1/6 8383-6 PM 31

US ENVIRONMENTAL PROTECTION AGENCY OFFICE OF PESTICIDES PROGRAMS REGISTRATION DIVISION (TS-767) WASHINGTON, DC 20460 **NOTICE OF PESTICIDE:** [X] REGISTRATION [ ] REREGISTRATION *(Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)*	EPA REGISTRATION NO.: 8383-6 DATE OF ISSUANCE: AUG 24 1987 TERM OF ISSUANCE: NAME OF PESTICIDE PRODUCT: [illegible] Concentrated [illegible]

NAME AND ADDRESS OF REGISTRANT *(Include ZIP code)*

[illegible]

NOTE: Changes in labeling formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above U.S. EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby Registered/Reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act.

A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith.

Registration is in no way to be construed as an indorsement or approval of this product by this Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

[illegible] section 3(c)(7) [illegible]

1. [illegible] all data required for registration/reregistration [illegible]

[illegible]

John H. Lee

[illegible]

BEST AVAILABLE COPY

[ ] ATTACHMENT IS APPLICABLE

SIGNATURE OF APPROVING OFFICIAL	DATE

EPA Form 8570-6 (Rev. 5-76) PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED.

T6702:T:Lee:L-13:KENCO:8/17/87:8/26/87:EK:vo:lisa:teg

AUG 24 1987

Sporicidin
4000 Massachusetts Avenue NW.
Washington, DC 20016

Attention: Dr. Curtis L. Lynch

Gentlemen:

Subject: Sporicidin-HD Concentrated for Hemodialysis
EPA File Symbol 8383-A
Your Submission Dated May 15, 1987

A review of the chemistry data submitted in your May 15, 1987 letter follows.

Submit a revised correct Confidential Statement of Formula. In column 13.a. change the amount of Glutaraldehyde 50% from 165 g to 130 g. In column 17 enter the total weight of batch 500 g.

Tell us the purity of "sodium phenate" used in buffer formulation. If sodium phenate is 100% pure then in the ingredient statement for the Activator plus Buffer you should declare 2.0% sodium phenate.

The referenced accelerated 30-day 50 °C storage and stability data are acceptable.

Sincerely yours,

John H. Lee
Product Manager (31)
Disinfectants Branch
Registration Division (TS-767C)

16702:I:Lee:L-13:KENCO:8/17/87:8/26/87:EX:vo:lisa:teg

CONCURRENCES								
SYMBOL	ORIGIONATOR							
SURNAME								
DATE								

FRONT PANEL

BUFFER SOLUTION

SPORICIDIN-HD CONCENTRATE
For Hemodialysis Machine Disinfection

A Glutaraldehyde-Phenate Solution
for Dialysis Machines

* VIRUCIDAL* * BACTERICIDAL * FUNGICIDAL * PSEUDOMONACIDAL

Equipment Safe Rapid Acting Non-staining

Active Ingredients: (Activator plus Buffer)

Glutaraldehyde	13.00%
Phenol	7.05%
Sodium Phenate	1.20
Inert Ingredients	78.75%

Note: Activator must be added to buffer before this product is effective. See Directions. Use solution within 21 days after activation.

KEEP OUT OF REACH OF CHILDREN

DANGER

BEST AVAILABLE COPY

See other precations on side label.

Contents: (Activator plus Buffer) 128 fl. oz. (3.8 liters)

EPA Reg. No. 8383-6

The Sporicidin Company
4000 Massachusetts Avenue, N.W.
Washington, D.C. 20016

ACCEPTED
[illegible]

AUG 24 1987

Under the [illegible] ... as amended, for the pesticide registered under EPA Reg. No. 8383-6

4/6

LEFT PANEL

SPORICIDIN-HD CONCENTRATE FOR HEMODIALYSIS MACHINE DISINFECTION

DIRECTIONS FOR ACTIVATION AND USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Follow specific equipment manufacturer's recommendation to cleansing and disinfecting. Flush equipment thoroughly with water before producing activated Sporicidin-HD. Add Activator to Buffer Solution. Use activated solution within 21 days of activation, but do not reuse.

DIALYSIS MACHINES

Single Patient Delivery Systems. Place 150 cc (5.0% oz) into the hemodialysate system. Allow the machine to run until all of the Sporicidin-HD is drawn into the concentrate line. This will allow for automatic proportioning of solution with water.

Multipatient Delivery Systems. Place 1.0 liter (33.8 ozs) into the hemodialysate delivery system. Allow the machine to run until all of the Sporicidin-HD is drawn into the concentrate line. This will allow for automatic proportioning of solution with water.

NOTE: Use of an insufficient quantity of activated Sporicidin-HD solution will result in inadequate treatment of the hemodialysate delivery system. Some systems may require a larger quantity of solution than specified in the directions above. To dilute 1:34 outside the automatic proportioning system, mix 1 part of activated Sporicidin-HD with 34 parts of water.

After filling the delivery system hold Sporicidin-HD in the system for a minimum of 10 minutes. Drain Sporicidin-HD from the system and thoroughly rinse with water. Test final rinse water for residual using the Sporicidin-HD Residual Test Kit to assure complete rinsing.

It is recommended that disinfection procedures be accomplished immediately preceding use of the hemodialysate system.

ACCEPTED
with COMMENTS
In EPA Letter Dated:

AUG 21 1987

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 8383-6

5/16

RIGHT LABEL

SPORICIDIN-HD CONCENTRATE FOR HEMODIALYSIS MACHINE DISINFECTION

FOR DIALYSIS MACHINES:

Sporicidin-HD is recommended for decontaminating single patient and multipatient hemodialsate delivery systems. It is an effective disinfectant (virucide, fungicide, bactericide, pseudomonacide) when tested by AOAC and EPA test methods. Sporicidin-HD exhibits virucidal* activity against both hydrophilic and lipophilic viruses including Polio Type 1, Herpes Simplex Type II and Influenza A_2 Japan on environmental hard surfaces diluted 1:34. Sporicidin-HD may not totally eliminate all vegetative microorganisms in hemodialysate delivery systems due to their construction and/or assembly but can be relied upon to reduce the number of microorganisms to acceptable levels when used as directed. This product should be used in a disinfection program which includes bacteriological monitoring of the hemodialysate delivery syster.

PRECAUTIONS

- Avoid eye contact. Causes eye irritation. In case of contact, flush with water immediately and get medical attention.
- Avoid skin contact. At full strength, possibility of skin sensitivity exists and may cause skin irritation. Flush thoroughly with water after contact.
- Harmful if swallowed. If swallowed, drink large quantities of water and call physician immediately.
- Avoid food contamination.

STORAGE AND DISPOSAL

Store at room temperature. Rinse empty container thoroughly with water and discard in trash.

CONTENTS: Activator plus Buffer
128 fl. oz. (3.6 liters)

ACCEPTED
with COMMENTS
In EPA Letter Dated:

AUG 24 1987

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

8383-6

SPORICIDIN-HD

ACTIVATOR SOLUTION

For use with Buffer Solution

DIRECTIONS FOR USE:

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

Add Activator to Sporicidin-HD buffer in the gallon container. Makes one gallon of activated Sporicidin-HD. Shake gently to mix.

PRECAUTIONS:

- Avoid eye contact. Causes eye irritation. In case of contact, flush with water immediately and get medical attention.
- Avoid skin contact. At full strength, possibility of sensitization exists and may cause skin irritation. Flush thoroughly with water after contact.
- Harmful if swallowed. If swallowed, drink large quantities of water and call physician immediately.
- Avoid food contamination.

Active Ingredient

Glutaraldehyde	50%	EPA Reg. No. 8383-5
Inert Ingredients	50%	

DANGER

KEEP OUT OF REACH OF CHILDREN

Contents: 1 Quart, 1.28 fl. ozs. (0.984 liters)

THE SPORICIDIN COMPANY
4000 Massachusetts Avenue, N.W.
Washington, D.C. 20016

ACCEPTED
with COMMENTS
In EPA Letter Dated:

AUG 24 1987

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 8383-6