UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460



SEPA United States Environmental Protection Office of Pesticide Programs Agency

MAR 20 2009

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

FILE COPY

Subject:

Caltech Industries, Inc.

Dispatch Hospital Cleaner Disinfectant Towels With

Bleach

EPA Registration No. 56392-8

Submission Dated: December 19, 2008 Receipt Dated: December 22, 2009

Dear Mr. Swain:

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

General Comments

The increase in the amount of Sodium Hypochlorite from 0.55% to 0.65% has been accepted and is reflected in the Ingredient Statement for this product.

The revised basic CSF dated January 6, 2009, is acceptable and supersedes all the previously accepted basic CSF's.

Please note that the policy on Antimicrobial Towelettes and Wipes are under consideration by the Antimicrobials Division. Once the policy has been finalized, registrants/consultants will be informed if there are any changes regarding the registration process and any additional data requirements.

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,

Warda y J.

Framily H. Mitchell

Product Manager - Team 32 Regulatory Management Branch II Antimicrobials Division (7510C)



DISPATCH® Hospital Cleaner Disinfectant Towels with Bleach

- [Contains 6500 ppm Sodium Hypochlorite]
- [Pre-Moistened Towels With 1:10 Dilution Of Bleach (6.0%) And Detergent]
- [Cleans [and], Disinfects, [& Deodorizes] In One Step]
- [Peel And Reseal Here {for flex packs only}]

Kills [99.99%] bacteria, viruses[†] & fungi in 1 Minute: Acinetobacter baumannii, [†]Avian Influenza A Virus, [†]Canine Parvovirus, Enterobacter aerogenes, Escherichia coli ESBL, [†]Feline Panleukopenia Virus, [†]Hepatitis A Virus (HAV), [†]Hepatitis B Virus (HBV), [†]Hepatitis C Virus (HCV), [†]Herpes Simplex Virus (HSV-2), [†]HIV-1 (AIDS Virus), [†]Influenza A Virus, Klebsiella pneumoniae, Methicillin resistant Staphylococcus aureus (MRSA), [†]Norovirus, [†]Poliovirus Type 1 (Mahoney), Pseudomonas aeruginosa, [†]Rhinovirus, [†]Rotavirus, Salmonella enterica, Staphylococcus aureus, Streptococcus pyogenes, Trichophyton mentagrophytes (Athlete's Foot Fungus), Vancomycin resistant Enterococcus faecalis (VRE) Kills Mycobacterium bovis (TB) in 2 Minutes

Active Ingredient: Sodium Hypochlorite	0.65%
Other Ingredients	99.35%
Total	.100.00%
(yields 0.62% 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

EPA Reg. No. 56392-8

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Manufactured for:

©2008 Caltech Industries, Inc.
4520 E. Ashman
Midland, MI 48642
1-800-234-7700
www.caltechindustries.com
®Trademark of Caltech Industries, Inc.

41925-WI-1^C
41925-WI-2^D
41925-WI-3^E
41925-WI-3^E
41925-WI-3^E

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Under the Federal Insecticide, Fungicide, and Rodenticide, Aci as amended, for the pesticide, registered under EPA Reg. No. 392-8

EPA Est. Nos. 50757-WI-1^G

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Pre-moistened disposable towels for use in healthcare and other areas where control of cross contamination is required. Meets OHSA Bloodborne Pathogen Standards. Surfaces: 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, laminated plastic countertops, and glass.

Use Sites:

Hospital and Healthcare: Clinics, Dental offices, Emergency rooms (ER), Hospitals, Hospital central service areas, Intensive Care Units (ICU), Laboratory, Nursing homes, Physical therapy, Physician offices, Radiology, Recovery rooms and Surgery.

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

Applications: Hard non-porous surfaces such as 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, 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.

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. Gloves should be worn.

{Individually wrapped Pack directions}

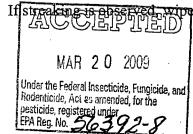
Tear open packet. Unfold and use as directed. Discard after single use. Gloves should be worn.

To Clean, Disinfect, and Deodorize in One Step: Wipe surface with towel until completely wet. Let stand for one minute. To kill TB, let stand for two minutes at room temperature $(20 - 25^{\circ}C)$. Wipe dry or allow to air dry. Gross soil must be removed prior to disinfecting. Gloves should be worn.

To Clean: Follow directions above, but no standing time is required. If streaking with a clean, damp cloth or paper towel.

**Ultrasound transducers and probes:

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



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

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]. Let stand for one minute. To kill TB, let stand for two minutes at room temperature.

[†]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, or 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 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. Nonrefillable container. Do not reuse or refill this 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. Nonrefillable container. Do not reuse or refill this container. 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

REORDER NO.

See expiration date on package.

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Under the Federal Insecticide, Fungicide, and Redemoids, Aut as amended, for the Note: Bracketed [] information is optional text. {Bracketed Text} is for administrative purposes ordy, and will not appear on the

{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.

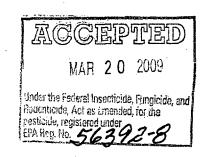
[Product Name] are intended for cleaning and disinfecting hard, non-porous surfaces where control of cross-contamination is required.

[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.

[Efficacy tests have demonstrated that Dispatch Hospital Cleaner Disinfectant Towels With Bleach [this product] is an effective bactericide, virucide, tuberculocide, and fungicide in the presence of organic soil (5% blood serum)]



(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.

