

19 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 records. 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

SYMBOL	H7505							
SURNAME	Harold S. Plank							
DATE	19 AUG 1993							

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

Sincerely,



Ruth G. Douglas
Product Manager (32)
Antimicrobial Program Branch
Registration Division (H7504C)

Contamination and Odor Control

SPORICIDIN
Brand
Disinfectant SprayContinuous Residual Activity
for Over 6 Months*

ACTIVE INGREDIENTS:

Phenol 1.56%
Sodium Phenate 0.06%

- BACTERICIDAL
- FUNGICIDAL
- VIRUCIDAL**
- TUBERCULOCIDAL
- ELIMINATES ODORS*
- PREVENTS MOLD AND MILDEW

INERT INGREDIENTS: 98.38%

Solution is alkaline, pH 7.9-8.6

Keep Out of Reach of Children

WARNING:

See additional precautions on back panel

EPA Reg. No. 8383-4

Net Wt. 22 oz.

ACCEPTED
with COMMENTS
to EPA Letter Dated:

19 AUG 1983

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

8383-4

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. Ensure 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.

BEST AVAILABLE COPY

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

ACCEPTED
with COMMENTS
in EPA Letter Dated:

18 AUG 1993

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

8383-4

SPORICIDIN BULLETIN NO. 403:

**Sporicidin Brand
Disinfectant Spray
EPA Reg No 8383-4**

- a. **Personal Protection:**
Persons handling items soiled with blood or body fluids likely to be contaminated with HIV-1 (AIDS virus) must protect themselves by use of disposable latex gloves, gowns, masks and eye covering.
- b. **Decontamination of Contaminated Objects:**
Immediately after use, items contaminated with blood, body fluids, or other soils that may contain HIV-1 (AIDS virus) must be sprayed to thoroughly 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. **Disinfection:**
Spray to thoroughly wet entire object or surface. HIV-1 (AIDS virus) 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 infectious waste disposal.

**ACCEPTED
with COMMENTS
in EPA Letter Dated**

19 AUG 1993

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

8383-4

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)**