

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JAN 28 1997

McCormick Distilling Company, Inc.
One McCormick Lane
Weston, MO 64098

Attn: Mark Hudnall
Quality Control Manager

Subject: Sep-T-Ban
EPA Registration No. 69264-1
Amendment Dated July 25, 1996

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to add additional efficacy claims, 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 labeling changes listed below before you release the product for shipment bearing the amended labeling.

a. On the front panel, remove the term "Benzalkonium chloride" following the chemical name of the first active ingredient in the ingredient section.

b. On the front panel, delete the fire hazard warning statement "Flammable. Keep away from heat and open flame" from next to the signal word "Warning".

c. Remove the statement "Contains 65.87% alcohol" from the Storage and Disposal instructions. This statement may be placed in close proximity to the ingredient statement. Change the word "alcohol" to "Ethanol" as "Contains 65.87% Ethanol".

CONCURRENCES

		CONCURRENCES							
SYMBOL	▶								
SURNAME	▶								
DATE	▶								

- d. Under the heading "Directions for Use", revise the statement "This product is not to be used as a disinfectant on any surface or instrument that;" to read "This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that;".
- e. The signal word "Warning" must be placed in close proximity to the statement "Keep Out of Reach of Children".
- f. Move the statement "See back panel for additional precautionary statements" from the back panel and place it on the front panel of your label.
- g. Change the statement "Hazards to Humans/Domestic Animals" to "Hazards to Humans and Domestic Animals".

3. The revised Confidential Statement of Formula dated July 19, 1996 is in compliance with PR Notice 91-2, agrees with the label and is acceptable.

4. 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 concerning this letter, please contact Martha Terry at (703) 305-6982.

Sincerely,

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

Enclosure

RECD EPA/OPP/DPD1

Hard Surface Disinfectant

'96 AUG -6 AIO :07

SEP-T-BAN™

Antimicrobial Spray

For use in medical, dental, veterinary facilities or hospitals and any other health care 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.

**BACTERICIDAL
TUBERCULOCIDAL**

**VIRUCIDAL*
FUNGICIDAL**

KEEP OUT OF REACH OF CHILDREN

WARNING: FLAMMABLE: KEEP AWAY FROM HEAT AND OPEN FLAMES:

(See back panel for additional precautionary statements).

Active Ingredients: Alkyl (C14-50%, C12-40%, C16-10%) dimethyl-
benzyl-ammonium chloride (Benzalkonium Chloride)

Ethanol

Inert Ingredients

Total Ingredients

00.09 wt %

65.87 wt %

34.04 wt %

100.00 wt %

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JAN-28-1997

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

69264-1

EPA Reg. No. 69264-1, EPA Est. No. 69264-MO-1, U.S. Patent Number 4,870,108

FDA NDC No. 58006-1001-04, FDA Est. No. 1912744, DIN#01988379

NET CONTENTS 128 FL. OUNCES (3.8 L) READY TO USE - DO NOT DILUTE

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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 SEP-T-BAN 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 disinfectant on any surface or instrument that;

1. Is introduced directly into the human body, either into or in contact with the blood stream 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.

For Use as a Pump Spray: Preclean 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 or allow to air dry.

For Use as a Bottled Solution: Preclean surface as indicated above, apply undiluted product with cloth, sponge, or mop so as

to wet surface thoroughly. Allow the surface to remain wet for 5 minutes. Wipe dry or allow to air dry.

SEP-T-BAN Antimicrobial Spray is effective as a tuberculocide, bactericide, virucide, and fungicide. Kills bacteria such as *Mycobacterium bovis* (bovine TB), *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Salmonella choleraesuis*, fungi such as *Trichophyton mentagrophytes*, and the following viruses: Herpes simplex Type 2; Rhinovirus; Hepatitis A in 5 min. at 20 C, and HIV-1 (AIDS Virus) in 5 min. at room temperature.

For Use in All Health Care Facilities: Scientifically formulated with additive germicides and patented, this product is excellent for decontamination of precleaned, hard nonporous surfaces. Safe for use on plastic, Formica, rubber, glass, or stainless steel. Will not stain clothing.

PRECAUTIONARY STATEMENTS:

Hazards to Humans/Domestic Animals:

Warning: Keep out of reach of children. 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.

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 a large quantity of water. Call physician immediately.

Physical/Chemical Hazards: Flammable. Keep away from heat and open flame.

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 65.87 wt % 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.

Manufactured for: McCormick Scientific Products, a Division of McCormick Distilling Co., Inc., Weston, MO 64098, Marketed by Steri-Source L.L.C., Leawood, KS 66208. (960614)

ACCEPTED
with COMMENTS
in EPA Letter Dated:

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

69264-1

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