

8383-7

1/18/2000

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JAN 18 2000

Harold E. Plank  
Sporicidin International  
5901 Montrose Road  
Rockville, MD 20852

Dear Mr. Plank:

Subject: Revised labeling  
Sporicidin Brand Disinfectant Towelette  
EPA Registration No. 8383-7  
Amendment application of November 22, 1999

The amendment referred to above, submitted in connection with registration under FIFRA sec. 3(c)(7)(A), is acceptable provided that you:

1. Make the following labeling changes:

Revised the sentence "For use on medical and dental equipment, beds, surgical carts, ..." to read "For use on medical and dental equipment such as beds, surgical carts, ...."

2. Submit two copies of your final printed labeling before you release the product for shipment. Refer to the A-79 Enclosure for further description of final printed labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

A stamped copy of the label is enclosed for you records.

Sincerely your,



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

Enclosure

*Continuous Residual Activity  
up to 6 Months\**

**Sporicidin**<sup>®</sup>  
BRAND

ALCOHOL  
FREE

## DISINFECTANT TOWELETTE

### Active Ingredients

Phenol .....1.56%

Sodium Phenate .....0.06%

Inert Ingredients .....98.38%

### PRECAUTIONARY STATEMENTS:

Hazard to Humans and Domestic Animals.

**Keep Out of Reach of Children**

### CAUTION:

Avoid direct food contact. Avoid eye contact. In case of contact, immediately flush with water.

If necessary, consult a physician.

Contents: (1) Towelette 12"x12" saturated with disinfectant

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

EPA REG. NO. 8383-7

EPA Est. No. 052631-NJ-001

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

JAN 18 2000

Label for Sporidol Insecticide,  
Sporidol Insecticide and Act as  
Sporidol Insecticide,  
EPA Reg. No. 8383-7

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FRONT PANEL

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# 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 hard surfaces.

**DEODORANT:** Provides continuous residual bacteriostatic activity against odor-causing organisms up to 6 months, in the presence of adequate moisture if not removed from surfaces including vinyl, glass and wood.

- Non-staining
- Contains no harmful abrasives
- Alcohol free

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

## PASSES AOAC EFFICACY STANDARDS FOR INSTITUTIONAL AND HOSPITAL DISINFECTION

- Kills HIV-1 (AIDS virus) in 1 minute on hard nonporous surfaces.
- Kills *Staphylococcus aureus*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa* and *Trichophyton mentagrophytes* (Athlete's Foot fungus) in 3 minutes on hard nonporous surfaces.
- Kills vegetative organisms including *Streptococcus pyogenes*, *Streptococcus salivarius*, *Escherichia coli*, \*\*Herpes simplex types 1 and 2 (oral, ocular and genital), Influenza A, (Japan 305/57 Asian strain), Vaccinia, Canine parvovirus, Cytomegalovirus, Coronavirus and Polio type 1 viruses on hard, nonporous inanimate surfaces and *Mycobacterium tuberculosis* in 10 minutes at 20°C/68°F or above.

**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.

**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 Sporicidin Bulletin No. 303 for HIV-1 (AIDS virus) instructions.

**TO PREVENT MOLD AND MILDEW:** Repeat application weekly, or sooner if new growth appears.

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

SPORICIDIN INTERNATIONAL Rockville, Maryland 20852

and dental equipment such as

ACCOUNTED  
with COMMENTS  
in the letter Dated:  
JAN 18 2000

U.S. Federal Insecticide,  
Fungicide and Rodenticide Act as

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8383-7 BACK PANEL

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