Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the biocidal product

Bioquell HPV-AQ

ECHA/BPC/296/2021

Adopted

13 October 2021

Opinion of the Biocidal Products Committee

on the Union authorisation of Bioquell HPV-AQ

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:	**Bioquell HPV-AQ**
Authorisation holder:	**Ecolab Deutschland GmbH**
Active substance common name:	**Hydrogen peroxide**
Product types:	**PT 2, 3 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 19 January 2017, recorded in R4BP3 under case number BC-ML029042-45, 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 29 March 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-40) and its Working Groups ([WG II 2021]). 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 13 October 2021.

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 Bioquell HPV-AQ 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 Bioquell HPV-AQ is a 35% aqueous hydrogen peroxide solution used in combination with the Bioquell Hydrogen Peroxide Vapour system, for professional use only. The product is vapourised in the machine and introduced into an enclosed sealed space, where air saturation and microcondensation occurs, resulting in disinfection of all exposed surfaces. The biocidal product does not contain non-active substances identified as a substance of concern.

The biocidal product Bioquell HPV-AQ has two intended uses: surface disinfection of small (0.25 – 4 m^3) and large (> 4 m^3) sealed enclosures, both for PT 2, 3 and 4 applied by vapourisation, for professional use only. The biocidal product has to be used with a device from a range of Bioquell devices under the name: "Bioquell vaporisation module".

Physico-chemical properties

The physical, chemical and technical properties of the product were sufficiently described. The active substance supplier provided information on the stabilizer(s) present in their hydrogen peroxide. Based on the information provided a shelf life of 18 months in HDPE commercial packaging at temperatures between 4 and 25 °C is supported. The product should not be stored at temperatures above 35 °C and should be protected from frost.

Based on known experience from the UN Transport Regulation, products with 20 to 60% hydrogen peroxide should be classified as oxidising liquid category 2. Hence, H272 is assigned to Bioquell HPV-AQ. Bioquell HPV-AQ is not corrosive to metals.

The analytical method (titration) used to determine the content of active substance has been fully validated as part of the active substance dossier.

Efficacy

Efficacy against bacteria, yeast, fungi, viruses, bacterial spores, mycobacteria and bacteriophages was evaluated for the two intended uses: surface disinfection of large

enclosures and small enclosures, both for PT 2, 3 and 4 applied by vapourisation. For both uses efficacy is demonstrated for PT 2 and 4. For PT 3 only a specific claim "pre-cleaned animal cages/racks within biomedical and animal laboratory facilities" is made. For this claim efficacy is demonstrated.

Human health

Bioquell HPV-AQ is classified as follows according to the harmonized classification and the information provided for the active substance as:

- Acute Tox 4, Oral.: H302 – Harmful if swallowed.
- Skin Irrit 2.: H315 – Causes skin irritation.
- Eye Dam 1.: H318 – Causes serious eye damage.
- STOT SE 3, Inhalation.: H335 – May cause respiratory irritation.

A (semi-) quantitative risk assessment was peformed for the inhalation route and a qualitative risk assessment was performed for all relevant routes of exposure (i.e. oral, dermal, inhalation).

Risk for professional users

Depending on the size of the enclosed space, decontamination can be performed up to 4 times a day.

Loading of the product onto the system is mainly performed using a closed dosing system; i.e. the sealed container is loaded directly into the machine. However, in some cases the operator may be required to manually pour the product into the machine.

After the disinfection dwell time is completed, the enclosed space is aerated. Re-entry to the treated area is only allowed after monitors indicate that the hydrogen peroxide levels in air are below the AEC of 1.25 mg/m^3 (0.9 ppm). Technical and engineering risk mitigation measures (RMMs) have to be in place to limit secondary exposure to hydrogen peroxide aerosols.

Based on the risk assessment, it is concluded that no adverse health effects are expected for the professional user after dermal and respiratory exposure to hydrogen peroxide as a result of the application of Bioquell HPV-AQ in accordance with the labelling instructions.

When the operator must open the product packaging for manual pouring of the product into the machine, professional exposure to the products is acceptable with the use of technical and organisational RMM, i.e. the use of Personal Protective Equipment (PPE) including gloves, coverall and goggles.

Should a user have cause to enter an enclosure before the concentration of hydrogen peroxide is ≤1.25 mg/m^3 (0.9 ppm), respiratory protective equipment (RPE) (type of RPE to be specified by the authorisation holder within the product information) must be worn in addition.

Risk for consumers via residues in food

Bioquell's hydrogen peroxide process occurs within sealed enclosures. Once the hydrogen peroxide has been applied to the surfaces and left for the contact time indicated, an aeration phase is initiated which removes the hydrogen peroxide. The concentration of hydrogen peroxide in the air is in equilibrium with the concentration of the hydrogen peroxide on the surface, so as hydrogen peroxide is removed from the air, the peroxide on the surface comes off of the surface as it strives to attain the equilibrium with the air. Bioquell's use instructions contain the risk mitigation measures that the enclosure must not be reoccupied until the concentration in the enclosure is less than or equal to 1.25 mg/m^3 (0.9 ppm) and that a calibrated low level hydrogen peroxide monitor must be used to measure the concentration

in the room. The use of a quantitative measurement device to confirm that the hydrogen peroxide is at or below 0.9 ppm in the air ensures that the hydrogen peroxide concentrations on the surfaces is also below 0.9 ppm. Considering this and that hydrogen peroxide breaks down rapidly into oxygen and water it can be concluded that after finalisation of the disinfection no significant residue levels are present at the surfaces that could lead to dietary exposure. Subsequently, a dietary exposure assessment is not considered necessary.

Animal health:

The product is used for PT 3. However, no animal exposure will occur as animals are removed from the enclosure during gassing. The general risk mitigation measures include the following: "No person or animals are allowed to be present in a room during treatment". Hydrogen peroxide breaks down into oxygen and water leaving no residues, therefore no secondary exposure of animals is expected.

Environment

Based on the environmental risk assessment, it was concluded that no unacceptable environmental effects are expected as a result of the application of Bioquell HPV-AQ in accordance with the labelling instructions. No risk mitigation measures are required. Bioquell HPV-AQ product is classified as Aquatic Chronic 3.

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 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(s) Hydrogen peroxide 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 was not needed.

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 biocidal product shall be authorised[1] for the use described under section 2.1 of this opinion, subject to compliance with the proposed SPC**.**

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[1] 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.