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United States Environmental Protection Agency
Office of Pesticide Programs (H7505G)
Washington, DC 20460

Application for Pesticide:

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

167013

Section I

1. Company/Product Number 8383-3	2. EPA Product Manager Walter C. Francis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Sporicidin Brand Disinfectant Solution	PM# 32	
5. Name and Address of Applicant (Include ZIP Code) Sporicidin International 5901 Montrose Road Rockville, MD 20852 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section II

<input type="checkbox"/> Amendment - Explain below	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

* See attached page

Advisory Statement

NOTIFICATION
AUG 26 1996

Section III

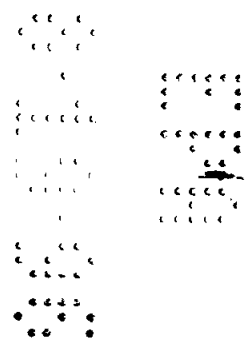
1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted.		If "Yes," Unit Package wgt.	No. per container	If "Yes," Package wgt.	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) of Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner In Which Label Is Affixed To Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other (_____)			

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Harold E. Plank, D.D.S.	Title Technical Director	Telephone No. (Include Area Code) (301) 231-7700
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature <i>Harold E. Plank</i>	3. Title Technical Director	
4. Typed Name Harold E. Plank, D.D.S.	5. Date August 16, 1996	

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 - Notification of minor label revision per PR Notice 95-2.
 - This notification is consistent with the provisions of PR Notice 95-2 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to wilfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 95-2 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.
 - This notification informs EPA of two minor label revisions for Sporicidin Brand Disinfectant Disinfectant, EPA Registration No. 8383-3 in order to accommodate California DPR comments.
 - The residual bacteriostatic claim is revised to read "...up to 6 months..." rather than "... for over 6 months...".
 - The caution statement is clarified by adding "Avoid eye contact."

These revisions comply with the notification criteria stated in PR Notice 95-2.



No change on front panel

FRONT PANEL

DISINFECTANT SOLUTION (PUMP SPRAY)

Contamination and Odor Control

SPORICIDIN
Brand
Disinfectant Solution

Continuous Residual Activity
for Over 6 Months*

NOTIFICATION

ACTIVE INGREDIENTS:

Phenol 1.56%
Sodium Phenate 0.06%

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

INERT INGREDIENTS: 98.38%

Solution is alkaline, pH 7.9-8.6

Keep Out of Reach of Children

CAUTION:

See additional precautions on back panel

EPA Reg. No. 8383-3

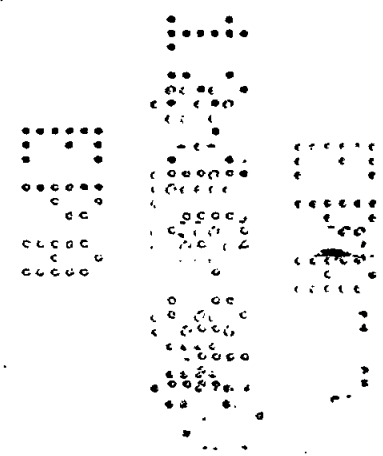
Net Wt. 22 fl. oz. (651 ml)

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JUN 5 1995

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

8383-3



4 7 4

BACK PANEL

DISINFECTANT SOLUTION (PUMP SPRAY)

HOSPITAL DISINFECTION

An effective 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. Acts effectively on germ-laden non-porous equipment and surfaces in medical treatment and patient rooms, operating rooms, emergency rooms, recovery rooms and bathrooms. For use on medical equipment and 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 environmental surfaces.

ACTIVE DEODORIZER. *It provides continuous residual bacteriostatic activity against odor-causing organisms, ~~for over~~^{up to} 6 months in the presence of adequate moisture if not removed from surfaces including plastics, latex, vinyl, glass, wood, metal, porcelain, tile and paint.

♦Kills Athlete's Foot fungus on bathroom, shower, and pool surfaces. ♦Self-sanitizes surfaces against odor-causing bacteria. ♦Penetrates cracks. ♦Non-staining. ♦Contains no harmful abrasives.

SPORICIDIN Brand DISINFECTANT SOLUTION is germicidal when used as directed for disinfection but differs in composition from other Sporidicin products.

PASSES THE AOAC EFFICACY STANDARDS FOR INSTITUTIONAL AND HOSPITAL DISINFECTION. Tested against *Staphylococcus aureus*, *Streptococcus pyogenes*, *Streptococcus salivarius*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Escherichia coli*, ***Herpes simplex* types 1 and 2 (oral and genital), Influenza A₂ (Japan 305/57 Asian strain), Vaccinia, and Polio type 1 viruses. HIV-1 (AIDS virus) on environmental surfaces, *Trichophyton mentagrophytes* (Athlete's Foot fungus) and *Mycobacterium tuberculosis* on environmental surfaces.

DIRECTIONS:

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 with paper towel, cloth or sponge.

TO DISINFECT AND DEODORIZE: Thoroughly wet pre-cleaned surface with disinfectant. Ensure surface remains moist for a 10 minute contact time at room temperature (20°C/68°F or above).
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.

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

TO CLEAN AIR DUCTS: Manually apply to hard non-porous precleaned duct surfaces. Rinse surfaces after application.

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

Avoid eye contact.

CAUTION: Avoid direct contact with food. In case of eye contact, immediately flush with water. If necessary, consult a physician.

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

with COMMENTS

in EPA Letter Dated:

SPORICIDIN INTERNATIONAL

JUN 5 1995

5901 Montrose Road
Rockville, MD 20852

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

6363-3