Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the single biocidal product

Soft Care Med H5

ECHA/BPC/401/2023

Adopted

22 November 2023

Opinion of the Biocidal Products Committee

on the Union authorisation of single biocidal product Soft Care Med H5

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:	**Soft Care Med H5**
Authorisation holder:	**Diversey Europe Operations B.V.**
Active substances common name:	**Propan-1-ol (CAS 71-23-8)**
	Propan-2-ol (CAS 67-63-0)
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 29 March 2019, recorded in R4BP3 under case number BC-MF050448-40, 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 July 2023. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-49) and its Working Groups (WG-III-2023). Revisions agreed upon were presented and the draft PAR and the draft SPC were finalised accordingly.

Adoption of the BPC opinion

Rapporteur: The Netherlands

The BPC opinion on the Union authorisation of the biocidal product was reached on 22 November 2023.

The BPC opinion was adopted by consensus.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the single biocidal product is eligible for Union authorisation in accordance with Article 42(1) of Regulation (EU) No 528/2012, as defined in Article 3(r).

The single 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 Soft Care Med H5 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

General

Soft Care Med H5 is used for the disinfection of hands by both professional, industrial and non-professional users and for the surgical disinfection of hands by professionals in hospitals. All uses fall under PT1. The applicant applied for two uses.

The biocidal product Soft Care Med H5 contains the active substances propan-1-ol (2.96% w/w) and propan-2-ol (70% w/w). An overview of the authorised uses is given in the following table:

AS content (%)	Substance of concern	User category	Use #	Use assessed	Use proposed to be authorised
propan-1-ol (2.96% w/w) propan-2-ol (70% w/w)	No substance of concern	Professional /industrial and Non-professional	#1	PT1: Hand disinfection use indoor and outdoor	Yes
propan-1-ol (2.96% w/w) propan-2-ol (70% w/w)	No substance of concern	Professional	#2	PT1: Surgical hand disinfection use indoor	Yes

Physico-chemical properties

Based on the provided storage stability studies, it can be concluded that the product is stable up to 2 years of storage in the commercial packaging materials High-density polyethylene (HDPE) and Low-density polyethylene (LDPE) when stored away from light at temperatures not exceeding 30°C.

The assessment of the physical hazards indicate that the product is to be classified as a Flammable Liquid Cat.2 (H225). No classification related to other physico-chemical risks is necessary.

The analytical methods (GC-FID) for the determination of both active substances are available and fully validated.

Efficacy

The target organisms are bacteria, yeast, tuberculosis bacilli, enveloped viruses and limited spectrum viruses (use #1) and bacteria, yeast, tuberculosis bacilli and limited spectrum viruses (use #2). Efficacy for both uses is substantiated by the required tests as described in the BPR efficacy guidance. It is therefore concluded that the use of Soft Care Med H5 as a hand disinfectant is acceptable.

Human health

Based on the active substance content, Soft Care Med H5 is classified as:

• Eye Irr. 2 - H319: Causes serious eye irritation

• STOT SE 3 - H336: May cause drowsiness or dizziness

A qualitative risk assessment for local effects during eye contact was performed due to the classification as H319.

Exposure of professional/industrial and non-professional users was evaluated for dermal and inhalation exposure routes and the inhalation route for professional bystanders for the scenarios summarised in the table below:

Scenario	**Primary and secondary exposure and description of the scenario**	**Conclusion of systemic exposure**
1a.	Primary exposure for professional users: dermal and inhalation exposure during decanting of the product from a larger container into a smaller container	Acceptable
1b.	Primary exposure for professional/industrial users: Hand disinfection: The product is applied directly to hands, up to 25 times/day.	Acceptable
2.	Primary exposure for professional/industrial users: Surgical hand disinfection: The product is applied directly to hands and forearms, up to 4 surgical hand rubs per shift.	Acceptable
3.	Secondary exposure for professional bystanders: Exposure of bystanders who are present in the room or vicinity whilst hands are being disinfected.	Acceptable
4.	Primary exposure for non-professional users (adults): Hand disinfection: The product is applied directly to hands, with user remaining in the same room and applying the product 3 times/day (long exposure duration)	Acceptable
5.	Primary exposure for non-professional users (adults): Hand disinfection: The product is applied directly to hands, with user not remaining in the same room and applying the product 8 times/day (short exposure duration)	Acceptable
6.	Primary exposure for non-professional users (toddlers): Hand disinfection: The product is applied directly to hands, up to 3 times per day.	Acceptable
7.	Secondary exposure for bystanders (): Exposure of bystanders who are present in the room or vicinity whilst hands are being disinfected.	Acceptable

The risk assessment for professional/industrial users, non-professional users and the general public (including bystanders) showed that no systemic health effects are expected due to exposure to propan-1-ol and propan-2-ol following use of the biocidal product in accordance with the SPC.

The local risk has been considered acceptable for all uses if the risk mitigation measures "Avoid contact with eyes" is implemented.

Residues in food or feed from the intended uses of the biocidal product are not expected. Due to the relatively high vapour pressures of propan-1-ol and propan-2-ol, the active substances are expected to evaporate completely within the time of application of the product to the treated hands. Therefore, no transfer of product residues from hands to food will occur. If in the unlikely event that residue transfer was to occur, the active substances will evaporate from the food before it is eaten. Therefore, dietary exposure from the use of the biocidal product is not expected.

Environment

The biocidal product Soft Care Med H5 is used as a human hygiene biocidal product (hand disinfectant) and will not be poured down the drain. The relatively high vapour pressures of propan-2-ol and propan-1-ol means that they will evaporate within a few minutes after application onto hands which are not likely to be washed before complete evaporation has occurred. Therefore the primary emission route to the environment will be to air not to the STP (via drain). An environmental risk assessment has been performed using the same assumption given in the Assessment Reports for both actives propan-2-ol and propan-1-ol, that 10% of each alcohol is emitted to waste water and therefore 90% of the applied propan-2-ol and propan-1-ol is emitted to air.

The biocidal product is used only on hands and hence there are no direct emissions to soil or water and no direct release to drain.

Evaporation to air or to the drain does not result in unacceptable risks for the environment as all predicted environmental concentrations (PECs) are well below the predicted no-effect concentrations (PNEC).

No unacceptable effect to the environment is expected for the product, neither for the sewage treatment plant, the aquatic compartment nor for the terrestrial compartment. No unacceptable risk of primary poisoning or secondary poisoning through the aquatic or the terrestrial food chain is to be expected.

The threshold value was exceeded for groundwater. However, at WG-VII-2018, it was agreed that for alcohols in general used in PT 2, 4 with a release path via air and via active sludge on land, no assessment for the groundwater compartment is needed. In these situations, FOCUS PEARL is unlikely to provide realistic concentrations and no risk for groundwater is assumed, based on expert judgement. It is considered that the whole feedback from the WG is also applicable to PT1. Taking precedence from the WG opinion, the exceedance of the groundwater trigger value for the intended uses of the product is considered acceptable.

b) Presentation of the biocidal product including classification and labelling

The description of the biocidal product and of the structure 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 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 substances propan-1-ol and propan-2-ol contained in the biocidal product do not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and are not considered as candidates for substitution. Therefore, no comparative assessment of the biocidal product was performed.

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 substances 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 or unnecessary suffering and pain for vertebrates;
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/biocidal product family

As the conditions of Article 19(1) are met it is proposed that the single biocidal product shall be authorised, for the uses described under section 2.1 of this opinion.

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