

Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the biocidal product family:

COLGATE-PALMOLIVE_LACTIC ACID_PT2

ECHA/BPC/317/2022

Adopted

2 March 2022

Opinion of the Biocidal Products Committee

on the Union authorisation of COLGATE-PALMOLIVE_LACTIC ACID_PT2

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:	COLGATE-PALMOLIVE_LACTIC ACID_PT2
Authorisation holder:	Colgate-Palmolive Sp. Z.o.o.
Active substance common name:	L(+) lactic acid (CAS number 79–33-4)
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 the 29 January 2019, recorded in R4BP3 under case number BC-HK051319-37, 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 the 25 August 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-42) and its Working Groups (WG-IV-2021]. Revisions agreed upon were presented and the draft PAR and the draft SPC were finalised accordingly.

Adoption of the BPC opinion

Rapporteur: France

The BPC opinion on the Union authorisation of the biocidal product family COLGATE-PALMOLIVE_LACTIC ACID_PT2 was reached on 2 March 2022.

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 COLGATE-PALMOLIVE_LACTIC_ACID_PT2 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 COLGATE-PALMOLIVE_LACTIC_ACID_PT2 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, COLGATE-PALMOLIVE_LACTIC ACID_PT2, is based on 1.5 to 4 % of L (+) lactic acid, is a product type 2 intended for surface disinfection. The products of this biocidal family are in the form of liquids, to be applied for the disinfection of hard surface and toilet bowl against bacteria by non-professional users.

Two co-formulants contained in the products of COLGATE-PALMOLIVE_LACTIC ACID_PT2 family have been identified as substances of concern for the human health (Decan-1-ol, ethoxylated and Propan-2-ol) and the environment (Propan-2-ol).

Two uses are claimed for all products of the biocidal product family (BPF):

- Use #1: disinfection of hard surfaces (domestic surfaces other than kitchen);
- Use #2: toilet bowl surfaces disinfection.

The BPF COLGATE-PALMOLIVE_LACTIC ACID_PT2 is composed of four Meta-SPC:

- Meta-SPC 1–2 - application by pouring on sponge and then spreading on the surface;
- Meta-SPC 3 – application by spraying;
- Meta-SPC 4 – application by spraying;
- Meta-SPC 5 – application with impregnated wipes.

Conclusions of the assessments of each section are given below.

Physico-chemical properties

The physico-chemical properties of the biocidal product family COLGATE-PALMOLIVE_LACTIC ACID_PT2 have been described and considered acceptable in the conditions of use detailed in the SPC.

The analytical method for the determination of the active substance, L (+) lactic acid in the biocidal product family is fully validated.

For self-reactive properties, DSC (Differential Scanning Calometry) tests of representative products of all Meta SPCs should be provided in post-authorisation within 6 months to confirm the non-classification in this hazard class. A waiver proposed by the applicant, based on the high water content of the products, was submitted. In consequence, the DSC test requested is added for confirmatory purposes only in agreement with Member States opinions during the peer-review.

Meta SPC 1-2:

The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in commercial packaging material.

The products of Meta SPC 1-2 must not be stored above 40 °C. The products should be protected from light.

Meta SPC 3:

The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in commercial packaging material.

The products of Meta SPC 3 are classified corrosive to metal, H290, Met Corr. I.

Meta SPC 4:

The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in commercial packaging material. The products should be protected from light.

Meta SPC 5:

The stability data indicate a shelf life of at least 1 year at ambient temperature when stored in commercial packaging material.

The products of Meta SPC 5 must not be stored above 30 °C.

The products of Meta SPC 5 are classified corrosive to metal, H290, Met Corr. I.

Efficacy

COLGATE-PALMOLIVE_LACTIC_ACID_PT2 product family has shown sufficient efficacy in accordance with the requirements of Guidance on BPR, Volume II Efficacy – Assessment and Evaluation (Parts B+C) for PT 2:

Meta SPC 1-2: By pouring on sponge and then spreading on the porous and non-porous hard surfaces:

- Use # 1 – Hard surface disinfection – domestic surfaces other than kitchen with dirty conditions:
 - Bacteria: 15 minutes, room temperature
- Use # 2 – Toilet bowl surfaces disinfection :
 - Bacteria: 15 minutes, room temperature

Meta SPC 3: By spraying on porous and non-porous hard surfaces:

- Use # 1 – Hard surface disinfection – domestic surfaces other than kitchen with dirty conditions:
 - Bacteria: 5 minutes, room temperature
- Use # 2 – Toilet bowl surfaces disinfection:
 - Bacteria: 5 minutes, room temperature

Meta SPC 4: By spraying on porous and non-porous hard surfaces:

- Use # 1 – Hard surface disinfection – domestic surfaces other than kitchen with dirty conditions:
 - Bacteria: 5 minutes, room temperature
- Use # 2 – Toilet bowl surface disinfection:
 - Bacteria: 5 minutes, room temperature

Meta SPC 5: By wiping on hard non-porous surfaces:

- Use # 1 – Hard surface disinfection – domestic surfaces other than kitchen with dirty conditions:
 - Bacteria: 5 minutes, room temperature
- Use # 2 – Toilet bowl surface disinfection:
 - Bacteria: 5 minutes, room temperature.

Regarding the claim against bacterial spores, the efficacy is not demonstrated.

Human health

Two substances of concern for Human health, [(Decan-1-ol, ethoxylated (>2.5 moles EO) and Propan-2-ol], have been identified in the COLGATE-PALMOLIVE_LACTIC ACID_PT2 family in Meta SPC 1-2 & 4 and Meta SPC 5, respectively. Decan-1-ol, ethoxylated (>2.5 moles EO) contributes to the classification for eye damage (H318). Therefore, a qualitative exposure and risk assessment to determine whether the labelling associated to classification is sufficient or whether other RMM should be applied have been performed. Propan-2-ol is a biocidal active substance acting as co-formulant, with available agreed reference values. A quantitative risk assessment (systemic) has therefore been performed.

For the active substance only a local effect assessment has been performed.

Meta SPC 1-2 (Uses#1 and #2)

Meta SPC 1-2 is classified Skin Irrit. 2, H315 and Eye Dam. 1., H318.

For the products of COLGATE-PALMOLIVE_LACTIC ACID_PT2 family packaged in bottle (named BDC for Bucket Dilutable Cleaner by applicant), the risk during hard surface

disinfection is acceptable considering the qualitative risk assessment for local effects with the following risk mitigation measures (RMM):

- Wash hands after use;
- Avoid contact with eyes;
- Avoid splashes and spills during pouring;

and:

- The bottles sized above 1 L and up to 2 L must be adapted with a handle;
- The packaging must be adapted with a childproof closure.

Meta SPC 3 & 4 (Uses#1 and #2)

Meta SPC 3 and 4 are classified Skin Irrit. 2, H315 and Eye Dam. 1., H318.

For the products of COLGATE-PALMOLIVE_LACTIC ACID_PT2 family packaged in trigger spray (Meta SPC 3 & 4), the risk during hard surface disinfection (domestic surfaces and toilet bowl) is not acceptable considering the qualitative risk assessment for local effects.

Indeed, the exposure to eyes cannot be excluded when the product is applied by spraying as it generates a cloud of corrosive droplets.

Meta SPC 5 (Uses#1 and #2)

Meta SPC 5 is classified Skin Irrit. 2, H315 and Eye Dam. 1., H318.

For the products of the COLGATE-PALMOLIVE_LACTIC ACID_PT2 family packaged in impregnated wipes (Meta SPC 5), the risk during hard surface disinfection is acceptable considering the systemic and local effects with the following risk mitigation measures (RMM):

- Wash hands after use;
- Avoid contact with eyes;
- Keep out of reach of children and non-target animals/pets.

For Meta SPC 1-2 and 5, the risk is considered acceptable for the secondary exposure of the general public with the application of risk mitigation measures listed below:

- Do not touch the surface until the surface is rinsed and dry;
- Children should not be present during disinfection and until the surface is rinsed and dry.

Dietary risk assessment

PT2 biocidal products are not intended for application on surfaces that are used for direct contact with food or feeding stuffs. Therefore, residues in food or feed are not expected.

Environment

One substance of concern for the environment has been identified in the COLGATE-PALMOLIVE_LACTIC ACID_PT2 family, Propan-2-ol, but since the substance of concern has minor impact on the mixture toxicity, no additional assessment is provided in the public PAR

for this substance. COLGATE-PALMOLIVE_LACTIC ACID_PT2 biocidal product family is not classified hazardous for the environment.

The environmental risk assessment was only performed for the active substance. The risks related to the uses of COLGATE-PALMOLIVE_LACTIC ACID_PT2 biocidal product family are acceptable for all the environmental compartments.

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 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 overall conclusions are presented in the table below for all Meta SPCs:

Meta SPC	Field of use	Composition	Application rate and uses	Conclusions
1-2	Hard surface disinfection domestic surfaces other than kitchen	1.5-2.8% Lactic acid (pure)	Indoor Non-professionals Pouring on sponge and then spreading on the surface (with rinsing afterwards) Contact time: 15min	Acceptable with RMM*
	Toilet bowl surfaces disinfection			
3	Hard surface disinfection domestic surfaces other than kitchen	3.2% lactic acid (pure)	Indoor Non-professionals Spraying (with rinsing afterwards) Contact time: 5min	Not acceptable: Unacceptable risks for human health (local effects)
	Toilet bowl surfaces disinfection			

4	Hard surface disinfection domestic surfaces other than kitchen	2.4% lactic acid (pure)		Not acceptable: Unacceptable risks for human health (local effects)
	Toilet bowl surfaces disinfection			
5	Hard surface disinfection domestic surfaces other than kitchen	3.5% – 4% Lactic acid (pure)	Indoor Non-professionals Wiping (with rinsing afterwards) Contact time: 5min	Acceptable with RMM*
	Toilet bowl surfaces disinfection			

*Please refer to the general and specific directions of use in the PAR and SPC for more details.

For the uses and meta-SPCs proposed for authorisation (Meta SPC 1-2 and 5) it has been concluded that:

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 (Meta SPCs 1-2 and 5), 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 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 biocidal product family shall be authorised¹, for the uses 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
DSC tests of representative products of all Meta SPCs to confirm for the self-reactive properties.	Within 6 months after the authorisation of BPF

It is noted that for the product family COLGATE-PALMOLIVE_LACTIC_ACID_PT2 the fact that data is to be provided after the authorisation is granted is for confirmatory purposes and 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.