

56392-7

10-4-2002

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OCT - 4 2002

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Catherine Anders
General Manager
Caltech Industries, Inc.
2420 Schuette Drive
Midland, MI. 48642

SUBJECT: Letter requesting label amendment April 5, 2002
EPA Registration Number 56392-7

Dear Ms. Anders:

The labeling amendment referred to above, submitted in connection with registration of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable with the following conditions. In summary, you have submitted additional data to resolve deficiencies cited in three product performance studies, MRID 456550-01, 456550-02, and 456550-03. We have reviewed this additional information and have concluded that your product performance data will support your requested label claims for Vancomycin resistant *Enterococcus faecalis* and Methicillin-resistant *staphylococcus aureus* and *mycobacterium tuberculosis* and *rotavirus*. A copy of our review is enclosed.

In addition to new use claims you must change the word Inert to Other so that it reads Other Ingredients. Change the word should to must so that it read "Gross soil must be removed" in the Directions For Use section. The First Aid statement needs to be revised as follows:

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 rinsing eye.
- Call a poison control center or doctor for further treatment advice.

If you have any questions regarding this letter, please contact Tom Luminello of my staff at (703) 308-8075.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Tom Luminello", written over the typed name.

Robert S. Brenniss
Product Manager 32
Regulatory Management Branch II
Antimicrobial Division

Enclosure

ACCEPTED
with COMMENTS
in EPA Letter Dated:

OCT - 4 2002



56392-7

DISPATCH®

Hospital Cleaner Disinfectant

with Bleach (5500 ppm NaOCl)

* Ready-to-use with stabilized bleach (5500 ppm) and
detergent solution

- May be used to clean & disinfect in one step

Kills bacteria & viruses in 1 Minute

- Staphylococcus aureus, Methicillin resistant Staphylococcus aureus (MRSA), Salmonella choleraesuis, Pseudomonas aeruginosa, Streptococcus pyogenes, Vancomycin resistant Enterococcus faecalis (VRE), Trichophyton mentagrophytes, HIV-1 (AIDS virus), Herpes Simplex (HSV-2), Poliovirus (Type 1, -Mahoney), Rotavirus

Kills TB in 30 Seconds

- * Mycobacterium tuberculosis

EPA Reg.No. 56392-7

EPA Est. Nos. 62801-MI-1, 52379-MI-2

Active Ingredient: Sodium Hypochlorite.....0.55%

Inert Ingredients.....99.45%

other

KEEP OUT OF REACH OF CHILDREN

CAUTION
NET CONTENTS

Revise APR 2001-1

READ COMPLETE DIRECTIONS AND PRECAUTIONS
ON REAR PANELS

* 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 rinsing eye.

* Call a poison control center or doctor for further treatment advice.

DISPATCH® Hospital Stainless & Plastic

Cleaner Disinfectant with Bleach (5500 ppm NaOCl)

*For hospital non-porous surfaces such as stainless steel, plastic, ceramic tile, laminated plastic countertops, vinyl, tile, linoleum, porcelain enamel, fiberglass, chrome, porcelain, and grout which must be cleaned and disinfected. A rapid acting cleaner disinfectant that can't scratch. Effective on organic stains such as fruit, coffee, tea, food residues, grease, fingerprints and laboratory stains. *Useful in outpatient clinic, central service area, kitchen and food service area (nonfood surfaces), laboratory, clinic, emergency room, radiology, operating room, physical therapy, nursing station reception counter, restroom, physician office, veterinary hospital, nursing home, dental operatory.

DIRECTIONS FOR USE

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

To Clean: Hold bottle 6-8" from surface. Direct gentle spray to soiled area or apply with damp applicator. Wipe clean with a damp applicator such as sponge/cloth/paper towel. Stubborn stains - allow 5 minute contact. No rinsing needed. If streaking is observed, rinse with water. Polish with dry cloth.

To Clean and Disinfect in One Step: Spray surface thoroughly until completely wet. Allow 1 minute at room temperature (68-77°F) to wet surface and disinfect. Wipe clean with a damp sponge, cloth or paper towel. No rinsing needed. To kill TB allow 30 seconds contact at room temperature. Gross soil must be removed prior to cleaning and disinfecting.

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.

KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS) 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 plastic gloves, gowns, masks, or eye coverings should be used. Cleaning Procedure: Blood and other 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.

STORAGE AND DISPOSAL

Store this product in a cool, dry area, away from direct sunlight and heat to avoid deterioration. In case of spill, flood areas with large quantities of water. Product or rinsates that cannot be used should be diluted with water before disposal in a sanitary sewer. Refill empty container only with DISPATCH Refill. 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: Flush eyes with plenty of water. Call a physician if irritation persists.

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.

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REORDER NO:

©1999 Caltech Industries, Inc.
Midland, MI 48642
1-800-234-7700

EXP. DATE:

NEPA HEALTH 0 FLAMMABILITY 0 REACTIVITY 1 SPECIFIC OX