

56392-7

12/1/2009

1029

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



United States  
Environmental Protection  
Agency

**Office of Pesticide Programs**

DEC - 1 2009

David Swain  
Agent for Caltech Industries, Inc.  
c/o SRC Scientific & Regulatory Consultants, Inc.  
P.O. Box 1014  
Columbia City, IN 46725

Subject: DISPATCH Hospital Cleaner Disinfectant with Bleach  
EPA Registration No. 56392-7  
Application Date: November 9, 2009  
Receipt Date: November 10, 2009

**FILE COPY**

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:**

- Addition of H1N1 label claims per EPA guidance

**General Comments:**

Based on a review of the material submitted, the following comment applies:

The notification application is acceptable and a copy has been placed 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  
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 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. 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 of (optional text additions in regards to Influenza A virus and Pandemic 2009 H1N1) per PR Notice 95-2. This notification is consistent with the provisions of PR Notice 95-2 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 95-2 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:					
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		2. Type of Container <input type="checkbox"/> Metal <input 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.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On label	
6. Manner in Which Label is Affixed to Product <input 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	
<b>Certification</b> 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 <i>David Swain</i>		3. Title Agent for Caltech Industries, Inc.	
4. Typed Name David Swain		5. Date 09 NOV 2009	

3069

**SRC**  
**Scientific & Regulatory**  
Consultants, Inc.

November 9, 2009

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

SUBJECT: Notification (Influenza A and Pandemic 2009 H1N1) per PR Notice 98-10  
DISPATCH Hospital Cleaner Disinfectant with Bleach  
EPA Reg. No.: 56392-7

Dear Ms. Mitchell:

On behalf of our client Caltech Industries, Inc., enclosed is a notification in compliance with the recent Agency "Guidance for Testing and Labeling Claims against Pandemic 2009 H1N1 Influenza A Virus (Formerly called Swine Flu)." This is a Notification per PR Notice 98-10; therefore, no PRIA fee is required.

The new statements, as specified in the guidance, have been added to the current accepted label as optional text. No additional changes to the existing label have been made. This application contains claims consistent with the statements in Section III of the EPA Guidance, therefore meeting the criteria for the Agency's expedited review of 20 business days.

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](mailto:dswain@srcconsultants.com) for electronic response and any questions should they arise.

Sincerely,

*David Swain*

David Swain  
Agent for Caltech Industries, Inc.

Cc: C. Anders

P.O. Box 1014  
Columbia City, IN 46725

[www.srcconsultants.com](http://www.srcconsultants.com)

Phone: 260-244-6270  
Fax: 260-244-6273

4069



**DISPATCH<sup>®</sup> HOSPITAL CLEANER DISINFECTANT  
WITH BLEACH**

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

**Active Ingredient:** Sodium Hypochlorite.....0.65%  
**Other Ingredients:**.....99.35%  
**TOTAL** .....100.00%

**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. Nos. 74592-OH-1<sup>N</sup>  
50757-WI-1<sup>G</sup>  
62801-MI-1<sup>F</sup>  
48181-IL-1<sup>H</sup>

(Superscript used is second letter of LGT No.)

**NOTIFICATION**  
Date Reviewed: 12/1/09  
Reviewed By: [Signature]

EPA Reg. No. 56392-7

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

509

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

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leaf 9

kill TB, let stand for 30 seconds at room temperature. Rinse all 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 HVC 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.

7049

**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.

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

8029

### 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. 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.

®Trademark of Caltech Industries, Inc.

REORDER NO:

See Expiration Date on Bottle

NEPA

HEALTH 0 FLAMMABILITY 0 REACTIVITY 1

SPECIFIC OX

0=None 1=Slight 2=Moderate 3=High 4=Extreme OX=Oxidizer

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9099

*{Optional Text. For use on product label or collateral labeling}*

Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by Influenza A virus.

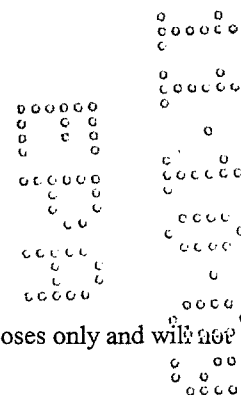
[Product Name] [This product] is a broad-spectrum hard surface disinfectant that has been shown to be effective against Influenza A virus and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).

[Product Name] [This product] has demonstrated effectiveness against Influenza A virus and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 Influenza A virus.

[Product Name] [This product] has demonstrated effectiveness against Influenza A virus and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).

Kills Pandemic 2009 H1N1 Influenza A virus (formerly called swine flu).

Kills Pandemic 2009 H1N1 Influenza A virus.



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