

1/6 7078-13 PM 31

JUL 30 1986

SURGIKOS, Inc.
P.O. Box 130
Arlington, TX 76010

Attention: Walter J. McQuade

Gentlemen:

Subject: NEPHREX® Concentrate Formula for Disinfecting
Hemodialyzers
EPA Registration No. 7078-13
Your Amendment Application Dated June 24, 1986

The amendment application referred to above to change the product name to NEPHREX® Concentrate Formula for Disinfecting Hemodialyzers and make label corrections is acceptable provided that you:

1. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:
 - a. On the center panel, change the term "Disinfecting Solution" to read "Disinfectant Concentrate."
 - b. On the center panel, replace "NEPHREX" with "NEPHREX®" which will be correct new nomenclature.
 - c. On the center panel under NOTE change the paragraph to read somewhat as follows: "This product is a concentrate and must be activated then diluted to a Disinfecting Solution immediately prior to use. The Activator must be added to the NEPHREX® Concentrate fluid before this product is effective for diluting to a Disinfecting Solution. See the directions on the left panel."

91091:Lee:L-12;KENCQ:7/22/86;7/31/86;TAR:lmf

CONCURRENCES


SYMBOL							
SURNAME							
DATE							

- d. On the left panel, change the second sentence to read as follows: "NEPHREX Concentrate is formulated to be diluted immediately after activation at a 32:1 dilution for disinfection of dialyzers in 60 minutes."
- e. On the left panel change the first heading to read as follows: "Directions for Activation and Dilution."
- f. There is no efficacy data to support a shelf-life of 7 days for the activated, diluted solution. The data only support efficacy of the solution when used immediately after activation and dilution. Therefore, delete all references to 7-day shelf-life or use-life and all references to the Effectiveness Test Kit, Expiration Date, etc.
2. Submit five copies of the final printed labeling before you release the product for shipment.

Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the each size labeling is enclosed for your records.

Sincerely yours,


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

Enclosure

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CENTER PANEL

Disinfecting Solution

Rapid-Acting/Nonrusting/Nonstaining
Pseudomonacidal Bactericidal
Virucidal† Fungicidal

NEPHREX™
Concentrate Formula for
Disinfecting Hemodialyzers

Active Ingredient
 Glutaraldehyde.....26%
Inert Ingredients.....74%
Total.....100%

NOTE: This product is a concentrate and must be activated and diluted immediately prior to use. Activator must be added to fluid before this product is effective. See directions.

Reorder Number 2445

EPA Reg. No. 7078-13
EPA Est. No. 36126-PR-1

KEEP OUT OF REACH OF CHILDREN
DANGER: See left side of panel
for precautions.

†See Directions for Disinfection

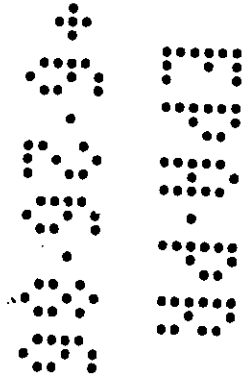
SURGIKOS

ACCEPTED
with COMMENTS
in EPA Letter Dated:

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

7078-13



*Trademark
BB6

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LEFT PANEL

Follow established procedure for dialyzer reuse. NEPHREX Concentrate is formulated to be used at a 32:1 dilution for disinfection of dialyzers in 60 minutes.

Clean dialyzers thoroughly and test for membrane integrity before introducing NEPHREX Solution.

Directions for Activation -

Add contents of attached vial to this container of NEPHREX Concentrate. Mix. When activated, concentrate changes color to yellow and is ready for dilution with water. Immediately dilute activated NEPHREX Concentrate to 8 gallons with softened water. The shelf-life of the unused activated and diluted solution is 7 days. DO NOT USE the activated and diluted solution beyond 7 days. Efficacy of this product during its use-life can be verified by the Effectiveness Test Kit for NEPHREX Dialyzer Disinfecting Solution.

Directions for Disinfecting -

It is a violation of federal law to use this product in a manner inconsistent with its labeling. For use in hospitals, dialysis centers and health care institutions.

Disinfect immediately after cleaning the dialyzer.

Fill dialyzer with NEPHREX Solution (both blood and dialysate sides). Hold the solution in the dialyzer for a minimum of 60 minutes. Within 60 minutes contact at 25°C, the solution will destroy vegetative pathogens including Pseudomonas aeruginosa, atypical water mycobacteria Mycobacterium chelonae and Mycobacterium fortuitum, pathogenic fungi and hydrophilic and lipophilic viruses (Poliovirus Type I, Coxsackievirus B-1, Influenza Type A₂ [Hong Kong], Herpes simplex Type 1) on inanimate surfaces. Prior to patient use, drain the solution and thoroughly rinse dialyzer with sterile physiological saline. To assure complete rinsing, test final rinse water using NEPHREX Residual Test Kit.

NEPHREX Solution has been demonstrated to be compatible with hollow fiber hemodialyzers having Cuprophane, regenerated cellulose or cellulose acetate membranes and has been shown to be safe for dialyzer storage.

This is a single use product.

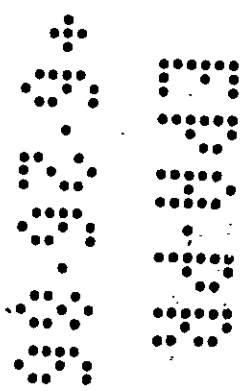
Note Dates Here

Mixing Date _____ Expiration Date _____

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RIGHT PANEL

Precautionary Statements -

DANGER:
Hazard to Humans
Follow All Label Directions

Prevent contact with skin or eyes by using eye protection and rubber gloves when handling or pouring.

- Eyes** -- Corrosive, causes eye damage. Do not get in eyes. In case of contact, flush with water immediately and get medical attention.
- Ingestion** -- Harmful if swallowed. Avoid contamination of food.
- Inhalation** -- Avoid spillage. Use in a well-ventilated area.
- Skin** -- Avoid skin contact, as possibility of sensitization exists. Can cause skin irritation. For skin contact, flush thoroughly with water. Get medical attention if irritation occurs.

Storage and Disposal -

Keep in a cool place. Triple rinse empty container with water and dispose in an incinerator or landfill approved for pesticide containers.

Contents: 28 fl. oz. (0.83 liters)
Made in U.S.A.
Control Number on Bottom

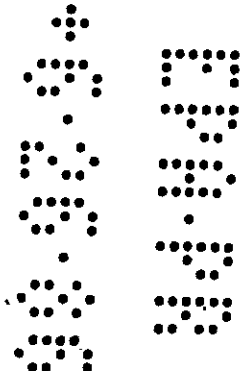
Distributed by:
SURGIKOS
a Johnson & Johnson Company
SURGIKOS, Inc., Arlington, Texas 76010

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ACTIVATOR LABEL

NEPHREX™

DANGER: Contact with eyes causes damage. In case of contact with eyes, flush with water immediately and get medical attention. For skin contact, flush thoroughly with water.

ACTIVATOR VIAL

DISPOSAL: Rinse empty container thoroughly with water and discard it.

For Use with NEPHREX Concentrate Fluid Only

Net contents: 24.5 grams

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