

Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the biocidal product family:

L+R Propanol PT1 Family

ECHA/BPC/291/2021

Adopted

7 October 2021

Opinion of the Biocidal Products Committee

on the Union authorisation of L+R Propanol PT1 Family

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:	L+R Propanol PT1 Family
Authorisation holder:	Lohmann & Rauscher International GmbH & Co. KG
Active substance(s) common name:	Propan-1-ol, Propan-2-ol
Product type:	PT 1

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 25.04.2019, recorded in R4BP3 under case number BC-MU051242-25, 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 29.03.2021. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-40) and its Working Groups (WG II 2021). Revisions agreed upon were presented and the draft PAR and the draft SPC were finalised accordingly.

Adoption of the BPC opinion

Rapporteur: Switzerland

The BPC opinion on the Union authorisation of the biocidal product family was reached on 7 October 2021.

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(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 L+R Propanol PT1 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

General

The biocidal products of the L+R Propanol PT1 Family are disinfectants for PT1 (Human Hygiene) purposes. The products are ready-to-use leave-on disinfectants for hygienic and surgical handrubs in health care facilities and industry without the use of washbasin and water (meta-SPC 1 – 2). All products are restricted for industrial and professional use only. The active substance Propan-1-ol is used in the concentration range 30 – 30 % w/w and Propan-2-ol is used in the concentration range 45 - 45 % w/w. The co-formulant Tetradecanol (0.95%) is identified as a substance of concern (SoC).

Physico-chemical properties

The physico-chemical properties of the L+R Propanol PT1 Family have been adequately characterised. The storage stability data for the L+R Propanol PT1 Family support the claim of a 3-year shelf life. During storage, the products need to be protected from direct sunlight. Furthermore, the following storage conditions have been defined:

- Store in dry, cool, well-ventilated place;
- Keep container tightly closed. Recommended storage temperature: 0-30 °C.

With regard to physical hazards, the products of meta-SPC 1 and 2 are classified as flammable liquids category 3 (H226: Flammable liquid and vapour). The products do not have oxidising properties and they are not explosive, self-heating, self-reactive or corrosive to metals.

Efficacy

The efficacy for surgical and hygienic handrubs was evaluated using laboratory suspensions tests (EN 13727, EN 13624, DGHM 2001, EN 14348, EN 14476, DVV) and simulated use tests (EN 1500, EN 12791).

The target organisms of the *L+R Propanol PT1 Family* are bacteria, mycobacteria, yeasts and viruses (limited spectrum virucidal activity). According to the Assessment Reports of the active substances, no known acquired resistance has been reported against the target species.

Sufficient efficacy is demonstrated for the following claimed uses:

Meta-SPC	Use code	Use	Target organisms and label claims
Meta-SPC 1	#1.1	PT 1: Hygienic handrub, liquid	<ul style="list-style-type: none"> • for hygienic handrub – 30 s • for surgical handrub– 90 • effective against bacteria • effective against yeasts • effective against mycobacteria • virucidal against enveloped viruses • limited spectrum virucidal activity
	#1.2	PT 1: Surgical handrub, liquid	
Meta-SPC 2	#2.1	PT 1: Hygienic handrub, liquid	
	#2.2	PT 1: Surgical handrub, liquid	

Human health

Based on the active substance content, the L+R Propanol PT1 Family is classified as:

- Eye Dam. 1 - H318: Causes serious eye damage;
- STOT SE 3 - H336: May cause drowsiness or dizziness;
- EUH066: Repeated exposure may cause skin dryness or cracking.

A qualitative risk assessment for local effects during skin and eye contact was performed due to the classification as H318 and EUH066.

Primary exposure:

Exposure of professional user (including industrial user) was evaluated for dermal and inhalation exposure routes and the inhalation route for professional bystanders for the scenarios summarised in the table below:

Scenario	Primary and secondary exposure and description of scenario	Conclusion of systemic exposure
Hand disinfection (PT 1, meta-SPC 1-2)	Primary exposure of the professional user resulting from application of an alcohol-based disinfectant in form of a ready to use product for hand disinfection in naturally ventilated rooms. Secondary exposure of a professional bystander who is present in the patient room where the hand disinfection is carried out can be expected.	Acceptable

No unacceptable risks were identified for primary and secondary systemic exposure of professional users and professional bystanders. The local risk has been considered acceptable for all professional/industrial uses if the risk mitigation measures "Avoid contact with eyes" is implemented.

The *L+R Propanol PT1 Family* is intended for professional use only. In order to prevent use by non-professional users, in the field of use and instruction of use the phrase "For professional use only" is included and the additional risk mitigation measure "Keep out of

reach of children" is added.

Secondary exposure:

The general public is exposed via the inhalation route when professional workers use the products of the *L+R Propanol PT1 Family* to disinfect their hands. According to the risk assessment, the risk is acceptable for the general public.

Environment

The environmental risk assessment for the L+R Propanol PT1 Family has taken into account the agreements made within both active substances assessments (propan-1-ol and propan-2-ol CARs) and considered a 90% loss to air and 10 % loss to sewer system after application of products for all emission scenarios.

The co-formulant Tetradecanol (0.95%) in the meta-SPC 1 has been identified as a substance of concern, as it is classified as Aquatic Chronic 1. Its concentration leads to a classification of the products as Aquatic Chronic 3. This substance has been considered in the environmental risk assessment.

A representative product including the substance of concern has been considered to cover the worst-case scenarios in the environmental exposure assessment.

For all environmental compartments, acceptable levels of risk have been demonstrated for the proposed uses of the BPF.

In conclusion, there is no unacceptable risk for the environment.

Overall conclusion

Uses	Target organisms	User categories	Authorised application rates	Use conditions : risk mitigations measures
Use # 1.1 – PT1 Hygienic handrub, RTU liquid	- Bacteria - Mycobacteria - Yeasts - Enveloped Viruses - Limited spectrum of virucidal activity	Professional / Industrial user	Dosage: At least 3 ml ¹ Contact time: 30 s	For professional use only RMM: - Avoid contact with eyes - Keep out of reach of children
Use # 1.2 – PT1 Surgical handrub, RTU liquid		Professional user	Dosage: Rub sufficient amount in portions of 3 ml ¹ Contact time: 90 s	For professional use only RMM: - Avoid contact with eyes - Keep out of reach of children
Use # 2.1 – PT1 Hygienic handrub, RTU liquid		Professional / Industrial user	Dosage: At least 3 ml ¹ Contact time: 30 s	For professional use only RMM: - Avoid contact with eyes - Keep out of reach of children
Use # 2.2 – PT1 Surgical handrub, liquid		Professional user	Dosage: Rub sufficient amount in portions of 3 ml ¹ Contact time: 90 s	For professional use only RMM: - Avoid contact with eyes - Keep out of reach of children

It is concluded that the evaluation has shown that sufficient data have been provided to permit the authorisation of the *L+R Propanol PT1 Family* for the use as hygienic and surgical handrubs (as mentioned under efficacy) for professional and industrial users. When using the products of the *L+R Propanol PT1 Family* according to the conditions as stated in the SPC, the products will be efficacious and will not present an unacceptable risk to human and animal health or to the environment.

¹ There is no restriction in the number and timing of applications. No safety intervals need to be considered between the application phases. The product may be used at any time and as often as required.

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 are 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 is available in the SPC.

d) Comparative assessment

The active substances Propan-1-ol and Propan-2-ol contained in the biocidal product family do not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and are not considered candidates 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 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 substances 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 authorised², for the uses described under section 2.1 of this opinion, subject to compliance with the proposed SPC.

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² 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.