

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUN 21 1995

Steriderm Corporation
1723 Cypress Pt Glen
Escondido, CA 92026

Attention: Leslie A. Page
President

Subject: STAT-5 Antimicrobial Spray
EPA Registration No. 64039-1
MOU Compliance Amendment dated January 23, 1995

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, will be acceptable provided that you make the labeling change listed below before you release the product for shipment bearing the amended label.

- Under the heading "To Disinfect with Bottled Solution:" add the statement "Allow the surface to remain wet for 5 minutes." prior to the sentence "Wipe dry or ..."

A stamped copy is enclosed for your records. Submit five (5) copies of the final printed label prior to release of product for shipment.

If you have any questions concerning this letter, please contact Wanda Mitchell at (703) 305-6141.

Sincerely,



Marion J. Johnson, Jr.
Product Manager (31)
Antimicrobial Program Branch
Registration Division (7505C)

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

192

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JUN 21 1995

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

64039-1

Hard Surface Disinfectant

STAT-5 Antimicrobial Spray

BACTERICIDAL FUNGICIDAL VIRUCIDAL* TUBERCULOCIDAL

For use in medical, dental, veterinary facilities or hospitals and any other healthcare facility as a pump spray or solution for decontamination of hard, nonporous precleaned surfaces such as counter and table tops, sinks, carts, basins, bedside and office furniture, drawer and cabinet pulls, telephones and other equipment.

Ready to Use - Do Not Dilute

Active Ingredients:

Alkyl (C14-50%, C12-40%, C16-10%) dimethyl benzylammonium chloride	0.06%
Ethanol	64.60%
INERT INGREDIENTS	35.12%
TOTAL INGREDIENTS	100.00%

KEEP OUT OF REACH OF CHILDREN

WARNING See back panel for additional precautionary statements.

EPA Reg. No. 64039-1 EPA Est. No. 84055-CA-1 U.S. Patent Number
FBA Reg. No. 56149-1000-03 FBA Est. No. 2012548 4,870,100

NET CONTENTS: 16 Fluid Ounces (473ml)

DIRECTIONS FOR USE:

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

Special Instructions for cleaning and decontamination against HIV-1 (AIDS virus) of surfaces of 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 STAT-5 Antimicrobial Spray. A disinfectant-soaked cloth, pad or towel may be used to wipe up contaminants.

Contact Time: Leave surface wet for 5 min.

Disposal of Infectious Materials: Blood or body fluids must be disposed of in accordance with local regulations for infectious waste disposal.

*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 Immuno-deficiency Virus Type 1 (HIV-1) associated with AIDS.

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 pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

For Use as a Pump Spray: Pre-clean surface as indicated above. Hold spray 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.

For Use as a Bottled Solution: Pre-clean surface as indicated above. Apply undiluted product with cloth, sponge, or mop so as to wet surface thoroughly. Wipe dry or allow to air dry.

STAT-5 Antimicrobial Spray is effective as a tuberculocide, virucide, and fungicide. Kills bacteria such as tuberculosis (var bovis), Staphylococcus aureus, Pseudomonas, Salmonella choleraesuis, fungi such as Trichophytes, and the following viruses, Herpes simplex at 20°C, and HIV-1 (AIDS Virus) in 5 min. at room temperature.

For Use in All Healthcare Facilities. Scientifically synergistic germicides and patented, this product is effective for decontamination of pre-cleaned, hard nonporous surfaces: plastic, formica, rubber, glass, or stainless steel. Will not stain.

PRECAUTIONARY STATEMENTS:

Hazards to Humans/Domestic Animals:

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

Statement of Practical Treatment. In case of eye contact, promptly flush eyes with plenty of water for 15 minutes. If swallowed, drink large amounts of water. Call physician immediately.

Physical/Chemical Hazards: Flammable. May burn. Do not heat and open flame.

Storage and Disposal: Do not contaminate water or disposal. Store in cool dry area away from flames, sources of heat or ignition. Contains 64% alcohol. Use appropriate chemical or CO2 extinguisher. If large quantity is spilled, use water and mop or wipe dry.

Pesticide Disposal: Dilute with water and pour down drain after rinsing with water.

Container Disposal: Empty containers may be recycled after rinsing with water.

Manufactured for
STERIDERM CORPORATION Escondido, California

BEST COPY AVAILABLE