Biocidal Products Committee (BPC)

Opinion on the Union authorisation of

Clearklens product based on IPA

ECHA/BPC/236/2019

Adopted

11 December 2019

Opinion of the Biocidal Products Committee

on the Union authorisation of

the Clearklens product based on IPA

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: Clearklens product based on IPA

Authorisation holder: Diversey Europe Operations B.V.

Active substance common name: Propan-2-ol

Product type: 2

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 May 2016, recorded in R4BP3 under case number HD024462-61, the evaluating Competent Authority (The Netherlands) submitted a draft product assessment report (PAR) containing the conclusions of its evaluation and the draft Summary of Product Characteristics (SPC) to ECHA on 3 June 2019. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-33) and its Working Groups (WG September 2019). 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 adopted on 11 December 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 biocidal product 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.

The biocidal product may be expected to fulfil 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 the Clearklens product based on IPA referred to in Article 22(2) of Regulation (EU) No 528/2012 (Annex I to this BPC opinion).

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 'Clearklens product based on IPA' contains the active substance propan-2-ol (63.1% w/w, 70% v/v) for non-porous hard surface and non-porous glove disinfection by professional users. No substances of concern are identified.

The following uses have been assessed:

- Use 1: Non-porous hard surface disinfectant – professionals – mopping;
- Use 2: Non-porous hard surface disinfectant – professionals – cloth;
- Use 3: Non-porous hard surface disinfectant – professionals – spraying;
- Use 4: Non-porous glove disinfectant – professionals – non-porous glove disinfection.

Use 1 is proposed for pharmaceutical and cosmetics manufacturing facilities and cleanrooms, while Use 2-4 are proposed for pharmaceutical and cosmetics manufacturing facilities, cleanrooms and for laboratories.

Physico-chemical properties

All physical and chemical properties were adequately addressed and it is expected the product can be applied as intended. The product is a transparent liquid with an alcohol-like odour. It has a shelf-life of 2 years in all packaging types applied for. It should be stored at temperatures below 30°C.

With regard to classification and labelling, the product is a category 2 flammable liquid (H225). It is not oxidising, explosive or auto-flammable.

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

Efficacy

The four claimed uses include non-porous hard surface and non-porous glove disinfection for professionals. In all uses efficacy against bacteria and yeast is claimed after a contact time of 30 seconds under clean conditions. All four uses include ready to use liquid, but differ in the application; mopping, wiping with cloth, spraying and non-porous glove disinfection. The biocidal product was demonstrated to be efficacious against bacteria and yeasts in phase 2 step 1 and phase 2 step 2 tests according to the European Standards EN 1276, EN 1650 and EN 13697 under clean conditions. These tests demonstrate efficacy of the biocidal product for the claimed disinfection of non-porous hard surfaces and non-porous gloves when used according to the use instructions.

Human health

The biocidal product 'Clearklens product based on IPA' is used by professionals in controlled environments such as cleanrooms. Based on the active substance content, the product is classified for:

- Eye irritation cat. 2 - H319: Causes serious eye irritation;
- STOT SE 3 - H336: May cause drowsiness or dizziness;
- EUH066: Repeated exposure may cause skin dryness or cracking.

Professional users are exposed through hard surface disinfection by mopping (only authorised in cleanrooms, pharmaceutical and cosmetic manufacturing facilities), wiping, or by trigger spraying, or through glove disinfection. Exposure may be primary and secondary (bystander inhalation exposure).

Secondary exposure (bystander inhalation exposure) for members of the general public is excluded considering the product is used in controlled environments only.

Professional user risk assessment

Due to the high volatility of propan-2-ol, inhalation of vapour is the major route for exposure for professionals. The calculation of exposure to vapour depends on many different parameters such as room size, ventilation rate of the room, application rate, product amount applied in a room and disinfection frequency. There is a HEAd hoc recommendation no.15 for these key parameters in cleanrooms. However, for this product different parameters than the harmonised values are used (based on the applicant information), as summarised in the table below:

Parameter	Cleanrooms	Pharmaceutical and cosmetic manufacturing facilities	Laboratories
Room volume	55 m^3	80 m^3	25 m^3
Ventilation rate	150 h^{-1}	60 h^{-1}	8 h^{-1}
Disinfection frequency	Mopping – 3 times/day Wiping – 20 times/day Spraying- 80 times/day Gloves- 80 times/day	Mopping – 1 time/day Wiping – 5 times/day Spraying- 80 times/day Gloves- 40 times/day	Wiping – 10 times/day Spraying- 10 times/day Gloves- 10 times/day

Due to the high volatility of propan-2-ol, inhalation is the primary exposure route. Exposure level via inhalation is influenced by different factors, and one of the important elements is the ventilation rate (air exchange rate) of the room. For this product high ventilation rates are assumed for the exposure assessment, as proposed by the applicant. In order to ensure these ventilation rates are used in practice the following risk mitigation measure is added: the product may be applied only in a sufficiently ventilated room. The minimum air change rates required are: 8/h in laboratories; 60/h in pharmaceutical and cosmetics manufacturing facilities; and 150/h in cleanrooms.

The active substance assessment for propan-2-ol informs that the AEC for professional users of 52.6 ppm for 8 hours/day (converted to a systemic AEL of 17.9 mg/kg bw/d) also sufficiently covers local irritant effects in the eyes/airways.

As the worst case, exposure of different activities (e.g. mopping, wiping) are combined to assume all disinfection will take place in one room within a day. When taking into account primary exposure from application of this product the following conclusions can be drawn:

- Cleanroom: acceptable exposure equivalent to 77% of the AEL with PPE (gloves);
- Pharmaceutical and cosmetic manufacturing facilities: acceptable exposure equivalent to 40% of the AEL with PPE (gloves);
- Laboratories (without mopping): acceptable exposure equivalent to 95% of the AEL with PPE (gloves).

Regarding secondary exposure of the bystanders (professionals present in the same room) from inhalation of volatalised residues the following conclusion can be drawn: as acceptable exposure has been identified for all professional user scenarios without RPE (respiratory protective equipment) no additional RMMs are required.

Environment

The biocidal product is used in laboratories, cleanrooms and pharmaceutical and cosmetics manufacturing facilities and therefore will not be poured down the drain. The high vapour pressure of propan-2-ol means that it will evaporate within a few minutes after application onto surfaces and therefore the primary emission route to the environment will be to air, not to the STP (via drain). A quantitative environmental risk assessment has been performed for propan-2-ol that 10% is emitted to waste water and therefore 90% of the applied propan-2-ol is emitted to air.

The biocidal product is used indoors only and hence there are no direct emissions to soil, water or surfaces and there is 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).

Therefore, there is no concern to the atmospheric-, STP-, aquatic- and terrestrial compartment from use of this product in accordance with the label instructions. Furthermore, no concern is identified for primary and secondary poisoning.

Overall conclusion

The BPC considers that using this biocidal 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 are available in the SPC.

c) Description of uses proposed to be authorised

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 family 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 products 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 products on non-target organisms,
- the impact of the biocidal products on biodiversity and the ecosystem.

The outcome of the evaluation, as reflected in the PAR, is that the intended uses, described in the SPC, may be authorised.

2.2 BPC opinion on the Union authorisation of the biocidal product family

It is proposed that biocidal product 'Clearklens product based on IPA' 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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