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7578-12

OCT 15 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 Amended Application Dated September 12, 1986

We have no objection to the name change to NEPHREX* Dialyzer Disinfecting Solution Concentrate.

The corrected labels are acceptable provided that you make the labeling changes listed below before you release the product for shipment bearing the amended labeling.

1. On the center panel the word Concentrate should be placed below the product name since the word Concentrate appears at the end not the beginning of the new product name.
2. The term Virucidal + on the Front Panel must be keyed by reference marks to the term hydrophilic and lipophilic viruses in the bottom main paragraph on the LEFT PANEL.

Submit five copies of the final printed concentrate label and five copies of the final printed activator label.

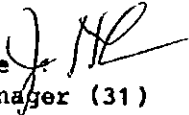
90335: Lee: L-4: KENCO: 10/1/86: 10/13/86: TAR: vo

CONCURRENTS

SYMBOL								
SURNAME								
DATE								

A stamped copy of the concentrated label and activator label is enclosed for your records.

Sincerely yours,

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

Enclosure

CENTER PANEL

Concentrate Formula for
Disinfecting Dialyzers

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

Concentrate
NEPHREX* Dialyzer
Disinfecting Solution

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 the concentrate and diluted before this product is effective. See directions for activation and dilution.

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

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Registration Division (TS-767)

*Trademark
BB6

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LEFT PANEL

Follow established procedure for dialyzer reuse. NEPHREX Concentrate is formulated to be diluted immediately after activation to 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 and Dilution -

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.

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 1, 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

ACCEPTED
VIALS
DATE

OCT 15 1986

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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

ACCEPTED
with conditions
E. I. du Pont de Nemours & Co.

OCT 15 1966

Under the provisions of the
Registration Act, the pesticide
is registered under EPA Reg. No.
7078-13

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SEP 17 1966

Registration Division (IS-767)

ACTIVATOR LABEL

Activator for use with
NEPHREX* Dialyzer Disinfecting
Solution Concentrate

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

DISPOSAL: Rinse empty container thor-
oughly with water and discard it.

Net contents: 24.5 grams

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

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