Labelling Insert for Bioquell HPV-AQ 35% hydrogen peroxide aqueous solution

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1 OVERVIEW 3
2 HPV BIO-DECONTAMINATION 3
2.1 CONDITIONING 3
2.2 GASSING 3
2.3 DWELL 3
2.4 AERATION 4
3 USER SAFETY REQUIREMENTS 4
3.1 HANDLING BIOQUELL HYDROGEN PEROXIDE 4
4 EFFICACY 6
5 BIO-DECONTAMINATION CYCLE PROTOCOL, (BCP) 6
5.1 STEP 2: NOTIFICATION 8
5.1.1 Personnel Briefing 8
5.1.2 Cycle Operator Briefing 8
5.2 STEP 4: TARGET ENCLOSURE PREPARATION 8
5.2.1 Cleaning 8
5.2.2 Absorbent Materials 9
5.2.3 Occluded Surfaces 9
5.2.4 Extremes of Temperature 9
5.3 STEP 5: CYCLE START 9
5.4 STEP 6: MONITORING 9
5.4.1 Leak Monitoring 10
5.4.2 Cycle Monitoring 10
5.5 STEP 7: CYCLE COMPLETION 10
5.5.1 Cycle Finish Verification 10
5.5.2 Cycle Success Criteria 10
6 VALIDATED AND NON-VALIDATED USE 11
6.1 VALIDATED USE IN ENCLOSURES 11
6.2 CUSTOMISED VALIDATED USE 11
6.2.1 Biological Indicators, BIs 12
6.2.2 Chemical Indicators, CIs 13

1 Overview

Bioquell HPV-AQ has been registered by Ecolab in accordance with the Biocidal Product Regulation for use in accordance with the instructions listed in this document. The contents may only be used with a Bioquell vaporisation module in line with the system user manual and must not be used for any purpose other than that described.

Before using Bioquell HPV-AQ operators should ensure they have undergone appropriate training on the Bioquell system and have been certified as such. If unsure, refresher training should be arranged before using the unit to run a bio-decontamination cycle.

2 HPV Bio-decontamination

When bio-decontaminating an enclosure using hydrogen peroxide vapour ("HPV"), the operator uses the Bioquell vaporisation module to inject HPV into the atmosphere of the enclosure resulting, once saturation conditions have been reached, with the formation of a very thin layer of 'micro-condensation' onto every exposed surface within the enclosure. It is the formation of this microscopic layer of hydrogen peroxide condensate that provides the rapid efficacy of the bio-decontamination process and thus the success of the bio-decontamination cycle itself.

Upon completion of the active phase of the bio-decontamination cycle, the HPV is removed and converted into oxygen and water vapour (humidity).

A typical hydrogen peroxide vapour bio-decontamination cycle is made up of 4 distinct phases, each of which is described below.

2.1 Conditioning

The conditioning phase is made up of internal system tests within the unit, along with the heating of the vaporizer in preparation for the start of the gassing cycle. The system confirms that the environmental conditions are suitable for the decontamination cycle to proceed.

2.2 Gassing

During the gassing phase the Bioquell vaporisation module flash evaporates the Bioquell HPV-AQ to generate HPV which is then injected into an air-stream. The active distribution system injects the HPV into the sealed target enclosure resulting in an increase in the concentration of HPV and, at saturation, producing micro-condensation deposition onto surfaces.

2.3 Dwell

Following the completion of the gassing phase, a pre-established, timed dwell phase results in the HPV circulating throughout the enclosure ensuring that the

HPV has sufficient contact time with the biological agents to achieve a successful bio-decontamination.

2.4 **Aeration**

The aeration phase results in the removal of the HPV from the enclosure, reducing the vapour concentration to < 0.9PPM, the required level in Europe. This is typically achieved by the catalytic conversion of the HPV into water vapour and oxygen.

3 User Safety Requirements

3.1 **Handling Bioquell Hydrogen Peroxide**

Bioquell HPV-AQ contains the active ingredient hydrogen peroxide. Liquid hydrogen peroxide is classified as corrosive and must be handled with the utmost care and whilst wearing appropriate personnel protection equipment, ("PPE"). After handling, users should remove all PPE immediately and wash their hands before eating, drinking, or using the bathroom. Hydrogen peroxide vapour is also harmful in high concentrations and as such liquid hydrogen peroxide should only be handled in open areas or those that have adequate ventilation.

A summary of the health and safety information concerning liquid hydrogen peroxide is shown below, and any PPE used when handling liquid hydrogen peroxide that is not disposable must be maintained in accordance with manufacturers' recommendations.

Skin 	Possible exposure effects: chemical burn – transient, non-permanent whitening of the skin. **IF ON SKIN:** Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation occurs: Get medical advice.
Eyes 	Possible exposure effects: potential for permanent damage. **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.
Mouth / Ingestion 	Possible exposure effects: Corrosive and irritating to the mouth, throat, and abdomen. Large doses may cause symptoms of abdominal pain, vomiting, and diarrhoea as well as blistering or tissue destruction. Stomach distensions (due to rapid liberation of oxygen), and risk of stomach perforation, convulsions, fluid on the lungs or brain, coma, and death are possible. **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.
Vapour 	Possible exposure effects: 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.
Fire 	During a fire, highly toxic gasses may be generated by thermal decomposition. Do not attempt to tackle a hydrogen peroxide fire. **Call the fire department and ask for chemical emergency team.** (Water **only** should be used on a hydrogen peroxide fire).

4 Efficacy

Bioquell HPV-AQ is to be used with a Bioquell vaporisation module as a disinfectant for surfaces and other inanimate objects in enclosures. When used correctly, it is a highly effective bio decontamination agent, active against spores, bacteria, viruses, mycobacteria, bacteriophage, yeasts and fungi on exposed, pre-cleaned non-porous surfaces in enclosures.

Bioquell HPV-AQ can be used in healthcare, pharmaceutical, defence, university and life sciences sectors. It is suitable for indoor use, with two approved fields of use:

- Hard, non-porous surfaces in small (0.25m^3 to 4m^3) sealed enclosures by vapourisation, with prior cleaning. For use in clean conditions in, for example, isolators, pass-through chambers, cabinets, material airlocks, cupboards, filling lines, emergency vehicles, aseptic filling lines, storage containers, and pre-cleaned animal cages/racks within biomedical and animal laboratory facilities.
- Hard, non-porous surfaces in large (>4 m^3) sealed enclosures by vapourisation, with prior cleaning. For use in 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, aseptic filling lines, food production facilities, storage containers, and pre-cleaned animal cages/racks within biomedical and animal laboratory facilities.

When Bioquell solution is used in conjunction with a Bioquell vaporisation module, the following validated cycles shall apply:

For small enclosures: 100 g/m^3 undiluted product, contact time of 35 minutes (after diffusion).

For large enclosures: 10 g/m^3 undiluted product, contact time of 35 minutes (after diffusion).

Aerate until the concentration of hydrogen peroxide is ≤0.9 ppm (1.25mg/m^3).

This product is designed to be used in a Bioquell vaporisation module and may not be used with any other equipment other than for which it was designed. Use of this product in any manner other than for which it was designed is strictly prohibited and may not produce the desired results. Bioquell HPV-AQ is not intended for use as a terminal sterilant / disinfectant for medical devices.

5 Bio-decontamination Cycle Protocol, (BCP)

Prior to commencing a bio-decontamination cycle of the enclosure the individual responsible for decontaminating the enclosure (the "Cycle Manager") must ensure that he / she has adequate and current training and in liaison with the appropriate parties (e.g. the building manager, or supervisor of the proposed enclosure) that

a bio-decontamination protocol has been established. This should cover all aspects of the bio-decontamination cycle and may include, but not be limited to:

- Health and safety considerations;
  - monitoring points and frequency,
  - an evacuation plan,
  - any impact on existing evacuation plans (i.e. will isolation of the target enclosure impact on an active fire escape),
  - emergency procedures,

- Practical considerations;
  - ventilation configuration within the target area,
  - power requirements,
  - access to the target area,
  - biological indicator regime, if any, and location plan,
  - equipment location plan,

The BCP should be comprehensive and may ultimately take the format of a checklist to ensure that every necessary task has been completed by the Cycle Manager. The BCP should relate to the enclosure and be appropriately detailed. The aim of the BCP is to ensure that each bio-decontamination cycle is run in a safe, considered and efficient manner - and may also form part of a validation process where consistency and repeatability are important.

As standard procedure, prior to undertaking a bio-decontamination cycle the Cycle Manager and any other operators should re-acquaint themselves with this packaging material, the user manual and any additional training materials supplied with the Bioquell system. These should be read in context with any existing BCPs that have been established for use within the enclosure, and any applicable local or state laws.

For facilities that are using HPV bio-decontamination technology for the first time a new BCP should be produced. Subsequent bio-decontaminations of the same enclosure may be conducted using an existing BCP. The following sections provide a template that a typical BCP may follow although it must be noted that each bio-decontamination and target facility are inherently different and, as such, this list is not exhaustive and each prospective cycle must be considered individually and will present its own points to address.

- A global plan/sketch of the area surrounding the enclosure showing evacuation routes and the location of emergency equipment (e.g. fire extinguishers, fire alarm 'break-glass' points, emergency shower/eye-wash stations, telephones).
- An evacuation plan in the event of an emergency listing muster points and a list of appropriate emergency contact telephone numbers including:
  - Cycle manager.
  - Target area responsible person (e.g. Unit Manager / supervisor).
  - On-site emergency personnel (if applicable).
  - Local emergency services (Fire, ambulance, police, hospitals).

Whilst it is essential that all areas are independently assessed for suitability, if there are a number of identical enclosures, or enclosures which are representative of each other, it is not essential that a new or full BCP is completed for every decontamination. However, the Cycle Manager must ensure that all processes and procedures are carried out in accordance with a generic dossier, with any enclosure specific alterations adhered to.

5.1 **Step 1: Notification**

5.1.1 Personnel Briefing

Prior to commencing any HPV bio-decontamination cycle it is of the utmost importance that all personnel who may have access to the target enclosure are made aware of the process. All staff/personnel should be briefed in-terms of the logistical factors (cycle timings, areas designated out-of-bounds, restricted access areas, monitoring points) and how their normal working practices may be impacted for the cycle duration and, of course, the health and safety aspects of HPV bio-decontamination.

If appropriate a briefing session should be arranged with key personnel that may routinely have access to the target enclosure and they should be made aware of relevant aspects of the bio-decontamination to be performed including:

- Proposed cycle timings and timescales.
- Emergency procedures and evacuation routes.
- Any impact on existing emergency procedures (i.e. does the target area obscure an active fire escape route if so alternative arrangements must be made prior to the cycle start).
- A background of HPV and the bio-decontamination process.

5.1.2 Cycle Operator Briefing

Prior to the cycle start the cycle operators should have a separate briefing in which all aspects of the BCP are discussed in order to ensure that all cycle personnel are familiar with the detail of the proposed bio-decontamination schedule.

5.2 **Step 2: Target Enclosure Preparation**

Prior to commencing any bio-decontamination cycle the target enclosure should be optimized in order to maximize the efficacy and achieve a rapid and consistent bio-decontamination. There are a number of steps to be taken and these are listed and discussed below.

5.2.1 Cleaning

Hydrogen peroxide vapour has limited penetrating power into dirt and other gross contamination and thus prior to commencing the bio-decontamination cycle the target enclosure must be subject to a minimum level of cleaning to ensure that the target enclosure is *visibly clean* – i.e. free from all gross contamination including dust, dirt, blood, faeces, animal feed. If large levels of dust or dirt are present upon commencing the cycle then viable micro-organisms may well be present below the gross contamination and could possibly survive the bio-decontamination process.

5.2.2 Absorbent Materials

Absorbent materials must be removed from within the target area and not be exposed to the bio-decontamination cycle.

5.2.3 Occluded Surfaces

HPV is not freely penetrating through many materials; as such it is vitally important that the occurrence of occluded (i.e. covered) surfaces is minimized

5.2.4 Extremes of Temperature

The hydrogen peroxide vapour bio-decontamination process relies on saturation of the atmosphere of the sealed target enclosure with vapour in order to form a layer of micro-condensation of hydrogen peroxide that in turn affects the bio-decontamination; as such any factors that can affect the formation of the condensate layer must be controlled. Temperature gradients within the target area should be avoided as cooler surfaces will see the formation of micro-condensation sooner and more plentifully than warmer areas. Failure to do so may potentially lead to reduced efficacy of the bio-decontamination cycle due to uneven vapour distribution throughout the target enclosure.

5.3 **Step 3: Cycle Start**

Before commencing the bio-decontamination cycle the Cycle Manager should go through the BCP as a checklist acknowledging that all necessary steps have been completed ensuring the safety of the cycle.

The Cycle Manager should also confirm that all personnel who work with the target Enclosure and any personnel who may have cause to access the area (e.g. cleaning or security staff) have been notified about the cycle and all evacuation and emergency procedures.

Upon completion of the acknowledgement procedures the Cycle Manager may then begin the bio-decontamination cycle.

5.4 **Step 4: Monitoring**

Monitoring the bio-decontamination cycle takes two distinct phases, monitoring the perimeter of the target enclosure for vapour leakage, and monitoring within

the target enclosure to monitor the cycle progress, and ultimately to confirm the end of the cycle.

5.4.1 Leak Monitoring

The cycle operators should use a hand held hydrogen peroxide sensor in order to verify that there is no escape of vapour from the target Enclosure, by monitoring the perimeter of the target Enclosure. Leak monitoring should continue through the gassing and dwell phases of the bio-decontamination cycle.

5.4.2 Cycle Monitoring

The progress of the bio-decontamination cycle itself should (where applicable) be monitored using remote sensory equipment placed within the target enclosure. The sensors should be configured such that they provide real-time data of the cycle parameters within the target enclosure. This data should then be logged at regular intervals throughout the cycle to record the cycle progress. On completion of the gassing and dwell phases, as the cycle moves into aeration the sensors support verification of the vapour concentration for post-cycle re-entry.

5.5 **Step 5: Cycle Completion**

5.5.1 Cycle Finish Verification

A bio-decontamination cycle is completed once the cycle is in the aeration phase and the vapour concentration is below the applicable local exposure limit for personnel re-entry, (≤0.9ppm). The vapour concentration should first be verified using remote sensors (where applicable) and if they read ≤0.9ppm (or other appropriate local exposure limit) then personnel may re-enter the target enclosure.

5.5.2 Cycle Success Criteria

A bio-decontamination cycle may be declared successful if the validation standards defined in the BCP have been satisfied, and the aeration phase has been completed with the vapour concentration within the target Enclosure confirmed as ≤0.9ppm (or other appropriate local exposure limit).

6 Validated and Non-Validated Use

6.1 Validated Use in enclosures

Validated bio-decontamination cycles utilising Bioquell HPV-AQ with a Bioquell vaporisation module have been developed for use as a sporicide, fungicide, bactericide, yeasticide, mycobactericide, phagicide and virucide in empty sealed enclosures based on standard test methods.

The cycle parameters are:

Inject HPV-AQ 10g/m^3, followed by a 35 minute dwell, followed by aeration until hydrogen peroxide levels are ≤0.9ppm.

For small enclosures: Inject HPV-AQ 100g/m^3, followed by a 35 minute dwell, followed by aeration until hydrogen peroxide levels are ≤0.9ppm.

6.2 Customised Validated Use

Bioquell hydrogen peroxide solution may also be used as a sporicide, fungicide, bactericide, yeasticide, mycobactericide, phagicide and virucide in sealed enclosures of various volumes with the development of a customised validated bio-decontamination cycle.

The set-up and cycle management phases of customized cycles are identical to those for a validated cycle with regard to the preparation of the bio-decontamination cycle protocol, ("BCP"), and target area set-up and sealing procedures.

In order for a customised cycle to be effective it is vital that the Cycle Manager gives due consideration to global vapour distribution throughout the target facility in order to ensure uniform formation of micro-condensation. As such, due consideration must be given to the number and location of Bioquell vaporisation modules deployed during the cycle, and the appropriate use of oscillating distribution fans or other appropriate equipment to ensure good vapour distribution. In accordance with the procedures described above the positions of all equipment used within the bio-decontamination cycle should be recorded on a facility plan within the BCP.

When performing customised validated cycles the cycle must be capable of attaining the required bio-burden reduction (as specified in the BCP), and have appropriate use of pre-determined indicators to ensure that the specified level is reached throughout the target facility.

On completion of the target area set-up and sealing procedures (including indicator placement) (sections 5.1 to 5.4 and 6.2.1), the Cycle Manager can begin the cycle; the cycle itself will have the same structure as a validated cycle with discrete conditioning, gassing, dwell and aeration phases.

Upon successful completion of the 'conditioning' phase (including system test) the cycle moves into the 'gassing' phase with HPV injected into the enclosure. The Cycle Manager should, as appropriate monitor the cycle environmental data from within the target enclosure recorded via the on-board sensory equipment in order to recognize the point of onset of micro-condensation, the dew-point. Once micro-condensation has been achieved within the enclosure the cycle then moves into the 'dwell' phase in which the vapour is allowed to circulate within the target enclosure and ensure adequate contact time is allowed between the hydrogen peroxide and the biological agents to affect a successful bio-decontamination.

Upon completion of the dwell phase the cycle moves into the aeration phase removing the HPV from the target area, reducing the vapour concentration to ≤ 0.9ppm, the required limit in Europe. Once the vapour concentration has been confirmed as ≤0.9ppm, the restricted access status of the target facility may be revoked and the facility 'released' back into normal operation.

Should a cycle fail to meet the pre-determined target challenge then the cycle has not been successful and the cycle should be repeated with the gassing and/or dwell periods increased, and the validation process repeated.

When conducting any bio-decontamination cycle validated or non-validated all user safety procedures listed in section 3 and operational procedures in section 5 (including monitoring and post cycle re-entry) must be adhered to and overseen by the Cycle Manager.

6.2.1 Biological Indicators, BIs

In order to assess the success of bio-decontamination cycles a standard challenge is used to ensure that the cycle has been effective. Whilst various validation methods can be used biological indicators, (BIs), are the industry standard method for validation of hydrogen peroxide bio-decontamination cycles as they present the most consistent, and repeatable challenge.

A number of organisms may be used although the accepted organism is *Geobacillus stearothermophilus;* according to the Spaulding classification Bacillus endospores are the most resistant class of organisms to deactivation and thus provide suitable challenge organisms. *Geobacillus stearothermophilus* also has inherent practical operational advantages in that it is thermophilic with an optimum incubation temperature of 57ºC, limiting the possibility of false positives due to the high incubation temperature. It is also a category 1 organism so is not harmful to humans and thus may be easily and safely handled.

The industrially accepted biological indicator challenge is a 6-log (i.e. > 1,000,000 spores per indicator) inoculum of *Geobacillus stearothermophilus* such as the Bioquell BI product. Experience has shown that the most consistent BIs are those that are inoculated onto a stainless steel substrate; other inoculum substrates including paper are available but experience has shown them to be less consistent and repeatable.

BIs should be placed throughout the target enclosure typically placed in the corners of rooms where a 'dead spot' in terms of vapour distribution is formed at the point where three walls meet. The number of indicators used is at the discretion of the cycle manager, and each location should be recorded on a plan of the target Enclosure and should be kept with the bio-decontamination plan.

Upon completion of the bio-decontamination cycle the BIs should be retrieved and incubated as per the organism protocols and the results available after the defined incubation period.

6.2.2 Chemical Indicators, CIs

Chemical indicators, (CIs) that change colour in the presence of hydrogen peroxide vapour are also commercially available such as the Bioquell Room-CI and Bioquell Isolator-CI products. CI's produce a graduated colour change validating the presence and oxidation effect of the HPV decontamination agent at that location.