

8383-3

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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 Solution**
EPA Registration No. 8383-3
Application Date: January 8, 2006
Receipt Date: January 11, 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. For non-residential container sizes, add the statement, "Do not contaminate water, food or feed by storage and disposal" immediately below the "Storage and Disposal" heading.
3. For Ready-t-Use and Coarse Spray Products Commercial, Industrial, Institutional, Agricultural and Residential Uses, add the following statement:

"For Avaiian influenza A, the use is only for surfaces which are not conducive to treatment by immersion or excess liquid (e.g., cages, equipment tables, lab benches, faucet handles, door knobs, and similar "high touch" surfaces.) For uses in hospital/medical/health facilities, the directions for hospital disinfection must be followed. For all other use sites, general disinfection directions must be followed."

General Comment:

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.

A copy of the accepted label amendment has been inserted in your file for future reference.

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,

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

*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%	EPA Reg. No. 8383-3
Sodium Phenate	0.06%	EPA Est. No. 047179-IL-001
Inert Ingredients	98.38%	Net Contents: 1 U.S. Gal. (3.79 ltr.)
Total	100%	

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:

3-15-07

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
an Antimicrobial Pesticide,
Registration No. EPA Reg. No. 8383-3

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Sporicidin Disinfectant Solution (Reg. No. 8383-3) – 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 SOLUTION is germicidal when used as directed for disinfection but differs 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: Thoroughly wet pre-cleaned surface with Sporicidin Disinfectant Solution and allow to remain wet for 10 minutes at room temperature (20°C/68°F or above) to kill listed organisms. Use Sporicidin Disinfectant Spray for surfaces that cannot be immersed nor soaked.

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 CLEAN, DEODORIZE AND REMOVE DEBRIS FROM CARPETS AND FABRICS: For manual cleaning, spray product onto carpet and wipe clean with cloth or sponge. Allow to air dry. For machine cleaning, apply product in accordance with the machine manufacturer's guidelines.

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

FOR FARM EQUIPMENT, ANIMAL AND POULTRY HOUSING, BARN, KENNELS, BREEDING PENS, HATCHERIES, TRUCKS AND OTHER VEHICLES: Remove poultry, animals, feed, water, trucks, coops and crates from premises. Remove litter droppings from floors, walls, and surfaces of facilities occupied or traversed by animals. Empty all troughs, racks, and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Apply Sporicidin Disinfectant and allow to remain wet for ten minutes. Ventilate buildings, coops, and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set, or dried. Thoroughly scrub treated feed racks, troughs automatic feeders, fountains, and water appliances with soap or detergent, and rinse with potable water before reuse. Disinfection of equipment: Apply Sporicidin Disinfectant to cover all surfaces for 10 minutes. Allow to air dry.

FOR FOOD PROCESSING PLANTS: Follow pre-cleaning and disinfecting instructions 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) contact 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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