

Summary of product characteristics for a biocidal product

Product name: Bioquell HPV-AQ

Product type(s): PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

PT03 - Veterinary hygiene (Disinfectants)

PT04 - Food and feed area (Disinfectants)

PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

PT03 - Veterinary hygiene (Disinfectants)

PT04 - Food and feed area (Disinfectants)

Authorisation number: EU-0027469-0000

R4BP 3 asset reference number: EU-0027469-0000

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Administrative information

1.1. Trade names of the product

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| 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 3 asset reference number | EU-0027469-0000 | |
| Date of the authorisation | 07/08/2022 | |
| Expiry date of the authorisation | 31/07/2032 | |

1.3. Manufacturer(s) of the biocidal products

| | |
|--|---|
| Name of the manufacturer | Ecolab SNC |
| Address of the 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 | 1315 - Hydrogen peroxide |
| Name of the manufacturer | Evonik Peroxide Spain |
| Address of the 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 biocidal product

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

2.2. Type of formulation

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|------------------------------|
| HN - Hot fogging concentrate |
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3. Hazard and precautionary statements

Hazard statements

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.

Precautionary statements

Keep away from clothing and other combustible materials.

Avoid breathing vapours.

Do no 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 Center 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.

4. Authorised use(s)

4.1 Use description

Use 1 - Surface disinfection in small (0.25m3 - 4m3) enclosures

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

Scientific name:
Common name: bacteria spores
Development stage:

Scientific name:
Common name: Mycobacteria
Development stage:

Scientific name:
Common name: Fungi
Development stage:

Scientific name:
Common name: Yeasts
Development stage:

Scientific name:
Common name: Viruses
Development stage:

Scientific name:
Common name: bacteriophage
Development stage:

Field(s) of use

Indoor

Hard, non-porous surfaces in small (0.25m³ to 4m³) sealed enclosures by vapourisation, 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: vapourisation
Detailed description:
Vapourisation with Bioquell Hydrogen Peroxide Vapour system followed by microcondensation – to deliver the disinfectant to surfaces in closed systems.
Temperature range: room temperature

Humidity range: 10% - 80%

Application rate(s) and frequencies

Application Rate: 100g/m³ 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

75ml, 150ml, 500ml, 950ml, 1000ml, 2000ml, 5000ml and 25L. 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

Use 2 - Surface disinfection within large (>4m³) 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)

Scientific name:
Common name: Bacteria
Development stage:

Scientific name:
Common name: Mycobacteria
Development stage:

Scientific name:
Common name: Bacteria spores
Development stage:

Scientific name:
Common name: Fungi
Development stage:

Scientific name:
Common name: Yeasts
Development stage:

| |
|--|
| <p>Scientific name: Common name: Viruses Development stage:</p> <p>Scientific name: Common name: bacteriophages Development stage:</p> |
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Field(s) of use

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| <p>Indoor</p> <p>Hard, non-porous surfaces in large (>4 m3) 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> |
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Application method(s)

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|--|
| <p>Method: vapourisation Detailed description:</p> <p>Vapourisation 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%</p> |
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Application rate(s) and frequencies

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|---|
| <p>Application Rate: 10g/m3 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.</p> |
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Category(ies) of users

| |
|---------------------|
| <p>Professional</p> |
|---------------------|

Pack sizes and packaging material

| |
|--|
| <p>75ml, 150ml, 500ml, 950ml, 1000ml, 2000ml, 5000ml and 25L. Bottles are constructed of HDPE.</p> |
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4.2.1 Use-specific instructions for use

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|---------------------------------------|
| <p>See general directions for use</p> |
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4.2.2 Use-specific risk mitigation measures

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|---------------------------------------|
| <p>See general directions for use</p> |
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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

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 vapourisation 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 vapourised 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/m³ (0.9ppm) 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 ≤ 0.9 ppm (1.25mg/m³).
The professional user may only enter the room in emergency situations when the hydrogen peroxide level has dropped below 36ppm (50 mg/m³) 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 ≤ 0.9 ppm (1.25mg/m³) prior to re-entry.
When opening the container and preparing contents wear suitable personal protective equipment (gloves, eye protection, coverall).
Wash hands after use.

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.