

FEB 06 1989

Caltech Industries, Inc.
P.O. Box 1139
Midland, MI 48641-1139

Attention: Charles D. Burton
Director of Research

Gentlemen:

Subject: Citrace Hospital Germicidal Deodorizer
EPA Registration No. 56392-2
Your Amendment Application Dated June 30, 1988

The submitted data meet the requirements to support effectiveness of the product as a virucide against HIV-1 (AIDS virus) on previously cleaned, hard, nonporous surfaces when used as an undiluted pressurized spray for a contact time of 1 minute at room temperature (20 to 25 °C).

The submitted tuberculocidal data meet the requirements of the Tuberculocidal Data Call-In Notice to support effectiveness of the product as a tuberculocide against Mycobacterium tuberculosis var bovis (BCG) when used as an undiluted pressurized spray on precleaned, hard, nonporous surfaces for a contact time of 10 minutes at room temperature (20 to 25 °C).

The amendment referred to above, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act, is acceptable provided that you:

1. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling.
 - a. The contact time of 1 minute employed for efficacy testing against HIV-1 does not correlate with the contact time of 10 minutes supported in previously accepted efficacy data for disinfection and the last accepted labeling for this product. Therefore, if a claim for shorter contact time is made for HIV-1, a statement similar to the following will be required "Although efficacy at a 1 minute contact time has

57152:I;Douglas:LK-6;KENCO:12/23/88:1/4/89:SG:vo:rw
R:57155;Douglas:LK-06;KENCO:01/05/89:01/18/89:CL

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

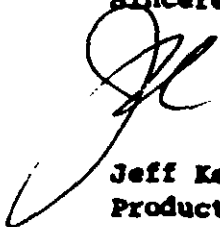
been shown to be adequate against HIV-1, this time would not be sufficient for other organisms. Use a 10-minute contact time for disinfection against all of the organisms claimed."

- b. The claim "Human Immunodeficiency Virus (HIV) Type 1 (HTLV-3)" should be revised to read "Human Immunodeficiency Virus Type 1 (HIV-1)."
 - c. Change "Kills HTLV-3 virus in 1 minute at 25 °C" to read "Kills HIV-1 (AIDS virus) in 1 minute at 25 °C."
 - d. The labeling requirements for antimicrobial pesticides used on hard surfaces against HIV-1 (AIDS virus) are indicated on the enclosure. It is important to note that featured statements/phrases, emphasized/enlarged lettering, special graphics, or any product name that employs the term "AIDS" are not acceptable, as indicated in item 2. Special instructions for this use pattern must be provided in the format indicated in item 4 of this enclosure.
 - e. Delete "contains sodium nitrite and 3.5% non-fluorocarbon propellant" from the ingredient statement. Note that it is not necessary to list inert ingredients, but if you do, all of them must be listed by their correct chemical names.
 - f. Place "Keep Out of Reach of Children" immediately above the signal word (WARNING) on the front panel.
2. Submit five (5) copies of your final printed labeling before you release the product for shipment. Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

If you have any questions in this regard, please contact Ms. Ruth Douglas at (703) 557-3842.

Sincerely yours,



Jeff Kampter
Product Manager (32)
Antimicrobial Program Branch
Registration Division (TS-767C)

Enclosures

PM32

56392-2

3 of 4

REAR PANEL

ACCEPTED
WITH COMMENTS
in EPA 100-10-1000

CITRACE*

FEB 06 1989

Hospital
Germicidal Deodorizer

STREPTOCIDAL STAPHYLOCIDAL
PSEUDOMONACIDAL FUNGICIDAL
SALMONELLACIDAL TUBERCULOCIDAL
VIRUCIDAL*

U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division
Washington, D.C. 20460
EPA Reg. No.
56392-2

- *Human Immunodeficiency Virus (HIV) Type I (HTLV-3)
- *Herpes Simplex Virus, Hominus, Type I (HSV I)
- Canine Parvovirus, ATCC VR-2006

This effective product eliminates odors in the air and at their source. Does not just mask odors. Kills dangerous germs such as "staph" and "strep" on environmental surfaces. Inhibits mold and mildew. Kills listed viruses on nonporous, inanimate surfaces.

For use in Hospitals, Clinics, Nursing Homes, HMO, Physician Offices, Dental Offices and Veterinary Facilities. Use this product in patient rooms, emergency rooms, outpatient facilities, exam rooms, operatory, radiology, physical therapy, central supply, and bathrooms.

Directions For Use: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

To Disinfect: Shake well. Hold can upright 6-8" from Surface. Spray pre-cleaned non-porous surface until thoroughly wet and allow to remain wet for 10 minutes. Wipe dry or allow to air dry. Remove heavy soil and thoroughly clean surface prior to application of product. Tuberculocidal in 10 minutes at 25°C. Kills HTLV-3 virus in one minute at 25°C.

To Eliminate Odors: Shake well. Hold upright. Spray center of room 1 - 2 seconds. For a moment there's the fresh smell of citrus and then it disappears taking unpleasant odors with it. Do not fog.

To Control Mold and Mildew: Clean surface prior to application. Spray surface until thoroughly wet and repeat weekly to prevent regrowth. Provides residual bacteriostatic action in the presence of moisture.

To Clean: 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.

Precautionary Statements
Hazards to Humans and Domestic Animals

WARNING: Do Not Spray in Eyes. Avoid Contact with Food.
~~Intentional misuse by concentrating and inhaling contents can be harmful or fatal.~~

In case of contact, flush eyes with plenty of water.

Physical Hazards:

Flammable. Contents under pressure. Keep away from heat, sparks and open flame. Exposure to temperatures above 130°F may cause bursting. Before using on painted or plastic surfaces, spot test on an inconspicuous area.

Storage: Do not use or store near heat or open flame. Store out of reach of children.

Disposal: Replace cap and discard empty container in trash. Do not puncture or incinerate.

Active ingredients:	
o-phenylphenol	00.12%
Ethanol	66.60%
Inert Ingredients: 33.28%	
Contains Sodium nitrite and 3.5% non-fluorocarbon propellant.	

Made and Printed in U.S.A.

Caltech Industries, Inc.
Midland, MI 48640

EPA Reg. No. 56392-2
EPA Est. 5590-IL-1 10744-IL-1 11525-RL-1 11525-CA-1
33915-MI-01

ACCEPTED
with COMMENTS
in EPA Reg. No. 56392-2

FEB 06 1989

Upjohn Company, Kalamazoo, Michigan.
Filing of this label in the Act as amended by the pesticide registration under EPA Reg. No. 56392-2