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 or bury in a safe place.

CONTENT 28 FL OZ (0.83 LITERS)
MADE IN U.S.A.
CONTROL NUMBER ON BOTTOM

2445C1-2

DISTRIBUTED BY
SURGIKOS
a Johnson & Johnson company
SURGIKOS INC. ARLINGTON, TEXAS 76010

Disinfecting Solution

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

Formulated for Disinfecting Hemodialyzers

Cidex.* Dialyzer

disinfecting solution concentrate

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

Reorder Number

2445

Keep out of reach of children.

DANGER: See left side panel for precautions.

†See Directions for Disinfection

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.

E.P.A. Reg. No. 7078-13

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

SURGIKOS

*TRADEMARK

Cidex. Dialyzer
disinfecting solution concentrate

ACTIVATOR

For use with CIDEX Dialyzer Fluid Only

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.

Rinse empty container thoroughly with water prior to discarding.

*TRADEMARK
© SURGIKOS 1983
2445-C1-2

DISTRIBUTED BY
SURGIKOS
a Johnson & Johnson company
SURGIKOS INC. ARLINGTON, TEXAS 76010

GENERAL CLASSIFICATION

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.

Follow established procedure for dialyzer reuse. CIDEX* Dialyzer Disinfecting Solution Concentrate is designed to be used at a 32:1 dilution for disinfection of dialyzers in 60 minutes.

Clean dialyzer thoroughly and test for membrane integrity before introducing CIDEX Dialyzer Disinfecting Solution.

DIRECTIONS FOR ACTIVATION:

Add contents of attached vial to this container of CIDEX Dialyzer Disinfecting Solution Concentrate. Mix. When activated, concentrate changes color to yellow and is ready for dilution with water. Immediately dilute the activated concentrate to 8 gallons with distilled, deionized or softened water.

DIRECTIONS FOR DISINFECTION:

Disinfect immediately after cleaning the dialyzer.

Fill dialyzer with CIDEX Dialyzer Disinfecting 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 I, Coxsackievirus B-1, Influenza Type A, (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 CIDEX HD Dialyzer Residual Test Kit.

CIDEX Dialyzer Disinfecting 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.

*TRADEMARK © SURGIKOS *

ACCEPTED
with COMMENTS
In EPA Letter Dated:

Under Experimental Use Permit No. 7078-13

U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDES PROGRAMS
REGISTRATION DIVISION (RD-567)
WASHINGTON, D.C. 20460

NOTICE OF PESTICIDE: ☐ REGISTRATION ☐ REREGISTRATION

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

EPA REGISTRATION NO.	DATE OF ISSUANCE
7078-1[illegible]	17 FEB 1984
TERM OF ISSUANCE	

NAME OF PESTICIDE PRODUCT
Cidex Dialyzer Disinfecting Solution Concentrate

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

Surgikos, Inc.
P.O. Box 130
Arlington, Texas 76010

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.

[illegible]

☐ ATTACHMENT IS APPLICABLE

SIGNATURE OF APPROVING OFFICIAL	DATE

EPA Form 8570-6 (Rev. 5-76) [illegible] MAY BE USED UNTIL SUPPLY IS EXHAUSTED.

[redacted]

7078-13

3. We inadvertently did not previously request the following information to complete the efficacy data test report submitted on this product. Please submit the following information concerning the test report on Mycobacterium chelonei and Mycobacterium fortuitum for inclusion in this file:

   a) Verify that the use-dilution employed in the tests was the recommended 1:31 dilution;

   b) Identify the strains or source of the test bacteria;

   c) Specify the subculture medium and incubation conditions (time and temperature) employed for the exposed carriers.

   d) Please provide a bibliographic reference (author, journal, etc.) and/or a copy of the cited report by CDC entitled "Microbiologic Evaluation of a New Glutaraldehyde-Based Disinfectant for Hemodialysis Systems".

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.

James W. Clarke
for John H. Lee