

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460United States
Environmental Protection
AgencyOffice 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 Towels With
Bleach
EPA Registration No. 56392-8
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 Towels 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. Efficacy data developed for the liquid product are being used to support efficacy of the towel product.

2. The proposed label claims that the product, Dispatch Hospital Cleaner Disinfectant Towels with Bleach, is an effective "one-step" disinfectant against Norovirus on hard, non-porous surfaces for a contact time of 1 minute. Data provided by the applicant support this claim. Efficacy data developed for the liquid product are being used to support efficacy of the towel product. In addition, as noted in an email message from EPA's Tajah Blackburn to the applicant's representative (dated October 17, 2006), "efficacy testing conducted against Rhinovirus using the towelette product is acceptable to bridge claims against Feline calicivirus, as both viruses are classified as small, non-enveloped viruses."

3. The last-accepted label (and proposed label) claims that the product, Dispatch Hospital Cleaner Disinfectant Towels 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.

4. The proposed label states that gloves should be worn when using the product [see "Directions for Use" section; "Canister Directions."] The proposed label needs to be revised to include the "Gloves should be worn" statement in the "Soft Pack Directions" and the "Individually Wrapped Pack Directions."

Note: Although the proposed label states that gloves should be worn, the "Precautionary Statements" section of the label does not mention that the user should avoid contacting skin with the product.

5. The following changes are required on the product label:

- On page 1 of the proposed label, change "*Enterococcus faecalis*" to read "*Enterococcus faecium*." ATCC 51559, *Enterococcus faecium* VRE, is listed on the Data Matrix.
- On page 3 of the proposed label, change "HVC" to "HCV"

6. Hepatitis A (HAV) is not classified as a bloodborne pathogen. Therefore, the inclusion of this virus in the Special Instructions section of the label is unwarranted.


7. Deodorizing instructions are required on the label, as the product makes claims to "deodorize...against odor-causing organisms...."

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)



DISPATCH®

Hospital Cleaner Disinfectant Towels with Bleach (5200ppm NaOCl)

- Ready-to-use towels
- Pre-moistened with stabilized bleach and detergent solution
- Cleans & disinfects in one step
- Kills bacteria, viruses[†] & fungi in 1 Minute
- Kills TB in 2 minutes
- Peel and reseal here {for flex packs only}

Kills bacteria, viruses[†] & fungi in 1 Minute: *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Salmonella enterica* (formerly *choleraesuis*), Methicillin resistant *Staphylococcus aureus* (MRSA), *Streptococcus pyogenes*, Vancomycin resistant *Enterococcus faecalis* (VRE), [REDACTED], *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)[†], Avian Influenza A Virus[†], Rhinovirus[†], Influenza A Virus[†], Canine parvovirus[†], Feline panleukopenia Virus[†], Norovirus[†]
 Kills *Mycobacterium tuberculosis* (TB) in 2 Minutes

Active Ingredient: Sodium Hypochlorite.....0.52%

Other Ingredients.....99.48%

Total.....100.00%

(yields 0.49% available chlorine)

KEEP OUT OF REACH OF CHILDREN**CAUTION**

NOT TO BE USED AS BABY WIPES

KEEP PACKAGE [OR CONTAINER] TIGHTLY SEALED WHEN NOT IN USE

Read Complete Directions and Precautions on Back [side] [rear] Panel

SELECT A SIZE (For Canister Only)

Net Contents

of towels and size

with COMMENTS

EPA Reg. No. 56392-8

EPA Letter Dated:

NOV 21 2007

EPA Est. Nos. 50757-WI-1

41925-WI-1

41925-WI-2

41925-WI-3

Manufactured for:

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Midland, MI 48642

1-800-234-7700

www.caltechind.com

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Under the Federal Insecticide,
 Fungicide, and Rodenticide Act as
 amended, for the pesticide,
 registered under EPA Reg. No. 56392-8

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

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

Dispenser directions:

{Canister directions}

To open: Remove lid. Discard inner seal from canister.

To thread: Find center of wipe roll, twist corner of first wipe into a point and thread through the hole in the canister lid. Pull through about one inch. Replace lid. Dispense remaining wipes as necessary by pulling out and tearing off. When not in use, keep center cap of lid closed to prevent moisture loss.

Gloves should be worn.

Select-A-Size: For a 7"x8" towel - pull one towel gently through the hole, angle sharply and detach at the first perforation. For a 7" x 16" towel - pull two towels gently straight up through the hole. Hold second towel, angle sharply and detach at the second perforation. NOTE: Select-A-Size feature for the larger size towel works best after several smaller towels have been used.

{Soft pack direction}:

Open package. Pull out wipes as needed and reseal. When not in use keep sealed to prevent moisture loss.

{Individually wrapped Pack directions}

Tear open packet. Unfold and use as directed. Discard after single use.

To Clean: Wipe surface with towel until clean. If streaking is observed, wipe with a damp cloth or paper towel.

To Clean and Disinfect in One Step: Wipe surface with towel until completely wet. Allow to remain wet for one (1) minute at room temperature (68-77°F). To kill TB, allow 2 minutes contact at room temperature. Wipe dry or allow to air dry. Gross soil must be removed prior to disinfecting. Gloves should be worn.

****Ultrasound transducers and probes:**

For use on external surfaces of ultrasound transducers and probes only.

To disinfect: Pre-clean gel from external surface of ultrasound transducer or probe to be disinfected with a paper towel or clean cloth. Then thoroughly wet the probe with a towelette [Product Name]. Treated surface must remain visibly wet for one (1) minute. To kill TB, allow to remain wet for two (2) minutes at room temperature.

[Product name] are pre-moistened disposable towels for use in healthcare and other areas where control of cross contamination is required. Surfaces: This product may be used on hard non-porous surfaces such as stainless steel, glazed ceramic tile, hard plastics, non-porous vinyl, painted surfaces, glazed porcelain, sealed fiberglass surfaces, Plexiglas, and glass.

Areas of Use:

Hospital and Healthcare: Clinics, Dental Offices, Emergency rooms, Hospitals, Hospital central service areas, ICU, Laboratory, Nursing homes, Physical therapy, Physician offices, Radiology treatment areas, Recovery rooms and Surgery.

Critical Care Areas: E.R., ICU, Neonatal Intensive Care Units (NICU), Pediatric Intensive Care Units (PICU) and Surgery.

Use Sites: Hard non-porous surfaces of autoclaves, bed railings, blood glucose monitors, cabinets, carts, chairs, counters, exam tables, gurneys, infant incubators and care cribs, IV poles, phlebotomy trays, PVC tubing, stretchers, tables;

Hard non-porous outside surfaces of: ambulance equipment, diagnostic equipment, dialysis machines, mammography equipment, patient monitoring equipment, respiratory equipment and ultrasound transducers and probes.

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

Add multiple organisms

Nursery or Daycare Centers: Changing tables, cribs, trash cans, toys and other hard, non-porous surfaces listed on this label.

†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.**

STORAGE AND DISPOSAL:

{For canisters}

Store this product in a cool, dry area away from direct sunlight and heat. When not in use keep center cap of lid closed to prevent moisture loss. Do not reuse empty container. Discard used towels and container in trash or take container to recycling center. [Do not flush towels down toilet.]

{For soft packs and individually wrapped packs}

Store this product in cool, dry area away from direct sunlight and heat. Discard used towel and empty package in trash. [Do not flush towels down toilet.]

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 of rinsing, 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.

REORDER NO.

{Optional Claims. They may be placed anywhere on label/container.}

An effective method to clean, deodorize and disinfect against odor-causing organisms on hard non-porous surfaces listed on this label.

An effective way to disinfect hard, non-porous environmental surfaces listed on this label.

Cleans, disinfects and deodorizes

Disinfects hard non-porous environmental surfaces listed on this label

Does not produce mist or overspray

No mixing

Premoistened

Ready to Use

[Product Name] are pre-moistened with a unique, stabilized bleach and detergent solution and are ready-to-use.

[Product Name] are intended for cleaning and disinfecting hard, non-porous surfaces where control of cross-contamination is required.

[Product Name] are useful in a variety of healthcare and nursery/daycare applications listed on the [this] label.

[Product Name] may be used to clean and disinfect in one step; see directions for use on this label for cleaning and disinfecting in one step.

Use of this product does not produce mist in the air.

(The following graphics are optional. They may be placed anywhere on label/container.)



RESEAL HERE
PULL TAB

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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