oj).

⁽³⁾ Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 109, 19.4.2013, p. 4, ELI: http://data.europa.eu/eli/reg_impl/2013/354/oj).

⁽⁴⁾ ECHA opinion on an administrative change of the Union authorisation of 'Lactic acid Family – QuatChem' of 12 March 2024, Opinion No. UTR-C-1719298-59-00/F, <https://echa.europa.eu/opinions-on-union-authorisation>.

- (7) Save for the amendment regarding the transfer of the authorisation to a new holder, all other information included in the summary of the biocidal product characteristics of 'Lactic acid Family – Quatchem' as set out in the Annex to Implementing Regulation (EU) 2023/1763 remains unchanged. In order to enhance clarity and to ease the access of users and interested parties to the final consolidated version of the summary of biocidal product characteristics which is to be published by the Agency, the Annex to Implementing Regulation (EU) 2023/1763 should be replaced in its entirety.

HAS ADOPTED THIS REGULATION:

Article 1

Implementing Regulation (EU) 2023/1763 is amended as follows:

- (1) in Article 1, first paragraph, the name 'Arrow Regulatory (Ireland) Limited' is replaced by the name 'Neogen Italia S.r.l.';
- (2) the Annex is replaced by the text in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 22 July 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT FAMILY

Lactic acid Family – Quatchem

Product type(s)

PT03: Veterinary hygiene

Authorisation number: EU-0030143-0000

R4BP asset number: EU-0030143-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. Family name

Name	Lactic acid Family – Quatchem
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1.2. Product type(s)

Product type(s)	PT03: Veterinary hygiene
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1.3. Authorisation holder

Name and address of the authorisation holder	Name	Neogen Italia S.r.l.
	Address	c/o REGUS Palazzo Bernini Centro Direzionale Milano Due, Via Fratelli Cervi snc 20054 - Segrate, Milano Italy
Authorisation number		EU-0030143-0000
R4BP asset number		EU-0030143-0000
Date of the authorisation		3 October 2023
Expiry date of the authorisation		30 September 2033

1.4. 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)

1.5. **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 FAMILY COMPOSITION AND FORMULATION**

2.1. **Qualitative and quantitative information on the composition of the family**

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

2.2. **Type(s) of formulation**

Formulation type(s)	AL Any other liquid
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PART II

SECOND INFORMATION LEVEL - META SPC(S)

1. **META SPC 1 ADMINISTRATIVE INFORMATION**

1.1. **Meta SPC 1 identifier**

Identifier	Meta SPC: meta SPC 1
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1.2. **Suffix to the authorisation number**

Number	1-1
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1.3. **Product type(s)**

Product type(s)	PT03: Veterinary hygiene
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2. META SPC 1 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 1

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

2.2. Type(s) of formulation of the meta SPC 1

Formulation type(s)	AL Any other liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

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) OF THE META SPC

4.1. Use description 1

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	1 000 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 for use

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 2**

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	1 000 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 for use*

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 USE OF THE META SPC 1**

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.

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

7. **THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1**

7.1. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	Synodex	Market area: EU
	Lactopost	Market area: EU
	Lactopost Y	Market area: EU
	Lactopost Plus	Market area: EU
	Lactopost Extra	Market area: EU
	Synodex Y	Market area: EU
	Synodex Extra	Market area: EU
	Synodex Plus	Market area: EU
	Udder X	Market area: EU
	Teat Care	Market area: EU
	Lacto Gold	Market area: EU
	Lacto Extra	Market area: EU
	Lactogold	Market area: EU
	Lacto Spray	Market area: EU

Authorisation number			EU-0030143-0001 1-1		
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		active substance	79-33-4	201-196-2	4

7.2. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	Laxsan	Market area: EU			
	Hexsan	Market area: EU			
	Lactopost R	Market area: EU			
	Laxsan R	Market area: EU			
	Hexfoam	Market area: EU			
	Deosan LA1	Market area: EU			
	Hexsan Extra	Market area: EU			
	Hexsan Plus	Market area: EU			
	Laxsan Plus	Market area: EU			
	Laxsan Extra	Market area: EU			
	Hexsan R	Market area: EU			
	LA1	Market area: EU			
	Condition Pink	Market area: EU			
Authorisation number			EU-0030143-0002 1-1		
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		active substance	79-33-4	201-196-2	4

1. META SPC 2 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 2 identifier

Identifier	Meta SPC: meta SPC 2
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1.2. Suffix to the authorisation number

Number	1-2
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1.3. Product type(s)

Product type(s)	PT03: Veterinary hygiene
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2. META SPC 2 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 2

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

2.2. Type(s) of formulation of the meta SPC 2

Formulation type(s)	AL Any other liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

Hazard statements	H315: Causes skin irritation. H318: Causes serious eye damage. EUH208: Contains <name of sensitising substance>. May produce an allergic reaction.
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) OF THE META SPC

4.1. Use description 1

Table 1.

Use # 3.1 – 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 product Number and timing of application: up to twice per day
Category(ies) of users	professional
Pack sizes and packaging material	1 000 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.

4.1.1. Use-specific instructions for use

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 2**

Table 2.

Use # 3.2 – 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	1 000 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 for use*

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 operators.

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 USE OF THE META SPC 2**

5.1. **Instructions for use**

See use-specific instruction for use of meta SPC 2.

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.
Shelf life: 24 months

6. **OTHER INFORMATION**

The full titles of the EN standards referred to in section 5.2 are the following:

EN ISO 16321 - Eye and face protection for occupational use

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

EN 455 - Medical gloves for single use

7. **THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 2**

7.1. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	Synoshield	Market area: EU
	Lactopost G	Market area: EU
	Synoshield P	Market area: EU
	Lactopost P	Market area: EU
	Synoshield G	Market area: EU
	Lactoshield	Market area: EU
	Lactoshield Plus	Market area: EU
	Lactoshield Extra	Market area: EU
	Synoshield Extra	Market area: EU
	Synoshield Plus	Market area: EU
	Lactopost Protect	Market area: EU
	Udder Shield	Market area: EU
	Teat Care	Market area: EU
	Mint Lacto Plus	Market area: EU
	Lacto Care G	Market area: EU

			Lactosal	Market area: EU		
			Lacto Care P	Market area: EU		
			Previoshield	Market area: EU		
Authorisation number			EU-0030143-0003 1-2			
Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
L-(+)-lactic acid		active substance	79-33-4	201-196-2	4	