

56392-7

03-05-2010

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



Office of Pesticide Programs

MAR - 5 2010

David Swain
Scientific & Regulatory Consultants, Inc.
P.O. Box 1014
Columbia City, IN 46725

FILE COPY

Subject: Caltech Industries, Inc.
Dispatch Hospital Cleaner Disinfectant With
Bleach
EPA Registration No. 56392-7
Submission Dated: March 1, 2010
Receipt Dated: March 2, 2010

Dear Mr. Swain:

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

Proposed Notification:

- . To revise the organism name for *Mycobacterium bovis* - BCG, (TB)

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 into your file for future reference.

Should you have any questions or comments concerning this letter, please contact me at Henson.Wanda@epa.gov or call (703) 308-6345.

Sincerely,

Wanda Y. Henson
Acting Product Manager (32)
Regulatory Management Branch II
Antimicrobials Division (7510P)



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 56392-7	2. EPA Product Manager Wanda Henson	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. 4520 E. Ashman Rd., Suite C 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.)

Notification to revise TB organism name per DPR instructions per PR Notice 98-10. 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 confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I 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 I 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 type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
* Certification must be submitted				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
				Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 8 oz, 22 oz, 32 oz, 64 oz, 1 gallon		5. Location of Label Directions <input checked="" type="checkbox"/> On label	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)				
Name David Swain		Title Agent for Caltech Industries, Inc.		
		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 for Caltech Industries, Inc.		
4. Typed Name David Swain		5. Date 3/1/10		

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SRC

Scientific & Regulatory

Consultants, Inc.

March 1, 2010

Ms. Wanda Henson (PM32)
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U. S. Environmental Protection Agency
Room S-4900, 4th Floor
One Potomac Yard
2777 S Crystal Drive
Arlington, VA 22202

SUBJECT: Notification per PR Notice 98-10
DISPATCH Hospital Cleaner Disinfectant with Bleach
EPA Reg. No.: 56392-7

Dear Ms. Henson:

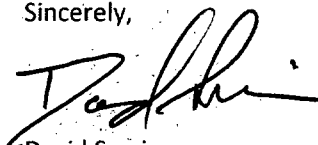
On behalf of our client Caltech Industries, Inc., enclosed is a notification to revise the organism name for *Mycobacterium bovis* – BCG, (TB). This notification is to comply with a requirement from California DPR to revise this organism name to more fully identify the type of strain. This is a Notification per PR Notice 98-10; therefore, no PRIA fee is required.

A label is attached with the change highlighted in red text.

This notification, as stipulated by the guidance, 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 confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I 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 I may be subject to enforcement action, and penalties under sections 12 and 14 of FIFRA.

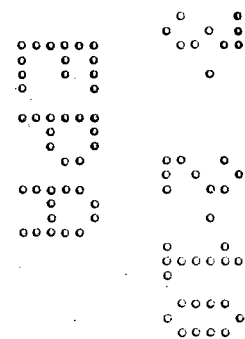
Please contact me at (260) 244-6270 or at dswain@srcconsultants.com if you have any questions.

Sincerely,



David Swain
Agent for Caltech Industries, Inc.

Cc: C. Anders



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**DISPATCH[®] HOSPITAL CLEANER DISINFECTANT
WITH BLEACH**

NOTIFICATION
Date Reviewed: 3/5/10
Reviewed By: Wanda Benson

- [Contains 6500 ppm Sodium Hypochlorite]
- [Cleans, [and], Disinfects, [& Deodorizes] In One Step]
- [Ready-to-use 1:10 Dilution of Bleach (6.0%) and Detergent]
- [For Hospital, Veterinary, & Food Contact Hard, Non-Porous Surfaces]
- [For Instrument Pre-cleaning & Disinfection Of Non-critical Instruments]
- [Kills Pandemic 2009 H1N1 Influenza A virus]

Kills [99.99%] bacteria, viruses[†] & fungi in 1 Minute on hard non-porous surfaces: *Acinetobacter baumannii*, [†]Avian Influenza A Virus, [†]Influenza A H1N1 [2009][Pandemic], [†]Canine Parvovirus, *Enterobacter aerogenes*, *Escherichia coli* ESBL, [†]Feline Panleukopenia Virus, [†]Hepatitis A Virus (HAV), [†]Hepatitis B Virus (HBV), [†]Hepatitis C Virus (HCV), [†]Herpes Simplex Virus (HSV-2), [†]HIV-1 (AIDS Virus), [†]Influenza A Virus, *Klebsiella pneumoniae*, Methicillin resistant *Staphylococcus aureus* (MRSA), [†]Norovirus, [†]Poliovirus Type 1 (Mahoney), *Pseudomonas aeruginosa*, [†]Rhinovirus, [†]Rotavirus, *Salmonella enterica*, *Staphylococcus aureus*, *Streptococcus pyogenes*, *Trichophyton mentagrophytes* (Athlete's Foot Fungus), Vancomycin resistant *Enterococcus faecium* (VRE)
Kills *Mycobacterium bovis* – BCG, (TB) in 30 seconds

Active Ingredient: Sodium Hypochlorite.....0.65%
Other Ingredients:.....99.35%
TOTAL100.00%

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

Read Complete Directions and Precautions on Package [Rear Panels] [Attached Complete Label]

NET CONTENTS

Manufactured for:
©2008 Caltech Industries, Inc.
4520 E. Ashman
Midland, MI 48642
1-800-234-7700
www.caltechindustries.com

EPA Est. No. 74592-CH-1^G
50757-WI-1^G
62801-MI-1^F
48181-IL-1^H
(Superscript used in second letter of Est. No.)
EPA Reg. No. 56302-7

Note: Bracketed [] information is optional text. {Bracketed Text} is for administrative purposes only and will not appear on the printed label.

Multipurpose, broad spectrum cleaner disinfectant for use in healthcare and other areas where control of cross contamination is required. Meets OSHA Bloodborne Pathogen Standards. May be used for instrument pre-cleaning and disinfection of non-critical instruments. **Surfaces:** May be used on hard, non-porous surfaces such as stainless steel, glazed ceramic tile, hard plastics, nonporous vinyl, painted surfaces, Plexiglas, laminated plastic countertops, fiberglass (sealed) surfaces, glazed porcelain, and glass. **Applications: Medical** – hard, non porous surfaces such as autoclaves, blood glucose monitors, external surfaces of medical equipment, IV poles, exam tables, bed railings, external surfaces of dialysis machines, gurneys, mammography equipment, plastic mattress covers, phlebotomy trays, reception counters, external surfaces of respiratory equipment, stretchers, external surfaces of ultrasound transducers and probes, wash basins, and wheelchairs. **Dental** – chairs, counters, operatory hard surfaces, and light lens covers. **Veterinary** – animal equipment, cages, fountains, vet clinic surfaces. **Other** –changing tables, doorknobs, hand railings, highchairs, playpens. **Food service** –both food and non food contact surfaces. **Use Sites: Medical** – ambulance, central service, critical care, dialysis clinics, emergency rooms, exam rooms, home health care, hospitals, intensive care, laboratories, neonatal nursery, nurses' stations, nursing homes, operating room, orthopedic clinics, outpatient clinics, patient rooms, physical therapy rooms, physician offices, radiology, recovery rooms, respiratory therapy, and surgery. **Dental** – dental clinics, labs. **Veterinary** – animal housing, veterinary clinics/hospitals. **Other** – blood banks, correctional facilities, day care, funeral homes, health clubs, recreational centers, restrooms, and schools.

{Following statement may appear on the label}

[Efficacy tests have demonstrated that Dispatch Hospital Cleaner Disinfectant With Bleach [this product] is an effective bactericide, virucide, tuberculocide, and fungicide in the presence of organic soil (5% blood serum)]

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

To Clean, Disinfect, and Deodorize in One Step: Spray 6" – 8" from surface until surface is completely wet or apply with a clean cloth, mop, or sponge saturated with DISPATCH until surface is completely wet. (When applying with a saturated cloth or sponge gloves should be worn.) To disinfect, let stand for one minute. To kill TB, let stand for 30 seconds at room temperature (20 – 25 C). Wipe with a clean, damp cloth or paper towel or allow to air dry. For food contact surfaces, rinse with potable water. For all other surfaces no rinsing is required. Gross soil must be removed prior to disinfecting.

To Clean: Follow directions above, but no standing time is required. If streaking is observed, wipe with a clean, damp cloth or paper towel.

To Clean and Disinfect in a Veterinary Application: Use to clean and disinfect hard, non-porous surfaces such as feeding and watering equipment, cages, utensils, instruments, kennels, stables, catteries, etc. Remove all animals and feed from premises, animal transportation vehicles, crates, etc. Remove all litter, droppings, and manure from walls, floors, and surfaces of facilities occupied or traversed by animals. Empty all feeding and watering equipment. Pre-clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with DISPATCH and let stand for one minute. To kill TB, let stand for 30 seconds at room temperature. Rinse all

Note: Bracketed [] information is optional text. {Bracketed Text} is for administrative purposes only and will not appear on the printed label.

surfaces with potable water. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treated surfaces have been thoroughly rinsed with water and allowed to dry. Thoroughly scrub all treating, feeding, and watering appliances with soap or detergent, and rinse with potable water before re-use.

To Preclean Instruments Prior to Terminal Sterilization/High Level Disinfection:

As a pre-cleaning spray – Place instruments into a suitable container. Spray DISPATCH onto instruments to thoroughly wet all surfaces. Let stand for up to 10 minutes. Rinse instruments.

As a pre-cleaning immersion solution – Fill appropriate size container with a sufficient amount of DISPATCH to completely submerge instruments. Place instruments into the container of DISPATCH, cover, and allow to soak for up to 10 minutes. Remove and rinse, and follow with an appropriate cleaning and disinfecting process. Change solution daily.

As a manual instrument cleaner – Thoroughly pre-rinse dirty instruments under running water to remove visible, gross debris. Immerse pre-rinsed instruments into an appropriate size container filled with DISPATCH. Scrub instruments using a stiff bristle brush until visibly clean. Submerge instruments while scrubbing. Rinse instruments thoroughly. Change solution daily. Follow with an appropriate disinfection process.

Cleaning of critical and semi-critical devices must be followed by an appropriate terminal sterilization/high-level disinfection process.

To Disinfect Non-Critical, Pre-Cleaned Instruments – Instruments must be thoroughly pre-cleaned to remove excess organic debris, rinsed, and rough dried. (Clean and rinse lumens of hollow instruments before filling with DISPATCH or before immersion.) **Immersion method** - using a soaking tray, immerse instruments into DISPATCH and let stand for one minute. To kill TB, immerse for 30 seconds at room temperature. Remove and wipe with a clean, damp cloth or paper towel and allow to air dry. Change solution for each use. **Spray method**–Spray all surfaces of instruments with DISPATCH until thoroughly wet. Let stand one minute. To kill TB, let stand 30 seconds at room temperature. Wipe with a clean, damp cloth or paper towel and allow to air dry.

Use DISPATCH on stainless steel instruments only.

† KILLS HIV, HBV and HCV 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), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV).

Special Instructions for Cleaning and Decontamination Against HIV-1 (AIDS Virus), HBV and HCV on Surfaces/Objects Soiled with Blood/Body Fluids. Personal Protection: When handling items soiled with blood/body fluids, personal protective equipment such as disposable gloves, gowns, masks, or eye coverings should be used. **Cleaning Procedure:** Blood/body fluids must be thoroughly cleaned from surfaces and objects before disinfecting. **Contact Time:** Let stand for one 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.

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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

{Statement for Refillable Containers}

Store this product in a cool, dry area, away from direct sunlight and heat. Refillable container. Refill empty DISPATCH spray container only from DISPATCH refill bottle. Cleaning before refilling is the responsibility of the refiller. Take care to update expiration date on refillable bottle and replace bottle if it becomes worn or damaged. Do not reuse this container for any other purpose. Rinse container with water prior to disposal. Cleaning the container before final disposal is the responsibility of the person disposing of the container. When discarding container, place in trash collection or take to recycling center. Do not contaminate water, food, or feed by storage and disposal.

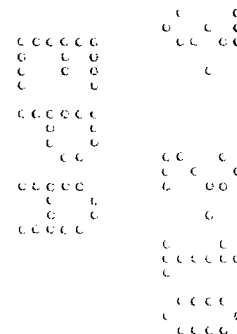
{Statement for Nonrefillable Containers}

Store this product in a cool, dry area, away from direct sunlight and heat. Nonrefillable container. Do not reuse or refill this container. When discarding container, place in trash collection or take to recycling center. Do not contaminate water, food, or feed by storage and disposal.

{For containers of 5 gallons or 50 lbs. or more}

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting agency has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.



Hazards to Humans and Domestic Animals

FIRST AID: If in Eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. If present, remove contact lenses after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for further treatment advice. Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

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.

REORDER

See Expiration Date on Bottle

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

A collection of 20 small, stylized line drawings of various birds, including sparrows, finches, and songbirds, arranged in a grid-like fashion. The drawings are simple, using only outlines and minimal shading to represent the birds' forms and features like beaks and wings.

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Kills Pandemic 2009 H1N1 Influenza A virus.