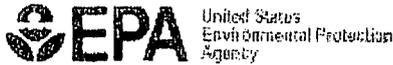


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460Office of Pesticide Programs

November 21, 2007

Rhonda Jones  
Scientific & Regulatory Consultants, Inc.  
P.O. Box 1014  
Columbia City, IN 46725

Subject: Caltech Industries, Inc.  
Dispatch Hospital Cleaner Disinfectant With  
Bleach  
EPA Registration No. 56392-7  
Application Date: July 16, 2007  
Receipt Date: July 23, 2007

Dear Ms. Jones:

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

1. The proposed label claims that the product, Dispatch Hospital Cleaner Disinfectant with Bleach, is an effective "one-step" disinfectant against the following microorganisms on hard, non-porous surfaces for a contact time of 1 minute:

*Acinetobacter baumannii*  
*Enterobacter aerogenes*  
*Escherichia coli* ESBL  
*Klebsiella pneumoniae*  
Canine parvovirus  
Feline panleukopenia virus  
Influenza A virus  
Rhinovirus

Data provided by the applicant support these claims.

2. The last-accepted label (and proposed label) claims that the product, Dispatch Hospital Cleaner Disinfectant with Bleach, is an effective disinfectant against *Clostridium difficile* (vegetative) on hard, non-porous surfaces. All references to *Clostridium difficile* must be removed from the product label. The Agency is no longer accepting claims for effectiveness against *Clostridium difficile* (vegetative cells).

Note: The Agency has re-evaluated its acceptance of the *Clostridium difficile* (vegetative form) on previously accepted claims and requests for new claims. Peer-reviewed scientific literature and case studies have consistently demonstrated that the *Clostridium difficile* spore is the source of public-health concern. In light of scientific guidance and supporting documentation, the Agency is certain that claims against the vegetative form of *Clostridium difficile* are true statements, but are used in such a way as to give a false or misleading impression to the purchaser (40 CFR 156.10(a)(5)(vii)). The Agency considers antimicrobial pesticides to be unique because of the critical nature of the threat to public health that may result from ineffective use of the products due to obsolete or misleading labeling. As a result, any reference to claims of effectiveness against *Clostridium difficile* (vegetative) OR *Clostridium difficile* (without having supporting data against *Clostridium difficile* spores) are unacceptable. To address the growing need for products in hospital/medical settings, the Agency is moving expeditiously to develop an appropriate test system and performance standards for *Clostridium difficile* spores.

3. The last-accepted (and proposed label) for the towel product, Dispatch Hospital Cleaner Disinfectant Towels with Bleach, states that gloves should be worn when using the product. However, the label for the liquid product, Dispatch Hospital Cleaner Disinfectant with Bleach, did not contain these instructions. The towel product contains 0.52% of the active ingredient; the liquid product contains 0.55% of the active ingredient. Revise accordingly.

4. The following change is required on the Data Matrix:

- On page 2 of the Data Matrix (in two locations), change "S. erterica" to read "S. enterica."

5. The following change is required on the product label:

- Under the "Storage and Disposal" section, add the statement: "Do not contaminate water, food, or feed by storage and disposal."

#### General Comments

A stamped copy of the accepted label 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 call Wanda Henson at (703) 308-6345.

Sincerely,



Emily H. Mitchell  
Product Manager - Team 32  
Regulatory Management Branch II  
Antimicrobials Division (7510P)

Add multiple organisms



**DISPATCH® HOSPITAL CLEANER DISINFECTANT  
WITH BLEACH (5500 ppm NaOCl)**

- Cleans & disinfects in one step
- Stabilized bleach & detergent solution
- Ready-to-use
- For Hospital, Veterinary, & Food Contact Hard, Non-Porous Surfaces
- For Instrument Pre-cleaning & Disinfection of Non-critical Instruments

Kills bacteria, viruses† & fungi in 1 Minute on hard non-porous surfaces: *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Salmonella enterica* (formerly *choleraesuis*), Methicillin resistant *Staphylococcus aureus* (MRSA), *Streptococcus pyogenes*, Vancomycin resistant *Enterococcus faecalis* (VRE), *Escherichia coli* ESBL, *Enterobacter aerogenes*, *Acinetobacter baumannii*, *Klebsiella pneumoniae*, *Trichophyton mentagrophytes* (Athlete's Foot Fungus), HIV-1 (AIDS Virus)†, Poliovirus Type 1 (Mahoney)†, Herpes Simplex Virus (HSV-2)†, Rotavirus†, Hepatitis A Virus (HAV)†, Hepatitis B Virus (HBV)†, Hepatitis C Virus (HCV)†, Norovirus†, Avian Influenza A Virus†, Rhinovirus†, Influenza A Virus†, Canine parvovirus†, Feline panleukopenia Virus†

Kills *Mycobacterium tuberculosis* (TB) in 30 seconds

<b>Active Ingredient:</b> Sodium Hypochlorite.....	0.55%
<b>Other Ingredients:</b> .....	99.45%
<b>TOTAL</b> .....	100.00%

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

Read Complete Directions and Precautions on Package [Rear Panels]

NET CONTENTS  
with COMMENTS  
EPA Letter Dated:

EPA Reg. No. 56392-7

EPA Est. Nos. 74592-OH-1  
50757-WI-1  
62801-MI-1

NOV 21 2007

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 56392-7

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

Add multiple organisms

**DISPATCH® HOSPITAL CLEANER DISINFECTANT WITH BLEACH**

Multipurpose, broad spectrum cleaner disinfectant for use on hard, non porous surfaces. Meets OSHA Bloodborne Pathogen Standards. May be used for instrument pre-cleaning and disinfection of non-critical instruments \* **Surfaces:** May be used on 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 hospital 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 room, 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, schools.

**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. To disinfect, let stand for one minute. To kill TB, allow 30 seconds contact at room temperature. Wipe with a clean, damp cloth or paper towel. 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 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 allow to remain wet for one minute. To kill TB, allow 30 seconds contact at room temperature. 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. Allow to 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

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

Add multiple organisms

DISPATCH<sup>®</sup>, 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<sup>®</sup>. 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<sup>®</sup> or before immersion.) **Immersion method** - using a soaking tray, immerse instruments into DISPATCH<sup>®</sup> and allow to remain submerged for one minute at room temperature (68-77°F). To kill TB, allow 30 seconds contact 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. Allow one minute contact time. To kill TB, allow 30 seconds contact at room temperature. Wipe with a clean, damp cloth or paper towel and allow to air dry.

**Use DISPATCH on stainless steel instruments only.**

**† 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), HAV, HBV and HVC 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:** Leave surfaces wet for 1 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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.**

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

Add multiple organisms

### STORAGE AND DISPOSAL

Store this product in a cool, dry area, away from direct sunlight and heat. Refill empty DISPATCH spray container only from DISPATCH refill bottle. Do not fill other spray containers. When discarding container, place in trash collection or take to recycling center.

### 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 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.

®Trademarks of Caltech Industries, Inc.

REORDER NO:

Manufactured for:

©2007 Caltech Industries, Inc.

Midland, MI 48642

1-800-234-7700

www.caltechind.com

See Expiration Date on Bottle

NFPA

HEALTH 0 FLAMMABILITY 0 REACTIVITY 1

SPECIFIC OX

0=None 1=Slight 2=Moderate 3=High 4=Extreme OX=Oxidizer