

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

DEC -8 2011

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

J. Evelyn Lawson Caltech Industries, Inc. c/o PS&RC P.O. Box 493 Pleasanton, CA 94566-0803

FILE COPY

Subject:

Caltech Industries, Inc.

Dispatch Hospital Cleaner Disinfectant With

Bleach

EPA Registration No. 56392-7

Submission Dated: November 17, 2011 Receipt Dated: November 18, 2011

Dear Ms. Lawson:

The following notification submitted in connection with registration under the provisions of PR Notice 98-10, Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)9 is acceptable.

Proposed Notification:

 To update the (Company contact, website address, trademark, establishment numbers, identify the organism tested and add packaging text) on proposed label.

Comments:

Based on a review of the material submitted, the following comments apply:

This application for notification, as referenced above, is acceptable. A copy has been placed in our records for future reference.

Please note that should you wish to add/retain a reference to the company's website on your label, than please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. 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. Therefore should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance

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

Sincerely,

Monisha Harris

Product Manager (32)

Regulatory Management Branch II Antimicrobials Division (7510P)

3048

| Please read instructions on | reverse before con | 'ng form. | | | Form App | prov | OMB No. 2 | 070-006 | 30. Approval expires 2-28 | |
|--|--|---|---|--|--|---|---|-------------------------------------|--|--|
| United States Environmental Protection Washington, DC 2046 | | | | on Agency | | 1 | Registration Amendment Other | | OPP Identifier Number TG0012 | |
| | | Applicati | on for | Pestic | ide - Sec | tion | 1 | | | |
| 1. Company/Product Number 56392-7 | | | 2. EPA Product Manage Monisha Harris | | | ager | 3. P | | Proposed Classification | |
| 4. Company/Product (Name) Dispatch® Hospital Cle | | 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 | | | | 6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. | | | | | | |
| Check if this | is a new address | | | Prod | uct Name | | | | | |
| Milliam William Views | | | Sec | tion - | 11 | | | ALC: | | |
| Resubmission in resp Notification - Explain Explanation: Use addition Notification of label updates updated (p. 1), we note that consistent with the provisions confidential statement of form understand that if this notificate be subject to enforcement and | per PR Notice 98-10: T Salmonella enterica was of PR Notice 98-10 al nula of this product. I u ation is not consistent v | ry. (For section in the Clorox comes tested as Sand EPA regulation in the terms of | pany's con Imonella cl tions at 40 it is a viola of PR Notice | ntact information in the contract information of 18 te 98-10 a | mation, website is (p.1), and we 46, and no oth U.S.C. § 1001 | lain be addre e incluer cha to wil | ess and tradem ded some pack nges have bee | aging tex n made to false sta | kt (p. 2),This notification is to the labeling or the tement to EPA. I further | |
| | | | | tion - | III | | | | | |
| 1. Material This Product Will | Be Packaged In: | | He in | | | | | | | |
| Child-Resistant Packaging Yes No * Certification must be submitted | Unit Packaging Yes No If "Yes" Unit Packaging wgt. No. per Container | | If "Ye | Water Soluble Packaging Yes No If "Yes" Package wgt No. per Container | | | 2. Type of Container Metal Plastic Glass Paper Other (Specify) | | | |
| 3. Location of Net Contents | Information container | 4. Size(s) Re | etail Conta | iner | | 5. Lo | cation of Labe | l Direction | ons _c | |
| 6. Manner in Which Label is | | Litho | graph r glued ciled | | Other | | - C-C | | 6 6 | |
| | | | | tion - | IV | 32-7 | £ ((| ccc | | |
| 1. Contact Point (Complete | items directly below | for identificati | | | | if nec | essary, to pro | cess this | application.) | |
| Name J. Evelyn Lawson | | | Title Fed | leral Reg | istration Spe | cialist | | | e No. (Include Area Code) | |
| I certify that the state I acknowledge that an both under applicable | y knowlingly false or | | d all attacl | | | | | | 6. Date Application Received (Stamped) | |
| 2. Signature | taratu | > | 3. Title | ederal R | egistration Spe | cialist | | | | |
| 4. Typed Name | | | 5. Date | | | | | | | |

11/17/2011

Tara Gomez

4. Typed Name

S392-7 Dispatch Hospital Cleaner Disinfectant with Bleach

DISPATCH®

Hospital Cleaner Disinfectant with Bleach

KEEP OUT OF REACH OF CHILDREN CAUTION

Read Complete Directions and Precautions on Package -and/or-Rear Panels -and/or- Attached Complete Label

| Active Ingredient: | |
|---------------------|---------|
| Sodium Hypochlorite | 0.65% |
| Other Ingredients: | 99.35% |
| Total | 100.00% |

[Net] [Contents]____

| | | 0500 | | 0 " | | |
|---|----------|------|-----|--------|-----------|------|
| • | Contains | 6500 | ppm | Sodium | Hypochlor | rite |

• [Cleans, [and], Disinfects, [& Deodorizes] in One Step]

• [For Hospital, Veterinary, & Food Contact Hard, Nonporous Surfaces]

• [For Instrument Pre-Cleaning & Disinfection of Non-Critical Instruments]

• [Kills [99.99%] bacteria, virusest, & fungi in 1 Minute on Hard, Nonporous Surfaces]

• [Kills Pandemic 2009 H1N1 Influenza A Virus]

• [Kills Clostridium difficile [spores] in 5 Minutes [on Precleaned, Hard, Nonporous Surfaces]][*]

• [Ready-to-Use 1:10 Dilution of Bleach [(6.0%)] and Detergent]

Kills [99.99%] bacteria, viruses†, & fungi in 1 Minute [on Hard Non-Porous Surfaces], [(see rear panel]: [Organisms] 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 (AIBS 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 tested as Salmonella choleraesuis, 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, Nonporous Surfaces][*]

QUESTIONS OR COMMENTS? Call (800) 234-7700.

For MSDS information, please go to www.cloroxhealthcare.com.

A list of this product's ingredients is available at www.CloroxCSR.com

Manufactured- for [:] [@ XXXX] Clorox Professional Products Company[,]

1221 Broadway, Oakland, CA 94612

Clorox and Clorox Healthcare are [registered] trademarks of -or- insert trademark is a

registered trademark of Clorox Professional Products Company

The Clorox Company. © XXXX Made in the U.S.A.

[Visit us at www.cloroxprofessional.com]

800-234-7700

[Clorox is a registered trademark of the Clorox Company]

[insert trademark is a registered trademark of Clorox Professional Products Company]

EPA Reg. No. 56392-7 EPA Est. No. 8251-OH-1 (Q6); 5813-GA-1 (A4); GA-2 (VG) Beginning of batch code indicates Est. No. Note: Bold, italicized text is information for the read information is optional text.] Underlined text is h..... Strike-through (text) means removed. Optional text may be placed anywhere on the label/container. R0886041

3392-7 Dispatch Hospital Cleaner Disinfectant with Bleach

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.

EPA Reg. M

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 lb 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.

| | | C C | | |
|--|------------------------------|-------|-------------|------|
| [REORDER NO.] [See Expiration Date on Bottle] | | 00000 | C C C | |
| | | | 0 | 6 15 |
| Peel for [additional] directions [for use] | Packaging Related Statements | | c c c c c c | |

11/15/11 9:57 AM

EPA Reg. 6392-7 Dispatch Hospital Cleaner Disinfectant with Bleach

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, nonporous 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, nonporous 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 $(20 - 25^{\circ} \text{ C})$. 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, nonporous 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.

[*] 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.

11/15/11 9:57 AM

6392-7 Dispatch Hospital Cleaner Disinfectant with Bleach
Page 4 of 5

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 contact time:

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.

11/15/11 9:57 AM

500000

EPA Reg. 6392-7 Dispatch Hospital Cleaner Disinfectant with Bleach Page 5 of 5

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, Nonporous 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.

| | \$ CCCCC\$ |
|---------|---------------|
| £ 6 6 6 | 0 |
| 000000 | cerece |
| CS | 0000 |
| CCCCC | 00 0 |
| | 6 c c c c c c |
| | ccccc |

CCCCCC