Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Propan-1-ol

Product type: 2

ECHA/BPC/151/2017

Adopted

27 April 2017

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Opinion of the Biocidal Products Committee

on the application for approval of the active substance propan-1-ol for product type 2

In accordance with Article 89(1) 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 (BPR), the Biocidal Products Committee (BPC) has adopted this opinion on the approval in product type 2 of the following active substance:

Common name:	**1-Propanol**
Chemical name:	**Propan-1-ol**
EC No.:	**200-746-9**
CAS No.:	**71-23-8**

Existing active substance

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority. The assessment report, as a supporting document to the opinion, contains the detailed grounds for the opinion.

Process for the adoption of BPC opinions

Following the submission of an application by the Task Force "1-Propanol" on 31 July 2007, the evaluating Competent Authority Germany submitted an assessment report and the conclusions of its evaluation to ECHA on 18 July 2016. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via BPC (BPC-20) and its Working Groups (WG I 2017). Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Adoption of the BPC opinion

Rapporteur: Germany

The BPC opinion on the approval of the active substance propan-1-ol in product type 2 was adopted on 27 April 2017.

The BPC opinion was adopted by consensus. The opinion is published on the ECHA webpage at: http://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the propan-1-ol in product type 2 may be approved. The detailed grounds for the overall conclusion are described in the assessment report.

2. BPC Opinion

2.1. BPC Conclusions of the evaluation

a) Presentation of the active substance including the classification and labelling of the active substance

This evaluation covers the use of propan-1-ol in product type 2. Specifications for the reference source are established.

The physico-chemical properties of the active substance and biocidal product have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the active substance and biocidal product.

Validated analytical methods are available for the active substance as manufactured in absence of any relevant and significant impurities. Validated analytical methods are required and available for the relevant matrix air.

The active substance has a harmonised classification and labelling. The classification and labelling for propan-1-ol according to Regulation (EC) No 1272/2008 (CLP Regulation) is:

Classification according to the CLP Regulation	
Hazard Class and Category Codes	Flam. Liq. 2 Eye Dam. 1 STOT SE 3
Labelling	
Pictogram codes	GHS02 GHS05 GHS07
Signal Word	Danger
Hazard Statement Codes	H225: Highly flammable liquid and vapour H318: Causes serious eye damage H336: May cause drowsiness or dizziness
Specific Concentration limits, M-Factors	-

A change of the classification and labelling is proposed by adding EUH066 (Repeated exposure may cause skin dryness or cracking):

Proposed classification according to the CLP Regulation	
Hazard Class and Category Codes	Flam. Liq. 2 Eye Dam. 1 STOT SE 3
Labelling	
Pictogram codes	GHS02 GHS05 GHS07
Signal Word	Danger
Hazard Statement Codes	H225: Highly flammable liquid and vapour H318: Causes serious eye damage H336: May cause drowsiness or dizziness EUH066: Repeated exposure may cause skin dryness or cracking.
Specific Concentration limits, M-Factors	-
Justification for the proposal	
In addition to current classification/labelling, EUH066 is proposed, based on local skin effects and reactions that have been described for human individuals exposed to formulations containing propan-1-ol or to propan-1-ol dilutions.	

b) Intended use, target species and effectiveness

Biocidal products containing the active substance propan-1-ol in PT 2 are intended to be used for disinfection of surfaces, inanimate objects and materials and equipment in private, public health and industrial areas by non-professional and professional users.
Propan-1-ol kills microorganisms via an unspecific mode of action by e.g. affecting the cell membrane and destroying the structure of the cytoplasm's proteins.

Efficacy data have demonstrated a basic efficacy of propan-1-ol at 70 % against bacteria (including one mycobacterium but excluding bacterial spores), yeast and some non-enveloped viruses (feline calicivirus, bovine rota virus). Basic efficacy against fungi was shown at a concentration of 80 % propan-1-ol. The studies performed are regarded as sufficient at the approval stage. Further data in accordance with the relevant guidance documents shall be provided in the scope of product authorisation.

Due to the unspecific mode of action of propan-1-ol, a development of resistance is not expected and not reported.

c) Overall conclusion of the evaluation including need for risk management measures

Human health

Propan-1-ol displayed low acute toxicity in experimental animals. Major effects resulting from acute oral exposure comprised neurological symptoms. Propan-1-ol was not irritating to the skin but may cause skin dryness and cracking. The results of a rabbit study confirmed the legal classification for serious eye damage. Data on pharmacovigilance revealed occurrence of very rare cases of skin reactions and eye irritation in relation to frequency of exposure from medicinal use of propan-1-ol –containing antiseptics. Propan-1-ol showed also low toxicity following repeated exposure. Developmental effects and impaired male fertility were reported following repeated inhalation exposure to very high doses of 5500 and 4500 mg/kg bw/d, respectively. NOAECs from these studies were used for deriving reference values for risk assessment. Propan-1-ol did not exhibit relevant

genotoxic or carcinogenic potential in animals. The available data did not provide evidence for endocrine disrupting properties.

The table below summarises the exposure scenarios assessed.

Summary table: human health scenarios			
Scenario	**Primary or secondary exposure and description of scenario**	**Exposed group**	**Conclusion**
Surface disinfection-Application of the biocidal product	Primary non-professional exposure (inhalation + dermal), surface disinfection in bathrooms by spraying. Product integrated RMMs preventing eye damage were assumed.	Non-professionals (adults)	Acceptable
Surface disinfection - Post-application	Secondary non-professional exposure via inhalation, re-entry after use of the biocidal product	General public (adults + children)	Acceptable
Disinfection of small surfaces	Primary inhalation and dermal exposure Disinfection of small surfaces (0.5 m^2) of e.g. working bench in laboratory, hospitals.	Professional user	Acceptable
Disinfection of small surfaces	Secondary inhalation exposure Disinfection of small surfaces	Professional bystander	Acceptable

For non-professionals all exposure estimates (primary and secondary) are below the respective systemic AEL. Thus, it can be concluded that exposure of non-professionals to propan-1-ol from the use of a biocidal product containing 70 % of this active substance is acceptable with respect to human health.

In addition relevant cumulative exposure estimates have been compared to the relevant AEL. It is concluded that cumulative exposure to propan-1-ol by application in PT 1, 2 and 4 is acceptable for human health.

Propan-1-ol is used as ready-to-use disinfection solution (70 % propan-1-ol) for professional disinfection of small surfaces (0.5 m^2) 10 times per shift, each lasting 1 minute and under presumption to an air exchange rate of 8 per hour.

For professional disinfection of small surfaces (0.5 m^2) and secondary exposure the estimated uptakes / reference values are below 100 % and thus safe uses are identified. Based on these results and conclusions on systemic health risks, a further refinement of the risk characterisation is considered not necessary.

Due to its intrinsic properties, damage of the eye can arise from exposure to propan-1-ol (classification with H 318). Therefore, a qualitative risk assessment for local effects was carried out. Since no contact of liquid with the eyes is expected for the non-professional and the professional user, eye protection for surface disinfection is not required. For non-professional users product integrated risk mitigation measures (RMMs) and labelling with "Avoid contact with eyes." was considered in the assessment.

Residues in food or feed from the intended use of propan-1-ol in PT2 biocidal products are not expected.

Environment

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
PT 2 - ready-to-use solution for disinfection of small surfaces in the sanitary sector – professional use	The biocidal product contains 0.56 kg a.s./L and for general purpose in private area a consumption of 5 mL/(cap*d) is assumed. The main emission path will be via air because a huge amount of active substance evaporates to indoor air. Indirect releases occur via STP to the aquatic compartment (surface water and sediment) as well as due to sewage sludge application on agricultural soil to the terrestrial compartment (soil and groundwater).	Acceptable

No unacceptable risks for soil, surface water, sediment and the STP were identified in connection with the evaluated intended use. Merely, the maximum permissible concentration of 0.1 µg/L a.s. in groundwater was found to be exceeded (according to Groundwater Directive 2006/118/EC and Drinking Water Directive 98/83/EC) in the first-tier assessment. The indicated risk for the groundwater compartment could, however, be eliminated by refining the groundwater assessment using the FOCUS PEARL model. The refined estimations with FOCUS PEARL revealed that the average concentration of propan-1-ol in groundwater (closest to the 80th percentile) remains below the criterion of 0.1 µg/L in one (for grassland) respectively two (for arable land) of the nine EU scenarios. Consequently, no unacceptable risks for the environment were identified in conjunction with the use of propan-1-ol for disinfection of small surfaces in the sanitary sector.

Whereas this is sufficient at active substance approval stage, for product authorisation a tier two refinement may be necessary to demonstrate that for other relevant (in case of national authorisation) or for all nine (in case of Union authorisation) predefined FOCUS PEARL scenarios the emission to groundwater is acceptable.

Overall conclusion

A safe use for human health and environment is identified for non-professional and professional use of the ready-to-use biocidal product for disinfection of small surfaces.

2.2. Exclusion, substitution and POP criteria

2.2.1. Exclusion and substitution criteria

The table below summarises the relevant information with respect to the assessment of exclusion and substitution criteria:

Property		Conclusions	
CMR properties	Carcinogenicity (C)	no classification required	Propan-1-ol does not fulfil criterion (a), (b) and (c) of Article 5(1)
	Mutagenicity (M)	no classification required	

	Toxic for reproduction (R)	no classification required	
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	not P or vP	Propan-1-ol does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1)
	Bioaccumulative (B) or very Bioaccumulative (vB)	not B or vB	
	Toxic (T)	not T	
Endocrine disrupting properties	Propan-1-ol is not considered to have endocrine disrupting properties and does not fulfil criterion (d) of Article 5(1).		
Respiratory sensitisation properties	No classification required. Propan-1-ol does not fulfil criterion (b) of Article 10(1).		
Concerns linked to critical effects	Propan-1-ol does not fulfil criterion (e) of Article 10(1).		
Proportion of non-active isomers or impurities	Propan-1-ol is not an isomeric substance and does therefore not fulfil criterion (f) of Article 10(1).		

Consequently, the following is concluded:

Propan-1-ol does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012.

Propan-1-ol does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not considered as a candidate for substitution. The exclusion and substitution criteria were assessed in line with the "Note on the principles for taking decisions on the approval of active substances under the BPR"[1] and in line with "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR"[2] agreed at the 54th and 58th meeting respectively, of the representatives of Member States Competent Authorities for the implementation of Regulation 528/2012 concerning the making available on the market and use of biocidal products. This implies that the assessment of the exclusion criteria is based on Article 5(1) and the assessment of substitution criteria is based on Article 10(1)(a, b, d, e and f).

2.2.2. POP criteria

Propan-1-ol does not fulfil the criterion for being a B substance. It is neither P nor does it show a potential for long-range transport. Hence, propan-1-ol does not meet the criteria for being a persistent organic pollutant.

[1] See document: Note on the principles for taking decisions on the approval of active substances under the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/c41b4ad4-356c-4852-9512-62e72cc919df/CA-March14-Doc.4.1%20-%20Final%20-%20Principles%20for%20substance%20approval.doc)
[2] See document: Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/dbac71e3-cd70-4ed7-bd40-fc1cb92cfe1c/CA-Nov14-Doc.4.4%20-%20Final%20-%20Further%20guidance%20on%20Art10(1).doc)

2.3. BPC opinion on the application for approval of the active substance propan-1-ol in product type 2

In view of the conclusions of the evaluation, it is proposed that propan-1-ol shall be approved and be included in the Union list of approved active substances, subject to the following specific conditions:

1. Specification: minimum purity of the active substance evaluated: 995 g/kg.

2. The authorisations of biocidal products are subject to the following condition:

    a. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance.

The active substance does not fulfil the criteria according to Article 28(1) to enable inclusion in Annex I of Regulation (EU) 528/2012 as it is classified as Flam. Liq. 2 and STOT SE 3.

2.4. Elements to be taken into account when authorising products

1. The following recommendations and risk mitigation measures have been identified for the uses assessed. Authorities should consider these risk mitigation measures when authorising products, together with possible other risk mitigation measures, and decide whether these measures are applicable for the concerned product:

    a. The risk characterisation for non-professionals took account of product integrated risk mitigation measures and labelling with "Avoid contact with eyes" and a safe use was identified. At product authorisation similar product integrated risk mitigation measures and labelling might be required.

2. Residues in food are not expected due to high vapour pressure. However, at product authorisation level it must be ensured that this assumption (evaporation of the active substance) does apply to the intended use of the biocidal product.

2.5. Requirement for further information

Sufficient data have been provided to verify the conclusions on the active substance, permitting the proposal for the approval of propan-1-ol.

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