7078-15, Pkl-31, 15

US ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDES PROGRAMS
REGISTRATION DIVISION (TS-767)
WASHINGTON, DC 20460

NOTICE OF PESTICIDE: ☒ REGISTRATION ☐ REREGISTRATION

(Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)

EPA REGISTRATION	DATE OF ISSUANCE
7078-15	DEC 10 1986

TERM OF ISSUANCE

NAME OF PESTICIDE PRODUCT

NEPHREX* Dialyzer Disinfectant Solution

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

Surgikos, Inc.
2500 Arbrook Blvd.
Arlington, TX 76014

Attn: W.J. McQuade

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.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. Add the phrase "EPA Registration No. 7078-15" to your label before you release the product for shipment.
3. Submit a revised "Certification with respect to citation of data" form
4. Submit five (5) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 Enclosure for a further description of final printed labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

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

Sincerely yours,

John H. Lee

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

Enclosure

☐ ATTACHMENT IS APPLICABLE

SIGNATURE OF APPROVING OFFICIAL	DATE

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

CENTER PANEL

Use-Dilution Formula
for Disinfecting Dialyzers

Rapid-Acting/Nonrusting/Nonstaining
Pseudomonacidal Bactericidal
Virucidal Fungicidal

NEPHREX* Dialyzer Disinfecting Solution

Active Ingredient
Glutaraldehyde.......0.8%
Inert Ingredients.....99.2%
Total................100.0%

Reorder Number

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

See Directions for Disinfection

NOTE: Attached vial contents must be added to fluid before this product is effective. See Directions for Activating.

E.P.A. Reg. No. 7078-
E.P.A. Est. No. 36126-PR-1

SURGIKOS

ACCEPTED

registered under EPA Reg. No. 7028-15

*Trademark
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LEFT PANEL

Follow established procedure for dialyzer reuse. NEPHREX Solution is formulated to be used as packaged for disinfection of dialyzers in 60 minutes.

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

Directions for Activating -

Add contents of attached vial to this container. Shake; solution is ready to use. When activated, solution changes color to yellow. The shelf life of the unused activated solution is 7 days. DO NOT USE activated solution beyond 7 days. Efficacy of this product during its shelf life can be verified by the NEPHREX Dialyzer Disinfecting Solution Effectiveness Test Kit.

Directions for Disinfection -

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 chelonei and Mycobacterium fortuitum), pathogenic fungi, and hydrophilic and lipophilic viruses (Poliovirus Type 1, Coxsackievirus B-1, Influenza Type A_2 [Hong Kong], Herpes simplex Type 1) on inaminate surfaces. Prior to patient use, drain the dialyzer 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 eyes by using eye protection 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 ventilated areas.
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: 128 fl. oz. (3.8 liters)
Made in U.S.A.
Control Number on Bottom

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

Registered under FIFRA No. ...
7028-15

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ACTIVATOR LABEL

NEPHREX* Dialyzer
Disinfecting Solution
Activator Vial

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.

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

Net Contents: 3.5 grams

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SURGIKOS, Inc., Arlington, Texas 76010

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