

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

OFFICE OF
PREVENTION. PESTICIDES
AND TOXIC SUBSTANCES

October 21, 2002

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 Dated: September 4, 2002 Receipt Date: September 4, 2002

Dear Mrs. Laird:

The Agency has completed its review of your letter, along with your supporting documents, of the date referred to above, submitted in response to the EPA letter dated July 3, 2002 and offer the following comments:

Based on the Agency letter and stamped label dated February 6, 1989, the following microorganisms are acceptable and may be retained on the label:

- -Chaetomium globosum
- -Aspergillus niger
- -Pellicularia filimentosa

In addition, the claim for "cleaning, deodorizing and decontaminating carpets" may be retained on the label as per a meeting on September 4, 2001 between the EPA staffs, you and members of SPORICIDIN International.

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

• With respect to claim for mold and mildew, delete the word kill and replace it with the phrase, "Prevent the growth of mold and mildew." In addition, the following statement must be included in the directions for mold and mildew: "Surfaces must be cleaned before applying this product."

A stamped copy of the accepted labeling 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 regarding this letter, please contact me at (703) 308-6422.

Sincerely,

Adam Heyward

Product Manager (34)

Regulatory Management Branch II Antimicrobials Division (7510C)

enclosure





CLEANS • DISINFECTS • DEODORIZES

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

Active Ingredients Phenol ...96.38%

EPA Reg. No. 8383-3 EPA Est. No. 047179-E-001 Not Contanta: 1 U.S. Gal. (3.79 ltr.)

Keep Out of Reach of Children

CAUTION
See additional precentions on back panel

Non-corrosive . Non-flammable . Non-staining

ACCEPTED with COMMENTS in EPA Letter Dated:

OCT 2 1 2002

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

8383-3



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, MON-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, manifeins, telephones, furniture, wheelchairs, walkers, sinks, floors, walts, light switches, linen hampers, shower stalls, tollet seats, trash containers and damp and musty areas, including animal enclosures. Reduces the hezards of cross-contamination.

ACTIVE DEGDORIZER*: Provides continuous residual bacteriostatic activity against odor-causing organisms for up to 8 months, if not removed from surfaces including plantics, 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-santizes surfaces against odor-causing bacteria.

SPORICION Brand DISINFECTANT SOLUTION is germicidel when used as directed for distribution but differs in composition from other Sociation products.

PASSES AGAC EFFICACY STANDARDS FOR INSTITUTIONAL AND HOSPITAL DIS-INFECTION

· Kills HIV-1 (AIDS virus) in one minute.

20°C/68°F or above

- Kills Staphylococcus aureus, Salmonella choleraesuls, Paeudomones aerugi-nosa, Methicillin resistant Staphylococcus aureus (MRSA), Vancomycin realistant Enterococcus faecium (VRE) and Trichophyton mentagrophytes (Athlete's Foot fun-
- · Kills vegetative organisms including Streptococcus pyogenes. Streptococcus salivarius, Escherichia coli, "Herpes simplex types 1/F and 2/G (oral, ocular, and genital), influenza A. (Japan 305/57 Asian strain), Pellicularia filamentosa, Penicillium variable, Protest mirabilia, Gandita albicana, Vaccinia, Canine parvovirus, Cytomegalovirus, Coronavirus and Polio type 1

eidin rinuses and Mycobacterium tuberculosis in ten minutes at INTERNATIONAL

Rockville, MD 20852

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

PRECLEAN surfaces using Sportcidin Brand Disinfectant Solution to remove soil and fifth. Wipe dry with paper towel, cloth or sponge.

TO DISSIFIECT AND DECODORIZE: Thoroughly wet pre-cleaned surface with disinfectant. ties contact times as stated above at room temperature (20°C/68°F or above) to kill listed organisms, NOTE: See Sporicidin Bulletin No. 303 for HV-1 (AIDS virus) instruc-

"TO KILL MOLD AND MILDEN: Apply product to the contaminated area. Repeat application if new growth appears. Effective squirest Stachybotrys charterum, Chaetomium pioboeum and Asperbillus niper.

TO CLEAN AND SANITUE AIR DUCTS: Apply product to hard, nonporous, precleaned

TO OLEAN, DECORDER AND DECONTARMMATE CAMPETS: For manual cleaning, agray product onto carpet and allow to dry. For machine cleaning, apply product in accordance with the machine manufacturer's guidelines.

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

PRECAUTIONARY STATEMENTS: Hazard to Humans and Domestic Animals.

CALITION: Avoid direct food contact. 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.

STORAGE AND DISPOSAL: Store at room temperature, Discard empty container in mouter tresh.

MOTE: 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 startle 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.

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