

Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the biocidal product family:

Taski-Room Care-Suma Family Based on Lactic Acid

ECHA/BPC/394/2023

Adopted

14 September 2023

Opinion of the Biocidal Products Committee

on the Union authorisation of Taski-Room Care-Suma Family Based on Lactic Acid

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:	Taski-Room Care-Suma Family Based on Lactic Acid
Authorisation holder:	Diversey Europe Operations B.V.
Active substance common name:	L(+) Lactic acid (CAS No.: 79-33-4)
Product types:	PT2, PT3 and PT4

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 April 26th 2019, recorded in R4BP3 under case number BC-FV051273-25, 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 28 February 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-48) and its Working Groups (WG-II-2023). 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 family was reached on 14 September 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 Taski-Room Care-Suma Family Based on Lactic Acid 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 Taski-Room Care-Suma Family Based on Lactic acid (BPF) is based on 0.352% w/w to 17.6% w/w of L(+) lactic acid and intended for product type 2, 3 and 4. The products are ready-to-use products and soluble concentrates. The products are used for hard non-porous surface disinfection against bacteria, yeast and enveloped virus only by professional users.

The following uses are claimed for the products of the BPF:

Use number	PT	Use description
1a	2	Disinfection of hard non-porous surfaces and small objects without food contact (e.g. industrial, institutional area (excluding healthcare area) and the use in vehicles for human transport).
1b	4	Disinfection of hard non-porous surfaces and small objects with food contact (food, industrial, institutional area and the use in vehicles for human transport)
2	2, 4	Disinfection of clean hard non-porous surfaces without and with food contact (food, industrial, institutional area including healthcare area).
3	3	Disinfection of clean hard non-porous surfaces and small objects in a veterinary area.
4	4	Disinfection of hard non-porous surfaces (incl. machines and equipment) with dairy food contact (food, industrial, institutional area)

The BPF is composed of four Meta-SPC.

Meta SPC	Uses	Type	L(+) lactic acid concentration
1	1a, 1b, 2, 3, 4	Concentrate	17.6% w/w
2	1a, 1b, 2, 3, 4	Concentrate	17.6% w/w
3	1a, 1b, 2, 3, 4	Concentrate	8.8% w/w
4	1a, 1b, 2	Ready-to-use	0.352% w/w

The BPF contains non-active substances which are considered as substances of concern for human health. Four co-formulants have been identified as substances of concern in frame of the BPF due to their contribution on the classification of meta SPCs.

Physico-chemical properties and analytical methods

The physico-chemical properties of the biocidal product family have been adequately addressed. The stability data indicate a shelf life of 2 years at ambient temperature in commercial packaging material. The following storage conditions have been defined for all meta-SPCs:

- Store in original container tightly closed.
- Store protected from light.
- Do not store above 40 °C.

In respect to physical hazards the biocidal products of meta-SPCs are classified as follows:

Classification of meta-SPC 1, 2 and 3	
Hazard category	Met. Corr. 1
Hazard statement	H290: May be corrosive to metals
Classification of meta-SPC 4	
Hazard category	N.A.
Hazard statement	N.A.

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. Validated analytical methods for the determination of substances of concern are not required as the formation of the substances of concern is not expected during storage and their concentrations remain unchanged.

Efficacy

The products are intended for hard non-porous surface disinfection against bacteria, yeast and enveloped viruses only. The products are applied on the surfaces by foam spraying or pouring and fully wetting the surface by product distribution with a cloth, brush, sponge, mop or wipe. In case of small objects, the dipping of the objects is applied.

The products of the family have shown a sufficient efficacy for the following uses:

	Uses	Concentration, %	Validated label claims
1a	<p>PT2 Disinfection of hard non-porous surfaces and small objects without food contact (e.g. industrial, institutional area (excluding healthcare area) and the use in vehicles for human transport).</p>	<p><i>Meta-SPC 1 and 2:</i> 2% v/v dilution corresponding to 0.38% w/w of L(+) lactic acid <i>Meta-SPC 3:</i> 4% v/v dilution corresponding to 0.38% w/w of L(+) lactic acid <i>Meta-SPC 4:</i> Ready-to-use products with 0.352% w/w of L(+) lactic acid</p>	<p>On hard/non-porous surfaces <u>without</u> prior cleaning. Active against bacteria, yeasts, enveloped viruses. Contact time: 5 minutes bacteria and enveloped viruses and 15 minutes yeasts.</p>
1b	<p>PT4 Disinfection of hard non-porous surfaces and small objects with food contact (e.g. food, industrial, institutional area and the use in vehicles for human transport).</p>	<p><i>Meta-SPC 1 and 2:</i> 2% v/v dilution corresponding to 0.38% w/w of L(+) lactic acid <i>Meta-SPC 3:</i> 4% v/v dilution corresponding to 0.38% w/w of L(+) lactic acid <i>Meta-SPC 4:</i> Ready-to-use products with 0.352% w/w of L(+) lactic acid</p>	<p>On hard/non-porous surfaces <u>without</u> prior cleaning Active against bacteria, yeasts, enveloped viruses only. Contact time: 15 minutes</p>
2	<p>PT2 and PT4 Disinfection of clean hard non-porous surfaces without and with food contact (e.g. food, industrial, institutional area including healthcare area).</p>	<p><i>Meta-SPC 1 and 2:</i> 2% v/v dilution corresponding to 0.38% w/w of L(+) lactic acid <i>Meta-SPC 3:</i> 4% v/v dilution corresponding to 0.38% w/w of L(+) lactic acid <i>Meta-SPC 4:</i> Ready-to-use products with 0.352% w/w of L(+) lactic acid</p>	<p>On hard/non-porous surfaces <u>with</u> prior cleaning Active against bacteria, yeasts, enveloped viruses only. Contact time: 5 minutes</p>
3	<p>PT3 Disinfection of clean hard non-porous surfaces and small objects in a veterinary area</p>	<p><i>Meta-SPC 1 and 2:</i> 3% v/v dilution corresponding to 0.57% w/w of L(+) lactic acid <i>Meta-SPC 3:</i> 6% v/v dilution corresponding to 0.57% w/w of L(+) lactic acid</p>	<p>On hard/non-porous surfaces <u>with</u> prior cleaning Active against bacteria and yeasts. Contact time: 5 minutes at room temperature and 30 minutes at +10°C</p>
4	<p>PT4 Disinfection of hard non-porous surfaces (incl. machines and equipment) with dairy food contact (food, industrial, institutional area)</p>	<p><i>Meta-SPC 1 and 2:</i> 3% v/v dilution corresponding to 0.57% w/w of L(+) lactic acid <i>Meta-SPC 3:</i> 6% v/v dilution corresponding to 0.57% w/w of L(+) lactic acid</p>	<p>On hard/non-porous surfaces <u>without</u> prior cleaning Active against bacteria and yeasts. Contact time: 5 minutes</p>

Human health

The biocidal products of meta-SPCs of the biocidal product family are classified as follows:

Classification of meta-SPC 1, 2 and 3	
Hazard category	Skin Corr. 1 Eye Dam. 1
Hazard statement	H314: Causes severe skin burns and eye damage H318: Causes serious eye damage
Supplementary Labelling	EUH071: Corrosive to the respiratory tract
	Meta-SPC 2 EUH208: Contains Ethyl 2,3-epoxy-3-phenylbutyrate, Delta-damascone and Damascenone. May produce an allergic reaction.
Classification of meta-SPC 4	
Hazard category	N.A.
Hazard statement	N.A.

The following co-formulants have been identified as substances of concern per meta-SPC:

- Meta-SPC 1 and 2: (1) Methanesulfonic acid (CAS No. 75-75-2), (2) Alkyl ether carboxylic acid (CAS No. 53563-70-5), (3) Sulphonic acids, C14-17-sec-alkane, sodium salts (CAS No. 97489-15-1) and (4) A mixture of: 2-ethylhexyl mono-D-glucopyranoside; 2-ethylhexyl di-D-glucopyranoside (CAS No. -)
- Meta-SPC 3: (1) Methanesulfonic acid (CAS No. 75-75-2) and (2) Alkyl ether carboxylic acid (CAS No. 53563-70-5).

Therefore, a qualitative exposure and risk assessment to determine whether the labelling associated to classification is sufficient or whether other RMMs should be applied has been performed.

Meta-SPC 1 to 3

Considering the dermal and eye damaging properties of the products, the local risk is acceptable during handling of the products by professional users considering the RMMs indicated in the SPC.

Meta-SPC 4

The risk is acceptable without specific RMMs.

Dietary risk assessment

PT 2 is not intended for direct application to humans or animals and is not used for direct contact with food or feeding stuffs.

Regarding the intended uses in PT 3 and 4, residues in food, feed or drinking water might be expected. However, based on the low concentration of L(+) lactic acid, the endogenous production and compared to naturally occurring levels in food, significant risk due to indirect exposure via intended uses is not expected.

Four non-active substances were identified as substances of concern for human health. Based on the characteristics of these substances, it was not considered necessary to derive toxicological reference values. The products applied on the surfaces are not classified for human health hazards. Therefore, risk for consumer via indirect exposure via food can be excluded.

Risk assessment for animal health

There are no unacceptable risks for livestock animals if the directions for use, as specified in the SPC, are followed.

Environment

The biocidal product family is not classified as hazardous for the environment.

No substance of concern has been defined for the environment.

Considering a worst case representative product with the maximum in-use concentration of L(+) lactic acid, all uses are considered acceptable for all the relevant compartments and for all the meta SPC.

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

The description 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

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

Use	PT	Target organism	Application rate	Use condition	Conclusion
Meta-SPC 1, 2 and 3					
1a	2	Bacteria Yeasts Enveloped viruses	0.38% w/w active substance Apply the product by fully wetting the surface (apply approx. 10 sprays /m ² or 13 ml/m ² or fully cover the object to be disinfected)	<ul style="list-style-type: none"> • Indoor • Professional • Without pre-cleaning • Dilution before the use • Surface disinfection by pouring or foam spraying. Cloth, brush, sponge, mop or wipe should be used to distribute on surface. • Dipping to wet small objects. • Contact time: 5 minutes bacteria and enveloped viruses and 15 minutes yeasts. 	Acceptable with RMMs

Use	PT	Target organism	Application rate	Use condition	Conclusion
1b	4	Bacteria Yeasts Enveloped viruses only	0.38% w/w active substance Apply the product by fully wetting the surface (apply approx. 10 sprays /m ² or 13 ml/m ² or fully cover the object to be disinfected)	<ul style="list-style-type: none"> Indoor Professional Without pre-cleaning Dilution before the use Surface disinfection by pouring or foam spraying. Cloth, brush, sponge, mop or wipe should be used to distribute on surface. Dipping to wet small objects. Contact time: 15 minutes 	Acceptable with RMMs
2	2, 4	Bacteria Yeasts Enveloped viruses only	0.38% w/w active substance Apply the product by fully wetting the surface (apply approx. 10 sprays /m ² or 13 ml/m ²)	<ul style="list-style-type: none"> Indoor Professional With pre-cleaning Dilution before the use Surface disinfection by pouring or foam spraying. Cloth, brush, sponge, mop or wipe should be used to distribute on surface. Contact time: 5 minutes 	Acceptable with RMMs
3	3	Bacteria Yeasts	0.57% w/w active substance Apply the product by fully wetting the surface (apply approx. 10 sprays /m ² or 13 ml/m ² or fully cover the object to be disinfected for 5 minutes and apply approx. 19 sprays /m ² or 25 ml/m ² for 30 minutes.)	<ul style="list-style-type: none"> Indoor Professional With pre-cleaning Dilution before the use Surface disinfection by pouring or foam spraying. Cloth, brush, sponge, mop or wipe should be used to distribute on surface. Dipping to wet small objects. Contact time: 5 minutes at room temperature and 30 minutes at +10°C 	Acceptable with RMMs
4	4	Bacteria Yeasts	0.57% w/w active substance Apply the product by fully wetting the surface (apply approx. 10 sprays /m ² or 13 ml/m ² or fully cover the object to be disinfected)	<ul style="list-style-type: none"> Indoor Professional Without pre-cleaning Dilution before the use Surface disinfection by pouring or foam spraying. Cloth, brush, sponge, mop or wipe should be used to distribute on surface. Dipping to wet small objects. Contact time: 5 minutes 	Acceptable with RMMs

Use	PT	Target organism	Application rate	Use condition	Conclusion
Meta-SPC 4					
1a	2	Bacteria Yeasts Enveloped viruses	0.352% w/w active substance Apply the product by fully wetting the surface (apply approx. 10 sprays /m ² or 13 ml/m ² or fully cover the object to be disinfected)	<ul style="list-style-type: none"> • Indoor • Professional • Without pre-cleaning • Surface disinfection by pouring or foam spraying. Cloth, brush, sponge, mop or wipe should be used to distribute on surface. • Dipping to wet small objects. • Contact time: 5 minutes bacteria and enveloped viruses and 15 minutes yeasts. 	Acceptable
1b	4	Bacteria Yeasts Enveloped viruses only	0.352% w/w active substance Apply the product by fully wetting the surface (apply approx. 10 sprays /m ² or 13 ml/m ² or fully cover the object to be disinfected)	<ul style="list-style-type: none"> • Indoor • Professional • Without pre-cleaning • Surface disinfection by pouring or foam spraying. Cloth, brush, sponge, mop or wipe should be used to distribute on surface. • Dipping to wet small objects. • Contact time: 15 minutes 	Acceptable
2	2, 4	Bacteria Yeasts Enveloped viruses only	0.352% w/w active substance Apply the product by fully wetting the surface (apply approx. 10 sprays /m ² or 13 ml/m ²)	<ul style="list-style-type: none"> • Indoor • Professional • With pre-cleaning • Surface disinfection by pouring or foam spraying. Cloth, brush, sponge, mop or wipe should be used to distribute on surface. • Contact time: 5 minutes 	Acceptable

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 authorised¹, for the uses described under section 2.1 of this opinion, subject to compliance with the proposed SPC.

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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.