

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

FEB 20 1997

Sporicidin International
5901 Montrose Road
Rockville, MD 20852

Attention Harold E Plank, D D.S.
Technical Director

Subject Sporicidin Brand Disinfectant Towelette
EPA Registration Number 8383-7
Your Resubmission Dated March 15, 1995

This is in response to your resubmission of revised labeling for the subject product.

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable, provided that you make the following label revisions listed below. Submit one copy of the final printed label prior to release of the product for shipment bearing the amended label

- 1 Revise "Directions" to read "Directions for Use"
- 2 Under the heading "Disinfectant", revise the statement "For use in lensed instruments, including animal enclosures" to read "For use on ** lensed instruments including animal enclosures."

At the bottom of the page add "*** other than critical and semi-critical instruments"

A stamped copy is enclosed for your records

CONCURRENCES

SYMBOL	7505W							
SURNAME	P. Harty							
DATE	2/26/97							

2/14

If you have any questions concerning this letter, please contact Pam Hasty at (703 308-7933)

Sincerely,



Robert S Brennis
Acting Product Manager (32)
Antimicrobial Program Branch
Registration Division (7505W)

Enclosure

File 3044

FRONT PANEL

DISINFECTANT TOWELETTE

Contamination and Odor Control

SPORICIDIN
Brand
Disinfectant Towelette

Continuous Residual Activity
for Over 6 Months*

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

Avoid direct food contact. On eye contact, flush with water.
If necessary, contact physician.

Contents

(1) Towelette saturated
with disinfectant

EPA Reg. No. 8383-7

ACCEPTED
w/comments
2/20/97

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended for the pesticide registered under
EPA Reg. No. 8383-7

4044

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 lensed instruments 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

DEODORANT *It provides continuous residual bacteriostatic activity against odor causing organisms, for over 6 months in the presence of adequate moisture if not removed from surfaces including vinyl glass and wood
♦ Non-staining ♦ Contains no harmful abrasives

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

PASSES THE AOAC EFFICACY STANDARDS FOR INSTITUTIONAL AND HOSPITAL DISINFECTION such as Staphylococcus aureus, Streptococcus pyogenes, Streptococcus salivarius, Salmonella choleraesuis, Pseudomonas aeruginosa Escherichia coli **Herpes simplex types 1 and 2 (oral and genital) Influenza A, (Japan 305/57 Asian strain), Polio type 1 virus, 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

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

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 preclean or decontaminate critical or semi critical medical devices prior to sterilization or high level disinfection

TO PREVENT MOLD AND MILDEW Repeat application weekly or sooner if new growth appears

NOTE See Sporocidin Bulletin No 303 for HIV 1 (AIDS virus) instructions

STORAGE AND DISPOSAL Store at room temperature Discard used towelettes and empty container in regular trash

Sporocidin International

5901 Montrose Road
Rockville, MD 20852

ACCEPTED
with COMMENTS
in EPA Letter Data

2/20/97

Labels #12

BEST AVAILABLE COPY

Under the provisions of the
Environmental Pesticide Act
as amended for the pesticides
registered under EPA Reg. No.