1 9 AUG 1993

Sporicidin International 5901 Montrose Road Rockville, MD 20852

Attn: Harold S. Plank, D.D.S.;

Technical Director

Subject: Sporicidin Brand Disinfectant Spray

EPA Registration No. 8383-4

Your Resubmission August 3, 1993

The submitted Confidential Statement of Formula (CSF), manufacturing process, product label and product chemistry all revised in support of the change in product formulation proposed in your May 15, 1993 submission, have been reviewed. Please note the following.

Product Chemistry

- 1. The submitted product chemistry data is satisfactory. No further product chemistry data on the subject formulation is required at this time.
- 2. The revised manufacturing process is in compliance with 40 CFR § 158.165 and is acceptable.
- 3. The revised and updated CSF agrees with the submitted manufacturing process and product label and is acceptable.

Product Labeling

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comments listed below. A stamped copy is enclosed for your Five copies of the finished labeling must be submitted before you release the product for shipment.

1. On the product bulletin, which is considered part of the subject product labeling, add the following sentence to the wording in paragraph "d": "This product should not be used for the disinfection of critical or semi-critical items.".

	CONCURRENCES	
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If you should have any questions concerning this letter, you may call Robert Travaglini on (703) 305-6909.

Sincerely,

Ruth G. Douglas

Product Manager (32) Antimicrobial Program Branch Registration Division (H7504C)

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Contamination and Odor Control

SPORICIDIN Brand Disinfectant Spray

Continuous Residual Activity for Over 6 Months*

ACTIVE INGREDIENTS:

Phenol

1.56%

Sodium Phenate

0.06%

INERT INGREDIENTS: 98.38%

Solution is alkaline, pH 7.9-8.6

BACTERICIDAL

FUNGICIDAL

VIRUCIDAL**

TUBERCULOCIDAL

ELIMINATES ODORS*

PREVENTS MOLD AND MILDEW

Keep Out of Reach of Children

WARNING:

See additional precautions on back panel

EPA Reg. No. 8383-4

Net Wt. 22 oz.

ACCEPTED WILL COLUMNIES in KPA Letter Dated:

1 9 AUG 1993

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HOSPITAL DISINFECTION

An effective disinfectant and active deodorant for hospitals, clinics, medical and veterinary offices, laboratories, industrial clean rooms, nursing homes, ambulances, hotels, restaurants, schools, airplanes, trains, boats, autos, buses, health spas and toilets.

DISINFECTANT. Acts effectively on germ-laden non-porous equipment and surfaces in medical treatment and patient rooms, operating rooms, emergency rooms, recovery rooms and bathrooms. For use on medical equipment and beds, surgical carts, counter tops, manikins, telephones, furniture, wheelchairs, walkers, sinks, floors, walls, light switches, linen hampers, shower stalls, toilet seats, trash containers, damp and musty areas, including animal enclosures. Reduces the hazards of cross-contamination on environmental surfaces.

ACTIVE DEODORIZER. *It provides continuous residual bacteriostatic activity against odor-causing organisms, for over 6 months in the presence of adequate moisture if not removed from surfaces including plastics, latex, vinyl, glass, wood, metal, porcelain, tile and paint.

♦ Kills Athlete's Foot fungus on bathroom, shower, and pool surfaces.
♦ Self-sanitizes surfaces against odor-causing bacteria.
♦ Penetrates cracks.
♦ Non-staining
♦ Contains no harmful abrasives.

SPORICIDIN Brand DISINFECTANT SPRAY is germicidal when used as directed for disinfection but differs in composition from other Sporicidin products.

PASSES THE AOAC EFFICACY STANDARDS FOR INSTITUTIONAL AND HOSPITAL DISINFECTION. Tested against Staphylococcus aureus, Streptococcus pyogenes, Streptococcus salivarius, Salmonella choleraesuis, Pseudomonas aeruginosa, Escherichia coli. **Herpes simplex types 1 and 2 (oral and genital), Influenza A, (Japan 305/57 Asian strain), Vaccinia, and Polio type 1 viruses. HIV-1 (AIDS virus) on environmental surfaces, Trichophyton mentagrophytes (Athlete's Foot fungus) and Mycobacterium tuberculosis on environmental surfaces.

DIRECTIONS:

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

PRECLEAN surface to remove soil and filth. Wipe dry with paper towel, cloth or sponge.

TO DISINFECT AND DEODORIZE: Shake well before using. Hold spray nozzle 6" to 8" from surface. Thoroughly wet pre-cleaned surface with disinfectant. Finsure surface remains moist for a 10 minute contact time at room temperature (20°C/68°F or above). NOTE: See Sporicidin Bulletin No. 403 for HIV-1 (AIDS virus) instructions.

TO PREVENT MOLD AND MILDEW: Repeat application weekly, or sooner if new growth appears.

TO ELIMINATE ODORS: Spray 2-4 seconds toward center of room.

WARNING: Avoid direct contact with food. In case of eye contact, immediately flush with water. If necessary, consult a physician.

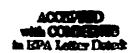
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STORAGE AND DISPOSAL: Store at room temperature. Discard empty container in regular trash.

CONTENTS UNDER PRESSURE: Do not use near fire, sparks, or flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.

Sporicidin International 5901 Montrose Road Rockville, MD 20852



Under the Federal Incested a Francisch, and household Act of the pentiste Registered under EPA Reg. No.

8383-4

SPORICIDIN BULLETIN NO. 403:

Sporieidin Brand Disinfectant Spray EPA Peg No 3383 31

a. Personal Protection:

Fersons pandling items soiled with plood or body fluids likely to be contaminated with HIV-1 (AIDS VIIUS) must protect themselves by use of disposable latex gioves, gowns, masks and eve covering

- b. Decontamination of Contaminated Objects: Immediately after use, items contaminated with plood. body fluids, or other soils that may contain HIV-1 (AIOS wrust must be sprayed to ingroughly wet with disinfectant for 1 minute before further processing.
- c. Cleaning Procedure: Following decontamination, objects and surfaces are moved to the cleaning and preparation area where they are washed rinsed and rough dried to remove all blood and body fluids before application of the disinfectant.
- d. Disintection: Spray to incroughly well enline object or surface. HIV-1 AIDS virust is killed within 1 minute contact time
- e. Disposal of Infectious Materials: Blood and other body fluids should be autoclaved and disposed of according to local regulations for infecfigus waste disposal

ACCEPTED with COMPLETTS in EPA Letter Dates

9 AUG 1993

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Sporicidin

BULLETIN NOS. 303, 403 and 503

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