Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the biocidal product:

Ecolab UA Lactic acid single product dossier

ECHA/BPC/294/2021

Adopted

12 October 2021

Opinion of the Biocidal Products Committee

on the Union authorisation of Ecolab UA Lactic acid single product dossier

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:	**Ecolab UA Lactic acid single product dossier**
Authorisation holder:	**Ecolab Deutschland GmbH**
Active substance common name:	**L(+)-Lactic acid**
Product type:	**2**

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 16 April 2019, recorded in R4BP3 under case number BC-XS050968-91, 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 24 March 2021. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-40) and its Working Groups (WG II 2021). Revisions agreed upon were presented and the draft PAR and the draft SPC were finalised accordingly.

Adoption of the BPC opinion

Rapporteur: Latvia

The BPC opinion on the Union authorisation of the biocidal product was reached on 12 October 2021.

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 is eligible for Union authorisation in accordance with Article 42(1) of Regulation (EU) No 528/2012.

The biocidal product meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012 and therefore may be authorised for the uses specified in this opinion. The detailed grounds for the overall conclusion are described in the PAR.

The BPC agreed on the draft SPC of Ecolab UA Lactic acid single product dossier 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 split into five sub-paragraphs. This contains a concise summary of the evaluation and conclusions of the risk assessment and which uses have been assessed.

General

The biocidal product Ecolab UA Lactic acid single product dossier is a ready to use water-based liquid intended to be used for inner toilet bowl disinfection by professional users. The product contains 13.2% L(+)-Lactic acid as active substance.

D-Glucopyranose, oligomers, decyl octyl glycosides (3.25%) and alcohols, C8-10 (even numbered), ethoxylated (< 2,5-EO) (1.0%) are considered substances of concern (SoC) due to human health concerns.

Physico-chemical properties

All physical and chemical properties were adequately addressed.

The product is clear and colourless gel liquid with a sweetish odour. The product is considered as surface-active.

The product in commercial packaging (HDPE bottle with PP/LDPE cap) is stable for 3 months at 40 ± 2°C and 4 ± 2°C during accelerated storage stability studies. No changes in the appearance of the tested item occur. Therefore, the product is expected to be stable after a long-term storage stability procedure of 24 months at ambient temperature in its commercial packaging considering the accelerated storage stability data and intermediate long term storage studies after 3-12 months. Based on this a provisional shelf-life of up to 2 years is proposed to be granted. A long-term storage stability test for 24 months is currently on-going and results will be provided with the purpose to confirm the granted shelf-life.

Label requirements:

- *Store in original container tightly closed;*

- *Store between + 5 °C and + 40 °C;*
- *Protect from frost.*

According to the CLP criteria the product is not classified for physical and chemical hazards.

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

Efficacy

The efficacy data provided demonstrates that the product is effective against bacteria and yeast on hard non-porous surfaces with a contact time of 15 minutes in dirty conditions.

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 13727, EN 13624 and EN 13697.

To ensure the efficacy of the product, the following instruction for use is defined in the SPC:

- *Lift up the toilet seat and carefully direct the nozzle under the toilet rim. Squeeze and apply slowly all around the inside of the bowl, allowing enough liquid to cover the whole inner toilet bowl surface. Leave for 15 minutes. Flush the toilet afterwards. May not be used with bleach or other cleaning agents. Inform the registration holder if the treatment is ineffective.*

Human health

Based on the active substance content and content of co-formulants, the biocidal product is classified and labelled as follows:

Skin Corr. 1C, H314 - Causes severe skin burns and eye damage;

Eye Dam. 1, H318 - Causes serious eye damage[1]*;*

EUH071 - Corrosive to the respiratory tract.

The biocidal product contains two substances of concerns which are present at concentrations sufficient to trigger the classification of the product by themselves. Based on risk assessment the relevant P-statements associated with concerned H statements are assigned. The risk mitigation is considered sufficient.

Professional user risk assessment

The professional user treats the interior of the toilet bowl by squeezing the bottle under the rim of the toilet bowl and covering the surface of the inside of the bowl. After a leave-on period, the toilet bowl is rinsed. Both dermal and inhalation exposure are considered. Oral exposure is not considered for professionals.

No adverse effects are expected from the use of the biocidal product.

The risk to professional users is demonstrated to be acceptable considering the packaging design, proper instruction of use, as well the risk mitigation measures which must appear on the SPC and label:

- Do not breathe vapours;
- Avoid contact with eyes and skin;
- Do not brush the product in toilet bowl;

[1] in accordance with Article 27 of CLP regulation the following principle of precedence for hazard statements may apply to labelling: if the statement H314 'Causes severe skin burns and eye damage' is assigned, the statement H318 'Causes serious eye damage' may be omitted.

- Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information);
- Wash hand thoroughly after handling.

Secondary exposure after flushing the toilet is not considered, because it will be negligible compared to the exposure during the disinfection task.

General public risk assessment

The biocidal product is not intended for use by the general public therefore no primary exposure scenario has been identified.

The secondary exposure is not considered, as once the toilet bowl is flushed the 'source' of L(+)-Lactic acid is removed. Therefore, the L(+)-Lactic acid air concentration is expected to be of a lower magnitude than the L(+)-Lactic acid air concentration during application. Dermal or oral contact with treated surface (inner toilet bowl surface) is not expected.

Environment

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 use of the biocidal product.

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

The description of the biocidal product is available in the SPC.

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

c) Description of uses proposed to be authorised

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

d) Comparative assessment

The active substance L(+)-Lactic acid contained in the biocidal product 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

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

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

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

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

1. the biocidal product is sufficiently effective;
2. the biocidal product 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 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 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 use 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) are met it is proposed that the biocidal product shall be authorised[2] for the use described under section 2.1 of this opinion, subject to compliance with the proposed SPC.

The authorisation holder shall complete, within the stated timeframe, the actions set out in the table below:

Description	**Due date**
Data showing satisfactory chemical and physical properties for the product after ambient storage in the commercial packaging for the required shelf life (24 months) must be provided. The specification proposed and properties tested should be in accordance with "Guidance on information requirements" (ECHA, Nov. 2014). All relevant properties should be determined prior to and after storage.	No later than 3 months after the authorisation date.

It is noted that for the Ecolab UA Lactic acid single product dossier the fact that data is to be provided after the authorisation is granted does not affect the conclusion on the fulfilment of the conditions under Article 19(1) on the basis of the existing data.

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[2] 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.