

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUL 30 1991

Sporicidin International
5901 Montrose Road
Rockville, MD 20852

Attention: Curtis Lynch, M.D., M.P.H.
Medical Director

Subject: Sporicidin Cold Sterilizing Solution
EPA Registration No. 8383-5
Amendment Dated May 15, 1991

The amendment 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 labeling changes below before you release the product for shipment.

- a. On the right panel, 3rd paragraph, change the wording ". . . for 100% hospital level disinfection . . ." to read ". . . for effective hospital disinfection . . .". Delete "100%" and "level".
- b. The wording "Note: A 1:8 dilution may be used to disinfect endoscopes and other hard to disinfect items" is not acceptable and must be revised. Change this statement to read "Use the 1:8 dilution to disinfect endoscopes and other hard, nonporous medical instruments/devices."

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CONCURRENCES

SYMBOL							
SURNAME							
DATE							

c. Revise the format of your ingredient statement to read:

ACTIVE INGREDIENTS:

(Activator plus Buffer)

Phenol	7.05%
Glutaraldehyde	2.00%
Sodium Phenate	1.20%
INERT INGREDIENTS	89.75%
TOTAL 100.00%	

Submit five (5) copies of final printed labeling before you release this product for shipment.

A Stamped copy of the label is enclosed for your records.

Sincerely yours,



John H. Lee
Product Manager 31
Antimicrobial Programs Branch
Registration Division (H7505C)

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PM 31 8383-5

BUFFER SOLUTION

**DILUTE FOR
STERILIZATION
AND DISINFECTION**

Sporicidin®

COLD STERILIZING SOLUTION

- SPORICIDAL • TUBERCULOCIDAL
- VIRUCIDAL • BACTERICIDAL
- FUNGICIDAL • PSEUDOMONACIDAL

Active Ingredients (Activator plus Buffer): Phenol 7.05%, Glutaraldehyde 2.00%, Sodium Phenate 1.20%

Inert Ingredients 89.75%

KEEP OUT OF REACH OF CHILDREN

WARNING
(See First-aid and Other Precautions on Back Label)

NSN 6840 01-104 5382 EPA Est. No. 60034 TN 001
EPA Reg. No. 8383-5 U.S. Patent No. 4,103,001

Contents (Activator plus Buffer) 32 ozs. (946 mles)

Sporicidin®

INTERNATIONAL

12000 Old Georgetown Rd., Rockville, Md 20852

Under the Federal Insecticide, Fungicide, and Rodenticide Act, amended for the pesticide registered under EPA Reg. No. 8383-5

ACCEPTED
with COMMENTS
in EPA Letter Dated:
JUL 30 1991

Medical instruments/devices

to disinfect endoscopes and other hard, non-immersible surfaces

1:8 dilution

Sporicidin®

COLD STERILIZING SOLUTION

For medical instruments, equipment and fiberoptics in endoscopy, ophthalmology and respiratory therapy. Used in hospitals, medical clinics/offices, nursing homes and ambulances.

DIRECTIONS

It is a violation of U.S. Federal Law to use this product in a manner inconsistent with the labeling.

1. Add Activator to Buffer. Activated solution has a shelf life of 30 days and reused during the 30 days, as directed, for both sterilization at room temperatures (68 F/20°C and above) in manual procedures and trays.
2. Thoroughly clean, rinse and rough dry objects before treatment.
3. **Disinfection. Use 1:18 dilution.** Completely immerse articles for 100% hospital level disinfection, including Mycobacterium tuberculosis, negative and gram positive bacteria, Staphylococcus aureus, Salmonella, Pseudomonas aeruginosa, pathogenic fungi, Polio virus, Cytomegalovirus, Rotavirus, Influenza A2/Japan, Coxsackie B-1 simplex (oral and genital). Rinse with potable or sterile water. If possible, an after-rinse treatment with 70% alcohol is recommended for other semi-critical devices.

For non-immersible surfaces, thoroughly wet with 1:18 dilution, sponge or mechanical spray and allow 10 minutes contact time.

4. **Sterilization: Use 1:8 dilution.** Completely immerse articles for the first 14 days of reuse and for 10 hours thereafter for complete pathogenic organisms. Rinse articles with sterile water using aseptic technique.
5. **Special Use Patterns With Unused Activated Solution**
 - (a) Undiluted solution is bactericidal in 2 minutes.
 - (b) Undiluted solution completely kills aerobic spores, including Bacillus anthracis, in 3 hours on immersed laboratory items contaminated by this organism in 6 3/4 hours.
 - (c) Freshly activated 1:32 dilution is bactericidal, fungicidal and virucidal against Polio Type 1 and Herpes simplex type 2 in 10 minutes.
6. To prepare 1 gallon for use:
 - (a) 1:8 dilution: add 16 oz. of activated solution to 112 oz. of tap water.
 - (b) 1:18 dilution: add 8 oz. of activated solution to 120 oz. of tap water.
 - (c) 1:32 dilution: add 4 oz. of activated solution to 124 oz. of tap water.

** Distilled water is recommended for use on endoscopes.
7. For plastics and rubber use disinfection directions. Not recommended for carbon inserts or as an overnight holding solution for carbon inserts used for injection needles.
8. For logging clean rooms, See Sporicidin Bulletin No. 102.
9. Refer to Sporicidin Bulletin No. 503 for HRV-1 (ARDS virus) kill on hard surfaces.

PRECAUTIONARY STATEMENTS

- Hazards to Humans and Domestic Animals**
- Avoid skin contact. Solution more concentrated than 1:18 may cause skin irritation. Flush thoroughly with water after contact.
 - Avoid eye contact. Causes eye irritation. In case of contact flush with water, and get medical attention.
 - Harmful if swallowed. Drink large quantities of water and call physician.
 - Use in ventilated areas.
 - Avoid food contamination.

WASH EMPTY CONTAINER THOROUGHLY WITH WATER AND DISPOSE IN PROPER RECEPTACLE.