Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Propan-2-ol

Product type: 1

ECHA/BPC/013/2014

Adopted

18 June 2014

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Opinion of the Biocidal Products Committee

on the approval of the biocidal active substance Propan-2-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, the Biocidal Products Committee (BPC) has adopted this opinion on the approval in product type 1 of the following active substance:

Common name:	**Propan-2-ol**
Chemical name(s):	**2-Propanol**
EC No.:	**200-661-7**
CAS No.:	**67-63-0**
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 (AR) and conclusions, as a supporting documents to the opinion, contain the detailed grounds for the opinion.

Process for the adoption of BPC opinions

Following the submission of an application by Task Force "2-Propanol" on 31 July 2007, the evaluating Competent Authority Germany (DE) submitted an assessment report and the conclusions of its evaluation to the Commission on 05 November 2012. In order to review the assessement report and the conclusions of the evaluation the Agency organised consultations via the BPC and the Commission via the Biocides Technical Meeting on September 2013. Revisions agreed upon were presented and the assessment report was amended accordingly.

Adoption of the BPC opinion

Rapporteur: Germany

The BPC opinion on the approval of the active substance propan-2-ol in product-type 1 was adopted on 18 June 2014.

The BPC opinion was adopted by consensus.

Detailed BPC opinion and background

1. Overall conclusion

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

2. Opinion

2.1. Conclusions of the evaluation

a) Presentation of the active substance and representative biocidal product including classification of the active substance

This evaluation covers the use of propan-2-ol in product type 1. Propan-2-ol exhibits an unspecific mechanism of effect. It affects the cell membrane causing alteration of membrane fluidity and leakage, enters the cytoplasm and destroys the inner structure of the cell molecules and of the cytoplasm's proteins. It similarly interacts with corresponding viral structures. This process (referred to as denaturation) and the enzymes' coagulation leads to a loss of cellular activity resulting in the cell's death.

The physico-chemical properties of the active substance have been evaluated and are deemed acceptable. The representative biocidal product is a dummy product which consists of the active substance and water. No product specific data were provided for this dummy product. The Task Force refers to the active substance, which is acceptable in the frame of active substance approval but not for product authorisation. Analytical methods for the determination of residues of propan-2-ol in soil, water (drinking water, surface water) and food and feeding stuffs are not deemed necessary, because residues are not expected. An acceptable primary method for the determination of propan-2-ol in air is available. For confirmation, a GC-MS method is available which has not been fully validated. Analytical methods for the determination of residues of propan-2-ol in body tissues or body fluids are not deemed necessary, because propan-2-ol is not classified as toxic or very toxic.

The current classification of propan-2-ol is based on table 3.2 of Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation):

Proposed classification according to the CLP Regulation		
Hazard Class and Category Codes / Hazard Statement Code(s)	Flam. Liq. 2 Eye Irrit. 2 STOT SE 3	H225 H319 H336 EUH066
Proposed labelling		
Pictograms	GHS02 GHS07	
Signal Word	Danger	
Hazard Statement Codes	H225 Highly flammable liquid and vapour H319 Causes serious eye irritation H336 May cause drowsiness or dizziness EUH066 Repeated exposure may cause skin dryness or cracking	
Justification for the proposal		
In addition to current classification according to table 3.1 of Annex VI of Regulation (EC) No 1272/2008, EUH066 (Repeated exposure may cause skin dryness or cracking) is proposed, based on local skin effects and reactions that have been described for human individuals exposed to formulations containing propan-2-ol or to propan-2-ol dilutions.		

b) Intended use, target species and effectiveness: containing a description of the use(s) evaluated in the assessment report

Propan-2-ol is used as a broad-spectrum biocide for hand disinfection within product type 1 for professional (e.g. health care professions) and non-professional (e.g. intensive care unit visitors) users. Target organisms are bacteria (including mycobacteria but excluding bacterial spores), fungi (yeast and moulds) and viruses. The submitted tests provide reliable results for the efficacy assessment in the frame of the approval of the active substance. The performed studies demonstrate a basic efficacy of propan-2-ol against selected relevant target organisms (bacteria, fungi including yeast and moulds and viruses) at concentrations not exceeding 70% corresponding to the concentration of propan-2-ol of the evaluated model formulation ("dummy product").

Due to the unspecific mode of action of 2-propanol, the development of resistance is not expected and not reported. A natural resistance against sporulated bacteria is known where 2-propanol is ineffective at any concentration. Likewise, 2-propanol is more effective against enveloped viruses compared to non-enveloped viruses. The non-enveloped viruses have one protein-layer (capsid), which shows a pronounced natural resistance against chemical and physical disinfection methods.

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

The table below summarises the exposure scenarios assessed.

Summary table: human health scenarios		
Scenario	**Primary or secondary exposure Description of scenario**	**Exposed group**
Professional Application	Primary exposure Hand disinfection	Professionals
Professional Application	Secondary exposure Hand disinfection	By-standers
Intensive care units visitors	Primary exposure Acute or medium-term exposure Disinfection before entry, dermal and inhalation exposure	Non-professional users
Home dialysis	Primary exposure Long-term exposure Disinfection before and during dialysis, dermal and inhalation exposure	Non-professional users
Visitors of home dialysis patients	Secondary exposure Acute or long-term exposure Adults staying in rooms during home dialysis	Bystanders, general public
Visitors of home dialysis patients	Secondary exposure Acute or long-term exposure Children staying in rooms during home dialysis	Bystanders, general public

Primary and secondary (indirect) exposure of professionals is considered acceptable. Risk mitigation measures for professionals with respect to human health exposure assessment and risk characterisation are not required.

Primary exposure of non-professionals is considered acceptable. Specific safety measures for non-professionals with respect to human health exposure assessment and risk characterisation are not required.

Secondary exposure of non-professionals and the general public is considered acceptable. Furthermore, residues in food or feed are not expected. Specific safety measurements for non-professionals and the general public with respect to human health exposure assessment and risk characterisation are not required.

Based on assessment of the scenarios listed above, it is concluded that primary and secondary exposure of non-professionals and the general public (including cumulative exposure of PTs 1, 2 and 4) is acceptable. Furthermore, residues in food or feed are not expected.

With respect to human health assessment for non-professionals and the general public as well as residue assessment, no risk management measures are needed.

An aggregate exposure assessment for all sources of exposure (including non-biocidal uses) is not possible at this time due to lack of guidance.

Environment

The table below summarises the exposure scenarios and affected environmental compartments assessed.

Summary table scenarios	
Scenario	**Description of main pathways and affected compartments**
Use as skin and hand disinfectant in hospitals	Emission to air during application Emission to wastewater due to leakage or rinse-off and via cleaning of treated area (sewage treatment plant (STP), surface water, sediment, soil, groundwater)

On basis of the risk assessment done for the different environmental compartments it is concluded that the use of the model formulation ("dummy product") containing the active substance propan-2-ol does not pose an unacceptable risk to the environment.

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		**Conclusion**
CMR properties	Carcinogenicity (C)	no classification required
	Mutagenicity (M)	no classification required
	Toxic for reproduction (R)	no classification required

PBT and vPvB properties	Persistent (P) or very Persistent (vP)	not P, not vP
	Bioaccumualtive (B) or very Bioaccumulative (vB)	not B, not vB
	Toxic (T)	not T
Endocrine disrupting properties	There is no indication of endocrine disrupting properties of the active substance.	

Consequently, the following is concluded:

Propan-2-ol does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012 and is therefore not considered as a candidate for substitution.

Propan-2-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" agreed at the 54th meeting 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 (CA-March14-Doc.4.1 - Final - Principles for the approval of AS.doc). This implies that the assessment of the exclusion criteria is based on Article 5(1) using the temporary criteria for the determination of endocrine-disrupting properties in Article 5(3) and the assessment of substitution criteria is based on Article 10(1)(a, b and d).

2.2.2 POP criteria

As propan-2-ol is not B, vB or P, it 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-2-ol in product type 1

In view of the conclusions of the evaluation, it is proposed that propan-2-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: ≥99.0% w/w.

2. 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(2) to enable inclusion in Annex I of Regulation (EU) 528/2012 due to its classification as highly flammable.

2.4. Elements to be taken into account when authorising products

1. Residues in food are not expected. However at product authorisation level it must be ensured that this assumption (evaporation of the a.s.) does apply to the intended use of the biocidal product.

2. The environmental exposure assessment is based on the distribution of releases between air and waste water at a ratio of 90 % and 10 % for the representative product. During product authorisation it has to be re-evaluated if this distribution

still holds for other product uses.

3. Using FOCUS PEARL for groundwater exposure assessment four safe scenarios are identified. During product authorisation the risks for groundwater have to be re-checked based on the respective decision of each Member State regarding the relevant scenarios for their countries.
4. Whilst the efficacy data provided is sufficient to recommend approval of the substance, data demonstrating the efficacy of the product at the minimum application rate against the range of proposed target organisms using the recommended application equipment must be provided at the product authorisation stage. Specifically:

    a. To support the full label claim further laboratory tests would be necessary, this especially refers to the label claim "virucidal".

    b. Additionally, further tests in the field of use have to be provided. At least the tests listed in EN 14885 for the respective field of use or comparable tests have to be provided in the frame of product authorisation.

    c. As an EN norm does not exist for all possible label claims, further testing will be necessary depending on the specific label claim.

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-2-ol. However, further data shall be required as detailed below:

2.5.1 Methods of analysis

An acceptable primary method for the determination of propan-2-ol in air is presented. For confirmation, a GC-MS method is available which has not been fully validated. Validation data for the confirmatory method must be provided as soon as possible but no later than 6 months before the date of approval to the evaluating Competent Authority (Germany).

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