

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

FEB - 6 2006

February 6, 2006

Ann M. Cozad, Agent for Caltech Industries, Inc. c/o Scientific and Regulatory Consultants, Inc. P.O. Box 1014
Columbia City, IN. 46725

Subject:

Resubmission of label and CSF for Amendment

Dispatch Hospital Cleaner Disinfectant Towels

EPA Registration Number 56392-8 Application Date: December 8, 2005

Dear Ms. Cozad:

The Agency has reviewed the revised Confidential Statement of Formula (CSF) and label you have submitted in accordance with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). In summary, both the basic and alternate CSFs have been accepted without comment.

The revised label is acceptable with the following conditions:

Change the 5500 ppm claim to 5200 ppm.

At the Ultrasound transducers and probes heading, add an asterisk. Place an accompanying asterisk (*) at the reference paragraph that is at the end of Directions for Use and begins "This product is not to be used as a terminal sterilant..."

In the paragraph above Areas of Use, qualify ceramic tile by adding the word glazed as a prefix.

Enclosed is a copy of our chemistry review (D324605). Should you have any questions or comments concerning this letter; please contact me at (703) 308-8583 or Tom Luminello at (703) 308-8075.

Jincerely

Emily H. Mitchell

Product Manager 32

Regulatory Management Branch II Antimicrobials Division (7510C)



DISPATCH® Hospital Cleaner Disinfectant Towels with Bleach

- Ready-to-use towels pre-moistened with stabilized bleach (5500 ppm) and detergent solution 5200
- Cleans & disinfects in one step
- Kills TB in 2 Minutes
- 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 choleraesuis, Streptococcus pyogenes, Trichophyton mentagrophytes, HIV-1 (AIDS Virus)[†], Poliovirus Type 1 (Mahoney)[†], Herpes Simplex Virus (HSV-2)[†] 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 **Net Contents** # of towels and size

EPA Reg. No.: 56392-8 EPA Est. No.: 50757-WI-1 41925-WI-1 with COMMINES m EPA Letter Dated: Manufactured by: FEB - 6 2006 Caltech Industries, Inc. Midland, MI 48642 1-800-234-7700 ®Trademark of Caltech Industries, Inc.

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: Pop up center cap of lid, grasp hinge and pull off lid. Discard inner seal from canister.

To start feed: Find center of wipe roll, remove first wipe for use, twist corner of next 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 at an angle. When not in use keep center cap of lid closed to prevent moisture loss. Gloves should be worn.

{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 1 minute at room temperature (68-77°F) to disinfect. Wipe clean. To kill TB, allow 2 minutes contact at room temperature. 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 by using a clean washcloth. Then thoroughly wet the probe with a towelette. Treated surface must remain visibly wet for a full two (2) minutes.

[Product name] is a pre-moistened disposable wipe 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, ceramic tile, hard plastics, non-porous vinyl, painted surfaces, glazed porcelain, sealed fiberglass surfaces, Plexiglas, and glass.

(glazed

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.

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

<u>Use Sites</u>: 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.

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

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Special Instructions for Cleaning and Decontamination Against HIV-1 (AIDS Virus) 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. A two minute contact time is required for TB •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 to avoid deterioration. When not in use keep center cap of lid closed to prevent moisture loss. Product or rinsates that cannot be used should be diluted with water before disposal in a sanitary sewer. Do not reuse empty container. Wrap container and put in trash collection. Do not contaminate food or feed by storage, disposal, or cleaning of equipment.

{For soft packs and individually wrapped packs}

Store this product in a cool, dry area away from direct sunlight and heat to avoid deterioration. Product or rinsates that cannot be used should be diluted with water before disposal in a sanitary sewer. When discarding container, place in trash collection. Do not contaminate food or feed by storage, disposal, or cleaning of equipment.

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. Remove contact lenses, if present, after the first 5 minutes, then continue rising 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 bowel cleaners. This product not intended for use on fabrics.

REORDER NO. 69101 or REORDER NO. 69260 or REORDER NO. 69160 69260-201-X or 69260-200-X or 69101-200-X or 69160-200-X

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{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.

ACCUSTON

variable conditions

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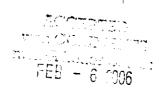
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(The following graphics are optional. They may be placed anywhere on label/container.



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



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