Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the biocidal product family:

Kersia's Lactic acid based products

ECHA/BPC/381/2023

Adopted

6 June 2023

Opinion of the Biocidal Products Committee

on the Union authorisation of Kersia's Lactic acid based products

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:	**Kersia's Lactic acid based products**
Authorisation holder:	**HYPRED SAS**
Active substance common name:	**L(+) Lactic acid (CAS No.: 79-33-4)**
Product type:	**PT 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 opini ons

Following the submission of an application on April 26th 2019, recorded in R4BP3 under case number BC-CH051281-59, 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 November 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-47) and its Working Groups (WG-I-2023). Revisions agreed upon were presented and the draft PAR and the draft SPC were finalised accordingly.

Adoption of the BPC opinion

Rapporteur: The Netherlands

The BPC opinion on the Union authorisation of the biocidal product family was reached on 6 June 2023.

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 Kersia's Lactic acid based products family 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.

Kersia's Lactic acid based products BPF contains 5 ready-to-use liquid products against bacteria and yeast containing 8.4 % of L(+) Lactic acid as the active substance. These products are used as non-medical teat-disinfectants in veterinary hygiene in PT 3 by professional users and are applied before and/or after milking by manual or automated dipping, spraying or foaming (for details please refer to sections 'authorised use' and 'general directions of use' of the PAR). Kersia's Lactic acid based products contains the following substances of concern, based on contribution to the irritation to eye classification (i.e. H319 - Causes serious eye irritation): Sodium p-cumenesulphonate; Sodium-2-ethylhexyl sulphate; Sulfonic acids, and Diethanolamine (DEA). Furthermore, DEA was also identified as a substance of concern based on "other grounds for concern" (article 3(f) of the BPR). DEA is a chemical substance with widespread uses and included in CoRAP due to concerns for potential formation of CMR transformation products. Moreover, a substance evaluation (SEv) conducted by the German authority (November 2021) concluded that follow-up at EU level is needed to update the harmonised classification (i.e. to include classification for carcinogenicity (Carc. 2) and reproductive toxicity (Repr. 1B). A risk assessment for DEA and the potential reaction product NDELA 2,2'-(nitrosoimino)bisethanol was therefore provided for human health. As the products included in the BPF are teat disinfection products DEA and NDELA were also considered in a risk assessment for animal health.

The biocidal product family contains 5 biocidal products which are attributed to the following 3 meta SPCs:

Meta SPC	Biocidel products
Meta SPC 1	NATIDINE
Meta SPC 2	FILMADINE LL
	FILMADINE LC
	FILMADINE
Meta SPC 3	PREFOAM

The biocidal product family contains 1 product type which is attributed to the following claimed uses and concerned Meta SPCs:

PTs	Claimed uses	Concerned META SPC	Remarks
3	Use # 1.1; # 3.1; – Disinfection of teats of milk producing animals by manual or automated dipping, foaming or spraying before milking	Meta SPC 1 Meta SPC 3	uses proposed not to be authorized based on the human health evaluation
	Use # 1.2 – Disinfection of teats of milk producing animals by manual or automated dipping, foaming or spraying after milking	Meta SPC 1	
	Use # 1.3 – Disinfection of teats of milk producing animals by manual or automated dipping, foaming or spraying before and after milking	Meta SPC 1	use proposed not to be authorized based on the human health evaluation
	Use # 2.1 – Disinfection of teats of milk producing animals by manual or automated dipping after milking	Meta SPC 2	

Identity, physical and chemical properties and analytical methods

Kersia's Lactic acid based products BPF contains 5 ready-to-use liquid products allocated to 3 meta-SPCs. All 3 meta-SPC's contain 8.4 % of L(+) Lactic acid as the active substance.

Data for all relevant endpoints have been provided. In particular, storage stability data (long-term storage for 24 months at ambient temperature and accelerated storage testing) has been performed on 4 of the individual products of the BPF; for the fifth product (FILMADINE LL) shelf life is supported by read across to FILMADINE LC. All products have been analysed with respect to low temperature stability, and were found stable. Based on the available data, a shelf life of 24 months as claimed is considered justified.

Since the stability of the representative product for meta-SPC 1 was assessed up to 54 °C, no temperature restriction for storage is required. For meta-SPCs 2 and 3, the stability of the products was assessed up to 30 °C. Therefore, products shall be stored below 30 °C.

The analytical method (HPLC-UV) used for the determination of the active substance content was fully validated in terms of linearity, recovery, precision and specificity.

No physical hazards were identified for any of the meta-SPC's.

Efficacy

Efficacy is substantiated for all (ready-to-use) products against bacteria and yeast. These products are used as non-medical teat-disinfectants in veterinary hygiene (i.e. PT 3) by professional users and are applied before and/or after milking by manual or automated dipping, spraying or foaming.

Human health

Products included in the BPF are classified with H319: Causes serious eye irritation.

Furthermore, during the commenting period of Kersia's Lactic acid based products BPF, concerns were raised for the co-formulant diethanolamine (DEA), based on the substance evaluation report (SEv; November 2021) for DEA carried out under REACH. Considering this report, and because DEA is also included in CoRAP, it was agreed that DEA is considered a Substance of Concern (SoC) based on "other grounds for concern". Therefore, a risk assessment for DEA and its potential reaction product 2,2'-(nitrosoimino)bisethanol (NDELA) was provided and discussed.

Overall conclusion on professional use

The overall conclusions take into account the exposure to the active substance L(+) Lactic acid, the SoC DEA, the potential transformation product NDELA and the classification of the biocidal products as H319.

As indicated above, there are concerns for DEA with regard to reprotoxic effects and carcinogenicity. However, the risk assessment for the professional use is based on the most sensitive endpoint, i.e. the effect of DEA on blood, liver and kidney. Considering all information from the SEv report (November 2021), the lowest LOAEL value of 6.8 mg/kg bw/d (based on general toxic effects, as derived from the EOGRTS study) was used for derivation of a reference value. Using the most sensitive endpoint, both reprotoxic effects (LOAEL 12.25 mg/kg bw/d from EOGRTS) and carcinogenic effects (LOAEL ≥ 40 mg/kg bw/d, from dermal long-term toxicity studies), respectively, are covered by the risk assessment performed.

Based on the risk assessment for the professional user, the following RMMs need to be included. Note that the set of RMMs is based on the combined exposure (i.e. mixing/loading, application by either dipping, foaming or spraying, followed by cleaning):

Overall conclusion on the risk assessment for human health from systemic exposure			
Use number	**Use description**	**Conclusion**	**Set of RMMs**
meta-SPC 1			
#1.1	Disinfection of teats of milk producing animals by manual or automated dipping, foaming or spraying before milking	manual application - by dipping / foaming: acceptable with gloves (90 % protection) - by spraying acceptable with gloves (90 % protection) automated application - by dipping / foaming / spraying acceptable without RMM	for manual application: Wear protective chemical resistant gloves during product handling phase (EN ISO 374). Wear chemical goggles or face protection. Keep out of reach of children
#1.2	Disinfection of teats of milk producing animals by manual or automated dipping, foaming or spraying after milking	manual application - by dipping / foaming acceptable without RMM - by spraying acceptable with gloves (90 % protection) automated application	for manual application by spraying: Wear protective chemical resistant gloves during product handling phase (EN ISO 374). Wear chemical goggles or face protection.

Overall conclusion on the risk assessment for human health from systemic exposure			
Use number	**Use description**	**Conclusion**	**Set of RMMs**
		- by dipping / foaming / spraying acceptable without RMM	Keep out of reach of children
#1.3	Disinfection of teats of milk producing animals by manual or automated dipping, foaming or spraying before and after milking	manual application - by dipping / foaming acceptable with gloves (90 % protection) - by spraying acceptable with new gloves per milking event (95 % protection) automated application - by dipping / foaming / spraying acceptable without RMM	for manual application: by dipping/foaming: Wear protective chemical resistant gloves during product handling phase (EN ISO 374). by spraying: Wear new protective chemical resistant gloves during product handling phase per milking event (EN ISO 374). Wear chemical goggles or face protection. Keep out of reach of children
meta-SPC 2			
#2.1	Disinfection of teats of milk producing animals by manual or automated dipping after milking	manual application - by dipping acceptable without RMM automated application - by dipping acceptable without RMM	Wear chemical goggles or face protection. Keep out of reach of children
meta-SPC 3			
#3.1	Disinfection of teats of milk producing animals by manual or automated dipping, foaming or spraying before milking	manual application - by dipping / foaming acceptable with gloves (90 % protection) - by spraying acceptable with gloves (90 % protection) automated application - by dipping / foaming / spraying acceptable without RMM	for manual application: Wear protective chemical resistant gloves during product handling phase (EN ISO 374). Wear chemical goggles or face protection. Keep out of reach of children

Overall conclusion on dietary exposure:

The overall conclusions take into account the exposure to the active substance L(+) Lactic acid, the SoC DEA, the potential transformation product NDELA and the classification of the biocidal products as H319.

In line with other evaluations it has been agreed to not perform the comparison of endogenous L(+) Lactic acid with systemic exposure levels at product authorization. Consequently, no calculation regarding the estimation of level of exposure of lactic acid is performed.

Considering the dietary risk assessment to DEA, some uses cannot be authorised as exposure values exceeded the acceptable daily intake (ADI). This is reflected in the table included below.

Overall conclusion on the dietary risk assessment			
Use number	**Use description**	**Conclusion**	**Acceptable**
meta-SPC 1			
#1.1	Disinfection of teats of milk producing animals by manual or automated dipping, foaming or spraying before milking	Exposure assessment resulted in values exceeding ADI for both the adult and toddler.	No
#1.2	Disinfection of teats of milk producing animals by manual or automated dipping, foaming or spraying after milking	Exposure assessment resulted in values below ADI for both the adult and toddler.	Yes
#1.3	Disinfection of teats of milk producing animals by manual or automated dipping, foaming or spraying before and after milking	Exposure assessment resulted in values exceeding ADI for both the adult and toddler.	No
meta-SPC 2			
#2.1	Disinfection of teats of milk producing animals by manual or automated dipping after milking	Exposure assessment resulted in values below ADI for both the adult and toddler.	Yes
meta-SPC 3			
#3.1	Disinfection of teats of milk producing animals by manual or automated dipping, foaming or spraying before milking	Exposure assessment resulted in values exceeding ADI for both the adult and toddler.	No

A qualitative assessment for the potential transformation product NDELA, which is classified as Carc Cat 1B, was provided. The assessment of NDELA includes many uncertainties, the main one being the concentration in milk as no measured data are available. The following was concluded:

i) It was considered not possible to assess the long-term carcinogenicity risk of NDELA formation because of insufficient information;

ii) this risk is low if exposure is short-term.

Taking together the human health and dietary risk assessment for the active substance L(+) Lactic acid, the SoC DEA, the potential transformation product NDELA and the classification of the biocidal products as H319, it is concluded that the intended uses for post-milking

treatment (i.e. uses #1.2 and #2.1) are eligible for authorisation as the conditions of Article 19(1)(b)(iii) are met.

Animal health

The overall conclusions are based on exposure to L(+) Lactic acid, DEA and NDELA and the local risk assessment. No adverse health effects are expected for the animals that are treated with teat disinfection products included in Kersia's Lactic acid based products BPF.

Environment

The biocidal products containing the active substance L(+) Lactic acid are used under PT 3 (veterinary hygiene) as teat disinfectants and depending on whether the cows (and/or other animals) are milked in the stable or in a milking parlour outside the stable, L(+) Lactic acid will be emitted either to slurry/manure or to waste water, respectively. Both emission pathways have been assessed in the risk assessment. The assessment was based on the Emission Scenario Document (ESD) for PT 3 of 2011 and recent amendments published in the ENV TAB. The resulting PEC/PNEC ratios confirm that no unacceptable risk is identified and the use as teat disinfectant can be considered as safe.

Regarding the groundwater assessment it was discussed and agreed that a quantitative groundwater assessment is not necessary as modelling of groundwater exposure in case of lactic acid largely overestimates concentrations and is considered unrealistic. Thus, no unacceptable risk for the groundwater compartment was identified and the use as teat disinfectant can be considered as safe.

In addition, according to the ESD for PT 3 of 2011 no exposure of the compartment air is foreseen (no data are given for an air fraction) and considerating the intrinsic properties of L(+) Lactic acid it is scientifically justifiable that the exposure of the air compartment is assumed as being negligible.

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, no comparative assessment of the biocidal product family was performed.

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
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[1], for the uses described under section 2.1 of this opinion.

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[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.