

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

March 21, 2006

Sally Hayes
Agent for Caltech Industries, Inc.
Scientific and Regulatory Consultants, Inc.
P.O. Box 1014
Columbia City, IN 46725

Subject: Citrace Hospital Germicidal Deodorizer
EPA Registration No. 56392-2
Application Date: March 7, 2006
EPA Received Date: March 9, 2006

Dear Ms. Hayes:

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3(c)9.

Proposed Notification

- Removal of Mycobacterium tuberculosis (TB) organism from the product label

General Comments

Based on a review of the materials submitted, the following comments apply:

The notification application is acceptable. A copy has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, please contact me at 703-308-6422.

Sincerely,

Adam Heyward
Product Manager 34

Regulatory Management Branch II
Antimicrobials Division (7510 C)

		CONCURRENCES				
YMBOL	JOC					
JRNAME	Jay					
ATE	3/21/06					

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SRC
Scientific & Regulatory
Consultants, Inc.

March 7, 2006

Mr. Adam Heyward, PM 34
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
U. S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1801 South Bell Street
Arlington, VA 22202

SUBJECT: CITRACE Hospital Germicide
EPA Reg. No. 56392-2

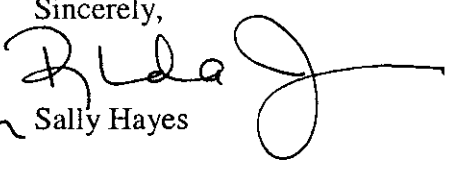
Dear Adam,

On behalf of Caltech Industries ("Caltech"), enclosed is a notification for Citrace Hospital Germicide ("CITRACE") to remove the claim for *Mycobacterium tuberculosis* ("TB") and all labeling related to this claim.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. Caltech understands that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. Caltech further understands that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and Caltech may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

If you have any questions or require additional information for this amendment action, please contact me at 260-244-6270.

Sincerely,


for Sally Hayes

cc: C. Anders



Read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

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United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 56392-2	2. EPA Product Manager Adam Heyward	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Citrace Hospital Germicide	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Caltech Industries, Inc. 2420 Schuette Rd. Midland, MI 48642 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Remove Mycobacterium tuberculosis (TB) from label.
This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. Caltech understands that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. Caltech further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and Caltech may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:					
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. see Attachment	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container see attached sheet		5. Location of Label Directions <input type="checkbox"/> on label side or back panels	
6. Manner in Which Label is Affixed to Product various - see Other			<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled	<input type="checkbox"/> Other Adhesive, silk screen and in-mold	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Sally Hayes	Title Agent, Caltech Industries	Telephone No. (Include Area Code) 260-244-6270			
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Agent, Caltech Industries			
4. Typed Name Sally Hayes		5. Date 3-7-06			



CITRACE

HOSPITAL GERMICIDE



- Citrus Scent
- Eliminates Odors
- For Hard, Non-Porous Surfaces
- Effective against HIV-1 (AIDS Virus) and Hepatitis B Virus (HBV) in 1 Minute
- Effective against Multiple Microorganisms in 10 Minutes:

Staphylococcus aureus; Pseudomonas aeruginosa; Streptococcus pyogenes; Salmonella choleraesuis; Vaccinia Virus; Influenza Virus Type A; Herpes Simplex Virus, Hominus, Type 1 (HSV-1); Poliovirus Type 1 (Mahoney Strain); Canine Parvovirus, ATCC VR-2006, Trichophyton interdigitale (Athlete's Foot Fungus)

EPA REG. NO. 56392-2

Active Ingredients:

o-Phenylphenol	00.12%
Ethanol	66.60%
Other Ingredients	33.28%
TOTAL	100.00%

Contains no CFCs or other ozone depleting substances. Federal regulations prohibit CFC propellants in aerosols.



KEEP OUT OF REACH OF CHILDREN

CAUTION

READ COMPLETE PRECAUTIONS AND DIRECTIONS ON REAR PANELS

NET WT. 14 oz.

CITRACE® HOSPITAL GERMICIDE

This effective product eliminates odors at their source. Does not just mask odors. Kills microorganisms on environmental surfaces (See front panel). Inhibits mold and mildew. **FOR USE IN HOSPITALS, CLINICS, NURSING HOMES, PHYSICIAN OFFICES, DENTAL OFFICES, AND VETERINARY FACILITIES.** Use this product in patient rooms, emergency rooms, outpatient facilities, exam rooms, operating, radiology, physical therapy, central supply, and bathrooms.

THIS PRODUCT IS NOT TO BE USED AS A TERMINAL STERILANT/HIGH LEVEL DISINFECTANT ON ANY SURFACE OR INSTRUMENT THAT (1) IS INTRODUCED DIRECTLY INTO THE HUMAN BODY, EITHER INTO OR IN CONTACT WITH THE BLOOD-STREAM OR NORMALLY STERILE AREAS OF THE BODY, OR (2) CONTACTS INTACT MUCOUS MEMBRANES BUT WHICH DOES NOT ORDINARILY PENETRATE THE BLOOD BARRIER OR OTHERWISE ENTER NORMALLY STERILE AREAS OF THE BODY. THIS PRODUCT MAY BE USED TO PRECLEAN OR DECONTAMINATE CRITICAL OR SEMI-CRITICAL MEDICAL DEVICES PRIOR TO STERILIZATION OR HIGH LEVEL DISINFECTION.

STORAGE AND DISPOSAL: Do not contaminate water, food, or feed by storage and disposal. Storage: Do not use or store near heat or open flame. Store out of reach of children. Disposal: This container may be recycled in the few but growing number of communities where (steel) aerosol can recycling is available. Before offering for recycling, empty the can by using the product according to the label. **(DO NOT PUNCTURE!)** If recycling is not available, wrap the container and discard in the trash.



PRECAUTIONARY STATEMENTS: Hazards to Humans and Domestic Animals. **CAUTION:** Do Not Spray in Eyes. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands before eating/drinking/using toilet. **FIRST AID:** **IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Have the product with you when calling a Poison Control Center or doctor or going for treatment. In case of emergency, call a doctor or National Poison Control Center at 800-222-1222. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting. Before using on painted or plastic surfaces, spot test on an inconspicuous area. Not recommended for use on acrylic plastics or vinyl.

REORDER NO. 49100
DOT 2Q

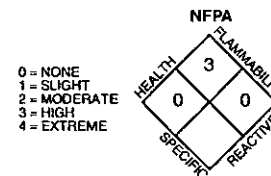


DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. **TO ELIMINATE ODORS:** Shake well. Hold upright. Spray surface 1-2 seconds. For a moment there's the fresh smell of citrus and then it disappears, taking unpleasant odors with it. **TO CLEAN:** Shake well. Spray lightly and immediately wipe dry with cloth or paper towel. Effective as a light duty cleaning agent to remove fingerprints and hand smudges. Use on stainless steel, chrome, mirrors.

TO DISINFECT: Shake well. Hold can upright 6-8" from surface. Spray pre-cleaned nonporous surface until thoroughly wet and allow to remain wet for the appropriate time, depending on the organism (See front panel). Wipe dry or allow to air dry. Remove heavy soil and thoroughly clean surface prior to disinfecting. Kills HIV-1 (AIDS Virus) and HBV in 1 minute at room temperature (68°-77°F, 20°-25°C). Kills other organisms claimed in 10 minutes at room temperature. Kills HIV-1 (AIDS Virus) and HBV on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in healthcare settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood/body fluids, and in which the surfaces/objects likely to be soiled with blood/body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS) and Hepatitis B Virus (HBV). Special Instructions for Cleaning and Decontamination Against HIV-1 (AIDS Virus) and HBV on Surfaces/Objects Soiled with Blood/Body Fluids: **Personal Protection:** When handling items soiled with blood/body fluids, appropriate personal protective equipment such as disposable plastic gloves, gowns, masks, or eye coverings should be considered. **Cleaning Procedure:** Blood/body fluids must be thoroughly cleaned from surfaces and objects prior to disinfecting. **Contact Time:** This product kills HIV-1 (AIDS Virus) and HBV in 1 minute. Contact time required to kill other organisms is 10 minutes. **Disposal of Infectious Materials:** Blood/body fluids and cleaning materials should be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal. **TO CONTROL MOLD AND MILDEW:** Shake well. Clean surface prior to application. Spray surface until thoroughly wet and repeat weekly to prevent regrowth. Provides residual bacteriostatic action in the presence of moisture.

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Midland, MI 48642
1-800-234-7700

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