

56392-7

8/26/2010



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

AUG 26 2010

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

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

**FILE COPY**

Subject: PRIA (D# 431911)  
Caltech Industries, Inc.  
Dispatch Hospital Cleaner Disinfectant With Bleach  
EPA Registration No. 56392-7  
Submission Dated: April 7, 2010  
Receipt Dated: April 8, 2010

Dear Mr: Swain:

This submission is to support the claim against *Clostridium difficile* spores in 5 minutes on pre-cleaned, hard non-porous surfaces for the spray product.

The following PRIA amendment submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable.

**General Comments:**

A stamped copy of the accepted labeling is enclosed. Submit one copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

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

Sincerely,

A handwritten signature in black ink that reads "Wanda Y. Henson".

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

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### 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 [99.99%] *bacteria*, viruses<sup>†</sup>, & *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]][\*]

**Kills [99.99%] *bacteria*, viruses<sup>†</sup>, & *fungi* in 1 Minute:** *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, <sup>†</sup>Influenza A H1N1 [2009][Pandemic], *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* – BCG, (TB) in 30 Seconds

Kills *Clostridium difficile* [spores] in 5 Minutes [on Precleaned, Hard, Non-Porous Surfaces] [\*]

<b>ACTIVE INGREDIENT:</b> Sodium Hypochlorite.....	0.65%
<b>OTHER INGREDIENTS:</b> .....	99.35%
<b>TOTAL</b> .....	100.00%

**KEEP OUT OF REACH OF CHILDREN**

### CAUTION

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

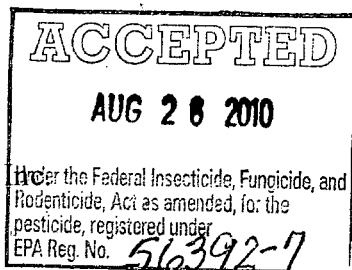
Manufactured for:  
©XXXX Caltech Industries, Inc.  
4520 E. Ashman  
Midland, MI 48642  
800-234-7700  
[www.caltechindustries.com](http://www.caltechindustries.com)

NET CONTENTS

EPA Reg. No. 56392-7  
EPA Est. Nos.

50757-WI-1<sup>G</sup>  
62801-MI-1<sup>F</sup>  
48181-IL-1<sup>H</sup>

(Superscript used is second letter of Lot No.)



®Trademark of Caltech Industries,

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

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, operator 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.

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

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.

**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.

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**†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.

## 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.

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{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.

#### 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.

REORDER NO:

See Expiration Date on Bottle

{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.

[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 Pre-cleaned, 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].