7078-16, PM-31, 1/5

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	DATE OF ISSUANCE
7078-16	DEC 10 1986
TERM OF ISSUANCE	

NAME OF PESTICIDE PRODUCT

NEPHREX* HD Disinfecting 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. 7078-16" 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
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
Decontaminating Batch Type
Hemodialysate Delivery Systems

Rapid-Acting/Nonrusting/Nonstaining
Pseudomonacidal Bactericidal
Virucidal Fungicidal

NEPHREX* HD Disinfecting Solution

Active Ingredients
Glutaraldehyde.....0.74%
Inert Ingredients..... 99.26%
Total.....100.00%

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

Reorder Number

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

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

See Directions for Disinfection

SURGIKOS

*Trademark
BB4

LEFT PANEL

Follow specific equipment manufacturers recommendation for cleansing and disinfecting the hemodialysate delivery system. NEPHREX HD Solution is formulated to be used as packaged for disinfection of batch type hemodialysate delivery systems in 15 minutes.

Directions for Activating -

Add contents of attached vial to this container. Shake: Solution is ready to use. When activated, solution changes color to blue. 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 HD 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.

It is recommended that disinfection be carried out immediately after and just prior to use of the batch type hemodialysate delivery system.

Flush equipment thoroughly with water prior to filling the batch delivery system with NEPHREX HD Solution. After filling the delivery system, hold NEPHREX HD Solution in the system for a minimum of 15 minutes. Within 15 minutes contact time at 20°C, NEPHREX HD Solution will destroy vegetative pathogens including Pseudomonas aeruginosa and hydrophilic and lipophilic viruses (Poliovirus Type 1; Coxsackievirus B-1, Influenza Type A_2 [Hong Kong]; Herpes simplex, Type I) on inaminate surfaces. Prior to machine use, drain NEPHREX HD Solution and thoroughly rinse with water. To assure complete rinsing, test final rinse water using NEPHREX Residual Test Kit.

This is a single use product.

Note Dates Here.

Mixing Date________ Expiration Date

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

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DEC 10 1986
7078-16

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RIGHT PANEL

NEPHREX HD Solution is recommended for decontaminating batch type hemodialysate delivery systems. NEPHREX HD Solution has been shown to be an effective disinfectant (virucide, fungicide, bactericide, pseudomonacide) when tested by AOAC and EPA Test Methods. NEPHREX HD Solution may not totally eliminate all vegetative microorganisms ir batch type 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 system. NEPHREX HD Solution is not recommended for use in hemodialyzers or reverse osmosis (RO) membranes.

Consult the guidelines for hemodialysis systems which are available from the Hepatitis Laboratories, CDC, Atlanta, Georgia, 30301.

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 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.

Content 128 fl.oz. (3.8 liters)
Made in U.S.A.
Control Number on Bottom

ACCEPTED

DEC 10 1986

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ACTIVATOR LABEL

[Concentrate]
NEPHREX* HD 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.

Net Contents 3.5 grams
Made in U.S.A.
Control Number on Bottom

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

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