Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the single biocidal product

ClearKlens wipes based on IPA

ECHA/BPC/402/2023

Adopted

22 November 2023

Opinion of the Biocidal Products Committee

on the Union authorisation of the single biocidal product ClearKlens wipes 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 wipes based on IPA**
Authorisation holder:	**Diversey Europe Operations B.V.**
Active substance common name:	**Propan-2-ol (CAS No. 67-63-0)**
Product type:	**PT 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 10 March 2020, recorded in R4BP3 under case number BC-XF057810-33, 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. 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 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 ClearKlens wipes based on IPA 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

The biocidal product ClearKlens wipes based on IPA is used for disinfection of non-porous hard surfaces by wiping (use #1) and mopping (use #2) in laboratories, cleanrooms, and pharmaceutical and cosmetics manufacturing facilities as well as for disinfection by wiping (use #3) of equipment and small surfaces in facilities (including hospitals, nursing homes and medical practices) with ready-to-use (RTU) wipes. All uses fall under PT2. The applicant applied for three uses and the product is used by professional and industrial users only.

ClearKlens wipes based on IPA contains propan-2-ol (CAS No. 67-63-0; 62.5% w/w) as active substance. 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
62.5% w/w propan-2-ol	No substance of concern	Industrial / Professional	#1	PT2: Hard surface disinfectant - wiping use Indoors	Yes
62.5% w/w propan-2-ol	No substance of concern	Industrial / Professional	#2	PT2: Hard surface disinfectant – mopping use Indoors	Yes
62.5% w/w propan-2-ol	No substance of concern	Industrial / Professional	#3	PT2: Hard surface disinfectant – wiping (equipment and small surfaces) use Indoors	Yes

Physico-chemical properties

The biocidal product ClearKlens wipes based on IPA is a colourless clear liquid which is used to presaturate wipes. The supported shelf-life is 24 months in Polyethylene terephthalate (PET) or Low-density polyethylene (LDPE) or High-density polyethylene (HDPE) for polyester (PS) or polypropylene (PP) or PS/Cellulose wipes. The product should be stored away from direct sunlight and below 40°C. A fully validated analytical method (GC-FID) was used to determine the amount of the active substance propan-2-ol. With respect to the physical hazards and respective characteristics, the biocidal product is classified as H225 Highly flammable liquid and vapour, category 2.

Efficacy

The efficacy data provided demonstrate that the RTU wipes are efficacious against bacteria and yeast under clean conditions with a contact time of 5 minutes.

Human health

The product ClearKlens wipes based on IPA is used for disinfection by professional and industrial users in two different areas: in industrial areas (pharmaceutical/cosmetic industry, cleanrooms, laboratories) and in health care areas. The product is classified according to CLP with H319: Causes serious eye irritation, H336: May cause drowsiness or dizziness and with EUH066: Repeated exposure may cause skin dryness or cracking.

All exposure scenarios show acceptable systemic and local exposure towards the active substance propan-2-ol. No adverse health effects are therefore expected for ClearKlens wipes based on IPA when the product is applied according to the use description. Due to the combined exposure, a minimum ventilation rate of 20/h is required when applying the product in cleanrooms. For use in other areas (including hospitals, nursing homes and medical practices) a minimum air change rate of 1.5/h applies, for laboratories this is 8/h and for pharmaceutical and cosmetics manufacturing facilities a minimum air change rate of 60/h applies. Use of gloves (EN 374) during application is required to prevent potential skin effects (skin dryness or cracking). The remark "avoid contact to eyes" has been included based on the local risk assessment.

All exposure scenarios for the general public show acceptable secondary systemic and local exposure towards the active substance propan-2-ol when the biocidal product ClearKlens wipes based on IPA is applied according to the use description. Potential dermal exposure to the general public can be neglected due to rapid evaporation and since the biocidal product is only used by professional and industrial users.

For secondary exposure, no adverse health effects are therefore expected for ClearKlens wipes based on IPA.

No exposure to food and animals is expected during the use of ClearKlens wipes based on IPA.

Environment

The biocidal product is used in laboratories, cleanrooms and pharmaceutical and cosmetics manufacturing facilities. The product is a leave-on product that is applied by pre-soaked tissues and not classified for environmental hazards. 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 the air and not to the sewage treatment plant (STP), via the drain.

Nevertheless, a quantitative environmental risk assessment has been performed for propan-2-ol released to the municipal sewer based on the assumption 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.

In addition, at AHEE-2 (December 2018), the following conclusion was drawn regarding the environmental exposure due to the disinfection of surfaces with RTU wipes in PT 2 and PT 4: 'The WG agreed that for pre-soaked RTU wipes containing very volatile AS (according to the VOC directive), where no rinsing occurs, no exposure and risk assessment is needed.'

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).

In addition, ENV 188 of the TAB provides the following additional argumentation: 'for products containing very volatile substances (according to the VOC directive) used in general, i.e., it is not distinguished between professionals and non-professionals, there is no need to conduct a risk assessment for subsequent environmental compartments following the release path via air. This conclusion concerns all relevant PTs. Specifically for the subsequent environmental compartment groundwater it should be further noted that exceedance of the groundwater trigger value is not likely''.

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

b) Presentation of the biocidal product/biocidal product family 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 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. Therefore no comparative assessment 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 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 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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