

S 6392-7

03-27-2011

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

MAR 27 2011

FILE COPY

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Ms. J. Evelyn Lawson
The Clorox Company
PO Box 493
Pleasanton, California 94566-0803

Subject: Dispatch® Hospital Cleaner Disinfectant with Bleach
EPA Registration No.: 56392-7
Notification Date: 05/05/2011
EPA Receipt Date: 05/06/2011

Proposed Notification

- Deletion of the Caltech logo
- Change of registrant name and address
- Change of website
- Addition of a new establishment number
- Deletion of several establishment numbers
- Addition of label graphic on page 5

General Comments

Based on a review of the submitted materials, your notification for the non-mandatory labeling changes above is acceptable and has been made a part of the records on file.

Also should you wish to retain a reference to the company's website on your label, then please be aware that such a reference transforms the website into labeling under the Federal Insecticide Fungicide and Rodenticide Act sec 2 (p) (2) and then the website is subject to review by the Agency. If the website content is false or misleading, the product would be misbranded and its sale or distribution unlawful to sell or distribute under FIFRA section 12(a)(1)(E). In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Although EPA has not yet determined the extent to which it will routinely review company websites, if the Agency finds or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from claims approved through the registration process, the website may be referred to the EPA's Office of Enforcement and Compliance Assurance.



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number
EL0295

Application for Pesticide - Section I

1. Company/Product Number 56392-7	2. EPA Product Manager Wanda Henson (acting)	3. Proposed Classification <input 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) Clorox Professional Products Company c/o PS&RC; P. O. Box 493 Pleasanton, CA 94566-0803 <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 non-mandatory labeling changes per PR Notice 98-10: we made changes on page 1 and 5. See cover letter for details. 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. I understand that it is a violation of 18 U.S.C. § 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 § 12 and § 14 of FIFRA. All changes to the label are either underlined or struck-out.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
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	If "Yes" Unit Packaging wgt. No. per 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" 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"/>	
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 J. Evelyn Lawson		Title Senior Regulatory Information Scientist		Telephone No. (Include Area Code) (925) 425-6842	
<p align="center">Certification</p> <p>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.</p>					6. Date Application Received (Stamped)
2. Signature <i>J. Evelyn Lawson</i>		3. Title Senior Regulatory Information Scientist			
4. Typed Name J. Evelyn Lawson		5. Date May 5, 2011			

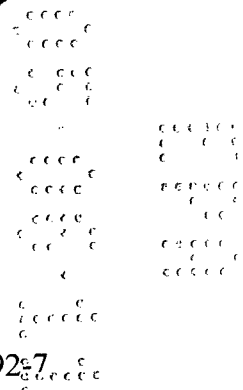


Clorox Professional Products Company



May 5, 2011.

Ms. Wanda Henson, Product Manager 32 (acting)
U.S. Environmental Protection Agency
Document Processing Desk (NOTIF)
Office of Pesticide Programs -7504P
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202



Re: Dispatch® Hospital Cleaner Disinfectant with Bleach, EPA Reg. No. 56392-7
OPP EL0295

Dear Ms. Henson:

Clorox Professional Products Company is submitting a label notification to:

- delete the Caltech logo
- change the registrant name and address
- change a website
- add one new establishment number
- delete several establishment numbers
- add a label graphic

In a letter dated April 14, 2011, the Agency recently approved the name change from Caltech Industries, Inc. to Clorox Professional Products Company.

All label changes are underlined (if newly added) or struck-out (if deleted). The changes to the label are on pages 1 and 5.

We enclose one strike-out/underlined label and 5 clean label copies.

Thank you for reviewing the enclosed submission. If you have any questions, please contact me at 925-425-6842 or Elisa Estremera at 925-425-6199.

Sincerely,

J. Evelyn Lawson
Senior Regulatory Information Scientist
Clorox Professional Products Company
CTCPSERC@Clorox.com

Should you have any questions or comments concerning this letter, you may contact me by telephone at (703) 308-6345 or by e-mail at henson.wanda@epa.gov or Jaclyn Carl by telephone at (703) 347-0213 or by e-mail at carl.jaclyn@epa.gov. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,



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

Note: **Bold, italicized text is information for the reader and is not part of the label.** [Bracketed information is optional text.] Underlined text is Strike-through (text) means removed. Optional text may be placed anywhere on the label/container.
R0886-2.1

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DISPATCH®

Hospital Cleaner Disinfectant with Bleach

KEEP OUT OF REACH OF CHILDREN CAUTION

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

Active Ingredient:
Sodium Hypochlorite0.65%
Other Ingredients:99.35%
Total100.00%

Net Contents _____

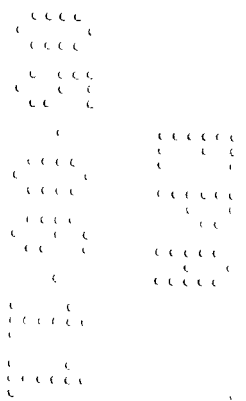
- [Contains 6500 ppm Sodium Hypochlorite]
- [Cleans, [and], Disinfects, [& Deodorizes] in One Step]
- [For Hospital, Veterinary, & Food Contact Hard, Non-Porous Surfaces]
- [For Instrument Pre-Cleaning & Disinfection of Non-Critical Instruments]
- [Kills [99.99%] bacteria, viruses†, & fungi in 1 Minute on Hard, Non-Porous Surfaces]
- [Kills Pandemic 2009 H1N1 Influenza A Virus]
- [Kills Clostridium difficile [spores] in 5 Minutes [on Precleaned, Hard, Non-Porous Surfaces]][*]
- [Ready-to-Use 1:10 Dilution of Bleach [(6.0%)] and Detergent]

Kills [99.99%] bacteria, viruses†, & fungi in 1 Minute: Acinetobacter baumannii, †Avian Influenza A Virus, †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, †Influenza A H1N1 [2009][Pandemic], 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
Kills Clostridium difficile [spores] in 5 Minutes [on Precleaned, Hard, Non-Porous Surfaces][*]

Manufactured for:
© XXXX Clorox Professional Products Company
1221 Broadway, Oakland, CA 94612
Visit us at www.cloroxprofessional.com 800-234-7700
® Trademark of Clorox Professional Products Company

EPA Reg. No. 56392-7
EPA Est. No. 8251-OH-1

NOTIFICATION
Date Reviewed: 5/27/2011
Reviewed By: *W. B. [Signature]*



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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 OR 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.

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.

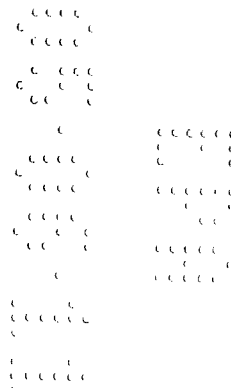
Statement for containers of 5 gallons or 50 lbs. or more

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.

REORDER NO.

See Expiration Date on Bottle



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Multipurpose, broad spectrum cleaner disinfectant for use in healthcare and other areas where control of cross contamination is required, [especially during outbreaks of *Clostridium difficile*] [and] [or] [other Healthcare Associated Infections [HAIs] listed on this label]. 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.

[*] Special Instructions for Cleaning Prior to Disinfection against *Clostridium difficile* spores. Personal Protection: Wear appropriate barrier protection such as gloves, gowns, masks, or eye covering. **Cleaning Procedure:** Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection by application with a clean cloth, mop, and/or sponge saturated with [Product Name] [this product]. Cleaning is to include vigorous wiping and/or scrubbing, until all visible soil is removed. Special attention is needed for high-touch surfaces. Surfaces in patient rooms are to be cleaned in an appropriate manner, such as from right to left or left to right, on horizontal surfaces, and top to bottom, on vertical surfaces, to minimize spreading of the spores. Restrooms are to be cleaned last. Do not reuse soiled cloths.

Infectious Materials Disposal: Materials used in the cleaning process that may contain feces/wastes are to be disposed of immediately in accordance with local regulations for infectious materials disposal.

Disinfection Procedure: Spray 6" – 8" from surface until surface is completely wet. Let stand for 5 minutes. Wipe with a clean, damp cloth or paper towel or allow to air dry.

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. [To kill *Clostridium difficile* (spores), let stand for five minutes]. 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.

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R0886-2.1

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DIRECTIONS FOR USE continued

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 for one minute. To kill TB, let stand for 30 seconds at room temperature. To kill *Clostridium difficile* (spores), let stand for five minutes. Wipe with a clean, damp cloth or paper towel and allow to air dry.

†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, and 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 must 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.

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Optional Text. For use on product label or collateral labeling

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 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.

[Passes] [Meets] [Satisfies] [EPA] requirements for killing [Clostridium difficile] [C. difficile] spores.

[Kills] [Is effective against] 99.9999% [Clostridium difficile] [C. difficile] spores in 5 [minutes] [min] [on Precleaned, Hard, Non-Porous Surfaces] [*].

Kills [bacteria] [viruses] [fungi] [C. difficile spores].

[Bactericidal] [Tuberculocidal] [Virucidal] [Fungicidal] [Sporicidal] [Disinfectant].

Effective against [Influenza A H1N1] [H1N1] [**Insert any organism from the list on page 1**] [and] [C. difficile spores].

Effective against Avian Influenza A and H1N1 [Pandemic] [Influenza A virus].



Optional graphics. May be placed anywhere on label/container or collateral labeling.

