

Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the biocidal product family:

Lactic acid Family - Quatchem

ECHA/BPC/371/2022

Adopted

24 November 2022

Opinion of the Biocidal Products Committee

on the Union authorisation of Lactic acid Family - Quatchem

In accordance with Article 44(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products, the Biocidal Products Committee (BPC) has adopted this opinion on the Union authorisation of:

Name of the biocidal product family:	Lactic acid Family - Quatchem
Authorisation holder:	Arrow Regulatory (Ireland) on behalf of Quatchem
Active substance common name:	L(+)-lactic acid (CAS No.: 79-33-4)
Product type:	3

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority (eCA).

Process for the adoption of BPC opinions

Following the submission of an application on 11 April 2019, recorded in R4BP3 under case number BC-WC050857-29, the evaluating Competent Authority submitted a draft product assessment report (PAR) containing the conclusions of its evaluation and the draft Summary of Product Characteristics (SPC) to ECHA on 16 May 2022. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-45) and its Working Groups (WG-III-2022). Revisions agreed upon were presented and the draft PAR and draft SPC were finalised accordingly.

Adoption of the BPC opinion

Rapporteur: Latvia

The BPC opinion on the Union authorisation of the biocidal product family was reached on 24 November 2022.

The BPC opinion was adopted by consensus. The opinion is published on the ECHA website.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the biocidal product family is eligible for Union authorisation in accordance with Article 42(1) of Regulation (EU) No 528/2012 and falls within the scope of the Regulation (EU) No 528/2012 as defined in Article 3(1)(s).

The biocidal product family meets the conditions laid down in Article 19(6) of Regulation (EU) No 528/2012 and therefore may be authorised. The detailed grounds for the overall conclusion are described in the PAR.

The BPC agreed on the draft SPC of **Lactic acid Family - Quatchem** referred to in Article 22(2) of Regulation (EU) No 528/2012.

2. BPC Opinion

2.1 BPC Conclusions of the evaluation

a) Summary of the evaluation and conclusions of the risk assessment

The sections below are a concise summary of the evaluation and conclusions of the assessment of the biocidal product family.

General

The biocidal product family Lactic acid Family - Quatchem comprises of three meta SPCs based on the active substance L(+)-lactic acid for the use as non-medical teat disinfectants in veterinary hygiene (PT3). The three meta SPCs includes four ready-to-use liquid products. The products are intended to be applied in the post-milking phase by manual dipping using a dip cup or hand-held sprayer. The products are for professional use only.

The biocidal product family does not contain any non-active substance which is considered as a substance of concern.

Following intended uses in 3 meta SPC have been assessed:

Meta SPC / Use No	Use
Meta SPC 1 / Use #1.1.	Post milking teat disinfection – manual dipping
Meta SPC 1 / Use #1.2.	Post milking teat disinfection - spraying
Meta SPC 2 / Use #2.1.	Post milking teat disinfection – manual dipping
Meta SPC 3 / Use #3.1.	Post milking teat disinfection – manual dipping
Meta SPC 3 / Use #3.2.	Post milking teat disinfection - spraying

Physico-chemical properties

The biocidal product family Lactic acid Family – Quatchem contain 4 water-based, liquid ready-to-use products allocated to 3 meta SPCs. All products were tested for relevant endpoints considering formulation type or respective non-submission justifications have been provided.

The physico-chemical properties of the biocidal product family Lactic acid Family – Quatchem have been described and considered acceptable.

Label requirements:

- Store in original container tightly closed;
- Store between 0 and 30 °C.

Shelf life: 24 months.

Biocidal product family Lactic acid Family – Quatchem is not classified with regard to physical hazards according to the Regulation (EU) No 1272/2008.

A HPLC-DAD method of analysis is available to monitor the concentration of the active substance in the product. No other methods, for relevant impurities or substances of concern, are necessary.

Efficacy

The efficacy data provided demonstrates that the products of meta SPC 1 and 3 are effective against bacteria and yeast with a contact time of 5 minutes.

The efficacy data provided for meta SPC 2 demonstrates that the products are effective against yeasts, however efficacy against bacteria is not demonstrated since required log reduction was not achieved.

Efficacy against bacteria and yeasts has been tested in phase 2 step 1 and phase 2 step 2 tests according to the international guidelines EN 1656, EN 1657, prEN 17422 and EN 16438.

To ensure the efficacy of the product, the following instruction for use is required: 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).

Human health

The biocidal product family is classified as follows according to the harmonized classification of the active substance and submitted *in vitro* studies:

- Skin Irrit. 2, H315 – Causes skin irritation;
- Eye Dam. 1, H318 – Causes serious eye damage;
- For meta SPC 3 only – EUH208: Contains peppermint oil. May produce an allergic reaction.

Professional user risk assessment

The products are intended to be applied in the post-milking phase by manual dipping using a dip cup or hand-held sprayer. The products are for professional use only. Relevant animals to be treated comprise dairy cows, camels, goats and sheep.

Exposure paths are not considered relevant for the active substance, because of very low systemic effects toxicity of L(+)-lactic acid, derivation of any systemic toxicological reference dose was regarded not necessary.

Acceptable risks are foreseen for professional using products of the biocidal product family.

The following RMMs are set for biocidal product family Lactic acid Family – Quatchem:

- The use of eye protection during handling of the product is mandatory;
- Avoid hand to eye transfer;
- Wear protective chemical resistant gloves during product handling phase (nitrile gloves – EN 374 or EN455);
- 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 wear the same type of PPE as themselves.

General public risk assessment

The biocidal product family is not intended for use by the general public.

Animal health risk assessment

A number of field trials were undertaken to assess whether there was any evidence for adverse effects on the teats of lactating cows, after milking, when animals were treated as use instruction recommended. Field data from repeated use on cows show no evidence of irritation or damage to the skin of the udder. Therefore, it can be concluded that no unacceptable risk for animal health is foreseen.

Environment

L(+)-lactic acid is a naturally occurring substance found in plants and animals and is found to be readily biodegradable. According to the CLP criteria the product is not classified for environmental hazards.

Acceptable levels of risk to all environmental compartments (air, STP, surface water, sediment, soil, groundwater) have been demonstrated for the proposed uses of the products in this family.

b) Presentation of the biocidal product family including classification and labelling

The description of the biocidal product and of the structure of the family is available in the SPC.

The hazard and precautionary statements of the biocidal product (family) according to the Regulation (EC) 1272/2008 is available in the SPC.

c) Description of uses proposed to be authorised

The uses claimed in the application and their assessment are described in the PAR. The description of the uses proposed to be authorised are available in the SPC.

d) Comparative assessment

The active substance L(+)-lactic acid contained in the biocidal product family does not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and is not

considered a candidate for substitution. Therefore, a comparative assessment of the biocidal product family in accordance with Article 23 of the BPR is not required.

e) Overall conclusion of the evaluation of the uses proposed to be authorised

An overview of the uses to be authorised is presented below:

Meta SPC	Use	User	Target organisms	Use conditions	Risk mitigation measures	Conclusion
1	Use # 1.1 – Post milking teat disinfection – manual dipping	professional	bacteria, yeasts	ready-to-use products (RTU, 2% free L(+) lactic acid at target pH=3-4) 5 minutes contact time	The use of eye protection during handling of the product is mandatory. Avoid hand to eye transfer. Wear protective chemical resistant gloves during product handling phase (nitrile gloves – EN 374 or EN455).	Acceptable with RMM
	Use # 1.2 – Post milking teat disinfection - spraying	professional	bacteria, yeasts	ready-to-use products (RTU, 2% free L(+) lactic acid at target pH=3-4) 5 minutes contact time	The use of eye protection during handling of the product is mandatory. Avoid hand to eye transfer. Wear protective chemical resistant gloves during product handling phase (nitrile gloves – EN 374 or EN455). Professional users have to ensure that professional bystanders	Acceptable with RMM

Meta SPC	Use	User	Target organisms	Use conditions	Risk mitigation measures	Conclusion
					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 wear the same type of PPE as themselves.	
2	Use # 2.1 – Post milking teat disinfection – manual dipping	professional	bacteria, yeasts	ready-to-use products (RTU, 3.2% free L(+) lactic acid at target pH=3-4)	The use of eye protection during handling of the product is mandatory. Avoid hand to eye transfer. Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).	Not acceptable: efficacy not demonstrated against bacteria
3	Use # 3.1 – Post milking teat disinfection – manual dipping	professional	bacteria, yeasts	ready-to-use products (RTU, 2% free L(+) lactic acid at target pH=3-4)	The use of eye protection during handling of the product is mandatory. Avoid hand to eye transfer.	Acceptable with RMM

Meta SPC	Use	User	Target organisms	Use conditions	Risk mitigation measures	Conclusion
				5 minutes contact time	Wear protective chemical resistant gloves during product handling phase (nitrile gloves – EN 374 or EN455).	
	Use # 3.2 – Post milking teat disinfection - spraying	professional	bacteria, yeasts	ready-to-use products (RTU, 2% free L(+) lactic acid at target pH=3-4) 5 minutes contact time	The use of eye protection during handling of the product is mandatory. Avoid hand to eye transfer. Wear protective chemical resistant gloves during product handling phase (nitrile gloves – EN 374 or EN455). 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	Acceptable with RMM

Meta SPC	Use	User	Target organisms	Use conditions	Risk mitigation measures	Conclusion
					ensure that those wear the same type of PPE as themselves.	

The physico-chemical properties, the safety for human and animal health and for the environment and the efficacy of the intended use(s) of the biocidal product family have been evaluated.

The chemical identity, quantity and technical equivalence requirements for the active substance in the biocidal product family are met.

The physico-chemical properties of the biocidal product family are deemed acceptable for the appropriate use, storage and transportation of the biocidal product.

For the proposed authorised uses, according to Article 19(1)(b) of the BPR, it has been concluded that:

1. the biocidal product family is sufficiently effective;
2. the biocidal product family has no unacceptable effects on the target organisms, in particular unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates;
3. the biocidal product family has no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans, including that of vulnerable groups, or animals, directly or through drinking water, food, feed, air, or through other indirect effects;
4. the biocidal product family has no unacceptable effects itself, or as a result of its residues, on the environment, having particular regard to the following considerations:
 - the fate and distribution of the biocidal product in the environment,
 - contamination of surface waters (including estuarial and seawater), groundwater and drinking water, air and soil, taking into account locations distant from its use following long-range environmental transportation,
 - the impact of the biocidal product on non-target organisms,
 - the impact of the biocidal product on biodiversity and the ecosystem.

The outcome of the evaluation, as reflected in the PAR, is that the uses described in the SPC, may be authorised.

2.2 BPC opinion on the Union authorisation of the biocidal product family

As the conditions of Article 19(1) are met it is proposed that the biocidal product family shall be authorised, for the uses described under section 2.1 of this opinion, subject to compliance with the proposed SPC.

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