

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Sporicidin International
5901 Montrose Road
Rockville, MD 20852

19 AUG 1993

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

Subject: Sporicidin Brand Disinfectant Towelette
EPA Registration No. 8383-7
Your Resubmission July 23, 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 Name and Labeling

1. The change in product name from "Permacide Brand Ristex Germicidal Disinfectant" to "Sporicidin Brand Disinfectant Towelette" is acceptable.

2. 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.

CONCURRENCES

SYMBOL							
SURNAME							
DATE	19 AUG 1993						

a. 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.".

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)

Contamination and Odor Control

SPORICIDIN
Brand
Disinfectant ToweletteContinuous 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

CAUTION:

Avoid direct food contact. On eye contact, flush with water.
If necessary, contact physician.

Contents:

(1) Towelette saturated
with disinfectant.

EPA Reg. No. 8383-7

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.

8383-7

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.

DEODORANT. *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 vinyl, glass and wood.

♦ Non-staining

♦ Contains no harmful abrasives

SPORICIDIN Brand DISINFECTANT TOWELETTES are germicidal when used as directed but differ in composition from other Sporidicin products.

PASSES THE AOAC EFFICACY STANDARDS FOR INSTITUTIONAL AND HOSPITAL DISINFECTION such as *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), Polio type 1 virus, 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.

TO DISINFECT AND DEODORIZE: Thoroughly wet surface with towelette. Ensure surface remains moist for a 10 minute contact time at room temperature (20°C/68°F or above).

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

NOTE: See Sporidicin Bulletin No. 303 for HIV-1 (AIDS virus) instructions.

STORAGE AND DISPOSAL

STORAGE: Store at room temperature.

DISPOSAL: Discard used towelettes and empty container in regular trash.

Sporidicin
International

5901 Montrose Road
Rockville, MD 20852

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in EPA Letter Dated:

19 AUG 1993

Under the Federal Insecticide,
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registered under EPA Reg. No.

8383-7

SPORICIDIN BULLETIN NO. 303:
Sporicidin Brand
Disinfectant Solution and Towelette
EPA Reg. Nos. 8383-3 and 8383-7

- 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 thoroughly wetted with Sporicidin brand disinfectant solution for at least 1 minute before further processing.
- c. **Cleaning Procedure:**
Following decontamination, objects and surfaces are moved to the cleaning and preparation areas where they are washed, rinsed and rough dried to remove all blood and body fluids before application of the disinfectant.
- d. **Disinfection:**
Thoroughly wet entire object or surface with solution or towelette. HIV-1 (AIDS virus) is killed within 1 minute contact time. *Note:* Use a 10 minute contact time for other organisms.
- e. **Disposal of Infectious Materials:**
Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

not for disinfection

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)**

**ACCEPTED
with COMMENTS
in EPA Letter Dated**

19 AUG 1983

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide
registered under EPA Reg. No.
8383-7

BEST AVAILABLE COPY