

FEB 06 1988

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

Attention: Charles D. Burton
Director of Research

Gentlemen:

Subject: Precise Hospital Foam Cleaner Disinfectant
EPA Registration No. 56392-1
Your Amendment Application Dated August 19, 1988

The submitted data meet the requirements to support effectiveness of the product as a virucide against HIV-1 (AIDS virus) on hard, nonporous surfaces in the presence of a moderate amount of organic soil (10% blood serum) when used undiluted (pressurized spray) for a contact time of 1 minute 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 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)."

57152:I:Douglas:LK-6:KENCO:12/23/88:1/4/89:SG:vo:rw

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

- c. Change "To Clean and Disinfect for HTLV Virus" to "To Clean and Disinfect for HIV-1 (AIDS virus)."
 - d. Change "Kills HTLV-3 virus in 1 minute at 25 °C (75 °F)" to read "Kills HIV-1 (AIDS virus) in 1 minute at 25 °C (75 °F)."
 - e. 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.
 - f. Refer to our last letter in regard to the Tuberculocidal Data Call-In Notice for additional labeling requirements.
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 Kempter
Product Manager (32)
Antimicrobial Program Branch
Registration Division (TS-767C)

Enclosures

(FRONT PANEL)

+ 376-2784



PRECISE*

Hospital Foam
Cleaner Disinfectant



For Hard Surfaces
Cleans, Shines
Disinfects
Deodorizes
Won't Scratch

EPA REG NO 56392-1

ACTIVE INGREDIENTS:
o-Phenylphenol 0.37%
INERT INGREDIENTS: (Includes
detergents, cleaners, and 5%
non-fluorocarbon propellant) ... 99.63%

HOSPITAL SIZE
NET WT. 20 OZ. (1 LB. 4 OZ.)

KEEP OUT OF REACH OF CHILDREN

WARNING
READ COMPLETE PRECAUTIONS AND
DIRECTIONS ON REAR PANEL

211 x 718 WIMA WELD

8.152 x 7.837

Enclosure 2

Page 1

ACCEPTED
FEB 06 19

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Superscript used in the back letter of 1st No. 42110 CA (1) 11525 CA (1) 11525 CA (1) 11525 CA (1) 11525 CA (1) 11525 CA (1)



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ACCEPTED
with COMMENTS
in EPA Letter Dated:

(Rear Panel)

SHAKE OFTEN

FEB 06 1988 SHAKE OFTEN

PRECISE*
Hospital Foam
Cleaner Disinfectant

Under the Federal Insecticide, Fungicide, and Rodenticide Act
EPA Reg. No. 56392-1

.STREPTOCIDAL
.STAPHYLOCIDAL
.PSEUDOMONACIDAL

.FUNGICIDAL+
.SALMONELLACIDAL
.TUBERCULOCIDAL

VIRUCIDAL++

- Kills Canine Parvo Virus
- +Controls pathogenic fungi such as athletes foot fungus
- ++Human Immunodeficiency Virus (HIV) Type 1 (HTLV-3)
- ++Herpes Simplex Virus Type 2 (HSV-2)
- ++Influenza A-2, strain Hong Kong (NCDC)

hard, nonporous surfaces

.For Hospital Hard Surfaces. Quick Spray and Wipe for Cleaning. Always properly mixed and ready to use. Put this product to work throughout the hospital.

.Cleans and shines all hospital washable surfaces--tile, tubs, bowls, basins, sinks, showers, urinals, empty bed pans, toilets, cabinets, doors and door handles, empty emesis basins, floors, walls, woodwork, work station tables and counter tops, vanity tops, vending machines, bed springs and frames, bedside furniture, dressing and surgical carts, wheel chairs, walkers, stainless steel, chrome, plastic, metal, vinyl, fiberglass, baked enamel, porcelain, examination and x-ray tables, film cassettes, chart holders, shower chairs, sitz baths, commodes and commode seats, instrument cabinets and trays, catheter trays, electrodes, bacteriology laboratory benches, centrifuges, whirlpool baths, operating tables, emergency vehicles, telephones, reception counters, dental hand pieces, dental chairs, medical instruments.

.Disinfects--Kills germs commonly found on hard non-porous hospital surfaces. See directions for disinfecting.

.Deodorizes--Kills odor causing germs on hard surfaces. Leaves surfaces smelling clean and fresh.

.Labor Saving--Just spray on--Wipe off. No rubbing, rinsing or scouring.

.Won't Scratch--Contains no abrasive to scratch or leave gritty deposit.

.Removes Hospital Soils--Grime, greasy soil, soap scum, water marks, scuff marks, blood, drainage, stains, emesis, fingermarks.

.Useful--patient rooms, emergency rooms, recovery rooms, operating rooms, laboratories, clinics, bathrooms, physician offices, physical therapy, nursing stations, radiology, morgue, housekeeping cars, dental operatories, veterinary hospitals.

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling
.Directions: Shake Well. Hold can six (6) inches from surface.

.To Clean: Quick spray and wipe clean with a damp sponge, cloth or paper towel. No rinsing needed.

.To Clean and Disinfect for HTLV virus: Spray surface thoroughly until completely covered with foam, allow 1 minute to wet surface and disinfect. Wipe clean with damp sponge, cloth or paper towel. No rinsing needed. Kills HTLV -3 virus in 1 minute at 25° C (75° F).

.To Clean and Disinfect for TB: Spray surface thoroughly until completely covered with foam, allow 10 minutes to wet surface and disinfect. Wipe clean with a damp sponge, cloth, or paper towel. No rinsing needed. Tuberculocidal activity requires 10 minutes contact at 20° C (68° F).

.To Disinfect: Spray precleaned surface thoroughly until completely covered with foam, allow 10 minutes to wet surface and disinfect. Wipe clean with a damp sponge, cloth or paper towel. No rinsing needed. If gross soil is present, remove prior to disinfecting.

*Precautions, Statements
Hazards to Humans and Domestic Animals*
.WARNING: Contents under pressure. May cause eye irritation. Avoid contact with eyes, *in case of contact flush eyes with water.* Use *plenty of water.* ~~only as directed.~~ Intentional misuse by concentrating and inhaling contents can be harmful or fatal.

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

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

*Trademark of Caltech Industries, Inc. REORDER NO. 40513

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P.O. BOX 1139
MIDLAND, MI 48640 517-636-7700

ACCEPTED
with COMMENTS
in EPA Letter Dated:

FEB 6 1989

Under the provisions of the
Federal Insecticide, Fungicide,
and Rodenticide Act, the
EPA hereby certifies that the
labeling of this product complies
with the requirements of the
Act.

56392-1