

Biocidal Products Committee (BPC)

Opinion on the Union authorisation of
CVAS Disinfectant product based on Propan-2-ol

ECHA/BPC/222/2019

Adopted

28 February 2019

Opinion of the Biocidal Products Committee

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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: CVAS Disinfectant product based on Propan-2-ol

Authorisation holder: CVAS Development GmbH

Active substance common name: Propan-2-ol

Product types: 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 29 June 2016 recorded in R4BP3 under case number BC-DH025620-60, 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 17 August 2018. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-29) and its Working Groups (WG-VII-2018). 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 was reached on 28 February 2019.

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 is eligible for Union authorisation in accordance with Article 42(1) of Regulation (EU) No 528/2012.

The biocidal product meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012 and therefore may be authorised for the uses specified in this opinion. The detailed grounds for the overall conclusion are described in the PAR.

The BPC agreed on the draft SPC of CVAS Disinfectant product based on Propan-2-ol 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.

General

The biocidal product CVAS Disinfectant product based on Propan-2-ol is a ready to use liquid for indoor use containing 68.8% v/v equal to 61.25% w/w of the active substance propan-2-ol. No substance of concern has been identified in the biocidal product.

The biocidal product is used as a disinfectant for the disinfection of clean non-porous surfaces in industry, small enterprises, institutions and domestic area (PT2 - Disinfectants and algacides not intended for direct application to humans or animals) as well as in kitchens, canteens, food processing industry (including breweries) and for gardening equipment (for human hygiene purpose only; PT4 – Disinfectants in food and feed area) by non professionals as well as professionals. The ready-to-use liquid is intended to be sprayed onto a surface (disinfection without mechanical action), poured onto a surface and wiped afterwards or sprayed onto a surface and wiped afterwards (disinfection with mechanical action).

Physico-chemical properties

The physical, chemical and technical properties have been determined for the liquid biocidal product and deemed acceptable.

According to the CLP criteria, the biocidal product has to be classified with regard to physical hazards as follows: Flam. Liq.2; (Flammable liquids, hazard category 2); and H225: Highly flammable liquid and vapour. Therefore, the packaging has to be stored tightly closed and the product has to be stored cool (not above 30°C).

As the biocidal product has to be stored below 30°C the applicant has not provided an accelerated storage test. The long term storage stability tests show that all products are chemically and physically stable for two years. Therefore, a shelf life of 24 month can be granted.

Efficacy

The ready-to-use biocidal product "CVAS Disinfectant product based on Propan-2-ol" shows sufficient bactericidal and yeasticidal activity on pre-cleaned, non-porous surfaces at room temperature as substantiated according to European Standards (EN) for the disinfection of surfaces in industry, small enterprises, institutions and domestic area (PT 2) as well as in kitchens, canteens, food processing industry (including breweries) and for gardening equipment (PT 4) under the following conditions:

For spraying:

- Bactericidal: contact time: 5 min at 20°C;
- Yeasticidal: contact time: 15 min at 20°C.

For spraying and wiping and pouring and wiping:

- Bactericidal and yeasticidal: contact time: 5 min at 20°C.

To ensure the efficacy of the products, the following use conditions have to be included on the label: "Clean surfaces before use"; and "Make sure to wet surfaces completely".

Resistance is not reported or known currently.

Human health

Classification and Labelling

Based on the intrinsic properties of single components the biocidal product has to be classified "Eye Irrit. 2" with the hazard statement "Causes serious eye irritation" (H319).

In fact H319 triggers the precautionary statement "Wear eye protection/face protection" (P280) for professional use. However, for non-professional use correct use of personal protective equipment cannot be assumed. Based on a qualitative risk assessment an additional instruction labelling with "Avoid contact with eyes" and the other precautionary statements "IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing." (P305 + P351 + P338) and "If eye irritation persists: Get medical advice/attention." (P337 + P313) are considered sufficient to protect the non-professional user from the corresponding risk.

H319 also triggers the precautionary statement "Wash ... thoroughly after handling" (P264). This precautionary statement is not required since propan-2-ol and the whole biocidal product is very volatile and will be evaporate from contaminated skin rapidly. Thus, washing of hands or other body parts is not necessary.

Based on the intrinsic properties of single components the biocidal product has to be classified also "STOT SE 3" with the hazard statement "May cause drowsiness or dizziness" (H336).

This hazard statement would trigger the precautionary statement "IF INHALED: Remove person to fresh air and keep comfortable for breathing" (P304 + P340). According to the Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008 (2016) this precautionary statement is considered as optional. Based on the low hazard from acute inhalation of the biocidal product this precautionary statement is not required.

Additionally, the supplemental hazard statement "Repeated exposure may cause skin dryness or cracking" (EUH066) has to be indicated on the label.

Professional use

For the purpose of the human health risk assessment, direct exposure to propan-2-ol arising from professional use via the inhalative and dermal route is considered. The exposure path for secondary exposure is arising only from inhalative exposure. Dietary exposure to humans of propan-2-ol as a biocide of PT 2 or PT 4 can be excluded due to use descriptions and the high vapour pressure of the active substance propan-2-ol at room temperature.

For the professional user the following scenarios have been assessed:

Scenario	Primary or secondary exposure Description of scenario
Small surface disinfection – in - between (PT 2)	<p>Primary exposure of the professional user resulting from application (pouring & wiping, spraying & wiping, spraying) of a propan-2-ol based disinfectant in form of a ready-to-use product on small surfaces in naturally ventilated rooms e.g. a patient room in a hospital.</p> <p>Secondary exposure of a professional bystander who is present in the patient room where the surface disinfection is carried out.</p>
Small surface disinfection in laboratory and medical practice (PT 2)	<p>Primary exposure of the professional user resulting from application (pouring & wiping, spraying & wiping, spraying) of a propan-2-ol based disinfectant in form of a ready-to-use product on small surfaces in technically ventilated rooms e.g. a work bench in a laboratory.</p> <p>Secondary exposure of a professional bystander who is present in the laboratory where the surface disinfection is carried out.</p>
Refilling	<p>Decanting/Refilling of disinfectant from canisters (5 - 50 L), drums (200 - 220 L), or Intermediate Bulk Container (IBC) (720 L) into handy sized packages (manually or with hand pumps, connecting lines).</p> <p>Secondary exposure of a professional bystander is expected.</p>
Small surface disinfection in kitchens and canteens (PT 4)	<p>Primary exposure of the professional user resulting from application (pouring & wiping, spraying & wiping, spraying) of a propan-2-ol based disinfectant in form of a ready-to-use product on small surfaces in food contact areas e.g. a work bench in a kitchen.</p> <p>Secondary exposure of a professional bystander who is present in the kitchen or canteen where the surface disinfection is carried out.</p>
Disinfection of food processing machinery (PT 4)	<p>Primary exposure of the professional user resulting from application (pouring & wiping, spraying & wiping, spraying) of a propan-2-ol based disinfectant in form of a ready-to-use product on food processing machinery and its parts in a technically ventilated production hall of e.g. a bakery (20° C), including lower temperatures e.g. in a meat processing factory (10 °C).</p>

Scenario	Primary or secondary exposure Description of scenario
Small surface disinfection of gardening equipment (PT 4)	<p>Primary exposure of the professional user resulting from application (pouring & wiping, spraying & wiping, spraying) of a propan-2-ol based disinfectant in form of a ready-to-use product for disinfection of gardening equipment.</p> <p>Secondary exposure of a professional bystander who is present in the room where the disinfection of gardening equipment is carried out.</p>

The applications assessed according to the listed scenarios are considered to represent a realistic worst case for all other potential applications. Also combined scenarios (including application and refilling) have been assessed. The assessment of the scenarios small surface disinfection - in-between disinfection, small surface disinfection in laboratory and medical practice, refilling, small surface disinfection in kitchens and canteens and disinfection of food processing machinery resulted in no risks for the professional user already in tier 1. For the scenario small surface disinfection of gardening equipment a risk for professional users was identified. However, when risk mitigation measures (increase of the air exchange rate to 2.5 per hour) are implemented the risk characterisation results in a safe use. Also, a risk characterisation for combined scenarios is carried out taking into account the refilling scenario in addition to the disinfection scenarios assessed for laboratory and medical practice (PT 2), in kitchens and canteens (PT 4), food processing machinery (PT 4) or gardening equipment (PT 4) respectively.

The systemic risk characterisation as well as the assessment of the local eye and skin effects of the biocidal product CVAS Disinfectant product based on Propan-2-ol via the inhalation and dermal route for these combined scenarios result in a safe use, when risk mitigation measures are implemented in tier 2.

Thus, the following instructions for use, occupational hygiene and risk mitigation measures are taken into account in order to ensure safe use of the biocidal product CVAS Disinfectant product based on propan-2-ol:

- For disinfection of small surfaces: Avoid contact with eyes;
- For disinfection of food processing machinery and refilling procedure: The use of eye protection during handling of the product is recommended;
- For disinfection of gardening equipment (PT04 professional): Provide adequate ventilation (industrial ventilation or keeping windows and doors open);
- Do not apply more than 50 ml per m²;
- The product must only be applied for disinfection of small surfaces;
- Used wipes must be disposed in a closed container;
- For refilling a funnel must be applied.

Non-professional user and non-professional bystander (general public)

For the purpose of the human health risk assessment, direct exposure to propan-2-ol arising for non-professional use via the inhalative and dermal route. The exposure path for secondary exposure is arising only from inhalative exposure. No residues in food or feed are expected to arise from the use of the product (PT 4) due to the high vapour pressure of the active substance (5780 Pa at 25°C).

For the non-professional user following scenarios have been assessed:

Scenario	Primary or secondary exposure Description of scenario	Exposed group
Application: small surface disinfection in bathrooms (PT 2)	Primary exposure of the non-professional user resulting from application (pouring & wiping, spraying & wiping, spraying) of an alcohol based disinfectant in form of a ready-to-use product on small surfaces	non-professionals
Application: small surface disinfection in kitchens and of gardening equipment (PT 4)	Primary exposure of the non-professional user resulting from application (pouring & wiping, spraying & wiping, spraying) of an alcohol based disinfectant in form of a ready-to-use product on small surfaces	non-professionals
Secondary exposure: small surface disinfection in bathrooms (PT 2)	Secondary exposure of a person of the general public (adult) who is present the room where the surface disinfection is carried out	general public, bystanders
Secondary exposure: small surface disinfection in bathrooms (PT 2)	Secondary exposure of a person of the general public (child) who is present in the room where the surface disinfection is carried out	general public, bystanders
Secondary exposure: small surface disinfection in bathrooms (PT 2)	Secondary exposure of a person of the general public (toddler) who is present in the room where the surface disinfection is carried out	general public, bystanders
Secondary exposure: small surface disinfection in kitchens and of gardening equipment (PT 4)	Secondary exposure of a person of the general public (adult) who is present the room where the surface disinfection is carried out	general public, bystanders
Secondary exposure small surface disinfection in kitchens and of gardening equipment (PT 4)	Secondary exposure of a person of the general public (child) who is present in the room where the surface disinfection is carried out	general public, bystanders
Secondary exposure small surface disinfection in kitchens and of gardening equipment (PT 4)	Secondary exposure of a person of the general public (toddler) who is present in the room where the surface disinfection is carried out	general public, bystanders

The applications assessed according to the listed scenarios are considered to represent also a realistic worst case for all other potential applications. Also combined scenarios have been assessed.

For non-professionals it can be generally assumed that they are adults or at least adolescents. Thus, the AEL for professionals is also applicable for this sub-population and for risk characterisation of non-professional primary exposure.

A human health risk has been identified for the combined primary exposure to PT 2 and PT 4 applications. Safe use is expected if application frequency for PT 2 does not exceed 3 times per day. Hence, the non-professional user has to be informed on the daily maximum application frequency. Assuming that the same product is used for both PT the maximum frequency is 4 d⁻¹. Taking this into account no human health risk from use of biocidal product by non-professional users was identified if the biocidal product is used as intended.

Also no risks from secondary exposure for the general public and bystanders were identified if all RMM and the instructions for use are followed. Based on the risk assessment for Scenario 3 (PT 2) and Scenario 4 (PT 4), re-entry of non-involved third parties, particularly toddlers and children to rooms, where treatment took place, is only acceptable after adequate ventilation.

Human health hazard for non-professionals based on the classification of the biocidal product as Eye Irrit. 2 (H319) and STOT SE 3 (H336) can be sufficiently controlled by the corresponding precautionary statements. In addition, a labelling advice to avoid contact to eyes is required. Specific local effects for the general public are not expected.

The following instructions for use and risk mitigation measures are taken into account in order to ensure safe use of the biocidal product CVAS Disinfectant product based on Propan-2-ol:

- For the non-professional uses only: the authorisation holder has to specify the typical application rate in a simple, easily understandable form on the label:
 - Trigger spray: Apply 20 spray strokes per 0.5 m²;
 - Pump spray: Apply 3 jets per 100 cm²;
 - Bottle: Apply one measuring cup per m²;
- Keep out of reach of children and pets;
- Avoid contact with eyes;
- Do not apply in the presence of small children;
- Keep children and pets away from rooms, where disinfection is taking place. Provide adequate ventilation before children enter treated rooms;
- Do not use for more than 4 applications per day.

Environment

As concluded in the product assessment report no unacceptable risks for the environment were identified, neither for surface water, sewage treatment plant, sediment, soil or groundwater. Furthermore, propan-2-ol does not fulfil the PBT- nor the vP/vB-criteria and there are no indications for endocrine disrupting properties of the active substance as well as for the co-formulants in the biocidal product. Thus, from the environmental point of view, the provisions for the authorisation of the biocidal product CVAS Disinfectant product based on Propan-2-ol are met.

Overall conclusion

The BPC considers that using the product according to the conditions as stated in the SPC, the product will be efficacious and will not present an unacceptable risk to human and animal health nor the environment.

b) Presentation of the biocidal product including classification and labelling

The description of the biocidal product is available in the SPC.

The hazard and precautionary statements of the biocidal product 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 assessments 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 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 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 have been evaluated.

The chemical identity, quantity and technical equivalence requirements for the active substance in the biocidal product are met.

The physico-chemical properties of the biocidal product 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 is sufficiently effective;
2. the biocidal product has no unacceptable effects on the target organisms, in particular unacceptable resistance or cross-resistance;
3. the biocidal product 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 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.

2.2 BPC opinion on the Union authorisation of the biocidal product

It is proposed that biocidal product shall be authorised, for the uses described under section 2.1 of this opinion, subject to compliance with the proposed SPC.

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Annex I: Draft Summary of Product Characteristics