

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

January 21, 2003

Mrs. Olivia D. Laird
President
Laird's Regulatory Consultant, Agent for
SPORICIDIN International
501 South Lincoln Avenue
Sterling, VA 20164-2024

Subject: **SPORICIDIN® Brand Disinfectant Solution**
EPA Registration Number 8383-3
Letter Date: January 17, 2003
EPA Receive Date: January 17, 2003

Dear Mrs. Laird:

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

Proposed Amendment:

- replacement label for submission dated November 21, 2002

Label comments:

Since this product is a toxicity Category III for the eye route of exposure, the following precautionary statement must be added to the label under the precautionary statement heading:

“Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling”

Referrer to EPA label review manual (2nd Edition) dated December 1996, chapter 8, page #10 for detail information

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General comments:

A stamped copy is enclosed for your records. For the file, you must submit three copies of the finished label prior to sale or distribution of this approved labeling.

Finally, you should note that section 12(a)(1)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, states that it is unlawful for any person to distribute or sell "any registered pesticide if any claims made for it as a part of it as a part of its statement required in connection with its registration under section 3;..." Thus, you will need to assure that any claims made for this product in advertising, on internet sites, or in other media comply with this provision governing claims.

Should you have any questions or comments regarding this letter, please contact me at (703) 308-6422 or Renae Whitaker at (703) 308-7003

Sincerely,

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

enclosure

cc: Connie Welch

CONCURRENCES

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*Continuous Residual Activity
up to 6 Months**



Sporicidin[®]

BRAND

DISINFECTANT SOLUTION

ALCOHOL
FREE

CLEANS • DISINFECTS • DEODORIZES

- BACTERICIDAL
- VIRUCIDAL **
- KILLS MOLD and MILDEW***
- FUNGICIDAL
- TUBERCULOCIDAL
- ELIMINATES ODORS

Active Ingredients

Phenol	1.56%
Sodium Phenate	0.06%
Inert Ingredients	98.38%
Total	100%

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

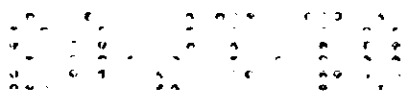
CAUTION

See additional precautions on back panel

Non-corrosive • Non-flammable • Non-staining

ACCEPTED
 with COMMENTS
 EPA Letter Dated:
 JAN 21 2003

Under the Federal Insecticide,
 Fungicide, and Rodenticide Act as
 amended, for the pesticide,
 registered under EPA Reg. No. **8383-3**



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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 AND DEODORIZER FOR HARD, NON-POROUS SURFACES in medical treatment and patient rooms, operating rooms, emergency rooms, recovery rooms and bathrooms. 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.

ACTIVE DEODORIZER*: Provides continuous residual bacteriostatic activity against odor-causing organisms for *up to 6 months*, if not removed from surfaces including plastics, latex, vinyl, glass, wood, metal, porcelain, tile and paint.

- Kills Trichophyton mentagrophytes (Virus that causes Athlete's Foot) 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) *in one minute*. (See Sporidicin Bulletin No. 303)
- Kills Staphylococcus aureus, Salmonella choleraesuis, Pseudomonas aeruginosa, Methicillin resistant Staphylococcus aureus (MRSA), Vancomycin resistant Enterococcus faecium (VRE) and Trichophyton mentagrophytes (Athlete's Foot fungus) *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 A₂ (Japan 305/57 Asian strain), Pellicularia filamentosa, Penicillium variable, Vaccinia, Canine parvovirus, Cytomegalovirus, Coronavirus and Polio type 1 viruses 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 surfaces using 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. Use 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 KILL, CLEAN AND PREVENT MOLD AND MILDEW:** Thoroughly wet pre-cleaned contaminated area with sprayer or saturated Sporidicin towelette. Repeat application if new growth appears. Effective against *Stachybotrys chartarum*, *Chaetomium globosum* and *Aspergillus niger*.

TO CLEAN AIR DUCTS: Apply to hard, nonporous, surfaces.

TO CLEAN, DEODORIZE AND DECONTAMINATE CARPETS: For manual cleaning, spray product onto carpet and allow to dry. For machine cleaning, apply product in accordance with the machine manufacturer's guidelines.

FOR FOGGING CLEAN ROOMS: See Sporidicin Bulletin No. 301.

PRECAUTIONARY STATEMENTS: Hazard to Humans and Domestic Animals.

FIRST AID: If in eyes, hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice. Have product container or label with you when calling a poison control center or doctor, or going for treatment.

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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.



Rockville, MD 20852



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