

8383-7

03/15/2007

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

March 15, 2007

Olivia Laird
Laird's Regulatory Consultants, Inc.
17804 Braemar Place
Leesburg, VA 20175-7046

Subject: **Sporicidin @ Disinfectant Towelettes**
EPA Registration No. 8383-7
Application Date: December 28, 2006
Receipt Date: December 28, 2006

Dear Ms. Laird:

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

1. The precautionary heading and the statement "hazard to humans and domestic animals" must be in the same large bold sizes.
2. On page #2, under the heading, ACTIVE DEODORIZER, revised the statementOdor causing organisms..... to ".....Odor causing bacteria....."

Submit three (3) copies of the final printed labeling bearing the revisions stated above. A copy of the stamped label is enclosed for your record.

Should you have any questions or comments concerning this letter, please contact me via email at heyward.adam@epa.gov or via telephone at (703) 308.6422, or Stacey Grigsby via email at grigsby.stacey@epa.gov or via telephone at (703) 305-6440.

Sincerely,

A handwritten signature in black ink, appearing to read "Adam Heyward".

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

Enclosure: Stamped labeling

*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. B383-7

EPA Est. No. 047179-IL-001

Insert
UPC code here

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ACCEPTED

3-15-2007

Under the Federal Insecticide, Fungicide, and
Rodenticide Act as amended, for the
EPA Reg. No. B383-7

2/3

Sporicidin Disinfectant Towelettes (Reg. No. 8383-7) -- Back Label

INSTITUTIONAL • FOOD PROCESSING • RESIDENTIAL

AN EFFECTIVE CLEANER, DISINFECTANT AND ACTIVE DEODORIZER FOR INSTRUMENTS, AND EQUIPMENT ON PRE-CLEANED, HARD, NON-POROUS SURFACES in health/hospital treatment and patient rooms, operating rooms, schools, ambulances, hotels, restaurants, boats, planes, buses, and the home. Recommended for medical and dental equipment, beds, surgical carts, counter tops, mannequins, telephones, keyboards, furniture, wheelchairs, walkers, sinks, floors, walls, light switches, linen hampers, shower stalls, toilet seats, trash containers and damp and musty areas, including animal areas. Self-sanitizes against odor-causing bacteria and fungi. Reduces the hazards of cross-contamination.

PASSES AOAC EFFICACY STANDARDS FOR DISINFECTION IN THE PRESENCE OF 5% ORGANIC SOIL. FOR INSTITUTIONAL, HOSPITAL AND FARM PREMISE USE.

- **Virucidal:** Avian Influenza A (H9N2), Influenza A₂ (Japan 305/57 Asian strain), Cytomegalovirus, Coronavirus, Polio Type 1 virus, Vaccinia, Canine parvovirus, Herpes simplex types 1/F and 2/G (oral, ocular and genital), HIV-1 (AIDS Virus). (See Sporicidin Bulletin NO. 303)
- **Bactericidal:** Staphylococcus aureus, Salmonella enterica, Pseudomonas aeruginosa, Methicillin resistant Staphylococcus aureus (MRSA), Vancomycin resistant Enterococcus faecium (VRE), E. coli, Streptococcus pyogenes, Streptococcus salivarius, Mycobacterium tuberculosis.
- **Fungicidal:** Chaetomium globosum, Aspergillus niger, Penicillium variable, Trichophyton mentagrophytes (Athlete's Foot fungus).

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, treated wood, metal, glazed porcelain, glazed tile and paint.

SPORICIDIN DISINFECTANT TOWELETTES are germicidal when used as directed for disinfection but differ in composition from other Sporicidin products.

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

DO NOT DILUTE OR MIX WITH OTHER CHEMICALS

PRECLEAN surfaces using Sporicidin Disinfectant Solution to remove soil and filth. Wipe dry with paper towel, cloth or sponge.

TO DISINFECT AND DEODORIZE ITEMS WHICH CANNOT BE IMMERSUED, such as electrical panels, cash registers, door knobs, handles, seats, dashboards and other "high touch" surfaces in and around farm equipment, animal and poultry housing, barns, kennels, breeding pens, hatcheries, trucks and vehicles: Thoroughly wet pre-cleaned surface with Sporicidin Disinfectant Towelettes and allow surface to remain wet for 10 minutes. Use as many towelettes as necessary for the treated area to remain wet for ten minutes at room temperature (20°C/68°F or above) to kill listed organisms.

TO KILL, CLEAN AND PREVENT MOLD AND MILDEW: Use procedure stated above. Repeat application if new growth appears.

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

TO SPOT CLEAN, DEODORIZE AND REMOVE DEBRIS FROM CARPETS AND FABRICS: Blot or scrub area to be treated with Sporicidin Disinfectant Towelette to remove soiling. Wipe dry with clean cloth or towel.

FOR FOOD PROCESSING PLANTS: Follow pre-cleaning and disinfecting instructions outlined above to disinfect hard, non-porous surfaces and materials in food handling areas, including poultry and meat packing facilities, slaughter houses, etc. All surfaces and materials that come in contact with food must be washed with soap or detergent and rinsed with potable water prior to use.

PRECAUTIONARY STATEMENTS: Hazard 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, remove contact lenses. Hold eye open and slowly rinse with water. If irritation persists for more than 5 minutes continue rinsing and consult a physician or poison control center.

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

FOR HOSPITAL DISINFECTION: 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.