



ADVICE SUMMARY

APPLICATION FOR REGISTRATION OF A CHEMICAL PRODUCT

Product name: BIOQUELL HPV-AQ DISINFECTANT
Applicant: BIOQUELL UK
Product number: 68380
Application number: 58257

Purpose of Application and Description of Use: Registration of a 35% hydrogen peroxide liquid product for sporicidal disinfectant for use in bio-decontamination of animal enclosures.

Active Constituent(s): HYDROGEN PEROXIDE

Regulatory Decision:

To grant the application subject to the following conditions:

Standard Conditions of Registration/Approval

1. Containers must meet AgVet Code Regulation 18
2. Label must contain a Date of Manufacture, Batch Number and Expiry Date no greater than 1 year after the DOM

For full conditions, refer to Standard Conditions for Applications on the APVMA website.

ADVICE

State/External Efficacy Reviewer

The results of six efficacy trials, together with literature from the public domain, were submitted in support of the efficacy of the proposed product (35% hydrogen peroxide liquid) as a sporicidal disinfectant in the biodecontamination of enclosures, when used in the Bioquell Z vaporising unit according to programmed cycles.

The trials investigated the performance of the proposed product in different environments against *Geobacillus stearothermophilus*. Three of the trials demonstrated inactivation of spores in test biological units placed on different surfaces to verify efficacy for both porous and non-porous surfaces. The other three trials were the results of site-sterilisation studies and demonstrated complete inactivation of test units with exposure to the proposed product.

All six trials demonstrated complete inactivation of 10^6 *G. stearothermophilus* spores by the proposed product delivered as a vapour to an enclosure using the Bioquell Z unit. The establishment of base-line parameters for dose and cycle parameters (and the adjustment of these factors by a margin of error between 20% to 100%) ensured sufficient exposure to hydrogen peroxide vapour for a completely lethal sterilisation. The use of colourimetric indicators provided further confirmation for biological indicators between validation runs.

The APVMA accepts the advice of the efficacy reviewer, and is satisfied that the proposed product should be safe and effective when used according to the proposed label instructions.

Data relied on to provide the advice

Data No	Data Source*	Author(s)	Title	Date	Data Type	Data Sub-type	Authorising Party	Inherited Application No.
89181	S	Susan Wood, bsc, cbiol, msb of Wickham Laboratories Ltd	Final study report: evaluation for bioquell; sporicidal activity of b-cap 35 antimicrobial agent as applied to bioquell cube rapid processing enclosures in accordance with epa requirements	26 November 2013	Efficacy and safety	Efficacy	Applicant	
89182	S	Bioquell UK LTD - Carl Haworth	Bioquell z-2 hydrogen peroxide gas generator gassing cycle development for room: k07	27 June 2013	Efficacy and safety	Efficacy	Applicant	
85196	S	Lien, B.	Sporicidal Activity of B-Cap 35 Antimicrobial Agent, EPA Reg. No. 72372-1 Applied Through BIOQUELL Vapor Generator	09 April 2009	Efficacy and safety	Efficacy	Applicant	
85195	S	Lien , B	Sporicidal Activity of B-Cap 35 Antimicrobial Agent, EPA Reg. No. 72372-1 Applied Through BIOQUELL Vapor	09 April 2009	Efficacy and safety	Efficacy	Applicant	

Data No	Data Source*	Author(s)	Title	Date	Data Type	Data Sub-type	Authorising Party	Inherited Application No.
			Generator					
85194	S	Lien, B	Sporicidal Activity of B-Cap 35 Antimicrobial Agent, EPA Reg. No. 72372-1 Applied Through BIOQUELL Vapor Generator	10 April 2009	Efficacy and safety	Efficacy	Applicant	
86826	S	Johnston MD, Lawson S, Otter JA,	Evaluation of hydrogen peroxide vapour as a method for the decontamination of surfaces contaminated with <i>Clostridium botulinum</i> spores.	2005	Efficacy and safety	Efficacy	Public	
86827	S	McDonnell G, Grignol G, Antloga K	Vapour-phase hydrogen peroxide decontamination of food contact surfaces.	2002	Efficacy and safety	Efficacy	Public	
86828	S	Bates CJ, Pearse R	Use of hydrogen peroxide vapour for environmental control during a <i>Serratia</i> outbreak in a neonatal intensive care unit.	2005	Efficacy and safety	Efficacy	Public	
86829	S	Kokubo M, Inoue T, Akers J	Resistance of common environmental spores of the genus <i>Bacillus</i> to vapor hydrogen peroxide.	1998	Efficacy and safety	Efficacy	Public	
86830	S	Fichet G, Antloga K, Comoy E, Deslys JP, McDonnell G	Prion inactivation using a new gaseous hydrogen peroxide sterilisation process.	2007	Efficacy and safety	Efficacy	Public	
86831	S	Hall L, Otter JA, Chewins J, Wengenack NL	Deactivation of the dimorphic fungi <i>Histoplasma capsulatum</i> , <i>Blastomyces dermatitidis</i> and <i>Coccidioides immitis</i> using hydrogen peroxide vapor.	2008	Efficacy and safety	Efficacy	Public	
86832	S	Pottage T, Richardson C, Parks S, Walker JT, Bennett AM	Evaluation of hydrogen peroxide gaseous disinfection systems to decontaminate viruses.	2010	Efficacy and safety	Efficacy	Public	
86833	S	Bentley K, Dove BK, Parks SR, Walter JT, Bennett AM	Hydrogen peroxide vapour decontamination of surfaces artificially contaminated with norovirus surrogate feline calicivirus.	2009	Efficacy and safety	Efficacy	Public	
86834	S	Rudnick SN, McDevitt JJ, First MW, Spengler JD	Inactivating influenza viruses on surfaces using hydrogen peroxide or triethylene glycol at low vapor concentrations.	2009	Efficacy and safety	Efficacy	Public	
86835	S	Berrie E, Andrews L, Yezli S, Otter JA,	Hydrogen peroxide vapour (HPV) inactivation of adenovirus.	2011	Efficacy and safety	Efficacy	Public	
86836	S	Heckert RA, Best M, Jordan LT, Dulac GC,	Efficacy of vaporized hydrogen peroxide against exotic animal viruses.	1997	Efficacy and safety	Efficacy	Public	

Data No	Data Source*	Author(s)	Title	Date	Data Type	Data Sub-type	Authorising Party	Inherited Application No.
		Eddington DL, Sterritt WG						
86837	S	Otter JA, Chewins J, Windsor D, Windsor H	Microbiological contamination in cell culture: a potential role for hydrogen peroxide vapour (HPV)?	2008	Efficacy and safety	Efficacy	Public	
86838	S	Rogers J, Richter WR, Shaw MQ, Choi YW	Vapour-phase hydrogen peroxide inactivates <i>Yersinia pestis</i> dried on polymers, steel and glass surfaces.	2008	Efficacy and safety	Efficacy	Public	
86839	S	Otter JA, Yezli S, Schouten MA, van Zanten AR, Houmes-Zielman G, Nohlmans-Paulssen M	Hydrogen peroxide vapor (HPV) decontamination of an intensive care unit to remove environmental reservoirs of multi-drug resistant Gram-negative rods during an outbreak.	2010	Efficacy and safety	Efficacy	Public	
86840	S	Rogers JV, Sabourin CI, Choi YW, Richter WR, Rudnicki DC, Riggs KB et al	Decontamination assessment of <i>Bacillus anthracis</i> , <i>Bacillus subtilis</i> , and <i>Geobacillus stearothermophilus</i> spores on indoor surfaces using a hydrogen peroxide gas generator.	2005	Efficacy and safety	Efficacy	Public	
86841	S	Dryden M, Parnaby R, Dailly S, Lewis T, Davis-Blues K, Otter JA et al	Hydrogen peroxide vapour decontamination in the control of a polyclonal methicillin-resistant <i>Staphylococcus aureus</i> outbreak on a surgical ward.	2008	Efficacy and safety	Efficacy	Public	
86842	S	Jeanes A, Rao G, Osman M, Merrick P	Eradication of persistent environmental MRSA.	2005	Efficacy and safety	Efficacy	Public	
86843	S	Otter JA, Cummins M, Ahmad F, van Tonder C, Drabu YJ	Assessing the biological efficacy and rate of recontamination following hydrogen peroxide vapour decontamination.	2007	Efficacy and safety	Efficacy	Public	
86844	S	French GL, Otter JA, Shannon KP, Adams NM, Watling D, Parks MJ	Tackling contamination of the hospital environment by methicillin-resistant <i>Staphylococcus aureus</i> (MRSA): a comparison between conventional terminal cleaning and hydrogen peroxide vapour decontamination.	2004	Efficacy and safety	Efficacy	Public	
86845	S	Hall L, Otter JA, Chewins J, Wengenack NL	Use of hydrogen peroxide vapor for deactivation of <i>Mycobacterium tuberculosis</i> in a biological safety cabinet and a room.	2007	Efficacy and safety	Efficacy	Public	
86846	S	Otter JA, French GL	Survival of nosocomial bacteria and spores on surfaces and inactivation by hydrogen peroxide.	2009	Efficacy and safety	Efficacy	Public	

Data No	Data Source*	Author(s)	Title	Date	Data Type	Data Sub-type	Authorising Party	Inherited Application No.
86847	S	Boyce JM, Havill NL, Otter JA, McDonald LC, Adams NM, Cooper T, et al	Impact of hydrogen peroxide vapor room decontamination on <i>Clostridium difficile</i> environmental contamination and transmission in a healthcare setting.	2008	Efficacy and safety	Efficacy	Public	
89176	S	Bioquell UK Ltd - Chris Berridge	Room bio-decontamination service - final report	04 July 2014	Efficacy and safety	Efficacy	Applicant	
89177	S	Bioquell UK Ltd - Martyn Broadbent	Room bio-decontamination service - final report	16 July 2014	Efficacy and safety	Efficacy	Applicant	
89178	S	Bioquell UK Ltd - Carl Haworth	Bioquell I-3 hydrogen peroxide gas generator. Gassing cycle development for chamber wic ff 4702.	21 May 2014	Efficacy and safety	Efficacy	Applicant	
89179	S	Bioquell Z Generator	Epa cycle print outs 1, 2 and 3 showing the gas concentration in the enclosure for studies project no: a07533 project no: a07532 project no: a07531	March 2009	Efficacy and safety	Efficacy	Applicant	
89180	S	Apex Labs, Bioquell UK Ltd, Wickham Labs Limited,	Apex laboratories inc, and apex laboratories inc certificate of analysis dvalue and population bioquell certificate of testing - dvalue wickham labs ltd - enumeration d-value and enumeration data for the biological indicators used in studies: project no: a07533 project no: a07532 project no: a07531	March 2009	Efficacy and safety	Efficacy	Applicant	
89183	S	Bioquell UK Ltd - George Olden	Room bio-decontamination service - final report	08 July 2014	Efficacy and safety	Efficacy	Applicant	
85197	S	Rogers JV, Sabourin CLK, Choi YW, Richter WR, Rudnicki DC, Riggs KB, Taylor ML, Chang J.	Decontamination assessment of <i>Bacillus anthracis</i> , <i>Bacillus subtilis</i> , and <i>Geobacillus stearothermophilus</i> spores on indoor surfaces using a hydrogen peroxide gas generator.	10 May 2005	Efficacy and safety	Other information	Public	
85198	S	Bioquell UK	Bioquell Z user manual hydrogen peroxide vapour generator system	26 February 2010	Efficacy and safety	Other information	Applicant	

* S = Data submitted with the application