

PM-34

9/9/97

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SEP 9 1997

Caltech Industries, Inc.
2420 Schuette Drive
Midland, MI 48642

Attention: Ms. Ann M. Watton
Regulatory Manager

Subject: Citrex Hospital Spray Disinfectant
EPA Registration Number 56392-4
Your Submission Dated August 12, 1996 and June 24, 1997

This is in response to your request to amend your proposed label to include a one minute tuberculocidal claim and data to support the one-step disinfection at one minute. The following comments apply:

The information submitted pertaining to the ATCC M. bovis strain # and the one minute contact time for tuberculocidal activity are acceptable. In addition, the request for additional efficacy data to support the change in use to a one-step disinfectant at one-minute contact time, which was outlined in the Agency letter dated May 7, 1997, is satisfied by the data submitted to support the aliphatic alcohol reregistration (MRID # 44011005) against Staphylococcus aureus, Salmonella choleraesuis, and Pseudomonas aeruginosa.

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comments listed below. A stamped draft label is enclosed for your records. One copy of the finished labeling must be submitted prior to releasing the product for shipment.

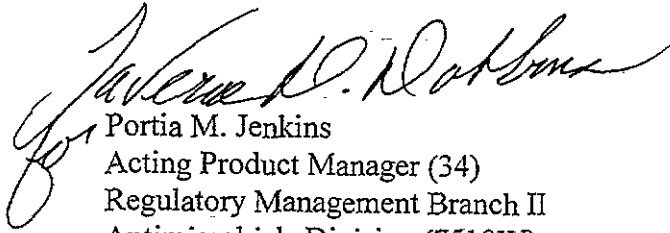
Under the heading "To Clean and Disinfect in One Step", remove the statement, Tuberculocidal activity requires 1 minute contact at room temperature (68-77F, 20 - 25C). One step claims are not acceptable for Tuberculocidal activity. A separate heading listing the tuberculocidal activity is appropriate.

Expand the terms staph, strep, pseudomonas, and salmonella, to read Staphylococcus aureus, Streptococcus pyogenes, Pseudomonas aeruginosa, and salmonella choleraesuis. Abbreviated terms may be listed in parentheses after the full genus and species. Revise the statement "athlete's foot fungus" to read; Trichophyton mentagrophytes (athlete's foot fungus)".

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

If you have any questions, please contact LaVerne Dobbins at (703) 308-6378.

Sincerely,


Portia M. Jenkins
Acting Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510W)

Enclosure:

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CITREX®

Hospital Spray Disinfectant

Eliminates Odors
Refreshens Air
Kills Household Germs
on Environmental Surfaces
Prevents Mold and Mildew

EPA REG. NO. 56392-4

ACTIVE INGREDIENTS:
o-Phenyphenol.....00.12%
Ethanol.....69.10%
INERT INGREDIENTS.....30.78%

ACCEPTED
with COMMENTS
to EPA Letter Dated:

SEP 9 1997

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

56392-4

NET WT. ___ OZ.

KEEP OUT OF REACH OF CHILDREN
CAUTION

READ COMPLETE PRECAUTIONS AND
DIRECTIONS ON REAR PANEL

(Front Panel)
Draft label 6/20/97

Copy 2 of 5

CITREX® Hospital Spray Disinfectant

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For use in Homes, Hospitals, Schools, and Offices

KILLS HOUSEHOLD GERMS: Spray as directed to kill staph, strep, pseudomonas, salmonella, HIV-1 (AIDS Virus), athlete's foot fungus, and most household germs on environmental surfaces — empty hampers, diaper pails and garbage pails, telephones, pet areas, bathroom basins, toilet seats, toys, light switches, door handles, bed springs, air ducts, and other hard nonporous surfaces.

ELIMINATES ODORS — REFRESHENS AIR: Spray as directed to eliminate bathroom odors, kitchen odors, cigarette odors, animal odors and stale musty air.

PREVENTS MOLD AND MILDEW: Spray as directed below. Effective for use on leather, fabric, bedding, bathroom surfaces, books, car or boat interiors. Use in bathroom, laundry room, and on contents of closets.

DIRECTIONS FOR USE

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

TO CLEAN: Shake well. Spray lightly and immediately wipe dry with cloth or paper towel. Effective as a light duty cleaning agent to remove fingerprints and hand smudges. Use on stainless steel, chrome, mirrors.

TO CLEAN AND DISINFECT IN ONE STEP: Shake well. Hold can upright 6-8" from surface. Spray non-porous surface until thoroughly wet and allow to remain wet for one minute. Wipe dry or allow to air dry. Tuberculocidal activity requires 1 minute contact at room temperature (68°-77°F, 20°-25°C). If gross soil is present, remove prior to disinfecting.

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 or body fluids, appropriate personal protective equipment such as disposable plastic gloves, gowns, masks or eye coverings should be considered. **Cleaning Procedure:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects prior to disinfecting. **Contact Time:** CITREX kills HIV-1 (AIDS Virus) in one minute at room temperature (68-77°F, 20-25°C). **Disposal of Infectious Materials:** Blood and other body fluids and cleaning materials should be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

TO DEODORIZE AND REFRESHEN AIR: Shake well. Hold upright. Spray center of room for 1-2 seconds.

TO PREVENT MOLD AND MILDEW: Clean surface prior to application. Shake well. Hold upright and spray surface until thoroughly wet. Repeat weekly to prevent regrowth.

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.

DISPOSAL: DO NOT REUSE EMPTY CONTAINER. WRAP CONTAINER AND PUT IN TRASH COLLECTION.

PRECAUTIONARY STATEMENTS — Hazards to Humans and Domestic Animals

CAUTION: Avoid contact with eyes. In case of contact, immediately flush eyes with plenty of water. Get medical attention if irritation persists. Avoid contamination of food. Use only as directed. Intentional misuse by concentrating and inhaling contents can be harmful or fatal.

Physical or Chemical Hazards

Flammable: Do not use near fire or flame. Contents under pressure. Do not puncture, incinerate or store in heat or sun. Exposure to temperatures above 130°F may cause bursting. Do not use on polished wood or rayon. Before using on painted or plastic surfaces, spot test on an inconspicuous area.

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P.O. Box 1139
Midland, MI 48641-1139
1-800-234-7700

(Back Panel)

Copy 2 of 5

ACCEPTED
with COMMENTS
in EPA Letter Dated:
SEP 9 1997

Draft Label 6/20/97

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide
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56392.4