

Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the biocidal product family:

Brenntag GmbH Propan-2-ol Product Family

ECHA/BPC/290/2021

Adopted

7 October 2021

Opinion of the Biocidal Products Committee

on the Union authorisation of Brenntag GmbH Propan-2-ol Product 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:	Brenntag GmbH Propan-2-ol Product Family
Authorisation holder:	Brenntag GmbH
Active substances common name:	Propan-2-ol
Product types:	PT 1, 2 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 30 June 2016, recorded in R4BP3 under case number BC-BL025673-43, 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 15 March 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: Germany

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 Brenntag GmbH Propan-2-ol Product 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 product family consists of products containing the active substance Propan-2-ol (62.7 - 70 %w/w) for hand disinfection (PT 1) and for disinfection of non-porous surfaces, which are not used for direct contact with food or feeding stuffs (PT 2) and for disinfection of non-porous surfaces in food and feed area (PT 4). No substance of concern was identified.

The biocidal product family consists of three meta SPCs with ready-to-use liquids.

The following uses have been assessed:

Meta SPC 1:

- Use 1: Hygienic handrub for professional users;

Meta SPC 2:

- Use 1: Disinfection of small surfaces – spraying - professional users;
- Use 2: Disinfection of small food contact surfaces – spraying - professional users;

Meta SPC 3:

- Use 1: Hygienic handrub for non-professional users.

Physico-chemical properties

The products in this family without dye are colourless and the products with dye are blue. For products containing perfume, the odour is characteristic perfume-like. For products that do not contain perfume, the odour is characteristic alcohol-like.

The pH of the products within the family ranges from approximately 5.4 to 7.9 and the relative density is around 0.86 – 0.88.

The products (ready-to-use liquids) have a shelf life of 24 months based on the results of the long term storage stability studies.

According to the CLP criteria, the individual products of the BPF, and thus the BPF itself, need to be classified with regard to physical hazards as follows:

- Flam. Liq. 2; (Flammable liquids, hazard category 2);
- H225: Highly flammable liquid and vapour.

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

Efficacy

The tested products of the product family showed sufficient bactericidal and yeasticidal activity according to lab tests (EN 1276, EN 13697, EN 13727, EN 1500, EN 14348, EN 1650, EN 13624) under test conditions defined for hygienic handrub, for the disinfection of non-porous surfaces in private, public, healthcare, industrial areas as well as for food sector and food processing industry (including breweries, dairy and meat industry).

For hygienic handrub activity against enveloped viruses was also substantiated (EN 14476).

For surface disinfection, efficacy was proven under dirty conditions. For hygienic handrub, efficacy was only proven under clean conditions.

It can be concluded that all products within the family are expected to be efficacious when used in accordance with the following use instructions:

Meta SPC 1 and 3:

- Bactericidal (including mycobactericidal), yeasticidal and activity against enveloped viruses - contact time at least 1 min when rubbing at least 3 ml product over both hands;

Meta SPC 2, Use 1:

- Small surface disinfection: Bactericidal (including mycobactericidal) and yeasticidal – contact time at least 1 min - for use at room temperature;
- In healthcare area: Bactericidal (including mycobactericidal) and yeasticidal – contact time at least 5 min - for use at room temperature;

Meta SPC 2, Use 2:

- Small surface disinfection: Bactericidal and yeasticidal – contact time at least 1 min - for use at room temperature;
- In Breweries / meat industry: Bactericidal and yeasticidal – contact time at least 5 min - for use at room temperature;
- In dairy industry: Bactericidal and yeasticidal – contact time 15 min – for use at room temperature.

To ensure the efficacy of the products, the following use conditions have been added to the SPC:

- For hygienic handrub (meta-SPC 1 + 3):
“Only apply on dry and visibly clean hands”;

- For surface disinfectants (meta-SPC 2):
“Make sure to wet surfaces completely”.

Resistance is not reported or known at the time being.

Human health

Classification and Labelling

According to the CLP criteria, the meta SPCs of this BPF need to be classified and labelled with regard to human health as follows:

- Eye Irrit. 2 (Eye Irritation, category 2), H319 (Causes serious eye irritation);
- STOT SE 3 (Specific target organ toxicity, single exposure, category 3), H336 (May cause drowsiness and dizziness);
- EUH066 (Repeated exposure may cause skin dryness or cracking).

Professional user

A human health risk assessment has been carried out for professional use of the biocidal product family for all intended uses.

The occupational risk assessment for biocidal products covered by meta SPC 1 and meta SPC 2 takes into account systemic and local effects of the active substance propan-2-ol.

In summary, a risk for professional users resulting from the use of the biocidal product family is unlikely. The following risk mitigation measures have to be taken into account in order to ensure safe use of the biocidal product family.

Meta SPC 1:

- Avoid contact with eyes.
- The following personal risk mitigation measure can be considered for refilling procedure unless it can be replaced by technical and / or organisational measures:
The use of eye protection during refilling of the product is recommended.
- For refilling a funnel must be applied.

Meta SPC 2, Use 1:

- The following personal risk mitigation measure can be considered for refilling procedure unless it can be replaced by technical and / or organisational measures:
The use of eye protection during refilling of the product is recommended.

Meta SPC 2, Use 2:

- The following personal risk mitigation measure can be considered for disinfection of food processing machinery and refilling procedure unless it can be replaced by technical and / or organisational measures:
The use of eye protection during handling of the product is recommended.

General risk mitigation measures for Meta SPC 2:

- Avoid contact with eyes;
- For refilling a funnel must be applied;
- The product must only be applied for disinfection of small surfaces.

Non-professional user

It must be expected that the biocidal products of meta SPC 3 (PT 1) are used by both adults and children for hand disinfection. For children it cannot be assumed that they will read and understand the instructions for use on the label. Based on the systemic and local risk assessment additional risk mitigation measures are required for a safe use (see below). Hence, adults have to supervise the children when the biocidal products are applied.

A human health risk has been identified for children if the biocidal products of meta SPC 3 (PT 1) are used more than 3 times per day in small, not ventilated rooms and the person stays there for a longer time interval. However, in Tier 2 safe use is demonstrated, if the room is well-ventilated. Also based on the classification with STOT SE 3, H336 use is limited to well-ventilated areas.

The biocidal product is classified as eye irritant. Hence, in addition to the corresponding first aid precautionary statements an advice to avoid contact with eyes is required. Eye protection is considered not appropriate for non-professional users.

Non-professional bystander (general public)

If biocidal products of meta SPC 1 and 3 (PT 1) are used as intended (5 per day in the private area, sufficient ventilation) no human health risks are expected. For use in public areas even use frequencies up to 5 per day are considered safe for adults and children if they are used as intended and sufficient ventilation is ensured. The slight exceedance for toddlers is considered not relevant since it is based on the very conservative assumptions regarding the use frequency.

If biocidal products of meta SPC 2 (PT 2 and 4) are used as intended, no human health risk is expected for adults and children exposed as bystanders. Based on the exposure assessment a human health risk for younger children (e.g. toddlers) can only be excluded if access to treated rooms is avoided for 30 minutes after application. The scenario is based on a ventilation rate of 2 h^{-1} . Under many circumstances even higher ventilation rates are possible (e.g. if windows are fully opened, hospitals with air condition systems) Hence, an advice is needed that adequate ventilation has to be ensured before re-entry of children.

Based on the classification and labelling with STOT SE 3, H336 the biocidal products of this family have to be used only in well-ventilated areas.

Indirect exposure via food

Due to its high vapour pressure, the active substance evaporates completely within the time of application of the biocidal products, therefore no transfer from treated hands or surfaces to food is expected. In the unlikely event that residue transfer does occur, the active substance will evaporate from the food before it is eaten. Therefore, dietary exposure to humans from the use of propan-2-ol as a biocide of PT1, PT 2 or PT4 can be excluded.

Environment

An environmental risk assessment has been conducted for the biocidal products family for all intended uses. No unacceptable risks for the environment have been identified in the environmental risk assessment. Hence, no negative effects for the environment are to be expected by the use of the biocidal products of the biocidal product family.

No classification and labelling according to the CLP criteria for environmental hazards is needed.

Overview of uses

Meta SPC	Use	Target organisms	User categories	Authorised application rates	Use conditions : risk mitigations measures for human health
1	1	Bacteria (incl. Mycobacteria), Yeast, Enveloped viruses	Professional user	<p>3 ml applied to one hand and complete surface of both hands are moistened and rubbed for 60 seconds per application.</p> <p>Up to 25 disinfections per day, 5 day(s) per week</p>	<p>1) Avoid contact with eyes.</p> <p>2) Keep out of reach of children and pets.</p> <p>3) Use only in well-ventilated areas.</p> <p>4) For refilling a funnel must be applied.</p> <p>5) The following personal risk mitigation measure can be considered for refilling procedure unless it can be replaced by technical and / or organisational measures:</p> <p>The use of eye protection during refilling of the product is recommended.</p>
2	1	Bacteria (incl. Mycobacteria), Yeast	Professional user	<p>For surface disinfection a ready-to-use spray solution (20 ml/m²) is applied on surfaces at room temperature. Application according to requirements, one application per use, 4 times per day.</p> <p>Small surface disinfection (other than healthcare):</p> <p>Bactericidal and yeasticidal: contact time at least 1 min</p> <p>In healthcare area:</p> <p>Bactericidal and yeasticidal:</p>	<p>1) Avoid contact with eyes.</p> <p>2) For refilling a funnel must be applied.</p> <p>3) The product must only be applied for disinfection of small surfaces.</p> <p>4) Keep out of reach of children and pets.</p> <p>5) Use only in well-ventilated areas.</p> <p>6) Keep children and pets away from rooms where disinfection is taking place.</p> <p>7) Provide adequate ventilation before children</p>

Meta SPC	Use	Target organisms	User categories	Authorised application rates	Use conditions : risk mitigations measures for human health
				<p>contact time at least 5 min</p>	<p>and pets enter treated rooms.</p> <p>8) The following personal risk mitigation measure can be considered for refilling procedure unless it can be replaced by technical and / or organisational measures:</p> <p>The use of eye protection during handling of the product is recommended.</p>
2	2	Bacteria, Yeast	Professional user	<p>For surface disinfection a ready-to-use spray solution (20 ml/m²) is applied on surfaces at room temperature. Application according to requirements, one application per use, 4 times per day.</p> <p>Small surface disinfection:</p> <p>Bactericidal and yeasticidal: contact time at least 1 min</p> <p>In Breweries/ meat industry:</p> <p>Bactericidal and yeasticidal: contact time at least 5 min</p> <p>In dairy industry:</p> <p>Bactericidal and yeasticidal: contact time at least 15 min</p>	<p>1) Avoid contact with eyes.</p> <p>2) For refilling a funnel must be applied.</p> <p>3) The product must only be applied for disinfection of small surfaces.</p> <p>4) Keep out of reach of children and pets.</p> <p>5) Use only in well-ventilated areas.</p> <p>6) Keep children and pets away from rooms where disinfection is taking place.</p> <p>7) Provide adequate ventilation before children and pets enter treated rooms.</p> <p>8) The following personal risk mitigation measure can be considered for disinfection of food processing machinery and refilling procedure unless it can be replaced by technical and / or organisational measures:</p> <p>The use of eye protection during handling of the</p>

Meta SPC	Use	Target organisms	User categories	Authorised application rates	Use conditions : risk mitigations measures for human health
					product is recommended.
3	1	Bacteria (incl. Mycobacteria), Yeast, Enveloped viruses	Non-professional user	3 ml applied to one hand and complete surface of both hands are moistened and rubbed for 60 seconds per application. Up to 5 disinfections per day, 5 day(s) per week	1) Avoid contact with eyes. 2) Use by children only under supervision of an adult. 3) Use only in well-ventilated areas.

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 propan-2-ol 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 in accordance with Article 23 of the BPR 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 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;
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.

f) 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.