UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

January 7, 2011

MEMORANDUM

Subject: Efficacy Review for EPA Reg. No. 56392-8, Dispatch Hospital Cleaner Disinfectant Towels with Bleach; DP Barcode: 383432

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Applicant: Caltech Industries, Inc.
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Formulation from the Label:

Active Ingredient(s)	% by wt.
Sodium Hypochlorite	0.65%
Other Ingredients	99.35%
Total	100.00%

I BACKGROUND

The product, Dispatch Hospital Cleaner Disinfectant Towels with Bleach (EPA Reg. No. 56392-8), is a registered disinfectant (bactericide, virucide, and fungicide), and tuberculocide on hard, non-porous surfaces in hospital, healthcare settings, critical care areas, and nursery/daycare centers. The current application was submitted to add an efficacy claim for *Clostridium difficile* spores. Efficacy data was generated at the (1) Center for Research on Environmental Microbiology at the University of Ottawa located at 451 Smyth Road in Ottawa, Canada, K1H 8M5, and (2) Antimicrobial Test Laboratories located at 3000 Joe DiMaggio Blvd, Suite 32, in Round Rock, Texas, 78665.

The current data package contained a letter from the registrant's representative (SRC, dated October 11, 2010), EPA Form 8570-35, Agency DER (dated December 7, 2009), Statement of No Data Confidentiality, two efficacy studies (MRID No. 482588-01 and-02), and the proposed label.

II USE DIRECTIONS

Directions on the proposed label provided the following instructions for the use and preparation of the product as sporicide against *Clostridium difficile* spores:

> Wipe surface with towel until completely wet. Let stand for five minutes. Wipe dry or allow to air dry. Gross soil must be removed prior to disinfecting.

III AGENCY STANDARDS FOR THE PROPOSED CLAIMS

Antimicrobial Products for Use on Hard Surfaces Using Pre-saturated or Impregnated Towelettes

Towelette products represent a unique combination of antimicrobial chemical and applicator, pre-packaged as a unit in fixed proportions. As such, the complete product, as offered for sale, should be tested according to the directions for use to ensure the product's effectiveness in treating hard surfaces. The standard test methods available for hard surface disinfectants and sanitizers, if followed exactly, would not closely simulate the way a towelette product is used. Agency guidelines recommend that a simulated-use test be conducted by modifying the standard test methods. Agency guidelines further recommend that instead of spraying the inoculated surface of the carrier, the product should be tested by wiping the surface of the carrier with the saturated towelette, and then subculturing the slides after a specified holding time. Performance standards of the current test methods must be met. These Agency standards are presented in EPA Pesticide Assessment Guidelines, Subdivision G, §91-2(h), Pre-saturated or impregnated towelettes; and the April 12, 2001 EPA Memorandum, Draft Interim Guidance for Non-Residual Sanitization of Hard Inanimate Food Contact Surfaces Using Pre-Saturated Towelettes.

Sporicidal Disinfectant against *Clostridium difficile*

The Agency has established interim guidance for the efficacy evaluation of antimicrobial products (e.g., dilutable products, ready-to-use products, spray products, towelettes) that are labeled for use to treat hard, non-porous surfaces in healthcare settings contaminated with spores of *Clostridium difficile*. The effectiveness of such a product must be substantiated by data derived from one of the following four test methods: Most recent version (2006) of AOAC Method 966.04: AOAC Sporicidal Activity of Disinfectants Test, Method I for *Clostridium sporogenes*; AOAC Method 2008.05: Quantitative Three Step Method (Efficacy of Liquid Sporicides Against Spores of *Bacillus subtilis* on a Hard Nonporous Surface); ASTM E 2414-05: Standard Test Method for Quantitative Sporicidal Three Step Method (TSM) to Determine Efficacy of Liquids, Liquid Sprays, and Vapor or Gases on Contaminated Carrier Surfaces; or ASTM E 2197-02: Standard Quantitative Carrier Test Method to Evaluate the Bactericidal, Fungicidal, Mycobactericidal, and Sporicidal Potencies of Liquid Chemical Germicides. Modifications to each test method will be necessary to specifically accommodate spores of *Clostridium difficile*. Because *Clostridium difficile* is an obligate anaerobe, testing should ensure adequate incubation conditions for the recovery of viable spores. The following toxigenic strains of *Clostridium difficile* may be used for testing: ATCC 700792, ATCC 43598, or ATCC 43599. All products must carry a pre-cleaning step, thus no organic soil should be added to the spore inoculum. Results must show a minimum 6 log reduction of viable spores in 10 minutes or less. Control carrier counts must be greater than 10^6 spores/carrier.

IV SYNOPSIS OF SUBMITTED EFFICACY STUDIES

1. "Testing of the Activity of the Expressed Liquid of a Disinfectant Towelette against the Spores of Clostridium difficile using the Second Tier of the Quantitative Carrier Test (QCT-2)" by Justo Perez. Study Completion Date—September 17, 2010. Laboratory Project Number—CREM-2009-11-20-QCT-2-CD-TW.

The product was tested against *Clostridium difficile* spores (ATCC# 43598). Three lots (Lot Nos. RC090812, UC090831, and VC090915) of the product, QF082009001, were tested using the second tier of the Quantitative Carrier Test (QCT-2) (protocol attached). The carrier disks were boiled for 5 minutes in water and thoroughly rinsed with running tap water. They were then soaked in a 1% solution of 7X detergent for about one hour and rinsed first in tap water, then in distilled water and finally in absolute ethanol. A clean, dry beaker was used to collect the expressed liquid from the pre-saturated towelettes. Wearing powder-free Nitirile exam gloves, the package was opened and approximately 30 wipes were removed. Of the 30 wipes removed, two wipes were used to wipe off the gloved hands in order to remove any contamination from the surface and another two were used to wipe down the inside and rim of the beaker. For testing, six towelettes were removed from the canister. The towelettes were rolled into a length of 4 inches or less. One end of the roll of towelettes was twisted clockwise and the other end was twisted counterclockwise to express the liquid solution out of the towelettes and into the beaker. The expressed liquid was transferred into a sterile plastic tube. The expressed liquid was used within 10 minutes post harvest. This procedure was repeated as needed to accomplish testing and

neutralization controls. The spore stock suspension was used to generate carriers. Spores were maintained in a peptone-salts liquid medium for several days anaerobically at 36±1°C. The spores were collected, cleaned, and heated at 70°C for 10 minutes and kept in double distilled water at 3±1°C. Spore purity was validated by spore staining and counting. From the spore stock suspension, a 1:10 water dilution was prepared, mixed by vortex mixing, sonicated for 5 minutes, and used for carrier inoculation. Carriers were placed in a sterile glass Petri dish lined with on the inside bottom with filter paper. Ten (10) µl of the test inoculum was placed at the center of each disk with a positive displacement pipette taking care not to spread the inoculum. Disks were dried in the hood for 30 minutes. The plate containing the carrier disks were transferred to desiccator connected to a vacuum line for 2 hours for continued carrier drying. Contaminated carrier disks were left in the operating vacuum overnight at room temperature. Dried carrier disks (10/lot and 3 controls) were placed with the contaminated side facing up on the bottom of a sterile 25 mL polycarbonate vial. Each carrier disk was treated with 50 µl of the expressed test substance. The control carrier disks were exposed to an equivalent volume of PBS + 0.1% Tween 80. Post contact time, 10 ml of neutralizer in vials was vortex mixed for three 30 second periods to elute survivors from the carrier. The eluate was passed from each vial through a 47 mm diameter membrane (0.22 µm pore diameter). Each vial was rinsed three times with 10 ml of PBS. The washes were passed through the same filter. Each filter was washed three times for a total of about 60 ml. Control carrier disks were treated with PBS + 0.1% Tween 80 to simulate the test substance application. Following neutralization, the eluate was serially diluted and passed through membrane filters as described above for the test. Filter membranes were placed on the surface on BHIYT agar plates and incubated in an anaerobic chamber at 36±1°C. The plates were examined first at the end of 48 hours of incubation and again at the end of five days of incubation to record the number of colonies. Controls included those for sterility, purity, initial suspension population, neutralization confirmation control, and carrier population.

2. MRID No. 482588-02, "Custom Towelette Wetness Test" by Jason Williams. Study Completion Date—February 18, 2010. Protocol Number P1029.

The test carriers were composed of new Formica (Black Matte Finish, e.g. style 909-58) cut to a 12" x 12" size. The test carriers were wiped with a damp cloth and allowed to air dry prior to initiation of the study in order to remove dust. The back of each test carrier was labeled with a unique identifier (e.g., "A", "B", "C") by permanent marker. The exposure portion of the test was controlled by a calibrated timer. One towelette was used to wipe each test carrier (one wipe treated one 12" x 12" carrier). Three towelettes were evaluated per lot. To begin the study, staff initiated the video recording the study. The first test carrier was weighed prior to treatment using a calibrated laboratory balance with an accuracy of 0.01g. The test carrier was placed on a flat lab bench so that it created a square shape in front of the test operator. Ten (10) towels were removed from the towelette package to demonstrate wetness throughout the towelette container. The next towelette was used for the initial test carrier. For the second carrier, 10 more towelettes were removed and the next towelette was used. For the third carrier, another 10 towelettes were removed and then the next towelette was used for the test. The towelette container was securely closed between removal of each set of 11 test towels described above. The towelette was unfolded, and then subsequently folded in half twice, once along the length and once along the width. The

towelette was placed on the top left corner of the test carrier. The test carrier was wiped in an up and down motion, each stoke slightly overlapping the last, until the entire test carrier was completely covered (7 total strokes with the wipe were used on each 12" x 12" carrier). After the entire test surface area was treated, the timer was started. The carrier was placed on the balance and the initial wet weight of the test carrier was recorded. The test carrier was allowed to sit undisturbed for the 5 minute contact time. Upon completion of the contact time, the final wet weight of the test carrier was recorded. Immediately after weighing, a single sheet of unfolded cigarette paper was wiped across the test surface to assist in visualization of wetness for the laboratory technician and video camera due to the clear, colorless nature of the test substance. Visual wetness of the cigarette paper was defined as wetness. The paper wetness was observed and recorded.

V RESULTS

Fields Counted	Spores	Vegetative Cells
0	831	19
1	818	45
2	627	16
3	768	14
4	551	48
5	861	22
Average	743	27
Percent Spore Purity	96.45%	

Control	Dilution Plated	Spore Counts/Replicate	Mean Results (Spore CFU)
Initial Suspension Population Control	10^{-4}	270, 285	2.95×10^{8}/ml
	10^{-5}	24, 26	
	10^{-6}	2, 4	
Carrier Population (Test Date 1-11-10)	10^{-3}	TNTC, TNTC, TNTC	2.81×10^{6}/carrier
	10^{-4}	TNTC, TNTC, TNTC	
	10^{-5}	23, 32, 44	
	10^{-6}	3, 2, 1	
Carrier Population (Test Date 1-22-10)	10^{-3}	TNTC, TNTC, TNTC	6.31×10^{6}/carrier
	10^{-4}	TNTC, TNTC, TNTC	
	10^{-5}	40, 53, 68	
	10^{-6}	7, 6, 7	

Lot	VC090915	UC090831	RC090812

Number						
	Control	Test	Control	Test	Control	Test
Average CFU/carrier	2.83×10^6	0	2.83×10^6	0	2.83×10^6	0
Log reduction	0	6.45230	0	6.45230	0	6.45230
% reduction	0	99.99996	0	99.99996	0	99.99996

Test Substance Lot	Carrier Number	Visual Wetness Confirmed
FG090723	1	Yes
	2	Yes
	3	Yes
HG090825	1	Yes
	2	Yes
	3	Yes
GG090818	1	Yes
	2	Yes
	3	Yes

Lot Number	Carrier Number	Initial Dry Carrier Weight (g)	Initial Wet Carrier Weight (g)	Final Carrier Weight (g)	Remaining Test Substance Weight	Wetness Confirmed
FG090723	1	106.64	107.38	107.05	0.41	Yes
	2	106.81	107.55	107.24	0.43	Yes
	3	106.63	107.66	107.27	0.64	Yes
HG090825	1	109.7	110.51	110.12	0.42	Yes
	2	108.28	108.94	108.66	0.38	Yes
	3	111.75	112.86	112.48	0.73	Yes
GG090818	1	106.26	106.97	106.57	0.31	Yes
	2	107.65	108.58	108.2	0.55	Yes
	3	112.6	113.68	113.23	0.63	Yes

VI CONCLUSIONS

1. The submitted confirmatory efficacy data (MRID No. 482588-01) support the use of the product, Dispatch Hospital Cleaner Disinfectant Towels with Bleach, as a disinfectant with sporicidal activity against *Clostridium difficile* – spore form on hard, non-porous surfaces in the absence of an organic soil load for a 5 minute contact time. Neutralization confirmation testing showed positive growth of the microorganisms. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth. Spore purity were acceptable.

2. The submitted efficacy data (MRID No. 482588-02) supports the use of the product, Dispatch Hospital Cleaner Disinfectant Towels with Bleach, as a disinfectant with sporicidal activity against *Clostridium difficile*—spore form on hard, non-porous surfaces in the absence of organic soil for a contact time of 5 minutes. Neutralization

confirmation testing showed positive growth of the microorganism. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth. Gravimetric testing/data and visual wetness confirmation were included. Video data demonstrated that slides were still wet after the exposure period. The enclosed DVD depicted the contact time using time-lapsed videography.

VII RECOMMENDATION

1. The proposed label claims are acceptable regarding the use of the product, Dispatch Hospital Cleaner Disinfectant Towels with Bleach, as a sporicide wipe against *Clostridium difficile* on hard, non-porous surfaces in the absence of organic soil for a 5-minute contact time. This claim is acceptable as it is supported by the submitted data.