

**COMMISSION IMPLEMENTING REGULATION (EU) 2022/1226**  
**of 14 July 2022**  
**granting a Union authorisation for the single biocidal product ‘Bioquell HPV-AQ’**  
**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products <sup>(1)</sup>, and in particular the first subparagraph of Article 44(5) thereof,

Whereas:

- (1) On 19 January 2017, Ecolab Deutschland GmbH submitted an application, in accordance with Article 43(1) of Regulation (EU) No 528/2012, for authorisation of a single biocidal product named ‘Bioquell HPV-AQ’ of product-types 2, 3 and 4 as described in Annex V to that Regulation, providing written confirmation that the competent authority of the Netherlands had agreed to evaluate the application. The application was recorded under case number BC-ML029042-45 in the Register for Biocidal Products.
- (2) ‘Bioquell HPV-AQ’ contains hydrogen peroxide as the active substance, which is included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012 for product-types 2, 3 and 4.
- (3) On 29 March 2021, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, an assessment report and the conclusions of its evaluation to the European Chemicals Agency (‘the Agency’).
- (4) On 4 November 2021, the Agency submitted to the Commission an opinion <sup>(2)</sup>, the draft summary of the biocidal product characteristics (‘SPC’) of ‘Bioquell HPV-AQ’ and the final assessment report on the single biocidal product in accordance with Article 44(3) of Regulation (EU) No 528/2012.
- (5) The opinion concludes that the biocidal product ‘Bioquell HPV-AQ’ is eligible for Union authorisation in accordance with Article 42(1) of that Regulation and that, subject to compliance with the draft SPC, it meets the conditions laid down in Article 19(1) of that Regulation.
- (6) On 25 November 2021, the Agency transmitted to the Commission the draft SPC in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.
- (7) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for ‘Bioquell HPV-AQ’.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

<sup>(1)</sup> OJ L 167, 27.6.2012, p. 1.

<sup>(2)</sup> ECHA opinion of 13 October 2021 on the Union authorisation of ‘Bioquell HPV-AQ’ (ECHA/BPC/296/2021), <https://echa.europa.eu/bpc-opinions-on-union-authorisation>

HAS ADOPTED THIS REGULATION:

*Article 1*

A Union authorisation with authorisation number EU-0027469-0000 is granted to Ecolab Deutschland GmbH for the making available on the market and use of the single biocidal product 'Bioquell HPV-AQ', in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 7 August 2022 until 31 July 2032.

*Article 2*

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 14 July 2022.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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## ANNEX

**Summary of product characteristics for a biocidal product**

Bioquell HPV-AQ

Product type 2 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

Product type 3 - Veterinary hygiene (Disinfectants)

Product type 4 - Food and feed area (Disinfectants)

Product type 2 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

Product type 3 - Veterinary hygiene (Disinfectants)

Product type 4 - Food and feed area (Disinfectants)

Authorisation number: EU-0027469-0000

R4BP asset number: EU-0027469-0000

1. ADMINISTRATIVE INFORMATION

1.1. **Trade name(s) of the product**

Trade name(s)	Bioquell HPV-AQ
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1.2. **Authorisation holder**

Name and address of the authorisation holder	Name	Ecolab Deutschland GmbH
	Address	Ecolab Allee 1, 40789 Monheim am Rhein Germany
Authorisation number	EU-0027469-0000	
R4BP asset number	EU-0027469-0000	
Date of the authorisation	7.8.2022	
Expiry date of the authorisation	31.7.2032	

1.3. **Manufacturer(s) of the product**

Name of manufacturer	Ecolab SNC
Address of manufacturer	153 Quai de Rancy, Bonneuil-sur-Marne, 94380 Paris France
Location of manufacturing sites	153 Quai de Rancy, Bonneuil-sur-Marne, 94380 Paris France 53 Royce Close, SP10 3TS Andover United Kingdom Unit E4, Eastway Business Park, Ballysimon Road, V94 K267 Limerick Ireland

1.4. **Manufacturer(s) of the active substance(s)**

Active substance	Hydrogen peroxide
Name of manufacturer	Evonik Peroxide Spain
Address of manufacturer	Beethoven 15, Sobreatico, 08021 Barcelona Spain
Location of manufacturing sites	C/ Afueras s/n La Zaida, 50784 Zaragoza Spain

## 2. PRODUCT COMPOSITION AND FORMULATION

2.1. **Qualitative and quantitative information on the composition of the product**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	35,0

2.2. **Type of formulation**

HN - Hot fogging concentrate

## 3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	<p>May intensify fire; oxidiser  Harmful if swallowed.  Causes skin irritation.  Causes serious eye damage.  May cause respiratory irritation.  Harmful to aquatic life with long lasting effects.</p>
Precautionary statements	<p>Keep away from clothing and other combustible materials.  Avoid breathing vapours.  Do not eat, drink or smoke when using this product.  Avoid release to the environment.  Wear protective gloves/protective clothing/eye protection.  IF SWALLOWED: Call a Poison Centre or doctor/physician if you feel unwell.  Rinse mouth.  IF ON SKIN: Wash with plenty of water.  If skin irritation occurs: Get medical attention.  Take off contaminated clothing. And wash it before reuse.  IF INHALED: Remove person to fresh air and keep comfortable for breathing.  IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  Immediately call a POISON CENTER or doctor/physician.  Call a POISON CENTER/doctor if you feel unwell.  In case of fire: Use water to extinguish.  Store in a well-ventilated place. Keep container tightly closed.  Store locked up.  Dispose of contents to waste in accordance with applicable local, national and international regulations.</p>

## 4. AUTHORISED USE(S)

## 4.1. Use description

Table 1.

**Use # 1 – Surface disinfection in small (0,25 m<sup>3</sup>-4 m<sup>3</sup>) enclosures**

Product type	PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants) PT03 - Veterinary hygiene (Disinfectants) PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: Bacteria Development stage: Common name: bacteria spores Development stage: Common name: Mycobacteria Development stage: Common name: Fungi Development stage: Common name: Yeasts Development stage: Common name: Viruses Development stage: Common name: bacteriophage Development stage:
Field(s) of use	Indoor Hard, non-porous surfaces in small (0,25 m <sup>3</sup> to 4 m <sup>3</sup> ) sealed enclosures by vaporisation, with prior cleaning. PT2 – clean conditions in, for example, isolators, pass-through chambers, cabinets, material airlocks, cupboards, filling lines, emergency vehicles. PT3 – pre-cleaned animal cages/racks within biomedical and animal laboratory facilities PT4 – clean conditions in, for example, aseptic filling lines, storage containers.
Application method(s)	Method: vaporisation Detailed description: Vaporisation with Bioquell Hydrogen Peroxide Vapour system followed by micro condensation – to deliver the disinfectant to surfaces in closed systems. Temperature range: room temperature Humidity range: 10 %-80 %
Application rate(s) and frequency	Application Rate: 100 g/m <sup>3</sup> of undiluted product, contact time of 35 minutes (after diffusion). Dilution (%): 0

	Number and timing of application: Users should carry out decontaminations in line with their requirements and operating procedures
Category(ies) of users	Professional
Pack sizes and packaging material	75 ml, 150 ml, 500 ml, 950 ml, 1 000 ml, 2 000 ml, 5 000 ml and 25 L. Bottles are constructed of HDPE

4.1.1. *Use-specific instructions for use*

See general directions for use.

4.1.2. *Use-specific risk mitigation measures*

See general directions for use.

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

Only recycle completely emptied packaging. Dispose of any residual product in accordance with EWC 160903

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

Protect from frost. Do not store at temperatures above 35 °C

Shelf life 18 months.

4.2. **Use description**

Table 2.

**Use # 2 – Surface disinfection within large (> 4 m<sup>3</sup>) enclosures**

Product type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT03 - Veterinary hygiene (Disinfectants) PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: Bacteria Development stage: Common name: Mycobacteria Development stage: Common name: Bacteria spores Development stage: Common name: Fungi Development stage: Common name: Yeasts Development stage:

	<p>Common name: Viruses Development stage:</p> <p>Common name: bacteriophages Development stage:</p>
Field(s) of use	<p>Indoor Hard, non-porous surfaces in large (&gt; 4 m<sup>3</sup>) sealed enclosures by vapourisation, with prior cleaning. PT2 – clean conditions in, for example hospitals, clean rooms, aseptic processing facilities, laboratories, nursing homes, research facilities, schools, cruise ships, emergency vehicles, veterinary hospitals (excluding animal housing), laboratories in veterinary institutions PT3 – pre-cleaned animal cages/racks within biomedical and animal laboratory facilities. PT4 – clean conditions in, for example, aseptic filling lines, food production facilities, storage containers</p>
Application method(s)	<p>Method: vapourisation</p> <p>Detailed description:</p> <p>Vapourisation with Bioquell Hydrogen Peroxide Vapour system followed by micro condensation – to deliver the disinfectant to surfaces in closed systems.</p> <p>Temperature range: Room temperature</p> <p>Humidity range: 10 %-80 %</p>
Application rate(s) and frequency	<p>Application Rate: 10 g/m<sup>3</sup> of undiluted product, contact time of 35 minutes (after diffusion)</p> <p>Dilution (%): 0</p> <p>Number and timing of application: Users should carry out decontaminations in line with their requirements and operating procedures.</p>
Category(ies) of users	Professional
Pack sizes and packaging material	75 ml, 150 ml, 500 ml, 950 ml, 1 000 ml, 2 000 ml, 5 000 ml and 25 L. Bottles are constructed of HDPE.

#### 4.2.1. Use-specific instructions for use

See general directions for use

#### 4.2.2. Use-specific risk mitigation measures

See general directions for use

#### 4.2.3. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use

4.2.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

Only recycle completely emptied packaging. Dispose of any residual product in accordance with EWC 160903

4.2.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

Protect from frost. Do not store at temperatures above 35 °C. Shelf life 18 months.

5. GENERAL DIRECTIONS FOR USE <sup>(1)</sup>

5.1. **Instructions for use**

Surfaces must be pre-cleaned and dry before disinfection and cupboard doors and drawers should be opened for the process to be effective.

Users should carry out decontaminations in line with their requirements and operating procedures.

For disinfection of pre-cleaned animal cages/racks within biomedical and animal laboratory facilities, disinfection can only take place on thoroughly cleaned non-porous surfaces (PT3), when possible use automated washing machines.

Do not mix with detergents or other chemicals. Undiluted.

Bioquell HPV-AQ is to be used with a Bioquell vaporisation module as a disinfectant for surfaces and other inanimate objects in enclosures.

Seal the enclosure (e.g. with tape) to ensure no leakage of the vaporised active substance outside the enclosure prior to initiating a cycle.

Refer to the Bioquell HPV-AQ Labelling insert prior to running a cycle.

At the end of the dwell period, the aeration phase is activated which removes the hydrogen peroxide. The aeration phase is deactivated by the user when the enclosure has been confirmed to be less than or equal to 1,25 mg/m<sup>3</sup> (0,9 ppm) using an independent calibrated low-level hydrogen peroxide sensor.

Biological validation should be performed for enclosures to be disinfected. Where environmental conditions within an enclosure are well controlled, a protocol for disinfection of the enclosure should be made and used thereafter. Validated quantitative chemical indicators can be used in place of biological indicators for routine disinfection.

Biological or chemical indicators shall be placed in the enclosure to validate the cycle.

Users should not carry out manual cleaning operations (for example sweeping) immediately post-decontamination.

5.2. **Risk mitigation measures**

No person or animals are allowed to be present in a room during treatment.

Treated areas may not be entered until the concentration of hydrogen peroxide is  $\leq 0,9$  ppm (1,25 mg/m<sup>3</sup>).

The professional user may only enter the room in emergency situations when the hydrogen peroxide level has dropped below 36 ppm (50 mg/m<sup>3</sup>) considering RPE with APF 40 (Type of RPE to be specified by the authorisation holder within the product information) and suitable protective equipment (gloves, eye protection, coverall) must be worn.

Use a calibrated sensor to confirm the enclosure is  $\leq 0,9$  ppm (1,25 mg/m<sup>3</sup>) prior to re-entry.

When opening the container and preparing contents wear suitable personal protective equipment (gloves, eye protection, coverall).

Wash hands after use.

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<sup>(1)</sup> Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.



5.3. **Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

Possible exposure effects:

Skin – chemical burn – transient, non-permanent whitening of the skin

Eyes – potential for permanent damage

Inhalation - irritation of the throat and nose

**IF INHALED:** Move to fresh air and keep at rest in a position comfortable for breathing.

If symptoms: Call 112/ambulance for medical assistance.

If no symptoms: Call a POISON CENTRE or a doctor.

Information to Healthcare personnel/doctor:

Initiate life support measures if needed, thereafter call a POISON CENTRE.

**IF SWALLOWED:** Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

**IF ON SKIN:** Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation occurs: Get medical advice.

**IF IN EYES:** Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.

5.4. **Instructions for safe disposal of the product and its packaging**

Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains. Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

5.5. **Conditions of storage and shelf-life of the product under normal conditions of storage**

Protect from Frost. Do not store at temperatures above 35 °C.

Shelf life 18 months.

6. OTHER INFORMATION

Bioquell HPV-AQ is not intended for use as a terminal sterilant/disinfectant for medical devices.

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