

MAR 04 1994

Steriderm Corporation
 1723 Cypress Pt. Glen
 Escondido, CA 92026

Attention: Leslie A. Page
 President

Subject: Stat-5 Antimicrobial Spray
 EPA Registration No. 64039-1
 Your Resubmissions Dated September 21, 1993
 and October 20, 1993.

The amendment (adding additional efficacy claims) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. Make the following labeling changes below before you release the product for shipment bearing the amended labeling.
 - a. Add the phrase "EPA Registration No. 64039-1".
 - b. Revise "Herpesvirus 2" to read: Herpes simplex Type 2
 - c. Revise "Distributed by" to read: Manufactured by
 - d. Include the reference asterick next to the word: Virucidal* (front panel).
 - e. Center the signal word: "Warning" to appear directly below the Keep Out of Reach of Children. (Center Panel)
 - f. Delete the statement "includes emollient for skin protection"
 - g. Revise the Physical/Chemical Hazards statement to read:
 Flammable. Keep away from heat and open flame.

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

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h. Revise the precautionary statement section to read:

Causes eye irritation. Do not get into eyes or on clothing. Harmful if swallowed. Avoid breathing vapors. Avoid contamination of food. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

i. Identify the type of surfaces intended for treatment. Such as floors, walls, table/counter tops

j. Include a statement in the use directions to include the necessity for removal of gross filth or heavy soil prior to cleaning.

k. Include the following headings:

Directions for Use

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

l. Under the HIV section, include the following subheading and statement.

CONTACT TIME: Leave surfaces wet for 5 minutes.

m. Add the following additional statement to read:

This product is not to be used as a 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.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). A release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

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

Sincerely,



Marshall Swindell
Acting Product Manager (31)
Antimicrobial Program Branch
Registration Division (H7505C)

Enclosures

CONCURRENCES

SYMBOL								
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FRONT PANEL

MASTER LABEL

MARCH 15, 1993

"STAT-5 ANTIMICROBIAL SPRAY"



BACTERICIDAL

TUBERCULOCIDAL

VIRUCIDAL

FUNGICIDAL

For Use in CRITICAL CARE AREAS of Hospitals, Medical, Dental, Veterinary or other Healthcare Facilities as a pump spray or solution for decontamination of hard nonporous surfaces.

ACTIVE INGREDIENTS

ALKYL (C14-50%;C12-40%;C16-10%) DIMETHYL BENZYL AMMONIUM CHLORIDE.....	0.08%
ETHANOL.....	64.80%

INERT INGREDIENTS*.....35.12%

TOTAL INGREDIENTS.....100.00%

WARNING: Keep Out of Reach of Children

See back panel for additional precautionary statements.

NET CONTENTS 16 Fluid Ounces (473 ml)

*includes emollient for skin protection

EPA Reg. No. _____	FDA NDC No. 56139-1000
EPA Est. No. 54218-CA-001	FDA Est. No. 2027250
U.S. Patent No. 4870108	

ACCEPTED with COMMENTS in EPA Letter Dated:

BEST AVAILABLE COPY

MAR 04 1994

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

64039-1

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LEFT BACK PANEL

RIGHT BACK PANEL

[REDACTED]
 for use in all healthcare facilities. Scientifically formulated with synergistic germicides and patented, it is excellent for decontamination of precleaned hard nonporous surfaces. Safe for use on formica, plastic, rubber, glass or stainless steel. Will not stain clothing.

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (AIDS VIRUS) OF SURFACES OR OBJECTS SOILED WITH BLOOD OR BODY FLUIDS:

PERSONAL PROTECTION: Wear disposable gloves, gowns, masks and eye protection when removing blood/body fluids from soiled surfaces.

CLEANING PROCEDURES: Blood/body fluids must be thoroughly removed from surfaces or objects before application of [REDACTED].

[REDACTED] A disinfectant-soaked cloth, pad or towel may be used to wipe up contaminants.

DISPOSAL OF INFECTIOUS MATERIALS: Blood/body fluids must be disposed of in accordance with local regulations for infectious waste disposal.

[REDACTED] kills HIV-1 on precleaned environmental surfaces or objects previously soiled with blood or body fluids in 5 minutes at room temperature in health care settings or other settings 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.

TO DISINFECT WITH PUMP SPRAY BOTTLE: Preclean surface as indicated above. Hold bottle 6-8" from surface and spray to wet all surfaces thoroughly. Allow surface to remain wet for 5 minutes. Wipe surface with cloth or paper towel.

TO DISINFECT WITH BOTTLED SOLUTION: Preclean surface as indicated above. Use product undiluted. Apply product with cloth, sponge or mop so as to wet surface thoroughly. Wipe dry or allow to air dry.

[REDACTED] is effective as a bactericide, tuberculocide, virucide, and fungicide. Kills bacteria such as *Staphylococcus aureus*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Mycobacteria bovis* (BCG), viruses such as *Herpesvirus 2* and fungi such as *Trichophyton mentagrophytes* (Athlete's foot fungus) in 5 minutes at 20°C. Kills HIV-1 (AIDS Virus) in 5 min. at room temperature.

PRECAUTIONARY STATEMENTS:

Hazards to Humans/Domestic Animals. Keep out of eyes, nose and ears. May cause irritation of mucous membranes. Harmful if swallowed. **Statement of Practical Treatment.** In case of eye contact, promptly flush eyes with plenty of water for 15 min. Get medical attention if irritation persists. If swallowed, drink large quantity of water. Call physician immediately.

Physical/Chemical Hazards: Flammable. Keep away from open flame or hot surfaces.

Storage and Disposal: Do not contaminate water or food by storage or disposal. Store in cool dry area away from flames, sparks or other sources of heat or ignition. Contains 64.8% alcohol. If ignited, use dry chemical or CO₂ extinguisher. If large quantity is spilled, dilute with water and mop or wipe dry.

Pesticide Disposal: Dilute with water and pour down sanitary drain.

Container Disposal: Empty containers may be discarded in trash after rinsing with water.

Distributed by
STERIDERM CORPORATION
 Escondido, CA 92026-1063
 619-746-5017

BEST AVAILABLE COPY

ACCEPTED
 with COMMENTS
 in EPA Letter Dated:

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