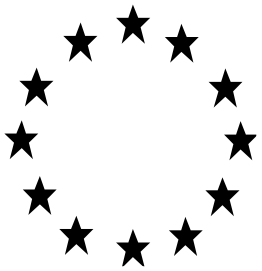
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR UNION AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



Bioquell HPV-AQ

Product types 2, 3 & 4

Active Substance: Hydrogen Peroxide

Case Number in R4BP: BC-ML029042-45

Evaluating Competent Authority: The Netherlands

Date: 29 October 2021

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1 CONCLUSION

The biocidal product Bioquell HPV-AQ is a hot fogging concentrate (HN) containing 35 % pure hydrogen peroxide as active substance. The physical, chemical and technical properties of the product were sufficiently described. 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.

The biocidal product does not need to be classified based on its physical hazards and characteristics.

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

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 PT02, PT03 and PT04 applied by vapourisation. For both uses efficacy is demonstrated for PT02 and PT04. For PT03 only a specific claim "pre-cleaned animal cages/racks within biomedical and animal laboratory facilities" efficacy is demonstrated.

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.

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.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product / product family

Identifier[1]	**Country (if relevant)**
Bioquell HPV-AQ	

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Ecolab Deutschland GmbH
	Address	Ecolab-Allee 1, 40789 Monheim, Germany
Pre-submission phase started on	28 June 2016	
Pre-submission phase concluded on	24 August 2016	
Authorisation number		
Date of the authorisation		
Expiry date of the authorisation		

2.1.1.3 Manufacturer(s) of the products of the family

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, Andover, Hampshire, UK, SP10 3TS Unit E4, Eastway Business Park, Ballysimon Road, V94 K267, Limerick, Ireland

2.1.1.4 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 50784 La Zaida (Zaragoza) Spain

[1] Please fill in here the identifying product name from R4BP 3.

2.1.2 Product (family) composition and formulation

NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes ☒
No ☐

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Hydrogen Peroxide
IUPAC or EC name	Hydrogen Peroxide
EC number	231-765-0
CAS number	7722-84-1
Index number in Annex VI of CLP	008-003-00-9
Minimum purity / content	35% (wet weight), 99.5% (dry weight)
Structural formula	H_2O_2

2.1.2.2 Candidate(s) for substitution

Hydrogen peroxide is not a candidate for substitution.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product[2]

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
Hydrogen Peroxide	Hydrogen Peroxide	Active substance	7722-84-1	231-765-0	100 (TK) 35 (TC) 34.83 (pure)

2.1.2.4 Qualitative and quantitative information on the composition of the biocidal product family[2]

Not applicable

2.1.2.5 Information on technical equivalence

The active substance is identical.

eCA NL note: The source applied for is included in the EU files and an accepted reference source. Information on the stabilizers in the TK are provided (included in a

[2] Please delete as appropriate.

confidential annex for member states only). All stabilizers used are listed in the reference specification of the active substance.

2.1.2.6 Information on the substance(s) of concern

The BP contains no substance of concern.

2.1.2.7 Type of formulation

HN – Hot fogging concentrate

2.1.3 Hazard and precautionary statements[3]

Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008

[3] For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work).

Classification	
Hazard category	Oxidising liquids cat. 2 Acute Tox 4, Oral. Skin Irrit 2. Eye Dam 1. STOT SE 3, Inhalation. Aquatic Chronic 3.
Hazard statement	H272 – May intensify fire; oxidiser H302 – Harmful if swallowed. H315 – Causes skin irritation. H318 – Causes serious eye damage. H335 – May cause respiratory irritation H412 – Harmful to aquatic life with long lasting effects
Labelling	
Signal words	Danger
Hazard statements	H272 – May intensify fire; oxidiser H302 – Harmful if swallowed. H315 – Causes skin irritation. H318 – Causes serious eye damage. H335 – May cause respiratory irritation H412 – Harmful to aquatic life with long lasting effects
Precautionary statements	P220 – Keep away from clothing and other combustible materials. P261 – Avoid breathing vapours. P270 – Do not eat, drink or smoke when using this product. P273 – Avoid release to the environment. P280 – Wear protective gloves/protective clothing/eye protection. P301 + P312 + P330 – IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. Rinse mouth. P302 + P352 – IF ON SKIN: Wash with plenty of water. P332 + P313 – If skin irritation occurs: Get medical advice/attention. P362 + P364 – Take off contaminated clothing and wash it before reuse P304 + P340 – IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305 + P351 + P338 + P310– 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. P312 – Call a POISON CENTER/doctor if you feel unwell. P370 + P378 – In case of fire: Use water to extinguish. P403 + P233 – Store in a well-ventilated place. Keep container tightly closed. P405 – Store locked up. P501 – Dispose of contents/container in accordance with applicable local, national and International regulations.

Note	Hydrogen peroxide (CAS 7722-84-1) contributes to the classification of the mixture as determined in article 18 (3) of the CLP. The following P-statements were triggered by the included H-statements, but not included based on the following justification: - P264 is triggered by H302 and H315, however, not assigned as covered by the included P280. - P321 is triggered by H315. However, this P-statement is highly recommended only in exceptional cases where specific treatment is known and required. No specific treatment is known, therefore P321 is not assigned.

eCA NL note: The applicant disagrees with the modification made by the eCA to the P273 statement to delete "of the liquid". The system is an environmental decontamination system, wherein the hydrogen peroxide vapour is released to the environment to enable it to be decontaminated. If one states "avoid release to the environment" the statement becomes non-sensical in relation to the use of the technology. If you cannot release it to the environment you cannot use the technology. However, eCA is of the opinion that the official phrases belonging to H and P sentences should not be adapted. According to the CLP Regulation, the text "avoid release to the environment'' relates to the recommended precautionary statement for prevention, P273. H and P sentences are related to the hazards and not to the risks posed by application of the products.
The products are intended for surface disinfection within large and small enclosures and emission to the environment can take place. The exposure and risk to the environment by application of the product is assessed in the PAR. (Accidental) spillage of the products to the environment needs to be prevented and therefore P273 is included in the classification and labelling of the products.

2.1.4 Authorised use(s)

2.1.4.1 Use description[4]

Table 1. Use #1 - Surface disinfection within large (>4m^3) enclosures

Product Type	PT 02, 03 & 04
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria, Mycobacteria, Spores, Yeasts, Fungi, Viruses, Bacteriophage
Field of use	Indoor Hard, non-porous surfaces in large (>4 m^3) 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
Application method(s)	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%
Application rate(s) and frequency	10 g/m^3 undiluted product, contact time of 35 minutes (after diffusion). 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.

2.1.4.2 Use-specific instructions for use[5]

See Section 2.1.5.1

2.1.4.3 Use-specific risk mitigation measures

See Section 2.1.5.2

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

See Section 2.1.5.3

2.1.4.5 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

2.1.4.6 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.

2.1.4.7 Use description[6]

Table 2. Use #2 - Surface disinfection within small (0.25 m^3 to 4 m^3) enclosures

Product Type	PT 02, 03 & 04
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria, Mycobacteria, Spores, Yeasts, Fungi, Viruses, Bacteriophage

4 Copy this section as many times as necessary (one table per use, together with any instructions for use, risk mitigation measures and other directions for use that are use-specific. It has to be noted that in accordance with Document CA-May14-Doc.5.6 – Final, the SPC of a biocidal product presents the authorised uses as a number of pre-defined uses to which the product label shall have full correspondence.

5 Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

6 Copy this section as many times as necessary (one table per use, together with any instructions for use, risk mitigation measures and other directions for use that are use-specific. It has to be noted that in accordance with Document CA-May14-Doc.5.6 – Final, the SPC of a biocidal product presents the authorised uses as a number of pre-defined uses to which the product label shall have full correspondence.

Field of use	Indoor Hard, non-porous surfaces in small (0.25 m^3 to 4 m^3) 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)	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 frequency	100 g/m^3 undiluted product , contact time of 35 minutes (after diffusion). 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.

2.1.4.8 Use-specific instructions for use[7]

See Section 2.1.5.1

2.1.4.9 Use-specific risk mitigation measures

See Section 2.1.5.2

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

See Section 2.1.5.3

2.1.4.11 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

[7] Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

2.1.4.12 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.

2.1.5 General directions for use

2.1.5.1 Instructions for use[8]

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 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/m^3 (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.

2.1.5.2 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 (1.25 mg/m^3).

8 Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

The professional user may only enter the room in emergency situations when the hydrogen peroxide level has dropped below 36 ppm (50 mg/ m^3), 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 ≤0.9ppm (1.25 mg/m^3) prior to re-entry.
When opening the container and preparing contents wear suitable personal protective equipment (gloves, eye protection, coverall).
Wash hands after use.

2.1.5.3 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.

2.1.5.4 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.

2.1.5.5 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.

2.1.6 Other information

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

2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Bottle	75mL	HDPE, black, opaque	HDPE vented Cap	Professional	Yes
Bottle	150mL	HDPE, black, opaque	HDPE vented Cap	Professional	Yes
Bottle	500mL	HDPE, black, opaque	HDPE vented Cap	Professional	Yes
Bottle	950mL	HDPE, black, opaque	HDPE vented Cap	Professional	Yes
Bottle	1000mL	HDPE, black, opaque	HDPE vented Cap	Professional	Yes
Bottle	2000mL	HDPE, black, opaque	HDPE vented Cap	Professional	Yes
Carbouy	5000mL	HDPE, white, translucent	HDPE vented Cap	Professional	Yes
Carbouy	25L	HDPE, white, translucent	HDPE vented Cap	Professional	Yes

Users should determine the size of the product packaging to be used based on the volume of the enclosure to be decontaminated, taking into consideration the required dosing levels. The smaller volumes are principally (but not exclusively) intended for use with small enclosures (i.e. 75mL, 150mL and 500mL). The larger volumes (including the 500mL) are principally intended for use with larger enclosures. The user can determine the amount of peroxide that is required for a cycle based on the dosing rates (i.e. 10g/m^3 for large enclosures or 100g/m^3 for small enclosures). A Bioquell vaporisation module will alarm to indicate if it runs out of peroxide during an application (i.e. insufficient quantity was provided). For further information refer to the Bioquell user manual for additional guidance.

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

Efficacy data in accordance with NFT 72-281:2014 to support the use scenarios.

Phase 2, step 1 efficacy test data to show the efficacy of liquid 35% hydrogen peroxide on claimed microorganisms.

Peer-reviewed scientific literature to support the efficacy of Bioquell HPV-AQ.

2.1.8.2 Access to documentation

Bioquell has a full letter of access from PeroxyChem Spain.

2.1.8.3 Similar conditions of use

The outcome of the consultation during the pre-submission phase was: "The biocidal product Bioquell HPV-AQ is deemed eligible for Union Authorisation". Please note that Bioquell HPV-AQ has been previously assessed by the CTGB and holds a national authorisation reference: 14770N.

2.2 Assessment of the biocidal product (family)

2.2.1 Intended use(s) as applied for by the applicant

Table 3. Intended use # 1 – Surface disinfection within large (>4m^3) enclosures

Product Type(s)	PT 02, 03 & 04
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria, Mycobacteria, Spores, Yeasts, Fungi, Viruses, Bacteriophage
Field of use	Indoor Hard, non-porous surfaces in large (>4m^3) sealed enclosures. 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 – clean conditions in, for example, pre-cleaned animal cage racks. PT4 – clean conditions in, for example, aseptic filling lines, food production facilities, storage containers.
Application method(s)	Vaporisation with Bioquell Hydrogen Peroxide Vapour system followed by microcondensation – to deliver the disinfectant to surfaces in closed systems. Temperature range: 15°C - 35°C Humidity range: 10% - 80%
Application rate(s) and frequency	Inject 10 g/m3 of HPV-AQ, dwell for 35 minutes. Users should carry out decontaminations in line with their requirements and operating procedures.
Category(ies) of user(s)	Professional
Pack sizes and packaging material	75ml, 150ml, 500ml, 950ml, 1000ml, 2000ml, 5000ml and 25L. Bottles are constructed of HDPE.

Table 2. Intended use # 2 – Surface disinfection of small enclosures

Product Type(s)	PT 02, 03 & 04
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria, Mycobacteria, Spores, Yeasts, Fungi, Viruses, Bacteriophage
Field of use	Indoor Hard, non-porous surfaces in small (0.25m3 to 4m3) sealed enclosures.

	PT2 – clean conditions in, for example, isolators, pass-through chambers, cabinets, material airlocks, cupboards, filling lines, emergency vehicles. PT3 – clean conditions in, for example, pre-cleaned animal cage racks. PT4 – clean conditions in, for example, aseptic filling lines, storage containers.
Application method(s)	Vaporisation with Bioquell Hydrogen Peroxide Vapour system followed by microcondensation – to deliver the disinfectant to surfaces in closed systems.
Application rate(s) and frequency	Inject 100 g/m^3 of HPV-AQ, dwell for 35 minutes. Users should carry out decontaminations in line with their requirements and operating procedures.
Category(ies) of user(s)	Professional
Pack sizes and packaging material	75ml, 150ml, 500ml, 950ml, 1000ml, 2000ml, 5000ml and 25L. Bottles are constructed of HDPE.

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	EPA Product Properties Guideline	35 Batch number: 3213016135	Clear Liquid	[redacted] (2016)
Colour at 20 °C and 101.3 kPa	EPA Product Properties Guideline	35 Batch number: 3213016135	Colourless	[redacted] (2016)
Odour at 20 °C and 101.3 kPa	EPA Product Properties Guideline	35 Batch number: 3213016135	Odourless	[redacted] (2016)
Acidity / alkalinity	CIPAC Methods MT 75.3, 191	35 Batch number: 3213016135	pH (neat) = 2.41 (24.5°C) pH (1% w/w) = 6.31 (24.6°C); acidity: 0.013 H_2SO_4 %(w/w)	[redacted] (2016)
Relative density / bulk density	OECD 109 / EU Method A.3	35 Batch number: 3213016135	D^{20}_4 = 1.135 undiluted	[redacted] (2016)
eCA NL note: The end-points above have been determined on the test item AOPACK 35% which has a similar composition with the product Bioquell HPV-AQ.				

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Storage stability test – **accelerated storage**	CIPAC MT46.3 / BQ SI070 Storage at 35°C (±2°C) for 12 weeks. Tested HDPE bottle sizes = 150ml, 500ml, 1000ml	35 Batch number: V-121075135-RA	A.s.: T=0: 36.63% T=12 weeks: 150 mL: 37.64% 500 mL: 38.11% 950 mL: 37.45% 1000 mL: 38.13% (+2.75 - 4.1%) Appearance: T=0: liquid, clear with no particulate matter, odour T=12 weeks: no change Packaging: T=0: black, smooth no deformity T=12 months: no change	Stability of Bioquell HPV-AQ Accelerated Storage Stability of Bioquell HPV-AQ [redacted] (2019)
eCA NL note: The product was tested for 12 weeks at 35 °C in the accelerated stability study. The results show that the product is stable up to 35 °C in HDPE commercial packaging. The content of a.s. was determined using a validated analytical method. The pH and density of the product have not been determined as part of this study. A pH value is included in the certificate of analysis.				
Storage stability test – **long term storage at ambient temperature**	CIPAC MT46.3 Storage at 4°C and 25°C for 18 months Tested in black opaque HDPE bottle sizes = 140ml, 500ml, 950ml, 1000ml,	35 Batch number: L-1018029135-RA	Hydrogen peroxide concentration: T=0: 36.33%, T=18 months: @4°C: 36.12 - 36.86 (-0.21 - 0.53 @25°C: 35.42 - 36.49 (-0.91 - 0.16) Appearance: T=0: liquid, clear with no particulate	Bioquell HPV-AQ shelf life test - 18 months, [redacted] 2020

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	2000ml and white translucent HDPE bottle sizes = 5000ml. Product stored in both light and dark conditions.		matter, no odour, T=18 months: no change. Packaging: T=0: black, smooth no deformity/white, translucent, smooth no deformity (5 L units), T=18 months: no change Bottle weight: @4°C: minimal change between T0 and T 18 months (one bottle had a max change of -0.4%) @25°C: mean bottle change between -0.6 - -4.4%	
eCA NL note: The test item was stored at 4 and 25 °C for 18 months in HDPE packaging of different sizes. The content of a.s. was determined by titration, a validated analytical method, before, during and after storage and no change >10% was observed. Appearance of the test item and packaging and change in bottle weight were also determined before and after storage. No other physical, chemical and technical characteristics have been determined as part of this study. After storage at ambient temperature, the pH of the product is not expected to change significantly. Information on persistent foaming and dilution stability are presented below. The product appears to be stable for the tested period supporting a shelf life of 18 months in HDPE packaging.				
Storage stability test – **low temperature stability test for liquids**	Not applicable, product should not be stored at ≤0°C. Conditions of storage contain the statement "Protect from frost."			
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	-	35% Batch number: L-1007085135-RA	Product unaffected by light when stored in black opaque HDPE 150ml, 500ml or 1000ml	Stability of Bioquell HPV-AQ Storage Stability of Bioquell HPV-AQ

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			containers or white translucent HDPE 5000ml containers for 18 months. See results above for storage stability studies.	[redacted] (2019)
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Temperature: See results above for the storage stability studies. The product is stable at temperatures between 4-35 °C. Conditions of storage contain the statement "Protect from frost." Humidity: Not applicable, product is a water-based formulation			
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	-	35% Batch number: L-1007085135-RA	Storage at 4°C and 25°C for 18 months has no effect on HDPE packaging material. See results above for both accelerated and long term stability studies	Stability of Bioquell HPV-AQ Storage Stability of Bioquell HPV-AQ [redacted] (2019) Bioquell HPV-AQ shelf life test - 18 months, [redacted] 2020
Wettability	Not applicable, the biocidal product is a water based liquid formulation			
Suspensibility, spontaneity and dispersion stability	Not applicable, the biocidal product is a water based liquid formulation			
Wet sieve analysis and dry sieve test	Not applicable, the biocidal product is a water based liquid formulation			
Emulsifiability, re-emulsifiability and emulsion stability	Not applicable, the biocidal product is a water based liquid formulation			
Disintegration time	Not applicable, the biocidal product is a water based liquid formulation			
Particle size distribution, content of dust/fines, attrition, friability	Not applicable, the proposed authorised use is only allowed in (en)closed environment. MMAD is not determined based on the absence of exposure if the			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	product is used in accordance with the instructions for use.			
Persistent foaming	CIPAC Methods MT 47.2	35 Batch number: 3213016135	Undiluted. No foam produced after 10 secs, 1, 3 and 12 minutes	[redacted] (2016)
eCA NL note: Persistent foaming has been determined on the test item AOPACK 35% which has a similar composition with the product Bioquell HPV AQ.				
Flowability/Pourability/Dustability	Not applicable, the biocidal product is a water based liquid formulation			
Burning rate — smoke generators	Not applicable, the biocidal product is not a smoke generator			
Burning completeness — smoke generators	Not applicable, the biocidal product is not a smoke generator			
Composition of smoke — smoke generators	Not applicable, the biocidal product is not a smoke generator			
Spraying pattern — aerosols	Not applicable, the biocidal product is not an aerosol			
Physical compatibility	Not applicable, the biocidal product is not intended to be used with other products			
Chemical compatibility	Not applicable, the biocidal product is not intended to be used with other products			
Degree of dissolution and dilution stability	CIPAC MT 41	35 Batch number: 3213016135	Initial – homogenous After 18 hours - homogenous	[redacted] (2016)
eCA NL note: Dilution stability has been determined on the test item AOPACK 35% which has a similar composition with the product Bioquell HPV AQ.				
Surface tension	OECD 115 / EU Method A.5	35 Batch number: 3213016135	67.4 mN/m at 20°C	[redacted] (2016)
eCA NL note: Surface tension has been determined on the test item AOPACK 35% which has a similar composition with the product Bioquell HPV AQ. The product is not considered to be surface active.				
Viscosity	OECD 114 (capillary viscometer)	35 Batch number: 3213016135	Kinematic viscosity: 0.6922 mm^2/s at 20°C 0.4803 mm^2/s at 40°C	[redacted] (2016)
eCA NL note: Viscosity has been determined on the test item AOPACK 35% which has a similar composition with the product Bioquell HPV AQ. Shear rates have not been provided. The product is considered to have properties characteristic to a Newtonian fluid.				

Conclusion on the physical, chemical and technical properties of the product
Bioquell HPV-AQ is an aqueous solution of hydrogen peroxide (35% w/w). It is a clear, colourless and odourless liquid that is homogenous and does not foam. The undiluted biocidal product has a pH of 2.41, acidity of 0.013 H_2SO_4 %(w/w) and a density of 1.135 g/mL. Kinematic viscosity of 0.6922 mm^2/s at 20°C 0.4803 mm^2/s at 40°C and a surface tension of 67.4 mN/m at 20°C. A shelf-life of 18 months in HDPE commercial packaging is supported at temperatures between 4 and 25 °C. The product should not be stored at temperatures above 35°C and should be protected from frost.

2.2.3 Physical hazards and respective characteristics

Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**
Explosives			See information in the AR of hydrogen peroxide (explosion limit ≥ 40 % (wt) as vapour ≥ 86 % (wt) in aqueous liquid)	
Flammable gases	Not applicable, the biocidal product is a water based liquid formulation.			
Flammable aerosols	Not applicable, the biocidal product is not an aerosol.			
Oxidising gases	Not applicable, the biocidal product is not a gas.			
Gases under pressure	Not applicable, the biocidal product is not a gas under pressure.			
Flammable liquids	Not applicable, 35% hydrogen peroxide is not flammable.			
eCA NL note: Considering that the boiling point of a 35 % H_2O_2 is > 100 °C no flash point is expected until 60 °C. The product is not classified as (highly) flammable.				
Flammable solids	Not applicable, the biocidal product is a water based liquid formulation.			
Self-reactive substances and mixtures	Not applicable, the product is an oxidising liquid.			
Pyrophoric liquids	Not applicable, based on experience in manufacturing and handling the product is not classified as pyrophoric liquid.			
Pyrophoric solids	Not applicable, the biocidal product is a liquid formulation.			
Self-heating substances and mixtures	Not applicable, the product is a liquid. Based on the fact that the surface of liquids is not large enough for reaction with air the testing method is not suitable for liquids. Therefore liquids are not classified as self-heating.			
Substances and mixtures which in contact with water emit flammable gases	Not applicable, the product is classified as oxidising liquid.			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Oxidising liquids	EU Method A.21	35 Batch number: L-3229115135-EV	Mean pressure rise time for: 65% aqueous nitric(V) acid and cellulose: 5109 ± 549 AOPACK 35% and cellulose: 20722 ± 5142. Not oxidising	[redacted] (2016)
eCA NL note: Oxidising properties have been determined on the test item AOPACK 35% which has a similar composition with the product Bioquell HPV AQ. Based on the results it can be concluded that the product does not have to be classified as an oxidizing liquid in the sense of Reg. (EU) No 1272/2008. However, based on known experience from the UN Transport Regulation, products with > 8 % hydrogen peroxide are classified as oxidising liquids. As in this case the transport regulation takes precedence the product is classified as oxidising liquid category 2.				
Oxidising solids	Not applicable, the biocidal product is a water based liquid formulation.			
Organic peroxides	Not applicable, based on its composition and the chemical structure of the components, the product is not an organic peroxide.			
Corrosive to metals	US EPA internal test method	30-35	Not considered to be corrosive to metals	US EPA report EPA/600/R-10/169
	UN Test C.1	Oxypure C 50% Batch number: N-1726105150-CL	Aluminium Test time = 168hrs Mass loss threshold = 13.5% Most corroded sample mass loss = 0.945% Corrosion rate <6.25mm/yr Steel Test time = 168hrs Mass loss threshold = 13.5% Most corroded sample mass loss = 0.216% Corrosion rate <6.25mm/yr	[redacted] (2016)
	UN Test C.1	Bioquel HPV-AQ	Aluminium Test time = 167hrs	[redacted] (2021)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		Batch number: ABF100015100303 1	Mass loss threshold = 13.5% Most corroded sample mass loss <0.1% Corrosion rate <6.25mm/yr No localized corrosion observed Steel Test time = 167hrs Mass loss threshold = 13.5% Most corroded sample mass loss = 0.3% Corrosion rate <6.25mm/yr No localized corrosion observed Tested product is not corrosive to metals.	
eCA NL note: Corrosion test UN Test C.1 has been performed with a different product from the same supplier (Oxypure 50%) and Bioquell HPV-AQ. Oxypure 50% has a hydrogen peroxide concentration of 50% and different stabilisers than Bioquell HPV-AQ. It was confirmed that fresh solution was provided to ensure enough reactive agent during the course of the test for the Oxypure 50% study. No information on the solution during testing was provided for the test with Bioquell HPV-AQ (other than that the volume was at least 1.5 L), nor was the hydrogen peroxide content determined at the end of the test. The low corrosion rates for both Oxypure 50% (for which fresh solution was provided during the test) and Bioquell HPV-AQ (for which it has not been confirmed that fresh solution was provided during the test) are low. Even assuming that Bioquell HPV-AQ was not refreshed during the test duration, it would be unlikely that the samples would show corrosion rates high enough to assign H290 to the product if the test was repeated with fresh product supplied during the test duration. It can be concluded that the product Bioquell HPV AQ does not need to be classified in the sense of Reg. (EU) No 1272/2008.				
Auto-ignition temperatures of products (liquids and gases)	Not applicable. 35% hydrogen peroxide does not have a flash-point up to 200 °C. See also the information included in Hydrogen peroxide AR.			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Relative self-ignition temperature for solids	Not applicable, the biocidal product is a water based liquid formulation.			
Dust explosion hazard	Not applicable, the biocidal product is a water based liquid formulation.			

Conclusion on the physical hazards and respective characteristics of the product
The product, Bioquell HPV-AQ, consists of a 35% hydrogen peroxide solution. The product is not considered explosive. It has no oxidising properties and is not corrosive to metals. No additional testing was conducted on the product as these were not applicable taking into consideration the physical state of the product, the formulation type (HN). Based on the test data the product has no classifications with respect to physical hazards.

2.2.4 Methods for detection and identification

Please refer to the Hydrogen Peroxide AR (assessment report 1315-02) for the methods of detection and identification for Hydrogen Peroxide.

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RSD		

eCA NL note: The analytical method (titration) used to determine the content of hydrogen peroxide is identical to the one used in the active substance dossier and is considered acceptable.

Conclusion on the methods for detection and identification of the product
The Hydrogen peroxide content in an aqueous solution (e.g.: Bioquell HPV-AQ) is determined by titration. The active substance AR contains analytical methods for determination of hydrogen peroxide in water and in air, accepted as post authorisation data.

In soil, hydrogen peroxide is decomposed very rapidly, and therefore the validation of an analytical method is not technically feasible.

An analytical method for hydrogen peroxide in body fluids and tissues of humans or animals is not required, since the substance is not classified as toxic or highly toxic.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

Bioquell HPV-AQ is intended to be used as a high level disinfectant for sealed enclosures, applied using a Bioquell vaporisation module. Bioquell HPV-AQ is intended to be used on hard non-porous surfaces for PT2, PT3 and PT4 which are free from gross/visible contamination.

2.2.5.2 Organisms to be controlled and products, organisms or objects to be protected

Bioquell HPV-AQ is intended to control vegetative form of bacteria, including mycobacteria and bacterialspores, yeasts, fungi, viruses and bacteriophage.

2.2.5.3 Effects on target organisms, including unacceptable suffering

Oxidative damage leading to death. The product causes irreversible damage to cellular components such as enzymes, membrane constituents and DNA.

2.2.5.4 Mode of action, including time delay

Hydrogen peroxide is an oxidiser and achieves its biocidal action through oxidation of the target organism.

2.2.5.5 Efficacy data

In accordance with ECHA guidance document Efficacy Data Requirements for PTs 1-5, phase 2 step 1 studies have been conducted, along with studies performed in accordance with NFT 72-281:2014.

Due to the inability of Bovine Enterovirus (ECBO) to survive when tested in accordance with NFT 72-281:2014, test data has been generated using Porcine Parvovirus, the test organism replacing ECBO in the new European standard EN 17272.

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / conditions /exposure time**	**Test results: effects**	**Reference**
High level disinfectant	*Large sealed enclosure*	*Bioquell HPV-AQ*	***Bacteria*** *Pseudomonas aeruginosa* (DSM 939) *Staphylococcus aureus* (DSM 799) *Enterococcus hirae* (DSM 3320) *Escherichia coli* (DSM 682) ***Mycobacteria*** *Mycobacterium avium* (DSM 44157) *Mycobacterium terrae* (DSM 43227) ***Spores*** *Bacillus subtilis* (DSM 347)	NFT 72-281:2014 (Phase 2 step 2 / semi-field test)	Apply 10g /m3 HPV-AQ, dwell for 35 minutes, aerate to 0.9ppm (1.25mg/m^3) or less Relative humidity: 40-70%. *Pseudomonas aeruginosa* *Staphylococcus aureus* *Enterococcus hirae* *Escherichia coli* *Mycobacterium terrae*: Clean Conditions: 1/20 skimmed milk, test enclosure: 81.7m^3, temp: room temp, dose: 9.44g/m^3, contact time: 35 min *Bacillus subtilis and Mycobacterium*	**Bacteria >5 log** **Mycobacteria >4 log** **Spores >3 log**	NFT 72 Bacteria + M.terrae Report – large enclosure NFT 72 B.subtilis + M.avium Report – Large enclosure

			Viruses* *Adenovirus Type 5* (ATCC VR-5) *Murine Norovirus* (S99) *Porcine Parvovirus* (NADL2)		*avium*: Clean conditions: 1/20 skimmed milk, test enclosure: 81.7m^3, temp: room temp, dose: 9.73g/m^3, contact time: 35 min *Adenovirus Type 5*: Clean conditions: 0.3g/L BSA, test enclosure: 81.7m^3, temp: room temp, dose: 9.49g/m^3 *Murine Norovirus*: Clean conditions: 0.3g/L BSA, test enclosure: 81.7m^3, temp: room temp, dose: 9.73g/m^3 *Porcine Parvovirus*: Clean conditions***: 0.3g/L BSA, test enclosure: 81.7m^3, temp: room temp, dose: 9.94g/m^3 *Aspergillus brasiliensis*, *Candida albicans*: Clean conditions: 1/20 skimmed milk,	**Adenovirus >4 log** **Murine Norovirus > 3.69 log**** **Porcine Parvovirus >2.60 log**** **Fungi >4 log** **Yeasts >4 log**	NFT 72 Adenovirus Report – Large enclosure NFT 72 Murine Noro (2) Report – large enclosure Large enclosure Parvovirus NFT 72 Candida + Aspergillus – large enclosure
			Fungi *Aspergillus brasiliensis* (DSM 1988) ***Yeasts*** *Candida albicans* (DSM 1386)				

			Bacteriophage *Bacteriophage P001* (DSM 4262*), Bacteriophage P008* (DSM 10567)		test enclosure: 81.7m^3, temp: room temp, dose: 9.66g/m^3 Bacteriophage P001, Bacteriophage P008: Clean conditions: acid whey, test enclosure: 81.7m^3, temp: room temp, dose: 9.73g/m^3	**Bacteriophage >4 log**	NFT 72 Bacteriophage Report – Large enclosure
High level disinfectant	*Small sealed enclosure*	*Bioquell HPV-AQ*	***Bacteria*** *Pseudomonas aeruginosa* (DSM 939) *Staphylococcus aureus* (DSM 799) *Enterococcus hirae* (DSM 3320) *Escherichia coli* (DSM 682) *Escherichia coli K12* (DSM 11250) ***Spores***	NFT 72-281:2014 (Phase 2 step 2 / semi-field test)	Apply 100g /m3 HPV-AQ, dwell for 35 minutes, aerate to 0.9ppm (1.25mg/m^3) or less Relative humidity: 50-60%. *Pseudomonas aeruginosa* *Staphylococcus aureus* *Enterococcus hirae* *Escherichia coli*: Clean Conditions: 1/20 skimmed milk, test enclosure: 0.45m^3, temp: room temp,	**Bacteria >5 log** **Spores >3 log**	NFT Small enclosure bacteria

			Bacillus subtilis (DSM 347)		dose: 99.91g/m^3, contact time: 35 min		NFT Small enclosure Spores & K12
			Viruses* *Adenovirus Type 5* (ATCC VR-5) *Murine Norovirus* (S99) *Porcine Parvovirus* (NADL2)		*Escherichia coli K12, Bacillus subtilis spores:* Clean conditions: 1/20 skimmed milk, test enclosure: 0.45m^3, temp: room temp, dose: 105.6g/m^3 *Adenovirus Type 5*: Clean conditions: 0.3g/L BSA, test enclosure 0.45m^3, temp: room temp, dose: 105.6g/m^3 *Murine Norovirus:* Clean conditions: 0.3g/L BSA, test enclosure 0.45m^3, temp: room temp, dose: 101.5g/m^3 *Porcine Parvovirus:* Clean conditions***: 0.3g/L BSA, test enclosure 0.45m^3, temp: room temp, dose: 101.5g/m^3	**Adenovirus >4 log** **Murine Norovirus > 3.52 log**** **Porcine Parvovirus > 3.50 log****	NFT Small enclosure Virus Small enclosure norovirus + Parvovirus
			Fungi *Aspergillus brasiliensis* (DSM 1988) ***Yeasts***			**Fungi >4 log** **Yeasts >4 log**	Yeast & Fungi NFT Small enclosure

			Candida albicans (DSM 1386) ***Mycobacteria*** *Mycobacterium avium* (DSM 44157) *Mycobacterium terrae* (DSM 43227) ***Bacteriophage*** *Bacteriophage P001* (DSM 4262) *Bacteriophage P008* (DSM 10567)		*Aspergillus brasiliensis*, *Candida albicans*: Clean conditions: 1/20 skimmed milk, test enclosure: 0.45m^3, temp: room temp, dose: 102.24g/m^3 *Mycobacterium terrae, Mycobacterium avium*: Clean conditions: 1/20 skimmed milk, test enclosure: 0.45m^3, temp: room temp, dose: 102.24g/m^3, contact time: 35 min Bacteriophage P001, Bacteriophage P008: Clean conditions: acid whey, test enclosure 0.45m^3, temp: room temp, dose: 98.42g/m^3	**Mycobacteria >4 log** **Bacteriophage >4 log**	NFT Small enclosure Mycobacterium NFT Small enclosure Phage

High level disinfectant	*Small and large enclosures*	*Bioquell HPV-AQ*	***Virus*** *Poliovirus-1 Lsc-2ab Adenovirus-5* (ATCC VR5) *Murine Norovirus* (s99 Berlin)	EN 14476:2013 + A1 2015	*Poliovirus, Adenovirus, Murine Norovirus*: Clean conditions: 0.3g/L bovine albumin, test dilution: NEAT (80% V/V), contact time: 5 mins, temp: 20°C	**Virus >4 log**	EN 14476 Report
			Virus *Bovine enterovirus-1 (ECBO)*	EN 14675: 2015	*Bovine Enterovirus*: Clean conditions: 3.0g/L bovine albumin, test dilution: 25% V/V, contact time: 30 mins, temp: 10°C	**Virus >4 log**	EN 14675 Report
			Bacteria *Escherichia coli* (ATCC 10536), *Pseudomonas aeruginosa* (ATCC 15442), *Staphylococcus aureus* (ATCC 6538), *Enterococcus hirae* (ATCC 8043), *Escherichia coli K12* (NCTC 10538), *Proteus vulgaris* (NCTC 4635)	EN 1276: 2009	*E.coli K12, Proteus vulgaris*: Clean conditions: 0.3g/L bovine albumin, test dilution: 10% V/V, contact time: 5 mins, temp: 20°C	**Bacteria >5 log**	EN 1276 ECK PV Report
					E.coli, P.aeruginosa: Clean conditions: 0.3g/L bovine albumin, test dilution: 10% V/V, contact time: 5 mins, temp: 20°C	**Bacteria >5 log**	EN 1276 PA EC EH SA Report

					S.aureus, E.hirae: Clean conditions: 0.3g/L bovine albumin, test dilution: 80% V/V, contact time: 5 mins, temp: 20°C	**Bacteria > 5 log**	EN 1276 PA EC EH SA Report
			Spores *Bacillus subtilis* (ATCC 6633)	EN 13704: 2018	*B.subtilis*: Clean conditions: 0.3g/L bovine albumin, test dilution: 80% V/V, contact time: 35 minutes, temp: 20°C	**Spores >4 log**	EN 13704 BS 35 minutes Report
			Fungi *Aspergillus brasiliensis* (ATCC 16404)	EN 1650: 2008 + A1 2013	*A.brasiliensis*: Clean conditions: 0.3g/L bovine albumin, test dilution 80% V/V, contact time: 15 mins, temp: 20°C	**Fungi >4 log**	EN 1650 CA AB Report
			Yeast *Candida albicans* (ATCC 10231)	EN 1650: 2008 + A1 2013	*Candida albicans*: Clean conditions: 0.3g/L bovine albumin, test dilution 80% V/V, contact time: 15 mins, temp: 20°C	**Yeast >4 log**	EN 1650 CA AB Report
			Bacteriophage	EN 13610: 2002	*Lactococcus lactis* P001: Clean	**Bacteriophage >4 log******	

			Lactococcus lactis P001		conditions: 1% acidic whey, test dilution 80% V/V, contact time: 15 mins, temp: 20°C		EN 13610 P001 report
			Mycobacteria *Mycobacterium avium* (ATCC 15769), *Mycobacterium terrae* (ATCC 15755)	EN 14348: 2005	*Mycobacterium avium, Mycobacterium terrae*: 0.3g/L bovine albumin, test dilution 80% V/V, contact time: 5 minutes, temp: 20°C	**Mycobacteria >4 log**	EN 14348 MA MT Report

* Bovine Enterovirus is not a suitable test organism for automated airborne disinfection systems as it does not survive. It has been replaced in EN 17272 with Porcine Parvovirus. Testing has been carried out against Porcine Parvovirus.

** Loss of titre on the controls due to drying, combined with cytotoxic effects on the cell line due to a lack of neutralisation within the NFT 72-281 methodology mean that a 4 log reduction cannot be calculated. In all results no virus was detected on any coupon post exposure to BQ HPV-AQ. Additional testing with Parvovirus at 60 minutes contact time provided similar results – no virus was detected on any coupon post gassing but a 4 log reduction could not be calculated (small enclosure = >3.70 log, large enclosure = >3.38 log)

***Porcine Parvovirus was tested in clean conditions representative of PT2, as BQ HPV-AQ is intended for pre-cleaned surfaces equivalent to PT2 areas, even within a PT3 environment. Standard PT3 soiling conditions do not apply to BQ HPV-AQ use.

**** In accordance with ECHA PT1-5 Efficacy Guidance Document Appendix 4, Note 29, EN 13610 testing is not required to support a bacteriophage claim when a virucidal claim is also made and is supported by test data using EN 14476. EN 13610 test data against Bacteriophage P001 has been presented as additional data as it is available and coupled with NFT 72-281 bacteriophage testing supports a phagocidal claim for Bioquell HPV-AQ.

Efficacy data provided during RCOM and evaluated during ad-hoc follow up

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied/ conditions /exposure time**	**Test results: effects**	**Reference**
High level disinfectant	Large sealed enclosure	Bioquell HPV-AQ Delivery system: Bioquell vaporization module	**Distribution test** *Staphylococcus aureus* **Efficacy test** **Bacteria** *Pseudomonas aeruginosa* *Staphylococcus aureus* *Enterococcus hirae* *Escherichia coli* *Acinetobacter baumanii* *Proteus hauseri* **Fungi** *Aspergillus brasiliensis* **Yeasts** *Candida albicans* **Mycobacteria** *Mycobacterium avium* *Mycobacterium terrae* **Spores** *Bacillus subtilis*	EN17272 (Phase 2 step 2 / semi-field test)	Apply 10g product/m3 HPV-AQ, dwell for 35 minutes, aerate to 0.9ppm (1.25mg/m³) or less Relative humidity: 50-75%. Clean Conditions: 0.3g/l BSA Test enclosure: 74.4m³, Temperature: 20 °C ± 2 °C Product used: 744.2 g applied dose: 10g product/m³ Total contact time (ADC): 81 min 30 s	**Distribution test** >5 log reduction **Efficacy test** Bacteria >5 log Fungi >4 log Yeasts >4 log Mycobacteria >4 log Spores >4 log	EN 17272 large enclosure testing. [redacted] (2021)

					Dwell time: 35 min Distance to carriers: 3.9 m		
High level disinfectant	Large sealed enclosure	Bioquell HPV-AQ Delivery system: Bioquell vaporization module	**Viruses** *Adenovirus type 5* *Murine norovirus* *Porcine Parvovirus*	EN17272 (Phase 2 step 2 / semi-field test)	Apply 10g product /m3 HPV-AQ, dwell for 35 minutes, aerate to 0.9ppm (1.25mg/m³) or less Relative humidity: 50-75% Clean conditions: 0.3g/l BSA Test enclosure: 74.4m³ Temperature: 20 °C ± 2 °C Product used: 744.2 g Exact applied dose: 10g product/m³ Total contact time (ADC): 81 min 30 s Dwell time: 35 min Distance to carriers: 3.9 m	**Efficacy test** *Adenovirus*: 4.03 log reduction *Murine norovirus*: 4.13 log reduction *Porcine Parvovirus:* 4.40 log reduction	EN 17272 large enclosure virus testing. [redacted] (2021)

High level disinfectant	Small sealed enclosure	Bioquell HPV-AQ Delivery system: Bioquell vaporization module	**Viruses** *Adenovirus type 5* *Murine norovirus* *Porcine Parvovirus*	EN17272 (Phase 2 step 2 / semi-field test)	Apply 100g product/m3 HPV-AQ, dwell for 35 minutes, aerate to 0.9ppm (1.25mg/m³) or less Relative humidity: 50-75%. Clean Conditions: 0.3g/l BSA Test enclosure: 0.45m³, Temperature: 20 °C ± 2 °C Product used: 45 g Exact applied dose: 100g/m³ Total contact time (ADC): 50 min Dwell time: 35 min Distance to carriers: 0.56m	**Efficacy test** *Adenovirus*: 4.38 log reduction *Murine norovirus*: 4.15 log reduction *Porcine Parvovirus*: 4.00 log reduction	EN 17272 small enclosure virus testing. [redacted] (2021)
High level disinfectant	Small sealed enclosure	Bioquell HPV-AQ Delivery system: Bioquell vaporization module	**Distribution test** *Staphylococcus aureus* **Efficacy test**	EN17272 (Phase 2 step 2 / semi-field test)	Apply 100g product/m3 HPV-AQ, dwell for 35 minutes, aerate to	**Distribution test** >5 log reduction **Efficacy test**	EN 17272 small enclosure testing.

			Bacteria *Pseudomonas aeruginosa* *Staphylococcus aureus* *Enterococcus hirae* *Escherichia coli* *Acinetobacter baumanii* *Proteus hauseri* **Fungi** *Aspergillus brasiliensis* **Yeasts** *Candida albicans* **Mycobacteria** *Mycobacterium avium* *Mycobacterium terrae* **Spores** *Bacillus subtilis*		0.9ppm (1.25mg/m³) or less Relative humidity: 50-75% Clean Conditions: 0.3g/l BSA Test enclosure: 0.45m³ Temperature: 20 ºC ± 2 ºC Product used: 45 g Exact applied dose: 100g product/m³ Total contact time (ADC): 50 min Dwell time: 35 min Distance to carriers: 0.56 m	Bacteria >5 log *Except for P. hauseri,* which did not meet the validation requirements Fungi >4 log Yeasts >4 log Mycobacteria >4 log Spores >4 log	[redacted] (2021)
Field study Supporting information	Large enclosure	Bioquell HPV-AQ Delivery system: Bioquell vaporization module	*Geobacillus stearothermophilus*	Room size: aprox. 2500m3, divided in several zones Bioquell generators: [redacted] Bioquell aeration units: [redacted]	Dwell time:30-96 min Used product: 25,360 g Humidity:48-72% Temperature: 21-26ºC	No growth on treated bioindicator, growth on control bioindicators	[redacted]

				Distribution fans [redacted]: Biological indicators: [redacted]			
Field study Supporting information	Large enclosure	Bioquell HPV-AQ Delivery system: Bioquell vaporization module	*Geobacillus stearothermophilus*	Room size: aprox. 1200m3, divided in several zones Bioquell generators: [redacted] Bioquell aeration units: [redacted] Distribution fans: [redacted] Biological indicators: [redacted]	Dwell time:30 min Used product: 12,280 g Humidity:42-44% Temperature: 23-24°C	No growth on treated bioindicator, growth on control bioindicators	[redacted]
Field study Supporting information	Large enclosure	Bioquell HPV-AQ Delivery system: Bioquell vaporization module	*Geobacillus stearothermophilus*	Room size: aprox. 2200m3, divided in several zones Bioquell generators: [redacted] Bioquell aeration units: [redacted] Distribution fans: [redacted] Biological indicators: [redacted]	Dwell time:30 min Used product: 20,860 g Humidity:42-44% Temperature: 23-24°C	No growth on treated bioindicator, growth on control bioindicators	[redacted]
Field study Supporting information	Large enclosure	Bioquell HPV-AQ Delivery system: Bioquell vaporization module	*Geobacillus stearothermophilus*	Room size: aprox. 4500m3, divided in several zones Bioquell generators: [redacted]	Dwell time:15-75 min Used product: 36,690 g	No growth on treated bioindicator, growth on control bioindicators	[redacted]

				Bioquell aeration units: [redacted] Distribution fans: [redacted] Biological indicators: [redacted]	Humidity:37-46% Temperature: 24-28°C		

Conclusion on the efficacy of the product

Conclusion on efficacy after evaluation

Use #1 "large enclosure"

Efficacy is demonstrated with a phase 2 step 1 test against bacteria, yeast, fungi, bacterial spores, viruses, mycobacteria and bacteriophages under clean conditions (PT 2 and PT4) at room temperature and with a maximum contact time of 30 minutes. Bovine enterovirus is tested at 10°C in the Phase 2 step 1 test.

For the phase 2 step 2 test a NFT 72-821 test is performed with a room size of 81.7m2 under clean conditions (PT2 and PT4) for all claimed target organisms at room temperature and with a humidity between 40-80% and application rate of about 10 g/m^3.

For the test with Murine norovirus and Porcine parvovirus there were issues with the drying of the test organisms and cytotoxicity of the cell lines which resulted in a log reduction below the required log reduction of 4. As the test indicates that there is no virus detected in the samples this is considered sufficient to demonstrate virucidal activity.

Soiling for PT3 clean conditions are not included in the efficacy test. For PT3 virucidal efficacy the phase 2 step 2 test is performed with Porcine parvovirus.

With the provided efficacy test, efficacy is demonstrated for a room size of 30-150m^3 with a relative humidity between 10-80% at room temperature with an application rate of 10 g/m^3 for PT2 and PT4.

Use #2 "small enclosure"

Efficacy is demonstrated with a phase 2 step 1 test against bacteria, yeast, fungi, bacterial spores, viruses, mycobacteria and bacteriophages under clean conditions at room temperature and with a maximum contact time of 30 minutes. Bovine enterovirus is tested at 10°C in the Phase 2 step 1 test.

For the phase 2 step 2 test a NFT 72-821 test is performed with a room size of 0.45 m^3 for all claimed target organisms at room temperature and with a humidity between 40-80% and application rate around 100 g/m^3.

The tested room size can be considered worst-case for the claimed room size due to air to surface ratio in the experiment.

For the test with Murine norovirus and Porcine parvovirus there were issues with the drying of the test organisms and cytotoxicity of the cell lines which resulted in a log reduction below the required log reduction of 4. As the test indicates that there is no virus detected in the samples this is considered sufficient to demonstrate virucidal activity.
The phase 2 step 2 tests are performed with an advised application rate of 100 g/m^3, in the report this is further specified to the exact application rate which deviates within 10% of 100g/m^3. As this deviation can be considered due to the application and is within a 10% range of 100 g/m^3, efficacy is considered substantiated for a claim of 100 g/m^3. In addition, it is necessary to perform a validation of the procedure in each room to be disinfected, to determine that the disinfection process is efficacious. Based on this evaluation and the addition of the validation in the use instructions the efficacy is substantiated.
Soiling for PT3 clean conditions (3.0 g/l BSA) is not included in the efficacy tests. For PT3 virucidal efficacy the phase 2 step 2 test is performed with Porcine parvovirus.
With the provided efficacy tests, efficacy is demonstrated for a room size of <4m^3 with a relative humidity between 10-80% at room temperature with an application rate of 100 g/m3 for PT2 and PT4.

Bioquell HPV-AQ is bactericidal, virucidal, fungicidal, sporicidal, yeasticidal, mycobactericidal and bacteriophagicidal in large and small enclosures when applied in accordance with its use instructions.

Every individual enclosure HPV decontamination is unique and MUST be validated using appropriate biological or chemical indicators.

eCA NL note:
At the submission of the dossier no guidance was available how to evaluate room disinfection by fogging. The performed Semi field tests in this dossier are performed according to the NFT 72-281:2014 protocol, with a room size of 81.7m^3 and 0.45m^3. In 2018 a TAB was published what room sizes can be claimed according to the tested volume. With the information provided by the TAB about the tested room size and the information presented in the guidelines of NFT 72-281:2014, we are of the opinion that the tested room size of 81.7 m^3 can be used to claim a room size of 30 -150 m^3 in the use. The use description of use 1 claims a room size of >4m^3. This claim is not in the range of the 30-150 m^3 as is substantiated with the efficacy tests. The applicant did not wish to adjust the claim to 30-150m^3 but requested to keep the claim. The new EN17272, which describes a wider claim of >4 m^3, was not available during the evaluation phase of the dossier yet. The submitted tests were performed with the NFT 72-281:2014 and therefore we were of the opinion that the claim of >4m^3 as room size was not substantiated. Therefore use 1 could not be authorized.
For use 2 with a claim of 0.4-4 m^3 a test with a room size of and 0.45m^3 was provided. As no guidance was present at the start of the evaluation, we considered that the small room size is worst case considering the air to surface ratio and therefore this claim was substantiated.
In use 1 and 2 a claim is made for PT03 in clean conditions, these conditions require testing with soiling of 3.0 g/l BSA. All tests are performed with 0.3 g/l BSA, therefore the claim for PT03 areas could not be authorized.

eCA: Conclusion after Working group discussion and ad-hoc follow up.

During the RCOM phase and the working group discussion the applicant provided additional data 1)to substantiate the claim >4m^3 room size and provided 2)additional information and specification of the PT03 claim to "*disinfection of pre-cleaned animal cages/racks within biomedical and animal laboratory facilities".* Additionally, new virucidal efficacy test were provided to address the issues raised by other MSCA's about the cytotoxicity problems with the virus tests present in the dossier. The data is added to the dossier and were evaluated during the ad-hoc follow up procedure.

Assessment and conclusions

The provided EN17272 for large enclosures for all target organisms is performed according to the test protocol and meets the validation requirements. The provided efficacy tests in accordance with EN17272 demonstrate that the required log reductions are achieved for bacteria, yeast, fungi, bacterial spores and mycobacteria and therefore substantiates a claim for enclosures >4m^3 with a dosage of 10 g/m^3 product. The newly provided data do not contain the organism bacteriophages which is included in the claim, however, based on the EN13610 and the NFT 72-281:2014 tests with bacteriophages efficacy is covered for bacteriophages.

Therefore the claim of >4m^3 for bacteria, yeast, fungi, bacteriophages, bacterial spores and mycobacteria with a dosage of 10 g/m^3 is substantiated.

The field studies provided cannot be used to substantiate the claimed use. This is due to the fact that the room size is provided by the applicant and is not found in the report, the area to be disinfected is separated in multiple rooms therefore disinfection occurs in multiple rooms and not one large room. The amount of product used in these separate area's is reported but it is not reported what the size of these area's is. Therefore it is not possible to estimate the application rate. Additionally, the temperatures measured during the testing are rather high and in some cases above the description of room temperature. Spores survival was measured in the field tests. Information is provided if growth of the bacterial spores occurs after treatment, but it does not describe the rate of growth and a certain log reduction cannot be determined based on the provided data. Therefore this data is considered supporting information.

The PT03 claim based on data with 0.3 g/L BSA as interfering substance in the tests is restricted to the use of "*disinfection of pre-cleaned animal cages/racks within biomedical and animal laboratory facilities".* The following instructions in the use instructions for use have been included "Only for use on thoroughly cleaned non-porous surfaces (PT3), when possible use automated washing machines". With this restriction efficacy is substantiated with the provided tests with 0.3 g/L BSA as soiling conditions.

The efficacy tests in accordance with NFT 72-281:2014 present in the dossier did not meet the validation requirements for virucidal activity. The new provided efficacy tests against viruses for small and large enclosures according to the EN17272 meet the validation requirements and demonstrate the required log 4 reduction against viruses. Therefore, the provided EN17272 tests demonstrate that the virucidal activity is substantiated for both uses in this dossier.

2.2.5.6 Occurrence of resistance and resistance management

None known

2.2.5.7 Known limitations

The efficacy of Bioquell HPV-AQ is reduced in the presence of gross organic contamination. In line with the use instructions, surfaces to be disinfected must be free of gross / visible contamination. For animal racks/cages pre-cleaning should take place, when possible use automated washing machines.

Every individual enclosure HPV decontamination is unique and MUST be validated using appropriate biological or chemical indicators.

2.2.5.8 Evaluation of the label claims

See conclusion on efficacy.

Every individual enclosure HPV decontamination is unique and MUST be validated using appropriate biological or chemical indicators.

2.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s)

Bioquell HPV-AQ is not intended to be used with other biocidal products.

2.2.6 Risk assessment for human health

No toxicity studies were performed for Bioquell HPV-AQ. Bioquell HPV-AQ contains only hydrogen peroxide and water, and therefore the classification is based on the calculation rules in accordance to CLP taking into account (SCLs from) the harmonised classification, information from the available MSDS and the use of information as included in the hydrogen peroxide CAR..

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Irritating to skin
Justification for the value/conclusion	Studies with Bioquell HPV-AQ are not available for skin irritation/ corrosion. Therefore, the toxicological profile and the classification of the formulation were determined by applying the calculation methodology according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP and DSD	Skin Irrit. 2, H315: Causes skin irritation

Data waiving	
Information requirement	8.1 skin corrosion or skin irritation
Justification	Bioquell HPV-AQ contains only hydrogen peroxide and water. Based on the harmonised classification of hydrogen peroxide, the following SCL are determined: Skin Corr. 1A; H314: C ≥ 70 % Skin Corr. 1B; H314: 50 % ≤ C <70 % Skin Irrit. 2; H315: 35 % ≤ C <50 % Eye Dam. 1; H318: 8 % ≤ C <50 % Eye Irrit. 2; H319: 5 % ≤ C < 8 % STOT SE 3; H335: C ≥ 35 % Considering that the formulation contains 35% hydrogen peroxide, H315 should be assigned. Since the formulation has a pH higher than 2.0 (concentrate and 1% dilution) and that the formulation contains only the a.s. and water, it is considered acceptable to apply the harmonised SLC for classification purposes.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Causes serious eye damage
Justification for the value/conclusion	Studies with Bioquell HPV-AQ are not available for eye irritation. Therefore, the toxicological profile and the classification of the formulation were determined by applying the calculation methodology according to Regulation (EC) No 1272/2008.

Classification of the product according to CLP and DSD	Eye Dam. 1; H318: "Causes serious eye damage"

Data waiving	
Information requirement	8.2 eye irritation
Justification	Bioquell HPV-AQ contains only hydrogen peroxide and water. Based on the harmonised classification of hydrogen peroxide, the following SCL are determined: Skin Corr. 1A; H314: C ≥ 70 % Skin Corr. 1B; H314: 50 % ≤ C <70 % Skin Irrit. 2; H315: 35 % ≤ C <50 % Eye Dam. 1; H318: 8 % ≤ C <50 % Eye Irrit. 2; H319: 5 % ≤ C < 8 % STOT SE 3; H335: C ≥ 35 % Considering that the formulation contains 35% hydrogen peroxide, H318 should be assigned. Since the formulation has a pH higher than 2.0 (concentrate and 1% dilution) and that the formulation contains only the a.s. and water, it is considered acceptable to apply the harmonised SLC for classification purposes.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	Irritating to the respiratory tract
Classification of the product according to CLP and DSD	STOT SE 3; H335: "May cause respiratory irritation"

Data waiving	
Information requirement	8.7.1 "other endpoints"
Justification	Bioquell HPV-AQ contains only hydrogen peroxide and water. Based on the harmonised classification of hydrogen peroxide, the following SCL are determined: Skin Corr. 1A; H314: C ≥ 70 % Skin Corr. 1B; H314: 50 % ≤ C <70 % Skin Irrit. 2; H315: 35 % ≤ C <50 % Eye Dam. 1; H318: 8 % ≤ C <50 % Eye Irrit. 2; H319: 5 % ≤ C < 8 % STOT SE 3; H335: C ≥ 35 %

	Considering that the formulation contains 35% hydrogen peroxide, H335 should be assigned.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not considered a skin sensitiser
Justification for the value/conclusion	Studies with Bioquell HPV-AQ are not available. Therefore, the toxicological profile and the classification of the formulation were determined by applying the calculation methodology according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP and DSD	not classified

Data waiving	
Information requirement	8.3 skin sensitisation
Justification	Bioquell HPV-AQ contains only hydrogen peroxide and water. These substances are not classified for skin sensitisation and therefore the formulation does not require classification for skin sensitisation.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not considered a respiratory sensitiser
Justification for the value/conclusion	Studies with Bioquell HPV-AQ are not available. Therefore, the toxicological profile and the classification of the formulation were determined by applying the calculation methodology according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP and DSD	No classification

Data waiving	
Information requirement	8.4 respiratory sensitisation
Justification	Bioquell HPV-AQ contains only hydrogen peroxide and water. These substances are not classified for skin sensitisation and therefore the formulation does not require classification for skin sensitisation.

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	420 mg/Kg bw (Rat LD_{50}), resulting in an ATEmix of 1200 mg/kg bw

Justification for the selected value	Studies with Bioquell HPV-AQ are not available. Therefore, the toxicological profile and the classification of the formulation were determined by applying the calculation methodology according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP and DSD	H302: Harmful if swallowed

Data waiving	
Information requirement	8.5.1 acute oral toxicity
Justification	Studies with Bioquell HPV-AQ are not available. Therefore, the toxicological profile and the classification of the formulation were determined by applying the calculation methodology according to Regulation (EC) No 1272/2008. Hydrogen peroxide is classified as H302. The ATE_{mix} of Bioquell HPV-AQ containing 35% hydrogen peroxide is calculated as follows: 100/ ATEmix = 35%/420 ATE_{mix} = 1200 mg/kg bw Since the estimated acute oral ATE_{mix} is greater than 300 mg/kg bw but less than 2000 mg/kg bw, the formulation needs to be classified with Acute Tox. 4; H302: "Harmful if swallowed".

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	ATEmix = 4.29 mg/L
Justification for the selected value	Studies with Bioquell HPV-AQ are not available. Therefore, the toxicological profile and the classification of the formulation were determined by applying the calculation methodology according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP and DSD	H332: Harmful if inhaled

Data waiving	
Information requirement	8.5.2 acute inhalation toxicity
Justification	Studies with Bioquell HPV-AQ are not available. Therefore, the toxicological profile and the classification of the formulation were determined by applying the calculation methodology according to Regulation (EC) No 1272/2008. Hydrogen peroxide is classified as H332. The ATE_{mix} of Bioquell HPV-AQ containing 35% hydrogen peroxide is calculated as follows: 100/ ATEmix = 35%/1.5 ATE_{mix} = 4.29 mg/L Since the estimated acute oral ATE_{mix} is greater than 1.0 mg/L but less than 5.0 mg/L, the formulation needs to be classified with Acute Tox. 4; H332: "Harmful if inhaled". **eCA NL note**: during commenting phase it was pointed out that for classification for acute toxicity by inhalation for previous UA dossiers it was concluded by WG to use the converted acute toxicity point estimate that corresponds to the state of the active substance originally tested for the harmonised classification (i.e. 11 mg/L for H332 classified vapours). As the referred study was performed with vapour (result >0.17 mg/L 4 h, highest attainable concentration of 49.3% HP). Considering the 11 mg/L, an ATEmix of 31 is derived, therefore no classification for acute inhalation toxicity needs to be assigned.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not applicable
Justification for the selected value	
Classification of the product according to CLP and DSD	Not classified.

Data waiving	
Information requirement	8.5.3 acute dermal toxicity
Justification	Bioquell HPV-AQ contains only hydrogen peroxide and water. These substances are not classified for acute dermal toxicity and therefore

	the formulation does not require classification for acute dermal toxicity.

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption			
Substance	Hydrogen peroxide		
Value(s)*	Not applicable		
Justification for the selected value(s)	Reference active substance – same product conclusions apply		

** please include the concentration range(s) the values are applicable for, if relevant*

Data waiving	
Information requirement	8.6 information on dermal absorption
Justification	According to the assessment report of hydrogen peroxide, systemic effects are not relevant as hydrogen peroxide causes local effects at the site of first contact only. Therefore, it is not required to determine a dermal absorption value since the risk assessment will be based on local effects only.

Available toxicological data relating to non active substance(s) (i.e. substance(s) of concern)

Not applicable – there are no co-formulants except for water.

Available toxicological data relating to a mixture

Not applicable – product is the same as the representative active substance

Other

The product breaks down into oxygen and water leaving no residue. Therefore, do not need to consider food and feed or additional studies.

Assessment for endocrine disrupting properties

According to the ED (endocrine disruptor) criteria with respect to humans established in the Commission Delegated Regulation (EU) 2017/2100, a substance shall be considered as having endocrine disrupting properties if it meets all of the following criteria:

a) it shows an adverse effect in [an intact organism or its progeny]/[non-target organisms], which is a change in the morphology, physiology, growth, development, reproduction or life span of an organism, system or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences;
b) it has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system;
c) the adverse effect is a consequence of the endocrine mode of action.

To examine if any of the co-formulants contained in the product may possess ED properties, a screening was performed by examining the co-formulants are

- Classified as CMR or PBT;
- Identified as ED in the DG Santé's Impact Assessment study on Screening of available evidence on chemical substances for the identification of endocrine disruptors;
- Identified as ED in the EU list of potential endocrine disruptors; or
- Listed in CoRAP linked to ED concerns.

However, besides the active substance, the formulation only contains water which does not have any concerns for adverse effect to meet the criteria as described above. Therefore no further ED assessment on co-formulants was required and the endocrine disruption properties of Bioquell HPV-AQ is covered by the endocrine disrupting properties of the active substance.
The following text is included in the BPC opinion of hydrogen peroxide: *Hydrogen peroxide is not considered to have endocrine disrupting properties*. Therefore, Bioquell HPV-AQ is not considered to have endocrine disrupting properties for human health.

2.2.6.2 Exposure assessment

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.

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 (0.9ppm). Technical and engineering RMM are in place to limit secondary exposure to hydrogen peroxide aerosols.

The primary effects and mode of action of hydrogen peroxide are limited to local effects at the site of first contact in or on the body. The rapid degradation of hydrogen peroxide at the site of first contact explains further the absence of systemic effects after repeated exposure to hydrogen peroxide via all routes of exposure. In the absence of clear systemic effects and the mode of action of hydrogen peroxide is characterized by local effects at the site of first contact only. For this reason, no systemic effects will be evaluated. Quantitative risk assessment is required only for the inhalation route, to compare the hydrogen peroxide concentration in the air with the determined AEC.

Qualitative risk assessment for dermal route will be performed later in the risk characterization section by taking into account appropriate risk mitigation measures.

Identification of main paths of human exposure towards active substance(s) and substances of concern from its use in biocidal product

Summary table: relevant paths of human exposure							
Exposure path	Primary (direct) exposure			Secondary (indirect) exposure			
	Industrial use	Professional use	Non-professional use	Industrial use	Professional use	General public	Via food
Inhalation	N/A	Yes	N/A	N/A	Yes	Yes	N/A
Dermal	N/A	Yes	N/A	N/A	Yes	Yes	N/A
Oral	N/A	No	N/A	N/A	No	No	N/A

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1.	Loading	Primary exposure Professional users may be dermally and respiratory exposed to hydrogen peroxide during loading of Bioquell HPV-AQ into the HPV equipment. Loading of canisters onto closed automated system and manually pouring from container into tank on machine. Hydrogen peroxide causes primarily local effects by exposure.	Professional
2.	Post application	Secondary exposure Dermal and inhalation exposure possible from residual vapours in treated rooms. Professional users and the general public may have negligible inhalation and dermal exposure once the enclosure has been released post gassing. Re-enty to rooms allowed once the atm concentration of hydrogen peroxide is <1.25 mg/m^3 (0.9ppm)	Professional General Public

Industrial exposure

No Industrial exposure is anticipated

Professional exposure

Scenario 1: Loading

Description of Scenario 1: Loading
The scenario for automated loading of the product onto a closed system has been addressed in the active substance AR. Bioquell HPV-AQ is packaged in bottles of 75ml, 150ml, 950ml, 1000ml, 2000ml, 5000ml and 25L. All enclosures should be sealed before initiating the disinfection cycle. The majority of loading tasks are performed using a closed dosing system; Professionals insert the sealed cartridge containing Bioquell HPV-AQ as delivered by the applicant into the HPV machine, seal the enclosed space / room and initiate the decontamination cycle. There will be no exposure of the professional to the product when dosing using via the closed system. In some cases, the product has to be poured manually from the container into the tank on the machine. Containers of up to 5000 mL size will be used for this task. The operator will open and pour the product into the tank directly before the decontamination cycle is initiated. Professional users may be dermally and respiratory exposed to hydrogen peroxide during loading of Bioquell HPV-AQ into the HPV equipment. Oral exposure is considered negligible: Dermal exposure: 35% hydrogen peroxide Inhalation (aerosol) exposure: TNsG model; Mixing and loading model 7 (TNsG part 2 p. 142 (corrected), pouring) Inhalation (vapour) exposure: ConsExpo; RIVM Pesticides factsheet - mixing and loading, liquids.

	Parameters	Value
Tier 1	Concentration of AS in product	395 g/L (35%)
	Max amount of product per loading	5 L
	Temperature	20°C
	Inhalation indicative value - aerosol[2]	0.94 mg/m^3
	Duration of task[1]	10 minute
	Max frequency	4 x per day
	Body weight[1]	60 kg
	Respiration rate[1]	1.25 m^3/h

1. Guidance on the Biocidal Products Regulation. Vol III: Human Health Parts B+C Version 1.2 May 2018 – Biocides Human Health Exposure Methodology
2. Mixing and loading model 7 (TNsG part 2 p. 142 (corrected)
3. ConsExpo Web; Pesticides Fact Sheet – mixing and loading

Consexpo Web – exposure to vapour, constant release

	Parameters acc. to WGVII2018_TOX_8-2, scenario D	**Value**
Tier 1	Exposure duration [1]	1.33 min
	Product amount [2]	2500 g
	Weight fraction substance	35 %
	Room size (personal breathing zone)	1 m^3
	Ventilation rate, worst-case value for unspecified room	0.6/h
	Vapour pressure (H_2O_2 AR)	299 Pa
	Application temperature	25 °C
	Mass transfer coefficient (new ConsExpo default)	10 m/hr
	Molecular weight matrix	18 g/mol
	Release area (opening of bottle)	20 cm^2
	Adult body weight	60 kg

[1] According to Consexpo Pest Control Fact Sheet, the exposure and application duration is 1.33 min.
[2] According to ConsExpo Cleaning Products Fact Sheet, the product amount is half the amount of the bottle content.

Calculations for Scenario 1

Maximum dermal exposure is 395g/L (35%).

Inhalation (aerosol) exposure: 0.94 mg/m^3 x 35% = 0.33 mg/m^3

Vapour exposure: 2.0×10^{-1} mg/m^3

Further information and considerations on scenario 1

Product is classified for local effects, for which suitable personal protective equipment (gloves, eye protection, coverall) is prescribed.

Scenario 2: post-application

Description of Scenario 2: Post application

This scenario is covered by the CAR for hydrogen peroxide but has been assessed in line with the information provided by the applicant for this use.

During the disinfection step, exposure to hydrogen peroxide is not possible as access to the vapour-treated area is denied. After the disinfection cycle is completed, the enclosure is aerated to remove the hydrogen peroxide. When the aeration cycle is complete, sensors inform when the hydrogen peroxide level is below 1.25 mg/m³ (AEC). Biological and chemical indicators can be collected to confirm the efficacy of the disinfection cycle.

Professional users and the general public may be exposed via the dermal and inhalation routes to the residual aerosols on re-entry to the treated areas.

During treatment, operators must not enter a target area until the concentration of hydrogen peroxide in the area has been measured to be ≤1.25 mg/m³ (0.9 ppm)(AEC specified in active substance AR).
RMM are applied to ensure that the treated area is not entered before the concentration of hydrogen peroxide is below 1.25 mg/m³(0.9ppm).

- 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 ≤1.25 mg/m3(0.9ppm).
- The professional user may only enter the room in emergency situations when the hydrogen peroxide level has dropped below 75 ppm (105 mg/ m³, IDHL value NIOSH) and respiratory protective equipment (Type of RPE to be specified by the authorisation holder within the product information) for re-entry at levels above 1.25 mg/m³) and suitable protective equipment (goggles, gloves and coverall) must be worn.
  Use a calibrated sensor to confirm the enclosure is ≤1.25 mg/m³(0.9ppm) prior to re-entry.

	Parameters	Value
Tier 1	RMM air	Machine aeration
	RMM – emergency re-entry (<75 ppm)	RPE for re-entry at levels above 1.25 mg/m³ (Type of RPE to be specified by the authorisation holder within the product information)
	Indicative value for air – aeration phase[1]	≤ 1.25 mg/m³ (0.9ppm)
	Indicative value for air – re-entry[1]	≤ 1.25 mg/m³ (0.9ppm)
	Dwell time	35 minutes
	Frequency	Up to 4 cycles per day

1. Recommendation from the active substance Assessment Report.

Summary table: estimated exposure for inhalation			
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure (mg/m3)**	
		Aerosol	**Vapour**
Scenario 1: Loading	1/None	0.33	0.20
Scenario 2: Post application	1/ None	1.25	1.25

Combined scenarios

Not relevant. The exposure only takes place during the loading operation, exposures in scenario 2 are considered lower than the AEC, because of the risk mitigation measures.

Non-professional exposure

Bioquell HPV-AQ is only intended to be used by professional users.

Exposure of the general public

Bioquell HPV is applied using a Bioquell vaporisation module. The general public are not allowed in the target areas during product application. After the treatment the target areas must be aerated. The target areas may not be entered when concentrations of hydrogen peroxide are >1.25 mg/m^3 (0.9 ppm).

Hydrogen peroxide vapour breaks down to oxygen and water leaving no residues.

Monitoring data

No monitoring data is available for this product.

Dietary exposure

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 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/m3 (0.9ppm) 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 0.9ppm in the air ensures that the hydrogen peroxide concentrations on the surfaces is also below 0.9ppm. 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. ***Exposure associated with production, formulation and disposal of the biocidal product***

Not applicable. The safety during production, formulation and disposal of the product is covered by other regulations.

Aggregated exposure

Aggregated risk assessment is not applicable for hydrogen peroxide due to the high reactivity of the active substance.

Summary of exposure assessment

Scenarios and values to be used in risk assessment				
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total exposure**	
			Dermal	**Inhalation**
1.	Professional	1/ None	35%	Aerosol: 0.33 mg/m³ Vapour: 0.20 mg/m³
2.	Professionals and the general public	1/ None	Negligible	≤1.25 mg/m³ (0.9ppm)

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Reference	**Study**	**NOAEL (LOAEL)**	**AF[1]**	**Correction for oral absorption**	**Value**
AEL inhalation long-term	90 day inhalation rat	10mg/m³ NOAEC in 90-day inhalation study (rat)	8	N/A	1.25 mg/m³ (0.9ppm)
AEL inhalation medium-term	90 day inhalation rat	10mg/m³ NOAEC in 90-day inhalation study (rat)	8	N/A	1.25 mg/m³ (0.9ppm)
AEL inhalation acute	90 day inhalation rat	10mg/m³ NOAEC in 90-day inhalation study (rat)	8	N/A	1.25 mg/m³ (0.9ppm)
AEL dermal	Not applicable – qualitative assessment for dermal effects only				
ARfD	not established				
ADI	ADI not established, the				

	substance is not systemically available. The agreed acceptable max concentration is 0.1 mg/L in human drinking water. In the main use in PT 5, drinking water of chicken, max concentration: 5 mg/L				

Maximum residue limits or equivalent

Hydrogen peroxide is approved as plant protection product, for which is indicated in Annex IV of Reg. (EU) 2017/1777 that no MRL is required. Furthermore, hydrogen peroxide is approved as plant protection product, for which is indicated in Annex IV of Reg. (EU) 2017/1777 that no MRL is required. Although hydrogen peroxide could not be found in the EU Veterinary Medicinal Product Database, a summary report from the CVMP on hydrogen peroxide was available (i.e. https://www.ema.europa.eu/en/documents/mrl-report/hydrogen-peroxide-summary-report-2-committee-veterinary-medicinal-products_en.pdf) which indicates that this substance can be included as a VMP product and that it is not necessary to set MRLs.

Risk for professional users

Only professional users will use the product in association with the Bioquell Hydrogen Peroxide Vapour System.

Systemic effects

Task/ Scenario	Tier	Systemic NOAEC mg/m³	AEC mg/m³	Estimated uptake mg/m³	Estimated uptake/ AEC (%)	Acceptable (yes/no)
Scenario 1: Loading - aerosol	1	10	1.25	0.33	26.4	Yes
Scenario 1: Loading - vapour	1	10	1.25	0.20	16.0	Yes
Scenario 1: Loading – combined exposure to aerosol and vapour	1	10	1.25	0.53	42.4	Yes

Scenario 2: Post application	1	10	1.25	< 1.25	< 100	Yes

There are no concerns for systemic effects via inhalation of aerosols and vapour from the proposed use. All exposures are below the AEC of 1.25 mg/m^3.

Local effects

Hazard	Exposure									Risk
Hazard category	*Effects in terms of C&L*		*PT*	*Who is exposed?*	*Tasks, uses, processes*	*Potential exposure route*	*Frequency and duration of potential exposure*	*Potential degree of exposure*	*Relevant RMM & PPE*	*Conclusion on risk*
HIGH	Skin Irrit. Cat. 2 H315 Eye Dam. Cat 1 H318 STOT SE 3 H335	AEC of 1.25 mg/m 3	2 4	Professional	Scenario 1: loading (manual pouring of product into machine)	Dermal (skin and eye) inhalation	1 - 4 x day 10 mins	Dermal: 35% Hydrogen peroxide Inhalation Aerosol: 0.33 mg/m³ Vapour: 0.20 mg/m³	RMM adequate for the high hazard category are achievable: RMM excluding risk for skin and, eyes: Manual pouring: - use of substance appropriate gloves, goggles ,coverall (EN 13034, 13962, 14605 or 943 according to pattern of exposure - Training of users Automated loading: - Sealed canisters loaded onto closed system Controlled inhalation exposure, air concentration maintained below AEC of 1.25 mg/m³ **Measures to control exposure, such as:** **Technics** - Minimisation of manual phases/work tasks, - Minimisation of splashes and spills; **Organisation** - Management/supervision in place to check that the RMMs in place are	Acceptable: No exposure expected since technical (PPE/RPE) and packaging RMM adequate for the high hazard category are achievable; - low exposure level compared to adverse effect concentration - high degree of organisational RMMs already in use or recommended and compliance expected - Package design eliminating exposure

									being used correctly and OCs followed; - Training for staff on good practice. - Good standard of personal hygiene	
additional information included for completeness		AEC of 1.25 mg/m3	24	Professional General public	Scenario 2: Post-application Secondary exposure to residual aerosols	Dermal (skin and eye) inhalation	1 x day	≤1.25mg/m^3(0.9 ppm)	RMM are applied to ensure that the treated area is not entered before the concentration of hydrogen peroxide is below 1.25 mg/m^3. - 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 ≤1.25 mg/m3. - The professional user may only enter the room in emergency situations when the hydrogen peroxide level has dropped below 75 ppm (105 mg/ m^3, IDHL value NIOSH) and respiratory protective equipment (Type of RPE to be specified by the authorisation holder within the product information) for re-entry at levels above 1.25 mg/m^3) and suitable protective equipment (goggles, gloves and coverall) must be worn. - Use a calibrated sensor to confirm the enclosure is ≤1.25 mg/m3 prior to re-entry.	Acceptable - low exposure level compared to adverse effect concentration - high degree of operational RMMs already in use or recommended and compliance expected: • High level of containment • Minimization of manual phases

Conclusion
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.

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 RMM are 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. Personal Protective Equipment (PPE);
PPE includes the use of 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 (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 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/m3 (0.9ppm) 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 0.9ppm in the air ensures that the hydrogen peroxide concentrations on the surfaces is also below 0.9ppm. 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.

Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

Not applicable, because the product contains only 1 active substance.

2.2.7 Risk assessment for animal health

The product is used for PT3, however, no animal exposure will occur as animals are removed from the enclosure during gassing. The general risk mitigation measures includes the following RMM: "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 are expected.

2.2.8 Risk assessment for the environment

Bioquell HPV-AQ is identical to the representative product in the CAR and is used in the same way. Both products are intended to be used for surface disinfection via a vapourised hydrogen peroxide process. The product in the CAR is assessed for use in PT2 and PT4, with the PT4 process identified as being the same as the PT2 process. The Bioquell HPV-AQ product is also intended for use in PTs 2 & 4, but also PT3 in clean conditions equivalent to those found in PT2 applications and thus the process for PT3 is identical to that for PT2 and PT4.

Refer to the Hydrogen Peroxide Assessment Report (2015) for the list of endpoints.

2.2.8.1 Effects assessment on the environment

The PNECs agreed for Hydrogen peroxide under the EU review and detailed in the AR (2015) are presented in the table below. No further ecotoxicology data are submitted.

Agreed PNECs for hydrogen peroxide

PNEC	PNEC (from AR 2015)	Justification
$PNEC_{STP}$	4.66 mg/L	Assessment factor of 100 applied to EC_{50} of 466 mg/L
$PNEC_{aquatic,\ freshwater}$	0.0126 mg/L	Assessment factor of 50 (as 2 long term studies available covering 2 trophic levels) applied to NOEC of 0.63 mg/L from the chronic Daphnia study.
$PNEC_{sediment,\ freshwater}$	0.0103 mg/kg wwt (0.0474 mg/kg dw)	Equilibrium partitioning method
$PNEC_{terrestrial}$	0.0018 mg/kg wwt (0.00208 mg/kg dw)	Equilibrium partitioning method
$PNEC_{secondary\ poisoning}$*	-	
Air	Not applicable	No hazard identified
*Not determined in Assessment Report (2015). Given the extremely low estimated log k_{ow} and short half-life, there should be no risk of secondary poisoning.		

Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required

The product is a formulation of the active substance in water; therefore classification of the product with regard to environmental hazard is based on the data for the active substance. No further data on the formulation are submitted.
Under the harmonised classification (Annex VI) of the 'Classification, labelling and packaging of substances and mixtures (CLP) Regulation (1272/2008)', hydrogen peroxide is 'Not Classified' as hazardous to the aquatic environment. However in the assessment report of hydrogen peroxide (2015), it was stated that Aquatic Chronic 3 (H412) classification should be applied according to the 2 ATP to CLP Regulation (Regulation (EC) No 286/2011). For the product containing 35% w/w hydrogen peroxide, the environmental classification H412 applies.

Further Ecotoxicological studies

No new data is available – see hydrogen peroxide CAR

Endocrine disruption activity of non-active substances

The Commission Delegated Regulation (EU) 2017/2100 specifying the scientific criteria for the determination of endocrine-disrupting properties (ED criteria) under Regulation (EU) No 528/2012 (BPR) establishes that the ED criteria become applicable by 7 June 2018 for biocides (https://www.ctgb.nl/onderwerpen/hormoon-verstoorders).

No further ecotoxicological studies are available for Bioquell HPV-AQ and this were not tested for potential endocrine disruption properties. Bioquell HPV-AQ contains the active substance hydrogen peroxide and water.

For the active substance, no ED assessment is required because for active substances which have been approved, the EU assessment should be followed. As discussed in the Assessment Report for hydrogen peroxide (March 2015), hydrogen peroxide is not included in the Commission staff working document on implementation of the Community Strategy for Endocrine Disrupters - a range of substances suspected of interfering with the hormone systems of humans and wildlife (COM (1999) 706)). There is no evidence of any endocrine disruption potential in the human health or ecotoxicological studies presented in the dossier.

An ED screening of co-formulants was not required as Bioquell HPV-AQ only consists of active substance and water.

Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)

No new data is available – see hydrogen peroxide CAR

Supervised trials to assess risks to non-target organisms under field conditions

No new data is available – see hydrogen peroxide CAR

Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk

No new data is available – see hydrogen peroxide CAR

Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)

Not Applicable

Foreseeable routes of entry into the environment on the basis of the use envisaged

The product is applied by vaporisation with Bioquell Hydrogen Peroxide Vapour (HPV) system followed by microcondensation in order to deliver the disinfectant to surfaces in closed systems. Air emissions are minor, since vaporised hydrogen peroxide is decomposed by the aeration system after disinfection. In a realistic worst-case, no relevant amounts of hydrogen peroxide would be expected to reach sewage or manure from this application. Once reaching sewage or manure, hydrogen peroxide will rapidly react with organic matter and be decomposed by microbial catalase and dissolved transition metal ions such as iron. None, or negligible, hydrogen peroxide would remain in sewage sludge or manure applied to soil.

Further studies on fate and behaviour in the environment (ADS)

No new data is available – see Hydrogen Peroxide CAR

Leaching behaviour (ADS)

Not applicable

Testing for distribution and dissipation in soil (ADS)

In a realistic worst-case, no relevant amounts of hydrogen peroxide would be expected to reach sewage or manure from this application. Once reaching sewage, hydrogen peroxide will rapidly react with organic matter and be decomposed by microbial catalase and dissolved transition metal ions such as iron. None, or negligible, hydrogen peroxide would remain in sewage sludge or manure applied to soil.

Testing for distribution and dissipation in water and sediment (ADS)

In a realistic worst-case, no relevant amounts of hydrogen peroxide would be expected to reach sewage from this application. Once reaching sewage, hydrogen peroxide will rapidly react with organic matter and be decomposed by microbial catalase and dissolved transition metal ions such as iron. None, or negligible, hydrogen peroxide would exit the sewage treatment plant to water or sediment.

Testing for distribution and dissipation in air (ADS)

No new data – see hydrogen peroxide CAR

There are no indications that hydrogen peroxide contributes to depletion of the ozone layer. The half-life for the purposes of risk assessment is 24 hours in air. The calculated half-life is below the trigger value of 2 days, which is used as a cut off value to identify chemicals that could be of potential concern for long range transport through the atmosphere. The environmental risk to air is considered acceptable.

If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)

Not applicable

If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)

Not applicable

2.2.8.2 Exposure assessment

General information

Assessed PT	PTs 2, 3 & 4
Assessed scenarios	Scenario 1: Surface disinfection within large (>4m^3) enclosures Scenario 2: Surface disinfection within small (0.25m^3 to 4m^3) enclosures
ESD(s) used	Evaluated in CAR
Approach	Scenario 1: Average consumption Scenario 2: Average consumption
Distribution in the environment	Guidance on the Biocidal Product Regulation. Volume IV: Environment - Part B+C: Assessment and Evaluation. European Chemicals Agency, Report no. ECHA-17-G-23-EN, Helsinki, Finland, 2017. (alternative: based on measured data) SimpleTreat version 4.0 with 3.1 settings Technical Agreements for Biocides Environment (ENV). Version 2.0, 29 August 2018. European Chemicals Agency, Helsinki, Finland.
Groundwater simulation	Not applicable
Confidential Annexes	No
Life cycle steps assessed	Scenario 1: Production: No Formulation No Use: Yes Service life: No Scenario 2: Production: No Formulation No Use: Yes Service life: No
Remarks	Bioquell HPV-AQ is applied in sealed enclosures and breaks down into oxygen and water leaving no residues. Once reaching sewage, hydrogen peroxide will rapidly react with microbes and organic matter, and be decomposed by

	microbial catalase and dissolved transition metal ions such as iron. These effects were accounted for using the half-life of 6 minutes (11.2 min transferred to 12 °C) from Document II A, Section 4.1.1.1 (Spain et al 1989) in studies using similar media regarding microbial density compared to raw sewage. Assuming single first-order kinetics and a residence time in sewage of 1 hour (default according to the ESD for PT5), a fraction of the discharged hydrogen peroxide reaching the STP is calculated as follows: Fsewage = exp(- ln(2)/DT50 * 60 min) = 0.024.

Emission estimation

Emission estimation is carried out for PTs 2, 3 & 4 together, as the uses are identical from an emission estimation perspective. Note that for PT3 applications, only negligible amounts of hydrogen peroxide may be present in manure when it is spread to soil because of degradation and therefore in line with the CAR this emission route is not assessed further.

Scenario 1, PTs 2,3 & 4

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: Surface disinfection within large (>4 m^3) enclosures			
Application rate of biocidal product	10	g/m^3	
Concentration of active substance in the product	395	g/L	35%
Room size	50,000	m^3	default volume for slaughterhouses disinfected by fogging/smoke generation according to ENV of TAB 2.0 (2018)
Number of applications (x day)	1		Applicant data
Fair	0.0036	-	Calculated in accordance with CAR
Fwater	0.05	-	CAR
Fsewage	0.024		CAR

In accordance with the CAR, the emission factor to air (Fair) was estimated as the quotient of the maximum residual concentration in air after a catalytic aeration step and the minimum target concentration in air (target concentration is 35% and corresponds to 250 ppm), i.e. 0.9 ppm/250 ppm = 0.36% (i.e. 0.0036).

<u>Calculations for Scenario 1</u>
ELocal water:
Calculated using a default volume of 50,000 m^3 for slaughterhouses decontaminated once per day (note the most common size enclosure decontaminated using HPV-AQ is 40 m^3) =50,000 m^3 x 10 g/m^3 x 0.35 x 0.05 x 1 per day = 8750 g/day.
ELocal air:
Calculated using an arbitrary worst case maximum enclosure size of 50,000 m^3 decontaminated using HPV-AQ once per day = 50,000 m^3 x 10 g/m^3 x 0.35 x 0.0036 x 1 per day = 630 g/day.

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	8.75 0.6	Before degradation After degradation in drain
Air	0.63	

Scenario 2, PTs 2, 3 & 4

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: Surface disinfection within small (0.25 m^3 to 4 m^3) enclosures			
Application rate of biocidal product	100	g/m^3	
Concentration of active substance in the product	395	g/L	35%
Room size	4	m^3	Applicant data
Number of applications (x day)	4		Applicant data
Fair	0.0036	-	Calculated in accordance with CAR
Fwater	0.05	-	CAR
Fsewage	0.024		CAR

In accordance with the CAR, the emission factor to air (Fair) was estimated as the quotient of the maximum residual concentration in air after a catalytic aeration step and the maximum target concentration in air, (target concentration is 35% and corresponds to 250 ppm), i.e. 0.9 ppm/250 ppm = 0.36%.

<u>Calculations for Scenario 2</u>
ELocal water:
Calculated based on the largest size "small volume" enclosure (4 m^3) decontaminated 4 times per day = 4 m^3 x 100 g/m^3 x 0.35 x 0.05 x 4 per day = 28 g/day.
ELocal air:
Calculated based on the largest size "small volume" enclosure (4 m^3) decontaminated 4 times per day = 4 m^3 x 100 g/m^3 x 0.35 x 0.0036 x 4 per day = 2.02 g/day

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	0.028	Before degradation

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
	0.00073	After degradation in drain
Air	0.00202	

Fate and distribution in exposed environmental compartments

The foreseeable routes of entry into the environment based on the intended use:

Intended Use	**Environments and groups of organisms exposed**					
	Sewage Treatment Plant	**Freshwater**	**Saltwater**	**Soil**	**Air**	**Birds & mammals**
Disinfection of surfaces indoor (PT2, PT3, PT4)	++	+	_	+	++	-

- = no exposure route
+ = indirect exposure
++ = direct exposure

Emissions from the process are low since the whole disinfection cycle is carried out within sealed enclosures and treated surfaces do not require rinsing after the application.

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks
Molecular weight	34.01	g/mol	Value from Assessment Report
Melting point	-0.43	°C	Value from Assessment Report
Boiling point	150.2	°C	Value from Assessment Report
Vapour pressure (at 20°C)	214	Pa	Value from Assessment Report
Water solubility (at 25°C)	100,000	mg/L	Hydrogen peroxide is miscible in water, hence highest recommended value used in the risk assessment as worst case
Log Octanol/water partition coefficient	-1.57	Log 10	Estimated value
Organic carbon/water partition coefficient (Koc)	1.598	L/kg	Estimated value

Henry's Law Constant (at 20°C)	0.00075	$Pa/m^3/mol$	Value from Assessment Report
Biodegradability	Yes		'Ready biodegradability' is not applicable for inorganic compounds, however hydrogen peroxide has shown a DT_{50} of 2 min in sewage sludge (at 20°C), so will not persist in the environment
DT_{50} for STP (at 20°C) $k_{deg\ stp}$	2 499	Min 1/d	Value from Assessment Report
DT_{50} for biodegradation in surface water (at 12°C)	5	d	Value from Assessment Report
DT_{50} for hydrolysis in surface water (at 12°C)	Stable	d	Value from Assessment Report
DT_{50} for photolysis in surface water	Stable	d	Value from Assessment Report
DT_{50} for degradation in soil (at 12°C)	12	hr	Value from Assessment Report
DT_{50} for degradation in air	24	hr	Value from Assessment Report
Bioaccumulation	BCF fish: 1.4 BCF earthworm: 0.84	L/kg ww	Estimated values

Calculated fate and distribution in the STP		
Compartment	Percentage [%]	Remarks
Air	0.0002	Source: calculated based on WGIV2019_ENV_6-3_Harmonisation of UA cases_PAA_C and WGIII2020_ENV_8-3a_Harmonisation of UA cases_PAA_INFO
Water	0.64	
Sludge	0.01	
Degraded in STP	99.32	

Calculated PEC values

Summary table on calculated PEC values								
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**PEC seawater**	**PEC seased**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[mg/L]	[mg/L]	[mg/kg_{wwt}]	[mg/L]	[mg/kg_{wwt}]	[mg/kg $_{wwt}$]	[µg/L]	[mg/m^3]
Scenario 1	7.26E-04	7.26E-05	5.93E-05	N.A.	N.A.	6.05E-05	0.01	[-]
Scenario 2	2.32E-06	2.32E-07	1.90E-07	N.A.	N.A.	1.93E-07	<0.001	[-]

N.A. not applicable

- Emission to air is negligible since the whole disinfection cycle is carried out within sealed enclosures.

2.2.8.3 Risk characterisation

Atmosphere

There are no indications that hydrogen peroxide contributes to depletion of the ozone layer. The half-life for the purposes of risk assessment is 24 hours in air. The calculated half-life is below the trigger value of 2 days, which is used as a cut off value to identify chemicals that could be of potential concern for long range transport through the atmosphere.

Emissions to air from biocidal uses are negligible and do not alter existing background concentrations in the troposphere to any relevant degree. Therefore, an assessment of PECs in air and emissions due to use of biocidal products is not relevant

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values	
	$PEC/PNEC_{STP}$
Scenario 1	< 0.001
Scenario 2	< 0.001

Conclusion: PEC/PNEC ratios are < 1. There is no concern for the STP from the proposed uses.

Aquatic compartment

Summary table on calculated PEC/PNEC values				
	$PEC/PNEC_{water}$	**$PEC/PNEC_{sed}$**	**$PEC/PNEC_{seawater}$**	**$PEC/PNEC_{seased}$**
Scenario 1	0.006	0.006	N.A	N.A.

Scenario 2	< 0.001	< 0.001	N.A	N.A.

Conclusion: PEC/PNEC ratios are < 1. There is no concern for the aquatic compartment from the proposed uses.

Terrestrial compartment

Calculated PEC/PNEC values		
	$PEC/PNEC_{soil}$	**Groundwater (µg/L)**
Scenario 1	0.034	0.01
Scenario 2	<0.001	<0.001

Conclusion: There is no concern for the indirect exposure of soil through the spreading of sewage sludge for application of the product for surface disinfection within large (>4 m^3) and small (0.25 m^3 to 4 m^3) enclosures as the PEC/PNEC ratio is < 1.

Groundwater

PEC groundwater is below the threshold of 0.1 µg/L for both scenarios; therefore, no unacceptable risks for groundwater are found for the proposed uses.

Primary and secondary poisoning

Primary poisoning

Primary poisoning is not expected based on the intended use.

Secondary poisoning

Conclusion: The estimated log Kow of hydrogen peroxide is -1.57 indicating negligible potential of bioconcentration in biota of the compound at all. This statement is also supported by BCF calculations (ESR risk assessment report, 2003) for fish and earthworm of 1.4 L/kg ww and 0.84 L/kg ww, respectively.

In regards of this evaluation, accumulation of hydrogen peroxide in the food chain is not expected, and the risk of secondary poisoning in aquatic and terrestrial predators is considered negligible.

Mixture toxicity

Not applicable

Aggregated exposure (combined for relevant emission sources)

Bioquell HPV-AQ is identical to the representative product in the CAR and is used in the same way. Both products are intended to be used for surface disinfection via a

vapourised hydrogen peroxide process. The product in the CAR is assessed for use in PT2 and PT4, with the PT4 process identified as being the same as the PT2 process. The Bioquell HPV-AQ product is also intended for use in PTs 2 & 4, but also PT3 in clean conditions equivalent to those found in PT2 applications and thus the process for PT3 is identical to that for PT2 and PT4.

In the Assessment Report for hydrogen peroxide (2015) the following is stated:

''According to Article 10(1) of BPD a cumulative risk assessment shall be performed where relevant. For hydrogen peroxide it was agreed at the WG V 2014 that an aggregate risk assessment is not regarded relevant due to the high reactivity of the substance.''

Therefore, the aggregated exposure for all applications of Bioquell HPV-AQ was not assessed.

Overall conclusion on the risk assessment for the environment of the product
Based on this 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.

2.2.9 Measures to protect man, animals and the environment

No risk mitigation measures were identified as necessary.

2.2.10 Assessment of a combination of biocidal products

Not applicable

2.2.11 Comparative assessment

Not applicable

3 Annexes[9]

3.1 List of studies for the biocidal product (family)

All relevant studies are contained within the IUCLID file

3.2 Output from exposure assessment tools

Scenario 1; mixing and loading – manual pouring
Vapour exposure – ConsExpo Web

Substance			
Name	Hydrogen peroxide		
CASNumber			
Molecular weight		34	g/mol
KOW		-1.57	10Log
Product			
Name	Bioquell		
Weight fraction substance		35	%
Population			
Name	EU framework Biocides adult		
Body weight		60	kg
Scenario mixing and loading liquid			
Frequency		4	per day
Description			
Inhalation			
Exposure model	Exposure to vapour - Evaporation Pestcides factsheet; mixing and loading liquids		
Exposure duration		1.33	minute
Product in pure form	No		
Molecular weight matrix		18	g/mol
The product is used in dilution	No		
Product amount		2500	g
Weight fraction substance		35	%
Room volume		1	m≥
Ventilation rate		0.6	per hour
Inhalation rate		1.25	m≥/hr
Application temperature		25	∞C
Vapour pressure		299	Pa
Molecular weight		34	g/mol
Mass transfer coefficient		10	m/hr

9 When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included.

Release area mode	Constant		
Release area		0.002	m3
Emission duration		1.33	minute
Absorption model	Fixed fraction		
Absorption fraction		100	%
Dermal			
Exposure model	n.a.		
Absorption model	n.a.		
Oral			
Exposure model	n.a.		
Absorption model	n.a.		
Results for scenario mixing and loading liquid			
Inhalation			
Mean event concentration		2.0×10^{-1}	mg/m3
Peak concentration (TWA 15 min)		2.0×10^{-1}	mg/m3
Mean concentration on day of exposure		7.4×10^{-4}	mg/m3
Year average concentration		7.4×10^{-4}	mg/m3

3.3 New information on the active substance

No new information

3.4 Residue behaviour

Not applicable

3.5 Summaries of the efficacy studies (B.5.10.1-xx)[10]

10 If an IUCLID file is not available, please indicate here the summaries of the efficacy studies.

Please refer to the IUCLID file

3.6 Confidential annex

The formulation is not confidential. See paragraph 2.1.2.3 of this assessment report.

3.7 Other

Not applicable