

Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the biocidal product family:

UL Hydrogen Peroxide Family 1

ECHA/BPC/344/2022

Adopted

15 June 2022

Opinion of the Biocidal Products Committee

on the Union authorisation of UL Hydrogen Peroxide Family 1

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:	UL Hydrogen Peroxide Family 1
Authorisation holder:	Unilever Europe BV
Active substance common name:	Hydrogen Peroxide (CAS nr 7722-84-1)
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 27 January 2017, recorded in R4BP3 under case number BC-MS029571-20, the evaluating Competent Authority submitted a draft product assessment report (PAR) containing the conclusions of its evaluation to ECHA on 20 December 2021. In order to review the draft PAR and the conclusions of the eCA, the Agency organised consultations via the BPC (BPC-43) and its Working Groups (WG I 2022). Revisions agreed upon were presented and the draft PAR was finalised accordingly.

Adoption of the BPC opinion

Rapporteur: Germany

The BPC opinion on the Union authorisation of the biocidal product family was reached on 15 June 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 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 does not meet the conditions laid down in Article 19(6) of Regulation (EU) No 528/2012 and therefore may not be authorised. The detailed grounds for the overall conclusion are described in the PAR.

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 "UL Hydrogen Peroxide Family 1" consists of products containing the active substance hydrogen peroxide in the range of 1.9-5%. The products are ready to use liquids gels. The BPF is used as a disinfectant not intended for direct application to humans or animals (product-type 2) for the control of bacteria, viruses and fungi.

The following substances of concern have been identified:

- Sulphamidic acid (CAS No. 5329-14-6): Based on its major contribution to the classification as Skin Corr. 1 and Eye Dam. 1 sulphamidic acid is considered as substance of concern.
- 2,2'-(C16-18 (even numbered) alkyl imino) diethanol ("PEG-2 hydrogenated tallow amine"; CAS No. 1218787-30-4): Its maximum content alone would trigger the classification of the products as Aquatic chronic 3.
- Ethanol, 2,2'-iminobis-, N-C12-18-alkyl derivs. ("PEG-2 Coco amine"; CAS No. 71786-60-2): Its maximum content alone would trigger the classification of the products as Aquatic chronic 2.

The biocidal product family is used by professional and non-professional users by manual application. The biocidal product family consists of one meta SPC with one use.

The following use was assessed:

Meta SPC-1:

PT2	DISINFECTANTS AND ALGAECIDES NOT INTENDED FOR DIRECT APPLICATION TO HUMANS OR ANIMALS	
Use	conclusion of the assessment	
1	"Toilet disinfectant" Manual application for toilet bowl disinfection by professional and non-professional users	not appropriate for authorisation

Based on the available information, no evidence of endocrine-disrupting properties was identified for the active substance and the co-formulants contained in the biocidal product family.

Physico-chemical properties

The biocidal product family with one meta SPC consists of liquid gels (formulation type AL) of different colours and fragrances. The pH of the biocidal product family is <4. A representative product of the family has a density of 1.0284 g/cm³ at 20°C. The BPF is considered to be corrosive to metals category 1.

An accelerated storage stability study was carried out for a product representing an “upper end” composition with the result that the product is stable for 8 weeks at 40 °C. Another accelerated storage stability study was carried out with a product representing a “lower end” composition with the lowest concentration of hydrogen peroxide and no added stabilizer. After 18 weeks at 30 °C the product showed significant decrease in hydrogen peroxide content (-15.4%) and moderate changes in appearance and physical-chemical data. Based on the two accelerated storage tests with significantly different results for the range of the biocidal product family, no preliminary shelf-life for the biocidal product family can be derived.

A long-term storage stability study at ambient temperature has been carried out with a product representing an “upper end” composition for 36 months. The viscosity decreases significantly after 12 months, for which no explanation has been provided. After 18 months the decrease in hydrogen peroxide content exceeds 10%, after 36 months a phase separation can be observed. Since the single tested product is also not representative for the whole family and only represents the “upper end” composition, **no shelf-life can be derived**. Further long-term storage stability studies with products that represent the whole composition range of the product family are ongoing.

For the endpoints explosives, flammable liquids, self-reactive substances, mixtures and auto-ignition temperature (liquids and gases) the submitted justifications are not sufficient to cover the endpoints. As the BPF was already considered for non-authorization no further data were requested for these endpoints but data gaps are identified in the PAR. Therefore, it is **not possible to conclude on classification and labelling** for these endpoints.

The analytical methods for detection and identification for the BPF are deemed acceptable.

For the substances of concern PEG-2 hydrogenated tallow amines and PEG-2 coco amines – both classified as dangerous for the environment – environmental exposure cannot be excluded. Analytical methods for monitoring residues of these substances in environmental compartments are missing. As the BPF was already considered for non-authorization no further data were requested.

Efficacy

The BPF has been shown to be efficacious against bacteria, fungi and viruses after 60 minutes contact time at 20 °C under dirty conditions. Therefore, efficacy has been proven for the intended use.

Human health

Classification and Labelling

According to the CLP criteria, the BPF needs to be classified and labelled with regard to human health as follows:

- Skin Corr. 1, H314 (Causes severe skin burns and eye damage)
- Eye Dam. 1, H318 (Causes serious eye damage)
- EUH208 (Contains cineole. May produce an allergic reaction)
- EUH071 (Corrosive to the respiratory tract)

Professional user

A human health risk assessment has been carried out for professional use of the biocidal product family. The occupational risk assessment takes into account systemic and local effects of the active substance hydrogen peroxide and the substance of concern sulphamidic acid.

The products are ready to use (RTU) products. The risk assessment takes into account the working steps of manual application and brushing/flushing of the toilet after the contact time of 60 minutes as applied for by the applicant and reflected in the efficacy studies.

An unacceptable risk was identified for the professional user from secondary inhalation exposure during the re-entry into the treated toilet room after 60 minutes for the flushing step, even if the biocidal product family is used as intended and all appropriate safety measures are followed. Measures to mitigate the identified risks (e.g. respiratory protection (half mask with gas filter) or air filtration systems and 60 min ventilation prior to re-entry of general public into toilet facilities after flushing) are not realistic and practical and therefore not feasible for the type of application. **Therefore, the conditions regarding article 19 (1) b) iii) of Regulation (EU) No 528/2012 are not fulfilled.**

Non-professional user

A human health risk assessment has been carried out for non-professional use of the biocidal product family. The risk assessment is based on the same parameters as the assessment for the professional use.

An **unacceptable risk was identified for the non-professional user** from secondary inhalation exposure during the re-entry into the toilet room after 60 minutes for the flushing step, even if the biocidal product family is used as intended and all safety measures are followed. Measures to mitigate the identified risks are not available or applicable. Therefore, **the conditions regarding article 19 (1) b) iii) of Regulation (EU) No 528/2012 are not fulfilled.**

Environment

According to the CLP criteria, the BPF needs to be classified and labelled with regard to the environment as follows:

- Aquatic chronic 2, H411 (Toxic to aquatic life with long-lasting effects)

An environmental risk assessment has been carried out for the single use (toilet disinfection) intended by the applicant. The risk assessment takes into account the effects of the active substance hydrogen peroxide and the substances of concern PEG-2 hydrogenated tallow amine and PEG-2 Coco amine separated and in combination.

The assessment data for the active substance were taken from the CAR (2015). The effects assessment for the substances of concern was carried out based on data from REACH registration dossiers and the European Risk Assessment Report for five primary alkyl amines. The input parameters used by the eCA have been agreed at ENV WG-VII-2020. Alternative input values presented by the applicant were deemed not sufficiently scientifically proven.

No unacceptable risks due to the use of the biocidal product family were identified for the atmosphere, surface water and secondary poisoning in the aquatic and terrestrial food chain. The groundwater trigger value is not exceeded by the substances of concern.

For the compartments **sediment and soil unacceptable environmental risks were identified caused by the substance of concern PEG-2 hydrogenated tallow amine** alone and consequently in mixture toxicity. No adequate risk mitigation measures exist for the type of use of the biocidal product family. Thus, **the conditions regarding article 19 (1) b) iv) of Regulation (EU) No 528/2012 are not fulfilled.**

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

Not relevant since the biocidal product family UL Hydrogen Peroxide Family 1 should not be authorised.

c) Description of uses proposed to be authorised

Not relevant since the biocidal product family UL Hydrogen Peroxide Family 1 should not be authorised.

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

Not relevant since the biocidal product family UL Hydrogen Peroxide Family 1 should not be authorised.

2.2 BPC opinion on the Union authorisation of the biocidal product family

As the conditions of Article 19(1) are not met it is proposed that the biocidal product family shall not be authorised because of:

- unacceptable risks for the environment (compartments sediment and soil):
- unacceptable risks for the human health of the professional and the non-professional user;
- identified data gaps for the endpoints explosives, flammable liquids, self-reactive substances, mixtures, and auto-ignition temperature (liquids and gases);
- the lack of a shelf-life for the whole composition range of the biocidal product family.