

## Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the biocidal product family:

Ecolab UA BPF 1-Propanol

ECHA/BPC/315/2022

Adopted

1 March 2022



## Opinion of the Biocidal Products Committee

on the Union authorisation of the biocidal product family  
Ecolab UA BPF 1-Propanol

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:	Ecolab UA BPF 1-Propanol
Authorisation holder:	Ecolab Deutschland GmbH
Active substance common name:	Propan-1-ol (CAS No 71-23-8)
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 26 March 2019, recorded in R4BP3 under case number BC-RS050191-24, 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 9 September 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-42) and its Working Groups (WG-IV-2021). Revisions agreed upon were presented and the draft PAR and the draft SPC were finalised accordingly.

## Adoption of the BPC opinion

Rapporteur: Sweden

The BPC opinion on the Union authorisation of the biocidal product family was reached on 1 March 2022.

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(1)(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 Ecolab UA BPF 1-Propanol 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

The sections below are a concise summary of the evaluation and conclusions of the assessment of the biocidal product family.

#### General

The biocidal product family ECOLAB UA BPF 1-PROPANOL, with propan-1-ol as active ingredient, consists of one Meta SPC with one use. The products are all intended for hand disinfection in food processing areas (industry, institutional and hospital kitchen areas) by industrial/professional users. The products are ready-to-use leave on disinfectants, applied manually (elbow lever or touchless) or automatic (pump), with a concentration range of 70-75 % w/w pure active substance (70.35-75.38 technical).

#### Physico-chemical properties

The product family consists of clear and colourless non-viscous liquids. The ambient temperature storage stability study supports a shelf-life of 4 years in packaging type applied for (HDPE bottles). The products are to be stored at 0 °C to 25 °C

Further requirements for storage:

Keep away from heat and sources of ignition. Keep in a cool, well-ventilated place. Keep away from oxidizing agents. Keep container tightly closed. Store in suitable labelled containers.

According to the CLP criteria regarding physical hazards, the product family is 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.

A GC-FID analysis method is presented to monitor the concentration of the active substance in the products. No other methods, for relevant impurities or substances of concern, are necessary

#### Efficacy

The product has been assessed using the Guidance on the Biocidal Products Regulation Efficacy - Assessment and Evaluation (Parts B+C) 2018 version 3.0. The product was shown

to be bactericidal, yeasticidal, tuberculocidal, virucidal against enveloped viruses and viruses (limited spectrum virucidal activity).

The product was shown to be efficacious with a contact time of 30 seconds in all tests except limited spectrum virucidal where a contact a time of 60 seconds was needed.

Due to the unspecific mode of action of propan-1-ol, the development of resistance is not expected and not reported. A natural resistance against sporulated bacteria is known where propan-1-ol is ineffective at any concentration.

### Human health

Hand disinfection products from this product family is limited to industrial and professional uses only. The human health risk assessments were conducted with the highest concentration of the active substance in the product family (75 % propan-1-ol).

Based on the active substance content the biocide product family is classified for:

- H318 - can cause serious eye damage;
- H336 - may cause drowsiness or dizziness;
- EUH066 - repeated exposure may cause skin dryness or cracking.

No substances of concern or alerts for endocrine disruptors are identified.

Read-across for dermal absorption to the propan-2-ol CAR was accepted.

#### *Professional user/ industrial user*

Primary exposure to professional use of hand disinfection occurs through dermal absorption when rubbing the substance to the skin (hand), maximum 10 times per day. Secondary exposure occurs via inhalation, since propan-1-ol is highly volatile. The exposure assessment of uptake both via skin and inhalation resulted in an exposure below the AEL (long-term) of 9.2 mg/kg bw/day.

A local qualitative risk assessment was performed due to the intrinsic properties (eye damage) of propan-1-ol. During application of the hand disinfection product no contact of the eyes is expected, however during re-filling of bottles eye protection is required. The product is not classified for skin irritation but the supplemental label phrase EUH066: Repeated exposure may cause skin dryness or cracking, has been added in line with both the CAR and the BPC opinion.

The identified risks can be handled through the following RMM:

- Avoid contact with the eyes;
- If refilling is needed, gloves and eye protection should be used;
- In case of skin dryness, use appropriate skin care lotion.

Human exposure to the biocidal products via food is not considered to be relevant. Residues in food from the intended use of propan-1-ol in PT 1 biocidal products are not expected, as no direct or indirect contact with food or feed is anticipated. Due to its high vapour pressure, the active substance evaporates before human exposure via food can occur.

## Environment

The Ecolab biocidal product family contains propan-1-ol as the only active substance and no substances of concern have been identified. Mixture toxicity is therefore not relevant.

Based on a quantitative risk assessment the biocidal product family can be concluded to present no unacceptable risks for the sewage treatment plant, surface water, sediment, soil compartment, or the atmosphere.

Based on the guidance provided in the Technical Agreements for Biocides Environment (ENV) July 2021, ENV 188, the use pattern of the biocidal product family and the properties of propan-1-ol, it can be concluded that exposure to groundwater will be negligible.

The risks of primary and secondary poisoning of non-targets organisms is assumed to be negligible due to the intended use as a hand disinfection product, and the low estimated BCF values in aquatic and terrestrial indicator species.

When using the products of the family "Ecolab UA BPF 1-Propanol" according to the conditions as stated in the SPC, the product will not present an unacceptable risk to the environment.

### 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-1-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 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 use 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 use, 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 use 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 authorised<sup>1</sup>, for the use described under section 2.1 of this opinion, subject to compliance with the proposed SPC.

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<sup>1</sup> 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.