Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Propan-1-ol

Product type: 1

ECHA/BPC/150/2017

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 1

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 1 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 1 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 1 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 1. 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

Propan-1-ol is a broad-spectrum biocide used for hand disinfection 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 inner structure of the cytoplasm's proteins.

Efficacy data have demonstrated innate efficacy of propan-1-ol at 60 % against bacteria (including one mycobacterium but excluding bacterial spores), yeast and some non-enveloped viruses (feline calicivirus, bovine rota virus). Propan-1-ol at a concentration of 60 % was furthermore sufficient to eliminate the bacterial load present on the fingertips of volunteers. No sufficient efficacy against fungi was shown at a concentration of 60 % 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 harmonised 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**
Hand disinfection - hospitals	Primary exposure (inhalation + dermal): Visitors of patients in intensive health care units use the ready-to-use biocidal product (70 % active substance) for hand disinfection.	Non-professionals (adults)	Acceptable
Hand disinfection – home dialysis	Primary exposure (inhalation + dermal): Home dialysis; patients disinfect their hands prior to home dialysis (70 % active substance)	Non-professionals (adults)	Acceptable
Secondary exposure – Hand disinfection	Secondary non-professional exposure during re-entry after use of the biocidal product via inhalation	General public (adults, children)	Acceptable
Hand disinfection - hospitals	Primary inhalation and dermal exposure during hand rub of a ready-to-use solution with 70 % or 60 % propan-1-ol	Professional user	Acceptable for 60 % of active substance Not acceptable for 70 % of active substance
Secondary exposure - Hand disinfection	Secondary inhalation exposure of a bystander close to the use of a ready-to-use solution with 70 % propan-1-ol	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. As the biocidal product is classified for serious eye damage a local risk assessment was performed. Given that eye exposure is not expected, no concern was identified from the use. Nonetheless, labelling with "Avoid contact with eyes." is recommended to minimise the possibility of exposure.

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 used by professionals, assumes 25 hand disinfections per shift. As an unacceptable risk is identified for products with 70 % propan-1-ol risk reduction measures are necessary. For hand disinfection wearing of gloves is not applicable. Respiratory protection equipment is not assumed to be worn in e.g. hospitals either. Therefore, a lower concentration of propan-1-ol in the product was assessed. According to efficacy evaluation, products with 60 % of active substance are still effective. Therefore, refinement of the risk assessment takes into account the concentration of 60 % active substance. A safe use is identified for the representative biocidal product with concentration of ≤60 % of propan-1-ol.

The local risk assessment for professional users showed that as no contact of liquid propan-

1-ol with the eyes is expected, no concern is identified and the use of eye protection for hand disinfection is not required.

Residues in food or feed from the intended use of propan-1-ol in PT1 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 1 - ready-to-use solution for hand and skin disinfection in health care areas and other areas – professional use	For professional use a model hospital with 400 beds and an average consumption of 15 g a.s. per day was 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 five of the nine EU scenarios for both grassland and arable land. Consequently, no unacceptable risks for the environment were identified in conjunction with the use of propan-1-ol for hand and skin disinfection.

Whereas these five scenarios are 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 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 professional use of the ready-to-use biocidal product containing ≤60 % of propan-1-ol. For non-professionals a safe use was identified with a ≤70 % solution.

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

[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)

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.

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

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(s):

    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.

    b. In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to:

        i. Professional users.

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. If an unacceptable risk is identified for professional users, safe operational procedures and appropriate organizational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means.

    b. An unacceptable risk for professional hand disinfection with concentrations ≥ 70% of propan-1-ol is identified. For the use assessed wearing personnel protective equipment is not considered appropriate. Hence, if the risk cannot be reduced to an acceptable level by other means, these uses should not be authorised.

    c. The risk characterisation for non-professionals took account of labelling with

[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)

"Avoid contact with eyes" and a safe use was identified. At product authorisation this 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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