

PM 34

8383-3

7/27/99

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## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUL 27 1999

Harold E. Plank, D.D.S.  
Sporicidin International  
5901 Montrose Road  
Rockville, MD 20852

Dear Mr. Plank:

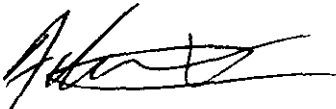
Subject: Revised labeling  
Sporicidin Brand Disinfectant Solution  
EPA Registration No. 8383-3  
Your submission of July 7, 1999

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable provided that you make the labeling changes indicated below prior to release for shipment of product bearing the amended labeling.

Delete the statement "....dental equipment" the statement "medical equipment" is sufficient.

Submit two copies of final printed labeling before you release the product for shipment. A stamped copy of the labeling is enclosed for your records.

Sincerely your,



Adam Heyward  
Product Manager (34)  
Regulatory Management Branch II  
Antimicrobials Division (7510C)

Enclosure

## CONCURRENCES

SYMBOL								
SURNAME								
DATE								

*Continuous Residual Activity  
up to 6 Months\**

**Sporicidin®**  
BRAND

**DISINFECTANT  
SOLUTION**

CITRUS  
SCENT

**PRESOAK AND DISINFECTANT**

- BACTERICIDAL
- VIRUCIDAL\*\*
- FUNGICIDAL
- TUBERCULOCIDAL

**Active Ingredients**

Phenol ..... 1.56%  
Sodium Phenate ..... 0.06%

Inert Ingredients ..... 98.38%

EPA Reg. No. 8383-3

EPA Est. No. 034346-NB-001

Net Contents: 1 U.S. Gal. (3.79 ltr.)

**Keep Out of Reach of Children**

**CAUTION**

See additional precautions on back panel

**AVAILABLE IN 22 OZ. SIZE**

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:  
JUL 27 1999

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the uses and  
registrations under FIFRA Reg. No. **8383-3**

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ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

JUL 27 1999

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

8383-3



**PRESOAK  
DISINFECT**



\*+H737R12841W\*

An effective cleaner, disinfectant and active deodorant for hospitals, clinics, medical and veterinary offices, laboratories, industrial clean rooms, homes, 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 and dental equipment, beds, surgical carts, counter tops, manikins, telephones, furniture, wheelchairs, walkers, sinks, floors, walls, light switches, linen hampers, shower stalls, toilet seats, trash containers and damp and musty areas, including animal enclosures. Reduces the hazards of cross-contamination on hard, nonporous surfaces.

**ACTIVE DEODORIZER\*:** Provides continuous residual bacteriostatic activity against odor-causing organisms for up to 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 •Penetrates cracks •Non-staining •Contains no harmful abrasives •Self-sanitizes surfaces against odor-causing bacteria.

**SPORICIDIN Brand DISINFECTANT SOLUTION** is germicidal when used as directed for disinfection but differs in composition from other Sporcidin products.

**PASSES AOAC EFFICACY STANDARDS FOR INSTITUTIONAL AND HOSPITAL DISINFECTION**

- Kills HIV-1 (AIDS virus) in one minute on hard, nonporous surfaces.
- Kills Staphylococcus aureus, Salmonella choleraesuis, Pseudomonas aeruginosa and Trichophyton mentagrophytes (Athlete's Foot fungus) in three minutes on hard nonporous surfaces.
- Kills vegetative organisms including Streptococcus pyogenes, Streptococcus salivarius, Escherichia coli, \*\*Herpes simplex types 1/F and 2/G (oral, ocular, and genital), Influenza A, (Japan 305/57 Asian strain), Vaccinia, Canine parvovirus, Cytomegalovirus, Coronavirus and Polio type 1 viruses on hard,

**Sporcidin**  
INTERNATIONAL

Rockville, MD 20852

nonporous inanimate surfaces and Mycobacterium tuberculosis in ten minutes at 20°C/68°F or above.

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

PRECLEAN instruments and other surfaces with Sporcidin Brand Disinfectant Solution to remove soil and filth. Wipe dry with paper towel, cloth or sponge.

**TO DISINFECT AND DEODORIZE:** Thoroughly wet pre-cleaned surface with disinfectant. Allow contact times as stated above at room temperature (20°C/68°F or above) to kill listed organisms. NOTE: See Sporcidin 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 Sporcidin Bulletin No. 301.

**TO CLEAN AIR DUCTS:** Manually apply to hard, non-porous, pre-cleaned duct surfaces. Rinse surfaces after application.

**PRECAUTIONARY STATEMENTS:** Hazard to Humans and Domestic Animals.

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

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

**NOTE:** This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream 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. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

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