

56392-1

12-14-2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

DEC 14 2009

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

December 11, 2009

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

Subject: **PRECISE Hospital Foam Cleaner Disinfectant**
EPA Registration No.: 56392-1
Application Date: November 19, 2009
Receipt Date: November 20, 2009

Dear Mr. Swain:

This acknowledges receipt of the notification identified above submitted under the provision section 3 (c) 9 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended and PR Notice 98-10.

Proposed Notification:

- Add Influenza A and Pandemic 2009 H1N1 Claim

General Comment:

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

A copy of this accepted notification has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, you may contact Stacey Grigsby by telephone at (703) 305-6440 or by e-mail at grigsby.stacey@epa.gov during the hours of 8:00am to 4:00pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

ShaRon Carlisle
(Acting) Product Manager (34)

CONCURRENT REGULATORY MANAGEMENT BRANCH II
Antimicrobials Division (7510P)

SYMBOL							
SURNAME							
DATE							



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 56392-1	2. EPA Product Manager ShaRon Carlisle	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) PRECISE Hospital Foam Cleaner Disinfectant	PM# 34	
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 wain@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	
* Certification must be submitted				<input type="checkbox"/> Plastic	
If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container	<input type="checkbox"/> Glass	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 20 oz.		5. Location of Label Directions <input type="checkbox"/> On label	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph 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 11/19/09	

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SRC
Scientific & Regulatory
Consultants, Inc.

November 19, 2009

Ms. ShaRon Carlisle (PM34)
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: **Nötification (Influenza A and Pandemic 2009 H1N1) per PR Notice 98-10**
PRECISE® Hospital Foam Cleaner Disinfectant
EPA Reg. No.: 56392-1

Dear Ms. Carlisle:

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 new statements, as specified in the guidance, have been included as optional text that follows the currently accepted labeling. The new statements are highlighted in red text on the enclosed label. No other changes in the existing labeling have been made.

Please contact me to provide an electronic response to dswain@srccconsultants.com or call (260) 244-6270 if you have any questions about this notification.

Sincerely,



David Swain
Agent for Caltech Industries, Inc.

Cc: C. Anders

P.O. Box 1014
Columbia City, IN 46725

www.srccconsultants.com

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

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PRECISE® HOSPITAL FOAM CLEANER DISINFECTANT

- Cleans, Disinfects, Deodorizes
- For Hard, Non -Porous Surfaces
- Won't Scratch
- [Kills Pandemic 2009 H1N1 influenza A virus]

Effective against HIV-1 (AIDS Virus), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV) in 1 MINUTE

Effective against Multiple Microorganisms in 10 MINUTES:

Mycobacterium bovis (TB), *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Streptococcus pyogenes*, *Salmonella choleraesuis*, Vaccinia Virus (ATCC VR-117), Influenza A-2 strain Hong Kong (NCDC), Influenza A H1N1 [2009][Pandemic], Herpes Simplex Virus, Hominus, Type 2 (HSV-2), Poliovirus Type 1 (Mahoney), Canine Parvovirus, *Trichophyton mentagrophytes*

Active Ingredients:	
o-Phenylphenol.....	00.37%
Other Ingredients.....	99.63%
TOTAL.....	100.00%

NOTIFICATION
 Date Reviewed: 12/14/09
 Reviewed By: *Tracey Briggsby*



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

KEEP OUT OF REACH OF CHILDREN
WARNING
READ COMPLETE PRECAUTIONS AND
DIRECTIONS ON REAR PANELS

NET WT.

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4520 E. Ashman
Midland, MI 48642
800-234-7700
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www.caltechindustries.com

EPA Reg. No. 56392-1
EPA Est. Nos. 10744-IL-1^B
11525-IL-1^C
33915-MI-1^D
62587-IL-1^K
62801-MI-1^F

(Superscript used is second letter of Loc No.)
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Note: Bracketed [] information is optional text. {Bracketed Text} is for administrative purposes only and will not appear on the printed label.

PRECISE® HOSPITAL FOAM CLEANER DISINFECTANT

FOR HOSPITAL HARD SURFACES: Quick spray and wipe for cleaning. Always properly mixed and ready to use. Put this product to work throughout the hospital.

USEFUL: Patient room, emergency room, recovery room, operating room, laboratory, clinic, bathroom, physician office, physical therapy, nursing station, radiology, morgue, dental operator, veterinary hospital.

CLEANS AND SHINES: All hospital washable surfaces – tile, tubs, bowls, basins, sinks, showers, urinals, empty bed pans, toilets, cabinets, doors and door handles, empty emesis basins, floors, walls, woodwork, workstation tables and countertops, housekeeping carts, vanity tops, vending machines, bed springs and frames, bedside furniture, dressing and surgical carts, wheelchairs, walkers, stainless steel, chrome, plastic, metal, vinyl, fiberglass, baked enamel, porcelain, examination and x-ray tables, film cassettes, chart holders, shower chairs, sitz baths, commodes and commode seats, instrument cabinets and trays, catheter trays, electrodes, bacteriology laboratory benches, centrifuges, whirlpool baths, operating tables, emergency vehicles, telephones, reception counters, dental chairs, medical equipment.

DISINFECTS: Kills organisms commonly found on hard nonporous hospital surfaces. See directions for disinfecting.

DEODORIZES: Kills odor causing organisms on hard surfaces. Leaves surfaces smelling clean and fresh.

LABOR SAVING: Just spray on, wipe off. No rubbing, rinsing or scouring.

WON'T SCRATCH: Contains no abrasive to scratch or leave gritty deposit.

REMOVES HOSPITAL SOILS: Grime, greasy soil, soap scum, water marks, scuff marks, blood, drainage, stains, emesis, fingermarks.

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

DIRECTIONS: Shake well. Hold can 6" from surface.

TO CLEAN: Quick spray and wipe clean with damp sponge, cloth or paper towel. No rinsing needed.

TO CLEAN AND DISINFECT IN 1 STEP: Spray surface thoroughly until completely covered with foam and allow to remain wet for the appropriate time, depending on the organism (See front panel). Wipe clean with damp sponge, cloth or paper towel. No rinsing needed.

Kills Mycobacterium bovis (TB) in 10 minutes at room temperature (68-77°F, 20-25°C). Gross soil must be removed prior to disinfecting.

Kills HIV-1 (AIDS Virus), 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, appropriate personal protective equipment such as disposable plastic gloves, gowns, masks, or eye coverings should be considered. **Cleaning Procedure:** Blood/body fluids must

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

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be thoroughly cleaned from surfaces and objects prior to disinfecting. **Contact Time:** This product kills HIV-1 (AIDS Virus), HBV and HCV in 1 minute at room temperature. 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.

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: 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

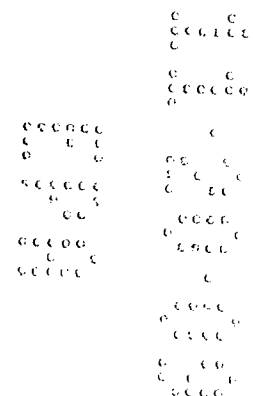
WARNING: Do Not Spray in Eyes. Causes mild eye irritation. Avoid contact with eyes or clothing. Wash hands before eating/drinking/using toilet.

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 an 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.

REORDER NO.

NFPA: HEALTH 0 FLAMMABILITY 2 REACTIVITY 0 SPECIFIC (NONE)

- 0 = NONE
- 1 = SLIGHT
- 2 = MODERATE
- 3 = HIGH
- 4 = EXTREME



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

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{Optional Text. May be placed anywhere on the label/container}

HOSPITAL SIZE

SHAKE OFTEN

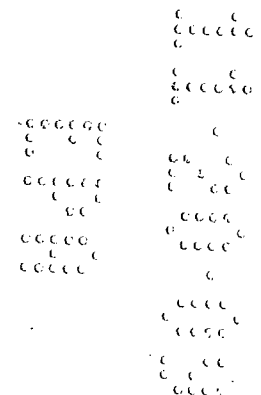
{Optional Text. For use on product label or collateral labeling claims against Pandemic 2009 H1N1 Influenza A Virus}

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.

[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).



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