

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460United States
Environmental Protection
AgencyOffice of Pesticide Programs

September 5, 2006

Sally Hayes
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: April 13, 2006
Receipt Date: April 17, 2006

Dear Ms. Hayes:

The following amendment submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended to add Norovirus and Avian Influenza, MRSA, VRE, C.difficile (vegetative), HAV, HBV, HCV, and Rotavirus are acceptable with comments.

The Dispatch Hospital Cleaner Disinfectant with Bleach product is not accepted against **Norovirus** on hard non-porous surfaces for a contact time of one minute, due to the inherent resistance associated with this enteric, non enveloped pathogen. The Agency requests that efficacy data be generated, using the towelette product, against Feline Calicivirus.

Although the submitted data supports the claims that the product is an effective disinfectant on hard, non-porous surfaces against Influenza A (Avian reassortant H3N2)(ATCC VR-2072), pump spray products and other similarly ready-to-use (RTU) packaged products do not adequately deliver the volume of liquid required to disinfect sites likely to be contaminated with avian influenza (i.e., poultry and/or farm premises.)

Therefore, the Agency is not accepting the proposed label claim for use of this product, in veterinary applications, against avian flu virus (H3N2). These claims will be removed from the label.

General Comments

A stamped copy of the labeling accepted with comments 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

- Ready-to-use towels pre-moistened with stabilized bleach (5200 ppm) and detergent solution
- Cleans & disinfects in one step
- Kills bacteria, viruses[†] & fungi in 1 Minute
- 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 faecilis* (VRE), *Clostridium difficile* (vegetative), *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)[†], [REDACTED]

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

Net Contents

of towels and size

ACCEPTED
 with **COMMENTS**
 EPA Letter Dated:

SEP - 5 2006

EPA Reg. No.: 56392-8
 EPA Est. No.: 50757-WI-1
 41925-WI-1
 41925-WI-2

Manufactured by:
 Caltech Industries, Inc.
 Midland, MI 48642
 1-800-234-7700
 ®Trademark of Caltech Industries, Inc.

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 and detach at the second perforation.

{Soft pack direction}:

Peel back label slowly. Pull out wipes as needed and reseal label. When not in use keep label 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). 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.

[Product name] is a pre-moistened disposable towel 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, Doctors Offices, Emergency rooms, Hospitals, Hospital central service areas, ICU, Laboratory, Nursing homes, Physical therapy, Physician's 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.

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

†KILLS HIV, HAV, 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 A Virus (HAV), 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 2 minutes. •**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.**

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 container in trash collection or take to recycling center.

{For soft packs and individually wrapped packs}

Store this product in a cool, dry area away from direct sunlight and heat. Discard empty package in trash.

PRECAUTIONARY STATEMENTS: Hazards to Humans and Domestic Animals CAUTION:

Causes moderate eye irritation. Avoid contact with eyes and 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. **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 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, [and] [&] disinfects

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.)



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

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