

8383-7

12/3/2003

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

December 3, 2003

Olivia D. Laird
Agent for
Sporicidin International
Laird's Regulatory Consultants, Inc.
501 South Lincoln Avenue
Sterling, VA 20164-2024

Subject: Sporicidin
EPA Registration No. 8383-7
Application Date: October 15, 2003
EPA Received Date: October 15, 2003

Dear Mr. Schifilliti:

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

Proposed Amendment

- Revision of First Aid Statements

Conditions

1. Revise the Precautionary Statements by distinguishing them from the Directions for Use by placing the heading "PRECAUTIONARY STATEMENTS" before the HAZARDS TO HUMANS AND DOMESTIC ANIMALS statement.

CONCURRENCES

SYMBOL	7500							
SURNAME	Gray							
DATE	12-3-03							

General Comments

A stamped copy of the labeling accepted with conditions is enclosed. Submit three(3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling. Should you have any questions or comments concerning this letter, please contact me at 703-308-6422.

Sincerely,



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

Continuous Residual Activity
up to 6 Months*

Sporicidin®

BRAND

ALCOHOL
FREE

DISINFECTANT TOWELETTES

An effective disinfectant and active deodorant for hospitals, clinics, medical, dental and veterinary offices, laboratories, industrial clean rooms, homes, nursing homes, ambulances, hotels, restaurants, schools, airplanes, trains, boats, autos, buses, health spas and toilets.

Active Ingredients
Phenol 1.56%
Sodium Phenate 0.06%
Inert Ingredients 98.38%
Total 100.00%

Keep Out of Reach of Children
CAUTION

Contents: 180 Towelettes 5" x 8" saturated with disinfectant

- BACTERICIDAL
- FUNGICIDAL
- VIRUCIDAL**
- TUBERCULOCIDAL
- PREVENTS MOLD AND MILDEW
- ELIMINATES ODORS*

EPA REG. NO. 8383-7

EPA Est. No. 047179-IL-001



DISINFECTANT: Acts effectively on germ laden nonporous 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, damp and musty areas, including animal enclosures. Reduces the hazards of cross contamination on hard, nonporous surfaces.

DEODORANT: 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 vinyl, glass and wood.

CLEANS • DISINFECTS • DEODORIZES

SPORICIDIN Brand DISINFECTANT TOWELETTES are germicidal when used as directed but differ 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, Trichophyton mentagrophytes (Athlete's Foot fungus), on hard, nonporous surfaces *in 3 minutes*.
- Kills vegetative organisms including Streptococcus pyogenes, Streptococcus salivarius, Escherichia coli, **Herpes simplex types 1/1 and 2/2 (oral, ocular and genital), Influenza A₂ (Japan 305/57 Asian strain) Vaccinia, Canine parvovirus, Cytomegalovirus, Coronavirus and Polio type 1 viruses on hard, nonporous inanimate surfaces and Mycobacterium tuberculosis at 20°C/68°F or above *in 10 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 surface to remove soil and filth. Wipe dry.

PREPARATION OF DISPENSER: Pull up tab and remove cover. Insert about one inch of towelette from center of roll through opening. Replace cover. Pull each sheet up at a sharp angle and snap off. Keep container tab closed between use.

TO DISINFECT AND DEODORIZE: Thoroughly wet pre-cleaned surface with towelette. 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.

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing.

Wash thoroughly with soap and water after handling.

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 the 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 used towelettes and 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



Sporicidin

INTERNATIONAL Rockville, Maryland 20852

9342

ACCEPTED
with COMMENTS
EPA Letter Dated:

DEC - 3 2003

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

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