

US EPA ARCHIVE DOCUMENT



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

July 9, 2001

MEMORANDUM:

Subject: Product Efficacy Review for EPA Reg. No.: 56392-7/ Dispatch
DP Barcode: D274454
Case No: 028757

To: Robert Brennis, PM 32 / *Wanda Mitchell*
Regulatory Management Branch
Antimicrobials Division (7510C)

From: Ian Blackwell, Biologist *Ian Blackwell*
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

Through: Emily Mitchell, Team Leader *Emily Mitchell 9/13/01*
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

Applicant: Caltech Industries, Inc.

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Sodium hypochlorite	0.55
<u>Other Ingredient(s):</u>	<u>99.45</u>
Total:	100.00%

BACKGROUND: Caltech Industries, Inc., has submitted a set of three antimicrobial efficacy studies to support the addition of efficacy labeling claims to the label of their product, "Dispatch". The studies were conducted by MicroBioTest, Inc. The MRID Numbers are 453835-01 through 453835-03.

The 4/2/2001 letter from the registrant states that they wish to add the following claims to the product label:

- a. Virucidal claim against Rotavirus.
- b. Bactericidal claim against Methicillin-resistant *Staphylococcus aureus* (MRSA).
- c. Bactericidal claim against Vancomycin-resistant *Enterococcus faecalis* (VRE).
- d. A thirty-second claim against *Mycobacterium tuberculosis*.

RECOMMENDATIONS: PSB findings are:

1. MRID Number 453835-01: "Virucidal Effectiveness Test. Rotavirus" by Donna B. Suchmann. MicroBioTest, Inc. Lab Project ID Number 338-128. Study Completion Date 6/2/00.

This study was conducted to determine the virucidal effectiveness of "Dispatch" on hard, non-porous surfaces contaminated with Rotavirus Strain SA-11 (ATCC VR-899). This was conducted by spraying the test material onto carriers inoculated with the virus from a distance of 6-8 inches until the carriers were saturated. The inoculated carriers were allowed contact with the disinfectant spray for one minute at 20°C. Under the conditions of this study, the virucidal effectiveness test demonstrated that EPA Reg. No. 56392-7 is an effective virucide on surfaces contaminated with Rotavirus Strain SA-11 (ATCC VR-899).

2. MRID Number 453835-02: "AOAC Germicidal Spray Test" by Donna B. Suchmann. MicroBioTest, Inc. Lab Project ID Number 338-127. Study Completion Date 1/24/00.

This study was conducted to determine the antimicrobial effectiveness of "Dispatch" against hard, non-porous surfaces contaminated with *Staphylococcus aureus* MRSA (ATCC 33592) or *Enterococcus faecium* VRE (ATCC 51559). An organic soil load of serum was added to the inoculum to bring the soil load up to 5%. The inoculated carriers were sprayed from a distance of 6-8 inches until wet. The sprayed carriers were given a contact time of one minute with the disinfectant liquid at 20°C.

This study is currently not acceptable because this report needed to demonstrate and document the antibiotic resistance of these strains of *Staphylococcus aureus* MRSA (ATCC 33592) or *Enterococcus faecium* VRE (ATCC 51559). Organisms to be labeled as "antibiotic resistant" must be identified by a specific organism number and origin (American Type Culture, CDC, clinical isolate) and scientific data

submitted to verify the resistance results. Data submitted must include the following:

- a. Results of the testing which includes the values for all antibiotics tested.
 - b. The scientific method used to obtain the results (Kirby-Bauer agar-disk diffusion, automated MIC procedures, agar gradient diffusion). If automated equipment is used, the manufacturer of such equipment must be specified.
 - c. Quality control procedures used to verify results.
 - d. A clear link of the identity of the organisms used in the efficacy testing to those which valid antibiotic susceptibility testing was performed.
3. MRID Number 453835-03: "AOAC Germicidal Spray test Using *Mycobacterium bovis*" by Donna B. Suchmann. MicroBioTest, Inc. Lab Project ID Number 338-126. Study Completion Date 3/20/00.

This study was conducted to determine the disinfectant effectiveness of EPA Reg. No. 56392-7 on hard, non-porous surfaces contaminated with *Mycobacterium bovis* BCG (secured from Organon Teknika). (*Mycobacterium bovis* is the organism used to demonstrate effectiveness against *Mycobacterium tuberculosis*.) Carriers were inoculated with cultures of *Mycobacterium bovis* including enough serum to equal a 5% soil load. The inoculated carriers were sprayed with the test product from a distance of 6-8 inches until thoroughly wet. The carriers remained wet with for test material at 20°C for a contact time of thirty seconds. Under the conditions of this study, EPA Reg. No. 56392-7 was demonstrated to be an effective tuberculocide when exposed to *M. bovis* for thirty seconds.

LABELING:

1. Due to the results of the three submitted studies, PSB/AD will permit the registrant to make the following claims:
 - a. Virucidal claims against Rotavirus.
 - b. A thirty second claim against *Mycobacterim tuberculosis*.
2. Due to the issues of antibiotic resistance, the registrant will not be allowed to make labeling claims against *Staphylococcus aureus* MRSA (ATCC 33592) or *Enterococcus faecium* VRE (ATCC 51559). In order to have this decision reconsidered, the registrant must submit data demonstrating that the *Staphylococcus aureus* MRSA (ATCC 33592) and *Enterococcus faecium* VRE (ATCC 51559) used in MRID Number 453835-02 (Lab Project ID Number 338-127) were actually antibiotic-resistant during the time that this study was conducted.