Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the biocidal product family:

Teat disinfectants L-(+)-lactic acid-based biocidal product family of Novadan

ECHA/BPC/413/2024

Adopted

27 February 2024

Opinion of the Biocidal Products Committee

on the Union authorisation of Teat disinfectants L-(+)-lactic acid-based biocidal product family of Novadan

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:	**Teat disinfectants L-(+)-lactic acid-based biocidal product family of Novadan**
Authorisation holder:	**ITW Novadan ApS**
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 30 April 2019, recorded in R4BP3 under case number BC-DB051458-55, 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 30 June 2023 for which the 180-day BPC opinion forming phase started on 25 September 2023. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-50) and its Working Groups (WG-IV-2023). Revisions agreed upon were presented and the draft PAR and the draft SPC were finalised accordingly.

Adoption of the BPC opinion

Rapporteur: Denmark

The BPC opinion on the Union authorisation of the biocidal product/biocidal product family was reached on **27 February 2024**.

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 (BPR) 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 Teat disinfectants L-(+)-lactic acid-based biocidal product family of Novadan 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

General

The biocidal product family Teat disinfectants L-(+)-lactic acid-based biocidal product family of Novadan consist of two meta-SPCs containing 5 products in total and contains the active substance L-(+)-lactic acid in a concentration of 4,1 %. The products are to be used by professional users for teat disinfection of dairy animals post-milking.

No substance of concern (SoC) is identified in the product formulation.

The following uses were assessed:

Use	Application method	eCA assessment
#1.1	Teat disinfectant of dairy animals: post-milking manual dipping (RTU) (applicable to meta-SPC 1 & 2)	Acceptable
#1.2	Teat disinfectant of dairy animals: post-milking, manual spraying, trigger sprayer (RTU) (applicable to meta-SPC 2)	Acceptable
#1.3	Teat disinfectant of dairy animals: post-milking manual spraying using an electronic sprayer (RTU) (applicable to meta-SPC 2)	Acceptable
#1.4	Teat disinfectant of dairy animals: post-milking automated dipping (RTU) (applicable to meta-SPC 1 & 2)	Acceptable
#1.5	Teat disinfectant of dairy animals: post-milking automated spraying by robot (RTU) (applicable to meta-SPC 2)	Acceptable

Physico-chemical properties

The physico-chemical properties of the biocidal products family have been evaluated and are deemed acceptable for the appropriate use, storage and transportation. During the evaluation of the product family, the formulations of the products were changed by a reduction in the active substance content along with some minor adjustments of the co-formulants. The original formulations of all products have been tested for each relevant endpoint, followed by representative tests of Viri TE Dip and Nova LA Spray to demonstrate that the submitted data are applicable to the new formulations. The read-across between the two formulations is considered acceptable.

All products of both meta-SPCs are water-based liquids assigned the formulation type AL – Any other liquid.

Based on the submitted storage stability studies, a shelf life of 24 months in the packaging material High-density polyethylene (HDPE) can be granted. Furthermore, these results demonstrate that the following storage conditions are required: protect from frost, protect from light.

The physical hazards of the biocidal products family were examined. No physical hazards were identified.

Two validated analytical methods for the determination of the concentration of active substance in the biocidal products family are available. No analytical methods for residues, relevant impurities or substances of concern were required. Methods for the detection of L-(+)-lactic acid in soil, air, water, and animal and human body fluids and tissues were provided and deemed acceptable at EU level.

Efficacy

The submitted efficacy data demonstrate that the products of Teat disinfectants L-(+)-lactic acid-based biocidal product family of Novadan are sufficiently effective when used as post-milking teat disinfection against bacteria and yeast with a 5-minute contact time.

Efficacy against bacteria and yeast has been tested in phase 2, step 1 and phase 2, step 2 test according to international guidelines EN 1656, EN 1657, prEN 17422 and EN 17422.

To ensure the efficacy of the products, the following instruction for use is included in the SPC:

- To ensure sufficient contact time, care shall be taken that the product is not removed after application. Leave the product until next milking. Keep the animals standing until the product has dried (at least 5 minutes).

Human health

The biocidal product family does not contain any non-active substances which are considered substances of concern.

All meta-SPCs of the biocidal product family are classified according to the harmonized classification of the active substance and the submitted *in vitro* study:

- Eye Damage 1, H318 – Causes serious eye damage

The read-across for skin irritation has been accepted only when products have a pH of 3 ± 0.1.

Professional user risk assessment

Systemic exposure to the active substance was not considered necessary given the endogenous production of lactic acid. A local risk assessment was performed based on the classification for eye effects, and acceptable risk was concluded with the following RMMs:

- The use of eye protection (EN 166) is mandatory during mixing and loading, manual spraying, -dipping and –cleaning tasks.

- Packaging and dosing aids reduce the risk of splashes and aerosols.

General public risk assessment

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

Dietary risk assessment

Dietary risk assessment is not relevant for this BPF, as the active substance is considered an endogenous substance.

Environment

The products in the biocidal product family are not classified for environmental hazards. The environmental risk assessment was performed according to the agreed approach, and no unacceptable risk were identified for the environment.

b) Presentation of the biocidal product/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 is not required.

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

The physico-chemical properties, the safety for human and animal health and for the environment and the efficacy of the intended uses 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/biocidal product family

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

o0o

[1] This is without prejudice of any specific conditions that might apply in the territory of Member State(s) in accordance with Article 44(5) of the BPR.