

Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the biocidal product family:

Lactic acid based products - CID LINES NV

ECHA/BPC/299/2021

Adopted

29 November 2021

Opinion of the Biocidal Products Committee

on the Union authorisation of the biocidal product family: Lactic acid based products - CID LINES NV

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 based products - CID LINES NV

Authorisation holder: CID LINES NV

Active substances common name: L-(+)-lactic acid (CAS number 79-33-4)

Product types: PT 1, 2, 3 and 4

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 18/04/2019, recorded in R4BP3 under case number BC-RC051007-54, 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 23/06/2021. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-41) and its Working Groups (WG-III-2021). Revisions agreed upon were presented and the draft PAR and the draft SPC were finalised accordingly.

Adoption of the BPC opinion

Rapporteur: Belgium

The BPC opinion on the Union authorisation of the biocidal product family was reached on 29 November 2021.

The BPC opinion was adopted by consensus.

The opinion is published on the ECHA website at: <https://echa.europa.eu/opinions-on-union-authorisation/bpc>

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(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 based products - CID LINES NV 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 "Lactic acid based products – CID LINES NV" contains disinfectant products with L-(+)-lactic acid as active substance that belong to PT 1, PT 2, PT 3 and PT 4.

The following Substances of concern were identified as co-formulants present in the biocidal product family:

- Sodium Lauryl Sulphate (band B), Sodium Lauryl Ether Sulfate (band B), Sulfonic acids, C14-17-sec-alkane, sodium salts (band B) and C6 alkyl glucoside (band B), as they contribute to the H318 classification of the mixtures;
- Isopropanol (band C) is an approved biocidal active substance (> 0.1% w/w);
- Methanesulfonic acid (band B) and Sulphuric acid (band B), as they contribute to the H314 classification of the mixtures;
- Butyldiglycol (band C) has an EU OEL.

The family applied for authorization consisted of 15 metaSPCs. An overview of the biocidal product family and the authorised uses is given in the following table:

L-(+)-lactic acid %	Substance of concern	user category	Application method
Meta SPC 1: hygienic handwash (PT 1)			
3.6%	Sodium Lauryl sulphate: 5%	professional ¹	Applied on hands by washing the hands
	Isopropanol: 4%		
Meta SPC 2: Ready to use algaecide (PT 2)			

L-(+)-lactic acid %	Substance of concern	user category	Application method
2%	/	professional and general public	Applied on hard/non-porous surfaces without prior cleaning by brushing, by spraying or pouring
Meta SPC 3: Concentrated algacide & hard surface disinfection in food and feed industry (PT 2 and 4)			
70%	Sodium Lauryl sulphate: 6%	professional	Applied on hard/non-porous surfaces without prior cleaning by spraying, soaking or pouring
Meta SPC 4: Concentrated surface disinfectants for sanitary hygiene and kitchens (PT 2 and 4)			
16%	Sodium Lauryl sulphate: 5%	professional and general public	Applied on hard/non-porous surfaces without prior cleaning by spraying or pouring
Meta SPC 5: Concentrated pre-dips (PT 3)			
8%	Sodium lauryl ether sulfate: 8.4%	professional	Teat disinfection (before milking) and intact skin wash/disinfection, by dipping, spraying or wiping
	Sulfonic acids, C14-17-sec-alkane, sodium salts: 2.25%		
Meta SPC 6: Ready to use pre-dips (PT 3)			
3.6%	Sodium lauryl sulfate: 5.25%	professional	Teat disinfection (before milking), by dipping, spraying or wiping.
Meta SPC 7: Ready to use wipes (PT 2 and 4)			
2%	Sodium lauryl sulfate: 0.6 – 0.9%	professional and general public	Hard surface disinfection on hard/non-porous surfaces and objects in Food and Feed industry, healthcare area and non-healthcare area, by wiping
Meta SPC 8: Ready to use post-dips (PT 3)			
3.6 – 7.5%	Sodium lauryl sulfate: 1.3%	professional	Teat disinfection (after milking), by dipping
	Isopropanol: 1 – 3%		
Meta SPC 9: Ready to use post-dips (PT 3)			
3.6 – 7.5%	Isopropanol: 3%	professional	Teat disinfection (after milking), by spraying or dipping

L-(+)-lactic acid %	Substance of concern	user category	Application method
Meta SPC 10: Ready to use post-dips (PT 3)			
3.6%	/	professional	Teat disinfection (after milking), by spraying or dipping
Meta SPC 11: Hard surface and equipment disinfection (PT 3 and 4)			
24%	Sodium lauryl sulfate: 12%	professional	Hard surface and equipment disinfection on hard/non-porous surfaces and objects in Food and Feed industry, veterinary field and public area, by spraying or soaking/immersion
	Isopropanol: 5%		
Meta SPC 12: Inner surface disinfectants by CIP with and without circulation and crate wash (PT 4)			
22%	C6 alkyl glucoside: 2.4%	professional	Hard surface and equipment disinfection on hard/non-porous inner surfaces by CIP (with or without circulation, and crate wash, in Food and Feed industry)
	Methanesulfonic acid or Sulphuric acid: 0 – 10.5%		
Meta SPC 13: Hard surface disinfection (PT 4)			
11%	Sodium lauryl sulfate: 4.5%	professional	Hard surface disinfection on hard/non-porous surfaces and in Food and Feed industry, by foaming
	Methanesulfonic acid: 10.5 – 19.5%		
Meta SPC 14 ² : Coronary band disinfection (PT3)			
32%	Sodium lauryl sulfate: 10.5%	professional	No safe uses are identified (see animal health assessment). The meta SPC is therefore not authorised. ²
Meta SPC 15 ² : Ready to use hygienic handrub (PT 1)			
3.6%	Sodium Lauryl sulphate: 2%	professional ¹	Applied on hands by rubbing the hands
	Isopropanol: 4%		
	Butyldiglycol: 10%		

¹ For non-professional use, according to the qualitative risk assessment (human health risk assessment), the risk is unacceptable because local exposure (eyes contact by splash or children who rub their eyes during the hand-washing process) to the corrosive product cannot be avoided.

² Meta SPC 14 could not be authorised, therefore, the current authorised meta SPC 14 is the former meta SPC 15.

Physico-chemical properties

The BPF is composed by 15 meta-SPCs, with all products ready-to-use or concentrate-to-dilute liquids, except the meta-SPC 7, containing impregnated wipes.

Meta SPCs 1 and 8 are viscous liquids, the rest of meta-SPCs contains colourless to coloured clear liquids. The pH of the products of the BPF is in the range -0.14 to 4.452. The relative density of the products is in the range 1.0044 to 1.1772.

2 years of shelf life could be granted, pending a submission of a long-term storage test. A long-term storage test is ongoing and results are to be provided as soon as available, in order to confirm the ambient storage of the biocidal product. This proposal is supported based on the accelerated storage tests and in accordance with the Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology: *"Accelerated storage data generated can be used to give an indication that the biocidal product will be stable for two years at ambient temperature. These data can be used to demonstrate that the product is likely to be stable for two years at ambient storage to support an authorisation. Yet, this does not negate the need to generate ambient storage data, which must be generated to confirm the ambient storage of the biocidal product."*

Persistent foaming tests on products to be used diluted (meta-SPC 3, 4, 5, 11, 13 and 14) show a volume exceeding 60 ml. However, for the use of the products, PPE are needed, and they cover the risk brought by the excessive foaming. The dilution stability of the products to be diluted is shown to be acceptable. The surface tension is between 20.96 mN/m and 34.27 mN/m for the highest in use concentrations of products. The viscosity is between < 10 cP and 1033 cP at 20 °C and very similar at 40 °C.

The products from the meta-SPCs 1, 2, 3, 4, 5, 6, 7, 8, 9, 11, 14, 15 do not present any physical hazards.

The products from the following meta-SPCs should be classified for the corresponding physical hazard:

- Meta SPC 10: Flam. Liq. 3;
- Meta SPC 12: Corr. to metals 1;
- Meta SPC 13: Corr. to metals 1.

Among the identified Substances of concern, Butylglycol and Isopropanol are identified as substances presentable in Band C, indicating a possibility for variability during storage. Other SoCs are not expected to vary during storage. Therefore, according to the TAB, no need in validated analytical method is necessary. Validated methods (HPLC-ULV) for the active substance, and for the SoCs butyldiglycol and isopropanol are available.

Efficacy

Meta SPC 1: hygienic handwash allows the reduction of "transient bacteria flora" on hands when used undiluted with 10 mL and water at room temperature in 1 min.

Meta SPC 2: ready-to-use algaecide is active against unicellular green algae and blue-green algae (cyanobacteria) at 100% at +20-25 °C in 3h contact time, on hard/non-porous surfaces without prior cleaning.

Meta SPC 3: concentrated algaecide is active against unicellular green algae and blue-green algae (cyanobacteria) at 0.5% at +20 °C in 3 h contact time on hard/non-porous surfaces without prior cleaning. The products are also effective against bacteria and yeasts at 4% at +40 °C in 5 sec. contact time on hard/non-porous surfaces without prior cleaning, in food

and feed industry.

Meta SPC 4: Activity against bacteria and yeasts at 20% at +20 °C in 15 min contact time on hard/non-porous surfaces without prior cleaning, for non-healthcare areas. The products are also effective for toilet bowl disinfection (bacteria and yeast) at 100% at +20°C in 5 min contact time.

Meta SPC 5: effective against bacteria and yeast for teat disinfection (pre-milking without prior cleaning) and intact skin wash/disinfection (of the udder of dairy and beef cattle before calving and of the udder of sows before farrowing) at 40% at +30°C in 1 min contact time.

Meta SPC 6: effective for teat disinfection (pre-milking with wipes without prior cleaning) against bacteria and yeast at 100% at +30°C in 1 min contact time.

Meta SPC 7: pre-impregnated wipes active against bacteria, yeasts and viruses at +20°C in 2 min contact time on hard/non-porous surfaces with prior cleaning, in healthcare and non-healthcare areas.

Meta SPC 8, 9 and 10: effective for teat disinfection (post-milking) against bacteria and yeast at 100% at +30°C in 5 min contact time.

Meta SPC 11:

- PT3 hard surface disinfection on hard/non-porous surfaces with prior cleaning: active against bacteria and yeasts at 4% at +10°C in 30 min contact time;
- PT4 hard/non-porous surface disinfection with prior cleaning by spraying/immersion: Active against bacteria and yeasts at 3% at +20°C in 2 min contact time / 1% at +20°C in 15 min contact time;
- PT4 hard/non-porous surfaces without prior cleaning: Active against bacteria and yeasts: at +7°C - 15% in 30 sec. contact time by dipping and at +7°C - 8% in 2 min contact time by spraying.

Meta SPC 12: Active against bacteria and yeasts at +50°C on hard/non-porous surfaces

- inner surface disinfection – CIP with circulation:
 - with prior cleaning: 2% in 2 min contact time / 1% in 30 min contact time;
 - without prior cleaning: 4% in 2 min contact time / 1% in 30 min contact time.
- in dairy industry: 2% in 15 min contact time.
- inner surface disinfection – without circulation:
 - with prior cleaning: 2% in 2 min contact time;
 - without prior cleaning: 4% in 2 min contact time / 2% in 30 min contact time.
- crate wash: Without prior cleaning: 4% in 2 min contact time.

Meta SPC 13: Hard/non-porous surface disinfection (bacteria and yeast) by foaming in food and feed industry with prior cleaning at 1% and without prior cleaning at 5% in 30 min (at +20°C).

Meta SPC 14: Coronary band & interdigital skin of hooves disinfection without prior cleaning (bacteria and yeast) at 6% - +30°C and 5 min contact time.

Meta SPC 15: Ready to use handrub effective at 6ml to against bacteria and yeast in

1 minute, on clean hands.

It can be concluded that all products in the family are efficacious, when used in accordance with the use instructions mentioned above and proposed in the SPC.

Human health

The following meta SPCs of the biocidal product family are classified as follows according to the harmonized classification of the active substance:

- Skin corrosion 1: Meta SPCs 3, 12, 13 and 14 (H314);
- Skin irritation 2: Meta SPCs 4 and 11 (H315);
- Eye Damage 1: Meta SPCs 1, 3, 4, 5, 6, 8, 9, 10, 11, 12, 13, 14 and 15 (H318);
- Eye irritation 2: MetaSPCs 2 and 7 (H319);
- Skin sensitization: Meta SPC 4 and 10 the classification EUH208 is required, due to the presence of co-formulants.

The family contains substances of concern as a co-formulant: sodium lauryl sulphate, sodium lauryl ether sulfate, sulfonic acids, C14-17-sec-alkane, sodium salts, C6 alkyl glucoside, methane sulfonic acid, sulphuric acid, isopropanol and butyldiglycol. Butyldiglycol has an EU workplace exposure limit (OEL). The substance is present in metaSPC 15 at a maximal concentration of 10%, indicating Butyldiglycol is a SoC Band C for metaSPC 15. Isopropanol has a Competent Authority Report for PT 1, PT 2 and PT 4. The substance is present in metaSPC 1, 8, 9, 11 and 15 at a maximal concentration of 4%, 3%, 3%, 5% and 4% respectively. Therefore, isopropanol is a SoC Band C for metaSPC 1, 8, 9, 11 and 15. For this reason, a risk assessment was performed for isopropanol and butyldiglycol.

Acceptable risks are foreseen for:

- professional using products of MetaSPC 1 and MetaSPC 15 for hand disinfection without PPE.
- professional using products of MetaSPC 2 and 7 for general surface disinfection including surface in contact with food, toilet disinfection and green remover without PPE
- professional using products of Meta SPC 5, 6, 8, 9 and 10 for teat disinfection. However, as metaSPC 5, 6, 8, 9 and 10 are classified H318, eye damage 1, chemical goggles need to be worn.
- professional using products of Meta SPC 4 and 11 for general surface disinfection including surface in contact with food, toilet disinfection and green remover. However, as the products of metaSPC 4 and 11 are irritant for skin/eye gloves and goggles are needed.
- professional using products of Meta SPC 3. As the products of Meta SPC 3 are corrosive for skin/eye gloves, goggles and protective coverall are needed. These PPE also cover the exposure to foam.
- professional using products of Meta SPC 12 for CIP. However, as the products of metaSPC 12 are corrosive for skin/eye gloves, goggles and protective coverall are needed.
- professional using products of Meta SPC 13. As the products of Meta SPC 13 are corrosive for skin/eye gloves, goggles and protective coverall are needed. These PPE also cover the exposure to foam.
- professional using products of Meta SPC 14 as animal skin disinfectant when PPE are worn. However, due to the animal health assessment, this use should not be authorised.

- non-professional using products of Meta SPC 2 and 7 for general surface disinfection including surface in contact with food, toilet disinfection and green remover without PPE (due to the reversible effect).
- non-professional using products of Meta SPC 4 for PT 2 surface disinfection by applying risk mitigation measures.

Unacceptable risks were identified for the following uses, and lead to the non-authorization of the uses:

- non-professionals using products of Meta SPC 1 and Meta SPC 15 for hand disinfection. Therefore this use #2 will not be allowed for non-professional use as the risk of exposure (eyes contact) to the corrosive product cannot be excluded.
- Non-professional spraying application in Meta SPC 4 classified as eye dam.1. No risk mitigation measures to prevent all risks of ocular exposure could ensure a sufficient level of safety for this class of users.
- Meta SPC 14 is classified as skin corr.1B, taking into account that the biocidal product is intended to be apply on animal skin (PT 3) the risk in not acceptable. Therefore, this meta SPC is not authorised.

Environment

L-lactic acid is a naturally occurring substance found in plants and animals and is found to be readily biodegradable. No unacceptable risks are identified for the products of the biocidal product 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 is not required.

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

Meta SPC	Use(s) assessed	User category	conclusion
1	Hygienic handwash (PT 1)	professional	authorized
		non-professional	not authorized
2	Ready to use algicide (PT 2)	professional	authorized
		non-professional	authorized
3	Concentrated algaecide (PT 2)	professional	authorized

Meta SPC	Use(s) assessed	User category	conclusion
	Disinfection of hard/non-porous surfaces in the food industry (e.g. processing machines) (PT 4)	professional	authorized
4	Hard surface disinfection for sanitary hygiene, other than in healthcare (PT 2)	professional	authorized
		non-professional	not authorized
	Hard surface disinfection for hygiene in kitchens (PT 4)	professional	authorized
		non-professional	not authorized
	Disinfection of toilet bowls (PT 2)	professional	authorized
		non-professional	authorized
5	Teat disinfection, before milking (PT 3)	professional	authorized
	Intact skin wash/disinfection (of the udder of dairy and beef cattle before calving and of the udder of sows before farrowing) (PT 3)	professional	authorized
6	Teat disinfection, before milking (PT 3)	professional	authorized
7	Hard surface disinfection in Food and Feed industry (PT 4)	professional	authorized
		non-professional	authorized
	Hard surface disinfection, use in healthcare (PT 2)	professional	authorized
		non-professional	authorized
	Hard surface disinfection, use other than in healthcare (PT 2)	professional	authorized
		non-professional	authorized
8	Teat disinfection after milking by dipping (PT 3)	professional	authorized
9	Teat disinfection after milking by spraying or dipping (PT 3)	professional	authorized
10	Teat disinfection after milking by spraying or dipping (PT 3)	professional	authorized
11	Hard surface disinfection in Food and feed industry (PT 4)	professional	authorized
	Equipment disinfection by soaking in Food and feed industry (PT 4)	professional	authorized
	Hard surfaces disinfection for veterinary hygiene (PT 3)	professional	authorized
12	Inner surface disinfection by CIP with circulation (PT 4)	professional	authorized
	Inner surface disinfection by CIP without circulation (PT 4)	professional	authorized
	Crate wash (PT 4)	professional	authorized
13	Hard surface disinfection (PT4)	professional	authorized
14	Hoof bath disinfectant (PT 3)	professional	not authorized
15	Hygienic handrub (PT 1)	professional	authorized
		non-professional	not authorized

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 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.

To fulfil the post-authorisation requirements related to the shelf life, the applicant shall provide the study to confirm a 2 year shelf life for the products in the family as soon as possible.

It is noted that for the product family 'Lactic acid based products - CID LINES NV' 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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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.