-	7078-15, PN: 31, 1	1/5
	PAREGISTRATION DATE OF ISSUANCE	
US ENVIRONMENTAL PROTECTION AGENCY	7078-15 AEC 4 0 1086	
OFFICE OF PESTICIDES PROGRAMS REGISTRATION DIVISION (75-767) WASHINGTON, DC 20460	TERM OF ISSUANCE	
NOTICE OF PESTICIDE: REGISTRATION	NAME OF PESTICIDE PRODUCT	
L] KEREGISTRATION	NEPHREX* Dialyzer Disinfectant Solution	
(Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)	, , , , , , , , , , , , , , , , , , ,	
NAME AND ADDRESS OF REGISTRANT (Include ZIP code)		
Survikee Inc	٦ (
outgros, the.	,	
2500 Arbrook Blvo. Arlington, TX 76014		
ALTINGUM, IX 10014		
Attn: W.J. McQuade		
L		
NOTE: Changes in labeling formula differing in substance fr submitted to and accepted by the Registration Division prior product always refer to the above U.S. EPA registration number	from that accepted in connection with this registration must be or to use of the label in commerce. In any correspondence on this other.	
On the basis of information furnished by the registrant, the a the Federal Insecticide, Fungicide, and Rodenticide Act.	above named pesticide is hereby Registered/Reregistered under	
A copy of the labeling accepted in connection with this Reg	gistration/Reregistration is returned herewith.	
health and the environment, the Administrator, on his motion icide in accordance with the Act. The acceptance of any nar	t or approval of this product by this Agency. In order to protect in, may at any time suspend or cancel the registration of a pestume in connection with the registration of a product under this o exclusive use of the name or to its use if it has been covered	
This product is conditionally regi	istered in accordance with FIFRA sec.	
3(c)(7)(A) provided that you:		
	equired for registration/reregistration	
of your product under FIFRA sec. 3(c)(5		
registrants of similar products to subm		
release the product for shipment.	ion No. 7078-15" to your label before you	
3. Submit a revised "Certification	on with respect to citation of data" form	
	r final printed labeling before you	
release the product for shipment. Refer		
description of final printed labeling.		
	ied with, the registration will be	
subject to cancellation in accordance w		
shipment of the product constitutes according to the label is end		
is beautiful copy or the moor is one	araba nor four roomans	
	Sincerely yours,	
(
· ·	Jahr 11. Xee	
	/Product Manager (31)	
ℓ	Disinfectants Branch	
	Registration Division (TS-767C)	
Enclosure		

ATTACHMENT IS APPLICABLE SIGNATURE OF APPROVING OFFICIAL

DATE

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

ACCOMPTION NO. 100 No.

*Trademark BB7

LEFT PANEL

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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.

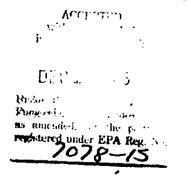
Disinfect immediately after cleaning the dialyzer.

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 A2 [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





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

ACTIVATOR LABEL

NEPHREX* Dialyzer Disinfecting Solution Activator Vial

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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

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

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