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COMMISSION IMPLEMENTING REGULATION (EU) 2025/1019

of 26 May 2025

granting a Union authorisation for the biocidal product family 'Lactic Acid Teatdip Products' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(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 44(5), first subparagraph, thereof,

Whereas:

(1) On 26 April 2019, GEA Farm Technologies GmbH submitted an application to the European Chemicals Agency ('the Agency') in accordance with Article 43(1) of Regulation (EU) No 528/2012 for Union authorisation of a biocidal product family named 'Lactic Acid Teatdip Products' of product-type 3 as described in Annex V to that Regulation, providing written confirmation that the competent authority of the Netherlands had agreed to evaluate the application. The application was recorded under case number BC-KN051277-28 in the Register for Biocidal Products.

(2) 'Lactic Acid Teatdip Products' contains L-(+)-lactic acid as the active substance, included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012 for product-type 3.

(3) On 19 March 2024, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, an assessment report and the conclusions of its evaluation to the Agency.

(4) On 10 October 2024, the Agency submitted to the Commission its opinion ([2]), the draft summary of the biocidal product characteristics ('SPC') of 'Lactic Acid Teatdip Products' and the final assessment report on the biocidal product family, in accordance with Article 44(3) of Regulation (EU) No 528/2012.

(5) The opinion concludes that 'Lactic Acid Teatdip Products' is a biocidal product family within the meaning of Article 3(1), point (s), of Regulation (EU) No 528/2012, that it is eligible for Union authorisation in accordance with Article 42(1) of that Regulation and that, subject to compliance with the draft SPC, it meets the conditions laid down in Article 19(6) of that Regulation.

(6) On 25 October 2024, the Agency transmitted to the Commission the draft SPC in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.

(7) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for the biocidal product family 'Lactic Acid Teatdip Products'.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

([1]) OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj.
([2]) ECHA opinion of 18 September 2024 on the Union authorisation of 'Lactic Acid Teatdip Products' (ECHA/BPC/440/2024), https://echa.europa.eu/opinions-on-union-authorisation.

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0033409-0000 is hereby granted to GEA Farm Technologies GmbH for the making available on the market and use of the biocidal product family 'Lactic Acid Teatdip Products' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 16 June 2025 until 31 May 2035.

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, 26 May 2025.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Summary of product characteristics for a biocidal product family

Lactic Acid Teatdip Products

Product type(s)

PT03: Veterinary hygiene

Authorisation number EU-0033409-0000

R4BP asset number EU-0033409-0000

PART I

FIRST INFORMATION LEVEL

1. **ADMINISTRATIVE INFORMATION**

1.1. **Family name**

Name	Lactic Acid Teatdip Products

1.2. **Product type(s)**

Product type(s)	PT03: Veterinary hygiene

1.3. **Authorisation holder**

Name and address of the authorisation holder	Name	GEA Farm Technologies GmbH
	Address	Siemensstraße 25-27 59199 Bönen DE
Authorisation number	EU-0033409-0000	
R4BP asset number	EU-0033409-0000	
Date of the authorisation	16 June 2025	
Expiry date of the authorisation	31 May 2035	

1.4. **Manufacturer(s) of the product**

Name of manufacturer	GEA Farm Technologies GMBH
Address of manufacturer	Siemensstraße 25-27, 59199 Bönen Germany
Location of manufacturing sites	GEA Farm Technologies GMBH site 1 Wylye Works, Watery Lane, BA12 9HT Warminster United Kingdom of Great Britain and Northern Ireland (the) GEA Farm Technologies GMBH site 2 Gewerbestraße 5 5325 Plainfeld Austria GEA Farm Technologies GMBH site 3 ul. Olowiana 10 85-461 Bydgoszcz Poland

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)

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	2,4 - 2,4 % (w/w)
Sodium Laureth Sulphate		Non-Active substance	68891-38-3	500-234-8	1,68 - 1,68 % (w/w)

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

Formulation type(s)	AL Any other liquid

PART II

SECOND INFORMATION LEVEL – META SPC(S)

1. **META SPC 1 ADMINISTRATIVE INFORMATION**

1.1. **Meta SPC 1 identifier**

Identifier	Meta SPC: Lactic acid post milking dip/spray

1.2. **Suffix to the authorisation number**

Number	1-1

1.3. **Product type(s)**

Product type(s)	PT03: Veterinary hygiene

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	2,4 - 2,4 % (w/w)
Sodium Laureth Sulphate		Non-Active substance	68891-38-3	500-234-8	1,68 - 1,68 % (w/w)

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

Formulation type(s)	AL Any other liquid

3. **HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1**

Hazard statements	H318: Causes serious eye damage. H315: Causes skin irritation. H290: May be corrosive to metals.
Precautionary statements	P280: Wear eye protection. P280: Wear protective gloves. P234: Keep only in original packaging. 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 POISON CENTER/doctor. P302+P352: IF ON SKIN: Wash with plenty of water. P332+P313: If skin irritation occurs: Get medical advice. P362+P364: Take off contaminated clothing and wash it before reuse. P390: Absorb spillage to prevent material damage.

4. **AUTHORISED USE(S) OF THE META SPC**

4.1. **Use description**

Table 1

Use # 2.8 – RTU Products – Professional RTU Liquid, for application post-milking – Automated in-liner dipping

Product type	PT03: Veterinary hygiene
Where relevant, an exact description of the authorised use	not relevant
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data
Field(s) of use	indoor use Indoor – post-milking
Application method(s)	Method: open system: dip treatment Detailed description: Application via automatic in liner dipping: Milking ceases. The milk line valve closes. Teat dip is dispensed directly into the rubber milking cluster liner. Cluster drops from teat following application of the teat dip and is flushed to remove milk and dip residues.
Application rate(s) and frequency	Application rate: Quantity of RTU product to be applied per application; - cows and buffaloes: 3 to 10ml (5 ml recommended) - sheep 1,5 to 5 ml (1,5 ml recommended) - goats 2,5 to 6 ml (2,5 ml recommended). Ready to use formulation. In use concentration 2,4% w/w lactic acid Number and timing of application: up to 3 post milking applications per animal, per day
Category(ies) of users	professional
Pack sizes and packaging material	Drum, Plastic: HDPE (High Density Polyethylene), 10 litres Drum, Plastic: HDPE , 20 litres Drum, Plastic: HDPE , 25 litres Drum, Plastic: HDPE , 200 litres IBC (intermediate bulk container), Plastic: HDPE , 1 000 litres Drum, Plastic: HDPE , 5 litres all drums excepting 200 litres (200 kg) and 1 000 litres (1 000 kg) could be either silver or natural (white translucent) in colour. 200 litres (200 kg) drums are either silver or blue in colour. IBCs are natural coloured.

	All drums are capped with tamper evident caps or bungs and are UN certified.

4.1.1. *Use-specific instructions*

Dip at least 2/3 of the teat length with RTU product immediately after milking

To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the animals standing at least 5 minutes).

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 # 2.9 – RTU Products – Professional RTU Liquid, for application post milking – via automatic spray system

Product type	PT03: Veterinary hygiene
Where relevant, an exact description of the authorised use	not relevant
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data
Field(s) of use	indoor use Indoor – post-milking
Application method(s)	Method: open system: spray treatment Detailed description: Immediately following milking, the milking cluster disengages automatically and the teat spray solution is applied either by spray nozzles embedded in the floor of the automated milking system or by an automated spray bar.

Application rate(s) and frequency	Application rate: Quantity of RTU product to be applied per application; - cows and buffaloes: 3 to 10ml (5 ml recommended) - sheep 1,5 to 5 ml (1,5 ml recommended) - goats 2,5 to 6 ml (2,5 ml recommended). Ready to use formulation. In use concentration 2,4 % Lactic Acid Number and timing of application: up to 3 post milking applications per animal, per day
Category(ies) of users	professional
Pack sizes and packaging material	Drum, Plastic: HDPE , 10 litres Drum, Plastic: HDPE , 20 litres Drum, Plastic: HDPE , 25 litres Drum, Plastic: HDPE , 200 litres IBC (intermediate bulk container), Plastic: HDPE , 1 000 litres Drum, Plastic: HDPE , 5 litres all drums excepting 200 litres (200 kg) and 1 000 litres (1 000 kg) could be either silver or natural (white translucent) in colour. 200 litres (200 kg) drums are either silver or blue in colour. IBCs are natural coloured. All drums are capped with tamper evident caps or bungs and are UN certified.

4.2.1. *Use-specific instructions*

Cover at least 2/3 of the teat length by automatically spraying RTU product immediately after milking

To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the animals standing at least 5 minutes).

4.2.2. *Use-specific risk mitigation measures*

See general directions for use.

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**

Ready to use product

The product must be brought to a temperature above 20°C before use

Product can be used during the entire lactation period

5.2. **Risk mitigation measures**

The following personal protective equipment (PPE) is stipulated without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work.

During mixing and loading: Wear protective gloves consistent with the European Standard EN 374 or equivalent and safety glasses with side shield or face protection consistent with the European Standard EN 166 or equivalent.

See section 6 for the full reference to this act and the European Standards

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

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.

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.

Large Spills: Contain and collect for disposal. Large spills should be contained using a chemical spill kit, soaked up using absorbent material such as kieselguhr and disposed of as hazardous waste

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 farm based wastewater treatment plant to prevent malfunctioning.

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

Protect from frost.

Store in a cool dry place away from direct sunlight.

Shelf life 12 months.

6. **OTHER INFORMATION**

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. 11–23 ELI: http://data.europa.eu/eli/dir/1998/24/oj

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

EN 166 – Eye protection against chemicals

With respect to the “Category (ies) of users” note: “Professionals (including industrial users) means trained professionals if this is required by national legislation.”

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)			SalvoSpray AMS	Market area: EU	
Authorisation number			EU-0033409-0001 1-1		
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		active substance	79-33-4	201-196-2	2,4 % (w/w)
Sodium Laureth Sulphate		Non-Active substance	68891-38-3	500-234-8	1,68 % (w/w)