

August 26, 2002

Harold E. Plank, D. D. S.
Technical Director
Sporicidin International
121 Congressional Lane
Rockville, MD 20852024

Subject: **Sporicidin Brand Disinfectant and Sanitizer**
EPA Registration Number 8383-3
Application Dated June 6 2002

Dear Dr. Plank:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with comments:

Proposed amendment:

- minor label revisions

General comments:

Revise the label as follows:

Under the subheading "Active Deodorizer," first bullet, revise the statement to read, "Kills *Trichophyton mentagrophytes* (Virus that cause Athlete Foot) on bathroom, shower, etc..."

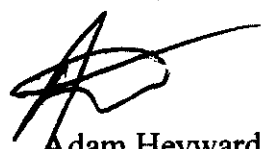
CONCURRENCES

SYMBOL								
SURNAME								
DATE								

A stamped copy of the accepted labeling is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product.

Should you have any questions, please contact me at (703) 308-6422.

Sincerely,



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

New Label

8383-3

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

AUG 26 2002

ACCEPTED
With COMMENTS
EPA Letter Dated:



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 such as 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 Sporidicin products.

PASSES AOAC EFFICACY STANDARDS FOR INSTITUTIONAL AND HOSPITAL DISINFECTION

- Kills HIV-1 (AIDS virus) on hard, nonporous surfaces in one minute.
- Kills Staphylococcus aureus, Salmonella choleraesuis, Pseudomonas aeruginosa and Trichophyton mentagrophytes (Athlete's Foot fungus) on hard nonporous surfaces in three minutes.
- Kills vegetative organisms including Streptococcus pyogenes, Streptococcus salivarius, Escherichia coli, **Herpes simplex types 1/F and 2/G (oral, ocular, and genital), Influenza A₁ (Japan 305/57 Asian strain), Vaccinia, Canine parvovirus, Cytomegalovirus,

Coronavirus and Polio type 1 viruses and Mycobacterium tuberculosis on hard, nonporous inanimate surfaces at 20°C/68°F or above in ten minutes.

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 Sporidicin 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 Sporidicin 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 Sporidicin Bulletin No. 301.

TO CLEAN AIR DUCTS: Apply to hard, non-porous, pre-cleaned duct surfaces.

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.

Sporidicin
INTERNATIONAL

Rockville, MD 20852

9109

Continuous Residual Activity
up to 6 Months*

Sporidicin

**DISINFECTANT
SOLUTION**



PRESOAK AND DISINFECTANT

- BACTERICIDAL
- FUNGICIDAL
- VIRUCIDAL**
- TUBERCULOCIDAL

Active Ingredients

Phenol 1.56%

Sodium Phenate 0.06%

Inert Ingredients 98.38%

EPA Reg. No. 8383-3

EPA Est. No. 047179-IL-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

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8
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