

56392-8

12/28/2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

December 28, 2009

David Swain, Agent **Caltech Industries, Inc.**

SRC

P.O. Box 1014

Columbia City, IN. ~~22311~~ 46725

Subject: Dispatch Hospital Cleaner Disinfectant Towels with Bleach  
EPA Registration Number 56392-8  
Application Date: December 3, 2009

Dear Mr. Swain:

This acknowledges receipt of your Notification submitted in accordance with the provisions of PR Notice 98-10 under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)9.

**Proposed Notification**

- Addition of Pandemic 2009 H1N1 Influenza A Virus claim and marketing language.

**General Comments**

Based on a review of the material submitted, the notification is acceptable.

Should you have any questions or comments concerning this letter, please contact Tom Luminello at (703) 308-8075.

Sincerely,

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

Please 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

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

**Application for Pesticide - Section I**

1. Company/Product Number 56392-8	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 Towels 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 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. Please contact David Swain for questions and provide an electronic response to vain@srconsultants.com or at 260-244-6273 (fax).

**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 checked="" 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 checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1 ct., 60 ct., 150 ct.		5. Location of Label Directions <input 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	
<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 both under applicable law.			6. Date Application Received (Stamped)
Signature 		3. Title Agent for Caltech Industries, Inc.	
4. Typed Name David Swain		5. Date 12/3/09	

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# **SRC**

## **Scientific & Regulatory**

*Consultants, Inc.*

December 3, 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 Towels with Bleach  
EPA Reg. No.: 56392-8

Dear Ms. Mitchell:

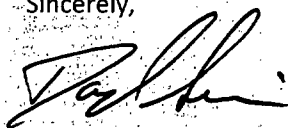
On behalf of our client Caltech Industries, Inc., enclosed is a notification in compliance with the recent Agency "Guidance for Testing and Labeling Claims against Pandemic 2009 H1N1 Influenza A Virus (Formerly called Swine Flu)". **This is a Notification per PR Notice 98-10; therefore no PRIA fee is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

The notification submitted on 11/12/09, contained new statements, as specified in the guidance that were included as optional text that follows the currently accepted labeling. The new statements were highlighted in red text on the enclosed label. An additional change to that label has been made to include the H1N1 claim in the organism list. This change has been highlighted with yellow. No other changes have been made.

Please contact me to provide an electronic response to [dswain@srcconsultants.com](mailto:dswain@srcconsultants.com) or call (260) 244-6270 with questions.

Sincerely,



David Swain  
Agent for Caltech Industries, Inc.



**DISPATCH<sup>®</sup>**

**Hospital Cleaner Disinfectant Towels with Bleach**

- [Contains 6500 ppm Sodium Hypochlorite]
- [Pre-Moistened Towels With 1:10 Dilution Of Bleach (6.0%) And Detergent]
- [Cleans [and], Disinfects, [& Deodorizes] In One Step]
- [Peel And Reseal Here {for flex packs only}]
- **[Kills Pandemic 2009 H1N1 influenza A virus]**

Kills [99.99%] bacteria, viruses<sup>†</sup> & fungi in 1 Minute: *Acinetobacter baumannii*, <sup>†</sup>Avian Influenza A Virus, <sup>†</sup>Influenza A H1N1 [2009][Pandemic], <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 faecalis* (VRE)  
Kills *Mycobacterium bovis* (TB) in 2 Minutes

Active Ingredient: Sodium Hypochlorite.....0.65%  
Other Ingredients.....99.35%  
Total.....100.00%  
(yields 0.62% available chlorine)

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

NOT TO BE USED AS BABY WIPES

KEEP PACKAGE [OR CONTAINER] TIGHTLY SEALED WHEN NOT IN USE

Read Complete Directions and Precautions on Back [side] [rear] Panel

SELECT A SIZE (For Canister Only)

Net Contents # of towels and size and weight

EPA Reg. No. 56392-8

EPA Est. Nos. 50758-WI-1<sup>G</sup>

41925-WI-1<sup>C</sup>

41925-WI-2<sup>D</sup>

41925-WI-3<sup>E</sup>

(Superscript used is second letter of Lot No.)

Manufactured for:

**©2009 Caltech Industries, Inc.**

4520 E. Ashman

Midland, MI 48642

1-800-234-7700

www.caltechindustries.com

®Trademark of Caltech Industries, Inc.

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

Pre-moistened disposable towels for use in healthcare and other areas where control of cross contamination is required. Meets OSHA Bloodborne Pathogen Standards. **Surfaces:** May be used on hard non-porous surfaces such as stainless steel, glazed ceramic tile, hard plastics, non-porous vinyl, painted surfaces, glazed porcelain, sealed fiberglass surfaces, Plexiglas, laminated plastic countertops, and glass.

**Use Sites:**

**Hospital and Healthcare:** Clinics, Dental offices, Emergency rooms (ER), Hospitals, Hospital central service areas, Intensive Care Units (ICU), Laboratory, Nursing homes, Physical therapy, Physician offices, Radiology, Recovery rooms and Surgery.

**Critical Care Areas:** ER, ICU, Neonatal Intensive Care Units (NICU), Pediatric Intensive Care Units (PICU) and Surgery.

**Applications:** Hard non-porous surfaces such as autoclaves, bed railings, blood glucose monitors, cabinets, carts, chairs, counters, exam tables, gurneys, infant incubators and care cribs, IV poles, phlebotomy trays, PVC tubing, stretchers, tables, ambulance equipment, diagnostic equipment, dialysis machines, mammography equipment, patient monitoring equipment, respiratory equipment and ultrasound transducers and probes.

**Nursery or Daycare Centers:** Changing tables, cribs, trash cans, toys and other hard, non-porous surfaces listed on this label.

**DIRECTIONS FOR USE:** It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Dispenser directions:

*{Canister directions}*

To open: Remove lid. Discard inner seal from canister.

To thread: Find center of wipe roll, twist corner of first wipe into a point and thread through the hole in the canister lid. Pull through about one inch. Replace lid. Dispense remaining wipes as necessary by pulling out and tearing off. When not in use, keep center cap of lid closed to prevent moisture loss.

Gloves should be worn.

Select-A-Size: For a 7"x8" towel - pull one towel gently through the hole, angle sharply and detach at the first perforation. For a 7" x 16" towel - pull two towels gently straight up through the hole. Hold second towel, angle sharply and detach at the second perforation. NOTE: Select-A-Size feature for the larger size towel works best after several smaller towels have been used.

*{Soft pack direction}:*

Open package. Pull out wipes as needed and reseal. When not in use keep sealed to prevent moisture loss. Gloves should be worn.

*{Individually wrapped Pack directions}*

Tear open packet. Unfold and use as directed. Discard after single use. Gloves should be worn.

To Clean, Disinfect, and Deodorize in One Step: Wipe surface with towel until completely wet. Let stand for one minute. To kill TB, let stand for two minutes at room temperature (20 - 25°C).

Wipe dry or allow to air dry. Gross soil must be removed prior to disinfecting. Gloves should be worn.

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

**\*\*Ultrasound transducers and probes:**

For use on external surfaces of ultrasound transducers and probes only.

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

To disinfect: Pre-clean gel from external surface of ultrasound transducer or probe to be disinfected with a paper towel or clean cloth. Then thoroughly wet the probe with a towelette [Product Name]. Let stand for one minute. To kill TB, let stand for two minutes at room temperature.

**†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.

**\*\*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 pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.**

#### **STORAGE AND DISPOSAL:**

*{For canisters}*

Store this product in a cool, dry area away from direct sunlight and heat. When not in use keep center cap of lid closed to prevent moisture loss. Nonrefillable container. Do not reuse or refill this container. Discard used towels and container in trash or take container to recycling center. [Do not flush towels down toilet.]

*{For soft packs and individually wrapped packs}*

Store this product in cool, dry area away from direct sunlight and heat. Nonrefillable container. Do not reuse or refill this container. Discard used towel and empty package in trash. [Do not flush towels down toilet.]

**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 of rinsing, 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 NO.

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

See expiration date on package.

{Optional Claims. They may be placed anywhere on label/container.}

An effective method to clean, deodorize and disinfect against odor-causing organisms on hard non-porous surfaces listed on this label.

An effective way to disinfect hard, non-porous environmental surfaces listed on this label.

Cleans, disinfects and deodorizes

Disinfects hard non-porous environmental surfaces listed on this label

Does not produce mist or overspray

No mixing

Premoistened

Ready to Use

[Product Name] are pre-moistened with a unique, stabilized bleach and detergent solution and are ready-to-use.

[Product Name] are intended for cleaning and disinfecting hard, non-porous surfaces where control of cross-contamination is required.

[Product Name] are useful in a variety of healthcare and nursery/daycare applications listed on the [this] label.

[Product Name] may be used to clean and disinfect in one step; see directions for use on this label for cleaning and disinfecting in one step.

Use of this product does not produce mist in the air.

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

Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by influenza A virus. [This product] [Product Name] is a broad-spectrum hard surface disinfectant that has been shown to be effective against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).

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

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

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

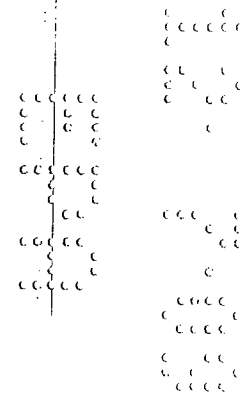
Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu).

*(The following graphics are optional. They may be placed anywhere on label/container.)*



RESEAL HERE  
PULL TAB

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



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