UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

October 07, 2009

MEMORANDUM

Subject: Efficacy Review for B-Cap® 35 Antimicrobial Agent (EPA Reg. No. 72372-1); DP Barcode: D366986.

From: Ibrahim Laniyan, Microbiologist
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Thru: Tajah Blackburn, Team Leader
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To: Demson Fuller / Marshall Swindell
Regulatory Management Branch I
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Applicant: FMC Corporation
Peroxygens Division
1735 Market Street
Philadelphia, PA 19103

Formulation from the Label:

Active Ingredient	% by wt.
Hydrogen Peroxide	35 %
Inert Ingredients:	65 %
Total	100 %

I. BACKGROUND

The product, B-Cap 35 Antimicrobial Agent (EPA Reg. No. 72372-1), is an EPA-approved microbiocide for use in controlling slime and sulfate-forming bacteria in process waters, air washing systems, recirculating and once through water cooling towers and systems, and packaging and storage vessels. The product is for industrial use only. The applicant requested that EPA amend the product's registration to include a claim for effectiveness as a sterilant for large room enclosures up to 3500ft^3 when used in conjunction with Bioquell HPV generators and following a validated application method. The applicant is also adding use directions for enclosures greater than 3500ft^3 with the development of a customized validation bio-decontamination cycle protocol. Studies were conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121.

This data package contained a letter from the applicant's representative to EPA (dated June 11, 2009), EPA Form 8570-4 (Confidential Statement of Formula), three studies (MRID 477783-01 through 477783-03), Statements of No Data Confidentiality Claims for all studies, a copy of the Use Manual, and the proposed label (October 7, 2009).

II. USE DIRECTIONS

The product is a sterilant for use in conjunction with the Bioquell Hydrogen Peroxide Vapor (HPV) generating equipment. The hydrogen peroxide vapor is intended for use as a sterilant in enclosures up to 3500 cubic feet (validated) or greater (non-validated). Directions on the proposed label provided the following information regarding preparation and use of the product as a sterilant:

For Enclosures up to 35 Cubic Feet

1. Ensure that all porous and non-porous surfaces are visibly clean and free from gross organic contamination.
2. Connect the BIOQUELL HPV generator and add B-Cap® 35 Antimicrobial Agent according to the BIOQUELL User Manual. Seal the enclosure to be sterilized.
3. Apply B-Cap® 35 Antimicrobial Agent at an injection rate of 3.1g/min for 55 minutes.
4. Allow vapor to remain for a minimum of 3 hours.
5. Aerate the chamber using the Bioquell HPV generator until hydrogen peroxide vapor is at or below 1.0 ppm. See the BIOQUELL User Manual for complete instructions for aeration and recommended methods of measuring hydrogen peroxide vapor.

For Enclosures Greater than 35 Cubic Feet to a Maximum of 3500 Cubic Feet

1. Ensure that all porous and non-porous surfaces are visibly clean and free from gross organic contamination.
2. Connect the BIOQUELL HPV generator(s) and add B-Cap® 35 Antimicrobial Agent according to the BIOQUELL User Manual. Seal the enclosure to be sterilized.
3. Apply B-Cap® 35 Antimicrobial Agent as directed in the Use Manual for Validated Enclosures. For a timed cycle apply at an injection rate of 10g/min for 2.5 hours.
4. Allow vapor to remain for a minimum of 15 minutes

5. Aerate the chamber using the Bioquell HPV generator until the hydrogen peroxide vapor is at or below 1.0ppm. See the BIOQUELL User Manual for complete instructions for aeration and recommended methods of measuring hydrogen peroxide vapor.

For Enclosures Greater than 3500 Cubic Feet

1. Ensure that all porous and non-porous surfaces are visibly clean and free from gross organic contamination.
2. Connect the BIOQUELL generator(s) and add B-Cap® 35 Antimicrobial Agent according to the BIOQUELL User Manual. Seal the enclosure to be sterilized.
3. Apply B-Cap® 35 Antimicrobial Agent as directed in the Use Manual for Validated Enclosures. For a timed cycle apply at an injection rate of 10g/min and for a time period sufficient to generate 215g / 500 ft^3 in the enclosure. For example, for a 7000 ft^3 enclosure inject at 10g/min for 5 hours 1 minute.
4. Allow vapor to remain for a minimum of 15 minutes
5. Aerate the chamber using the Bioquell HPV generator until the hydrogen peroxide vapor is at or below 1.0ppm. See the BIOQUELL User Manual for complete instructions for aeration and recommended methods of measuring hydrogen peroxide vapor.
6. Validate the cycle using appropriate biological indicators as per the Use Manual.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Sterilizers: The AOAC Sporicidal Test is required for substantiating sterilizing claims. The following information applies to all products represented as sporicidal or sterilizing agents. Sixty carriers, representing each of 2 types of surfaces (porcelain penicylinders and silk suture loops), must be tested against spores of both *Bacillus subtilis* (ATCC 19659) and *Clostridium sporogenes* (ATCC 3584) on 3 product samples representing 3 different product lots, one of which is at least 60 days old (240 carriers per sample; a total of 720 carriers). Any sterilizing agent (liquid, vapor, or gas) that is recommended for use in a specific device must be tested by the AOAC Sporicidal Test in that specific device and according to the directions for use. Killing on all of the 720 carriers is required; no failures are permitted. Data to support sterilizing claims must be confirmed by tests conducted by a second, independent laboratory of the applicant's choice (other than the laboratory that developed the original data). The following minimal confirmatory data must be developed on one sample of the product: Thirty carriers with each of the 2 types of surfaces (silk suture loops and porcelain penicylinders) against spores of both *Bacillus subtilis* and *Clostridium sporogenes* (a total of 120 carriers) by the AOAC Sporicidal Test. These Agency standards are presented in DIS/TSS-9.

IV. BRIEF DESCRIPTION OF THE DATA

1. MRID 477783-01 "Sporicidal Activity of B-Cap 35 Antimicrobial Agent, EPA Reg. No. 72372-1 Applied Through BIOQUELL Vapor Generator;" Test organism: *Geobacillus stearothermophilus* (ATCC 12980) by Becky Lien. Study conducted at ATS Labs. Study completion date – April 10, 2009. Project Number A07531.

This study was conducted against *Geobacillus stearothermophilus* (ATCC 12980). One lot (batch # 866623) of the product, B-Cap® 35 Antimicrobial Agent, was tested according to EPA-approved ATS Labs protocol BQL01022409.CUST.1 (copy provided). The product lot was at least 60 days old at the time of testing. The product was tested ready-to-use. No organic load

was used in testing. Testing was conducted for a 150-minute exposure time at 22±2°C at 50±5% relative humidity. Seventy-two (72) Apex Laboratories Inc. (Apex, NC 27502) biological indicators (with 1-2x10^6 spores/stainless steel carrier) in Tyvek® pouches were placed throughout a 99 m^3 (3500 ft^3) test chamber. The room was carpeted and painted, and contained cabinets, counters, mattress and box springs, chair, wooden desk, carpet, painted plasterboard, painted timber, glass, samples of stainless steel, desktop computer, laptop computer, aluminum, curtains,.... The room was precleaned then sealed prior to testing. The product was vaporized with Bioquell hydrogen peroxide vapor (HPV) generator injected into the sealed enclosure at a rate of 10g/min for 150 minutes followed by a 15 minute dwell. Bioquell R20 aeration unit was used to aerate for a period of less than two hours (until the hydrogen peroxide vapor concentration in the room is at or below 1.0ppm). The Tyvek® pouches were collected and each exposed carrier was removed from the Tyvek® pouch, transferred to 10 ml of Tryptic Soy Broth. All subculture tubes were incubated for 7 days at 55-60°C, and then examined for growth. Controls included those for sterility, viability, and carrier population count. The reported average titer per carrier is: ***Geobacillus stearothermophilus* ~1.723 x 10^6**.

Note: Protocol amendment reported in the study was reviewed and found to be acceptable.

Note: The neutralization of the H_2O_2 occurs within the sealed enclosure at the end of the exposure period when the H_2O_2 vapor in the air is recirculated through a catalytic converter in the Bioquell machine. This recirculation/aeration period brings the concentration of H_2O_2 to zero in the air and on the surfaces in the enclosure. This is why the system does not require a chemical neutralization broth.

2. MRID 477783-02 "Sporicidal Activity of B-Cap 35 Antimicrobial Agent, EPA Reg. No. 72372-1 Applied Through BIOQUELL Vapor Generator;" Test organism: *Geobacillus stearothermophilus* (ATCC 12980) by Becky Lien. Study conducted at ATS Labs. Study completion date – April 9, 2009. Project Number A07532.

This study was conducted against *Geobacillus stearothermophilus* (ATCC 12980). One lot (batch # 924955) of the product, B-Cap® 35 Antimicrobial Agent, was tested according to EPA-approved ATS Labs protocol BQL01022409.CUST.2 (copy provided). The product lot was at least 60 days old at the time of testing. The product was tested ready-to-use. No organic load was used in testing. Testing was conducted for a 150-minute exposure time at 22±2°C at 50±5% relative humidity. Seventy-two (72) Apex Laboratories Inc. (Apex, NC 27502) biological indicators (with 1-2x10^6 spores/stainless steel carrier) in Tyvek® pouches were placed throughout a 99 m^3 (3500 ft^3) test chamber. The room was carpeted and painted, and contained cabinets, counters, mattress and box springs, chair, wooden desk, carpet, painted plasterboard, painted timber, glass, samples of stainless steel, desktop computer, laptop computer, aluminum, curtains,.... The room was precleaned then sealed prior to testing. The product was vaporized with Bioquell hydrogen peroxide vapor (HPV) generator injected into the sealed enclosure at a rate of 10g/min for 150 minutes followed by a 15 minute dwell. Bioquell R20 aeration unit was used to aerate for a period of less than two hours (until the hydrogen peroxide vapor concentration in the room is at or below 1.0ppm). The Tyvek® pouches were collected and each exposed carrier was removed from the Tyvek® pouch, transferred to 10 ml of Tryptic Soy Broth. All subculture tubes were incubated for 7 days at 55-60°C, and then examined for growth. Controls included those for sterility, viability, and carrier population count. The reported average titer per carrier is: ***Geobacillus stearothermophilus* ~1.496 x 10^6**.

Note: The neutralization of the H_2O_2 occurs within the sealed enclosure at the end of the exposure period when the H_2O_2 vapor in the air is recirculated through a catalytic converter in the Bioquell machine. This recirculation/aeration period brings the concentration of H_2O_2 to zero in the air and on the surfaces in the enclosure. This is why the system does not require a chemical neutralization broth.

3. MRID 477783-03 "Sporicidal Activity of B-Cap 35 Antimicrobial Agent, EPA Reg. No. 72372-1 Applied Through BIOQUELL Vapor Generator;" Test organism: *Geobacillus stearothermophilus* (ATCC 12980) by Becky Lien. Study conducted at ATS Labs. Study completion date – April 9, 2009. Project Number A07533.

This study was conducted against *Geobacillus stearothermophilus* (ATCC 12980). One lot (batch # 930988) of the product, B-Cap® 35 Antimicrobial Agent, was tested according to EPA-approved ATS Labs protocol BQL01022409.CUST.3 (copy provided). The product lot was at least 60 days old at the time of testing. The product was tested ready-to-use. No organic load was used in testing. Testing was conducted for a 150-minute exposure time at 22±2°C at 50±5% relative humidity. Seventy-two (72) Apex Laboratories Inc. (Apex, NC 27502) biological indicators (with 1-2x10^6 spores/stainless steel carrier) in Tyvek® pouches were placed throughout a 99 m^3 (3500 ft^3) test chamber. The room was carpeted and painted, and contained cabinets, counters, mattress and box springs, chair, wooden desk, carpet, painted plasterboard, painted timber, glass, samples of stainless steel, desktop computer, laptop computer, aluminum, curtains,.... The room was precleaned then sealed prior to testing. The product was vaporized with Bioquell hydrogen peroxide vapor (HPV) generator injected into the sealed enclosure at a rate of 10g/min for 150 minutes followed by a 15 minute dwell. Bioquell R20 aeration unit was used to aerate for a period of less than two hours (until the hydrogen peroxide vapor concentration in the room is at or below 1.0ppm). The Tyvek® pouches were collected and each exposed carrier was removed from the Tyvek® pouch, transferred to 10 ml of Tryptic Soy Broth. All subculture tubes were incubated for 7 days at 55-60°C, and then examined for growth. Controls included those for sterility, viability, and carrier population count. The reported average titer per carrier is: ***Geobacillus stearothermophilus* ~1.95 x 10^6**.

Note: The neutralization of the H_2O_2 occurs within the sealed enclosure at the end of the exposure period when the H_2O_2 vapor in the air is recirculated through a catalytic converter in the Bioquell machine. This recirculation/aeration period brings the concentration of H_2O_2 to zero in the air and on the surfaces in the enclosure. This is why the system does not require a chemical neutralization broth.

V. RESULTS

MRID Number	Organism	Batch #	No. Exhibiting Growth / Total No. Tested	Biological Indicator Count (CFU/Carrier)
477783-01	*Geobacillus stearothermophilus*	866623	0/72	~1.723 x 10^6
477783-02	*Geobacillus stearothermophilus*	924955	0/72	~1.496 x 10^6
477783-03	*Geobacillus stearothermophilus*	930988	0/72	~1.95 x 10^6

VI. CONCLUSIONS

1. The submitted efficacy data (MRID 477783-01 through 477783-03) **support** the use of the product, B-Cap 35 Antimicrobial Agent (also known as "Durox LR" or Durox LR Hydrogen Peroxide), when applied through BIOQUELL HPV Generator, as a sterilant against *Geobacillus stearothermophilus.* Conditions of the application were as follows: product injection rate of 10 g/minute for 120 minutes; exposure time of 15 minutes; 99 m^3 (i.e. 3500 ft^3) enclosure.

VII. RECOMMENDATIONS

1. The proposed label claims that the product, B-Cap® 35 Antimicrobial Agent is an effective sterilant, when applied through BIOQUELL Vapor Generator, for treating enclosures up to 3500 ft^3. A product injection rate of 10 g/minute for 150 minutes and 15 minutes dwell time follow by aeration period using the Bioquell HPV generator until the hydrogen peroxide vapor is at or below 1.0ppm. **Data provided by the applicant support these claims**.