

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

56392-7

2/17/2006

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February 17, 2006

Sally Hayes
Agent for: Caltech Industries
2420 Schuette Rd.
Midland, MI 48642

Subject: DISPATCH Hospital Cleaner Disinfectant with Bleach
EPA Registration No. 56392-7
Application Date: January 23, 2006
Receipt Date: January 24, 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)" and related text from label

General Comments

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

The notification application is acceptable and 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) 308-6345.

Sincerely,

Wanda Y. Henson
Product Reviewer (32)
Regulatory Management Branch II
Antimicrobials Division (7510C)

CONCURRENCES

SYMBOL	7510C	7510C					
SURNAME	E. Berg	Henson					
DATE	2/17/06	2/17/06					



2 8 4

Read instructions on reverse before completing form.

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



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 56392-7	2. EPA Product Manager Emily Mitchell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) DISPATCH Hospital Cleaner Disinfectant with Bleach	PM# 32	
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:				2. Type of Container	
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		<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)
Signature 		3. Title Agent, Caltech Industries			
4. Typed Name Sally Hayes		5. Date 01/21/06			

3 8 4

SRC
Scientific & Regulatory
Consultants, Inc.

January 23, 2006

Ms. Emily Mitchell, PM 32
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 22202-4501

SUBJECT: DISPATCH® Hospital Cleaner Disinfectant with Bleach
EPA Reg. No. 56392-7

Dear Ms. Mitchell,

On behalf of Caltech Industries ("Caltech"), enclosed is a notification for DISPATCH® Hospital Cleaner Disinfectant with Bleach ("DISPATCH") 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,


Sally Hayes

cc: C. Anders



DISPATCH®

Hospital Cleaner Disinfectant

with Bleach (5500 ppm)

- **Clean & disinfects in one step**
- **Stabilized**
- **Ready-to-use**
- **Bleach & detergent solution**

Kills bacteria, viruses[†] & fungi on hard non-porous surfaces in 1 Minute

Staphylococcus aureus, Methicillin resistant Staphylococcus

aureus (MRSA), Salmonella choleraesuis, Pseudomonas aeruginosa,

Streptococcus pyogenes, Vancomycin resistant Enterococcus faecalis

(VRE), Clostridium difficile (vegetative), Trichophyton mentagrophytes,

HIV-1 (AIDS virus)[†], Herpes Simplex (HSV-2)[†], Rotavirus, Poliovirus,

Hepatitis B Virus (HBV)[†], Hepatitis C Virus (HCV)[†],

EPA Reg.No.56392-7 EPA Est. Nos. 74592-OH-1, 50757-WI-1

Active Ingredient: Sodium Hypochlorite.....0.55%

Other Ingredients.....99.45%

KEEP OUT OF REACH OF CHILDREN

CAUTION

**READ COMPLETE DIRECTIONS AND PRECAUTIONS
ON REAR PANELS**

NET CONTENTS

**DISPATCH® Hospital
Cleaner Disinfectant with Bleach**

4 2 4

*For hospital non-porous surfaces such as stainless steel, plastic, ceramic tile, laminated plastic countertops, vinyl, fiberglass, and porcelain which must be cleaned and disinfected. A rapid acting cleaner disinfectant that can't scratch. *Useful in outpatient clinic, laboratory, clinic, emergency room, radiology, operating room, physical therapy, physician office, nursing home, dental operator, hospital central service area, kitchen and food service area (nonfood surfaces).

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. **To Clean:** Hold bottle 6-8" from surface. Direct gentle spray to soiled area or apply with damp applicator. Wipe clean with a damp applicator such as sponge/cloth/paper towel. Stubborn stains - allow 5 minute contact. No rinsing needed. If streaking is observed, rinse with water. Polish with dry cloth.

To Clean and Disinfect in One Step: Spray surface thoroughly until completely wet. Allow 1 minute at room temperature (68-77°F) to wet surface and disinfect. Wipe clean with a damp sponge, cloth or paper towel. No rinsing needed. Gross soil must be removed prior to cleaning and disinfecting.

To Preclean Instruments Prior to Terminal Sterilization/high level disinfection: Place instruments in a suitable container. Spray to thoroughly drench all surfaces or pour sufficient undiluted product over instruments to allow for complete submersion. Remove instruments, rinse and follow with an appropriate disinfection process. (Critical and semi-critical devices must be followed by the appropriate terminal sterilization/high level disinfection process).

Special Instructions for Cleaning and Decontamination Against HIV-1(AIDS virus) on Surfaces/Objects Soiled with Blood/Body Fluids. KILLS HIV, HBV and HCV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV). **Personal Protection:** When handling items soiled with blood/body fluids, personal protective equipment such as disposable plastic gloves, gowns, masks, or eye coverings should be used. **Cleaning Procedure:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before disinfecting. **Contact time:** Leave surfaces wet for 1 minute. **Disposal of Infectious Materials:** Blood, body fluids, and cleaning materials should be autoclaved and disposed according to federal, state and local regulations for infectious waste disposal.

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 bloodstream 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

Store this product in a cool, dry area, away from direct sunlight and heat to avoid deterioration. In case of spill, flood areas with large quantities of water. Product or rinsates that cannot be used should be diluted with water before disposal in a sanitary sewer. Refill empty container only with DISPATCH Hospital Cleaner Disinfectant with Bleach Refill. When discarding container, place in trash collection. Do not contaminate food or feed by storage, disposal, or cleaning of equipment.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

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 eye. Call poison control center or doctor for further treatment advice.

PHYSICAL AND CHEMICAL HAZARDS: Do not use this product with ammonia or acids such as vinegar, rust removers, or toilet bowl cleaners. This product not intended for use on fabrics.

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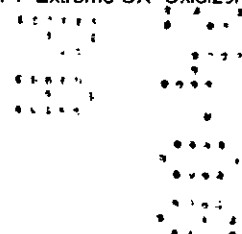
Midland, MI 48642
1-800-234-7700

NFPA

HEALTH 0 FLAMMABILITY 0 REACTIVITY 1 • SPECIFIC OX
0=None 1=Slight 2=Moderate 3=High 4=Extreme OX=Oxidizer

REORDER NO:
EXP. DATE:

LOT NO:



**DISPATCH® Hospital
Cleaner Disinfectant with Bleach**