

US EPA ARCHIVE DOCUMENT

Antimicrobial Program Branch / EEMTS Section

IN 03/08/91 OUT 04/22/91  
 Reviewed by Bruce H. Mann Date 04/22/91  
 EPA Reg. No. or File Symbol # 8383-3  
 EPA Petition or EUP No. None  
 Date Division Received 02/21/91  
 Type Product(s): Hospital/General disinfectant  
 Data Acc., No(s) No data were submitted for review.  
 Product Mgr. No. PM 32 (Francis)  
 Product Name Permacide Brand Ristex Germicidal Disinfectant  
 Company Name(s) Sporicidal International  
 Submission Purpose An amendment to proposed revised labeling  
 Chemical & Formulation A ready-to-use liquid.

Active Ingredient(s):

	<u>g</u>
Phenol .....	1.41
Sodium tetraborate .....	0.47
sodium Phenate .....	0.24

200.0 Introduction:

PT I

200.1 Use(s):

See the attached proposed label, dated 02-21-91, and the proposed bulletin no. 303 dated 02-27-91.  
 Also, refer to the last accepted label dated 02-06-89.

The submission received 03-08-91, is an amendment which includes proposed revised labeling. The label comments are indicated below.

201.0 Data Summary(MRID #) No data were submitted for the review.  
 PM-32 has requested a review for the addition of the new uses.



AN EXCELLENT  
DISINFECTANT AND ACTIVE  
DEODORIZER FOR HOSPITAL, MEDICAL,  
VETERINARY, CLINIC AND OFFICE USES

as well as laboratories, industrial clean rooms, nursing homes, ambulances, buses, autos, hotels, restaurants, schools, airplanes, trains, boats, health spas and public toilets.

## 100% HOSPITAL LEVEL DISINFECTION

- **Disinfectant.** Acts quickly on germ-laden non-porous equipment and surfaces in medical treatment and patient rooms, operating rooms, emergency rooms, bathrooms and recovery rooms. For use on equipment, toilet seats, sinks, discarded injection syringes, respirators, tubing thermometers, manikins, telephones, handsets, counter tops, furniture, light switches, walls, floors, shower stalls, garbage cans, linen hampers, air ducts, windows, surgical carts, wheelchairs, walkers, damp and musty areas, including animal enclosures. Reduces the hazards of cross-contamination.
- **Active Deodorizer.** It provides continuous residual bacteriostatic activity, including odor-causing organisms, for over 6 months in the presence of adequate moisture if not removed from the surface of paper, fabrics, plastics, latex, vinyl, glass, wood, metal, porcelain, tile and paint.
- Kills Athlete's Foot fungus on bathroom, shower, pool and shoe surfaces.
- Self-sanitizing against odor-causing organisms. • Penetrates cracks.
- Non-staining. • Non-flammable. • 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 RIGID AOAC EFFICACY STANDARDS FOR 100% INSTITUTIONAL AND HOSPITAL LEVEL DISINFECTION.** Tested against *Staphylococcus aureus*, *Streptococcus salivarius*, *Streptococcus pyogenes*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Escherichia coli*. \*\*Herpes simplex types 1 and 2 (oral and genital), Influenza A<sub>2</sub> (Japan 305/57 Asian strain), Vaccinia, Polio I, *Trichophyton mentagrophytes* (Athlete's Foot fungus), *M. tuberculosis* and HIV-1 (AIDS virus).

### DIRECTIONS:

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

**TO CLEAN:** Wet surface. Wipe dry with paper towel, cloth or sponge.

**TO DISINFECT AND DEODORIZE:** Thoroughly wet pre-cleaned surface with disinfectant. Allow 10 minute contact time at room temperature (20°C/68°F or above). NOTE: See Sporicidin Bulletin No. 303 for HIV-1 (AIDS virus) instructions

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

**FOR FOGGING CLEAN ROOMS:** See Sporicidin Bulletin No. 301.

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

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

EPA Reg. No. 8383-3

EPA Est. No. 37615-MD-01

**Sporicidin**<sup>®</sup>  
**INTERNATIONAL**

12000 Old Georgetown Road • Rockville, MD 20852

medical waste?

# Sporicidin

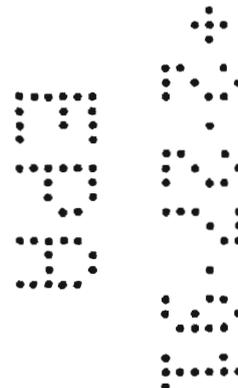
BULLETIN NOS.  
303, 403 and 503

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

## 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.



202.0 Recommendations & Comments:202.1 Claims Related to Human Health

## 203.0 Labeling:

Claims Related to Human Health: The comments are applicable to the subject product "Permacide Brand Ristex Germicidal Detergent", EPA Reg No. 8383-3, dated 02-21-91.

- A. On the back panel, change the wording "excellent" to read "effective".
- B. On the back panel, revise 100% Hospital level Disinfection" to read "Hospital Disinfection".
- C. On the back panel, 2nd paragraph, the wording "discarded injection syringes" must be deleted. The claim constitutes a medical waste claim. Since a policy for the disinfection of medical waste has not been formulated, we do not allow such claims.

In the same paragraph, the Agency does not allow disinfection claims for "air ducts". The claim for "air ducts" is unwarranted and not acceptable and must be deleted.

Also, in the 2nd paragraph, revise "...acts quickly on germ..." to read "acts effectively on germ...".

- D. Revise the phrase "Kills Athlete's Foot fungus..." delete "and shoe", the phrase should read " Kills Athlete's Foot Fungus on bathroom, shower, and pool surfaces".
- E. In the 5th phrase, delete the word "rigid" and delete the numerical value "100%". Also, delete the wording "level". After the listing "HIV-1(AIDS virus)", add "on environmental surfaces".

## 204.0 Bulletin:

Until the applicant submits copies of Sporidicin Bulletin Nos. 403 and 503 for a label determination, bulletins no. 403 and 503 must be removed from Sporidicin Bulletin No. 303.

Also, the listing of EPA Reg No. 8383-7 cannot be listed as currently proposed until a verification/documentation that the HIV-1(AIDS virus) claim has been accepted for EPA Reg. No.8383-7. Until the clarifications are provided, delete the listings of Bulletins Nos. 403 and 503, delete the number 8383-7.