UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

December 22, 2010

MEMORANDUM

Subject: Efficacy Review for B-Cap® 35 Antimicrobial Agent;
EPA Reg. No. 72372-1;
DP Barcode: D382572

From: Lorilyn M. Montford
Product Science Branch
Antimicrobials Division (7510P)

Thru: Tajah Blackburn, Team Leader
Product Science Branch
Antimicrobials Division (7510P)

12/22/10

To: Marshall Swindell PM 33/Abigail Downs
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: FMC Corporation
Peroxygens Division
1735 Market Street
Philadelphia, PA 19103

Formulation from the Label:

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

I. BACKGROUND

The product, B-Cap 35 Antimicrobial Agent (EPA Reg. No. 72372-1), is an EPA-approved, ready-to-use, microbiocide solution for use in controlling slime and sulfate-forming bacteria in process waters, air washing systems, re-circulating and once through water cooling towers and systems, including pasteurizer cooling water systems and industrial closed re-circulating process water 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 use for aseptic food processing operations to achieve sterility of commercial food packaging and equipment with a 20 second contact time. The study was conducted at ATS Labs located on 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121.

This data package contained a letter from the applicant's representative to the Agency, (dated August 25, 2010), EPA Form 8570-4 (Confidential Statement of Formula), EPA Form 8570-34 (Certification with Respect to Citation of Data), EPA Form 8570-35 (Data Matrix), one study (MRID 482059-1), Statement of No Data Confidentiality Claim, a copy of the User Manual for the Clarus Hydrogen Peroxide Vapour Generator, and the proposed label.

II. USE DIRECTIONS

The current registrant is to support claims for aseptic food processing operations. Directions on the proposed label provided the following information regarding preparation and use of the product as a commercial sterilant: Apply product on the exterior and interior of food containers and closure systems (cap, seals, etc.) or appropriate food processing equipment surfaces. Use techniques such as, but not limited to, immersion, coarse spray, or circulation to sterilize the equipment. Apply the product at a minimum temperature of 75°C. The product must remain in contact with the packaging surface for a minimum of 20 seconds; longer contact times may be required in certain aseptic food processing lines.

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 482059-01 "Modification of the AOAC Sporicidal Method to Determine Efficacy of Products Used In Aseptic Filling Applications: Test Organisms: *Bacillus subtilis* (ATCC 19659) and *Clostridium sporogenes* (ATCC 3584)." by Amy S. Jeske. Study conducted at ATS Lab located at 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121. Study completion date – August 10, 2010. Project Number A08823.

This study was conducted against *Bacillus subtilis* (ATCC 19659) and *Clostridium sporogenes* (ATCC 3584). The microorganisms used in the study were obtained from the American Type Culture Collection in Manassas, VA. The *Clostridium sporogenes* was prepared by inoculating a tube of Soil Extract Cooked Meat Medium from a stock source and incubating for 3 days at 35-37°C. This was the initial suspension. The *Bacillus subtilis* was prepared by inoculating a 10mL tube of nutrient broth from frozen stock and incubating for 23 hours at 35-37°C on an orbital shaker set to approximately 250 RPM. Stainless steel penicylinders were used to represent hard, non-porous surfaces. All penicylinders were screened according to AOAC Official Methods of Analysis and any carrier positive for growth was discarded. Sets of carriers were immersed for 15 minutes in either a 72±4 hour old broth culture of *Clostridium sporogenes* or in an unadjusted suspension of *Bacillus subtilis* spores at a ratio of 1 carrier per 1.0mL broth culture and then placed into a Petri dish matted with 2 layers of filter paper. The contaminated carriers were transferred to vacuum desiccator for a minimum of 24 hours prior to use in testing. The contaminated carriers used in testing were dried from 3 to 5 days prior to use. Ten (10.0) mL of the test substance was aliquoted into individual sterile 25 x 150 mm tubes. The tubes were placed into a water bath at 75±2°C and allowed to equilibrate prior to testing. Each contaminated carrier was placed into a separate tube containing 10.0 mL of test substance for the 20 second exposure period at 75±2°C. Following completion of the exposure time, each medicated carrier was transferred by hook needle to primary subculture tubes containing 10 mL of Fluid Thioglycollate Medium + 0.2% Catalase. Primary tubes containing the carriers were shaken to assure adequate missing at the carrier neutralizer interface. At least 30 minutes after completion of the primary subcultures, carriers were transferred from primary subculture tubes into individual secondary subculture tubes containing 10 mL of Fluid Thioglycollate Medium. Tubes not showing turbidity at the 21 day reading were heat shocked for 20 minutes at 80±2°C and incubated for an additional 72±4 hours at 35-37°C. Following incubation, the subculture tubes were visually examined for growth.

V. RESULTS

MRID 482059-01

MRID Number	Test Organism	Carrier Type	No. Exhibiting Growth / Total No. Tested		Average (CFU/Carrier)
			Primary	After Heat Shock	
B-Cap 35 Lot# T-9312	*Bacillus subtilis*	Stainless Steel Penicylinders	0/60	0/60	*Bacillus subtilis* 1.51×10^6
	Clostridium sporogenes		0/60	0/60	
B-Cap 35 Lot#2 Drum 830570	*Bacillus subtilis*		0/60	1/60	
	Clostridium sporogenes		0/60	0/60	
B-Cap 35 Lot#3 Drum 647331	*Bacillus subtilis*		0/60	0/60	*Clostridium sporogenes* 1.12×10^6
	Clostridium sporogenes		0/60	0/60	
B-Cap 35 Lot#4 A312041610	*Bacillus subtilis*		0/60	0/60	
	Clostridium sporogenes		0/60	0/60	

VI. CONCLUSION

1. The submitted efficacy data (MRID 482059-01) **support** the use of the product, B-Cap 35 Antimicrobial Agent (also known as "Durox LR" or Durox LR Hydrogen Peroxide as a sterilant against *Bacillus subtilis* and *Clostridium sporogenes* following a 20 second exposure time at 75±2°C.

VII. RECOMMENDATIONS

1. The proposed label claims are acceptable regarding the use of the product, B-Cap® 35 Antimicrobial Agent against the following organisms following a 20 second contact time at 75±2°C:

Bacillus subtilis (ATCC 19659)
Clostridium sporogenes (ATCC 3584)

Data provided by the applicant support these claims.

2. The applicant must make the following changes to the proposed label:

- The following proposed label language is not permitted: On page 3 under "**Aseptic Food Processing Operations**", remove the proposed label language that begins, **"Validated food processing systems that have control over the contaminant load on food packaging prior to fill and appropriate food processing**

equipment surfaces may vary concentrations, temperatures, and contact time to achieve commercial sterility.....113 and 114."