NOTICE OF PESTICIDE:

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

NAME OF PESTICIDE PRODUCT
Renalin® Dialyzer Reprocessing Concentrate

NAME AND ADDRESS OF REGISTRANT (Include ZIP code)

- Renal Systems, Inc.
  1400 28th Avenue North
  Minneapolis, MN 55441

Attn: Lee May, Fishman

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 endorsement 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 the use of it if it has been covered by others.

The product is a pesticide registered with EPA sec.

Please provide the following:

1. Submit a copy of all data required for registration.
2. Notice of intent to reregister under FIFRA sec. 3(c)(5) when the agency requires all contractors of similar products to reregister.
3. Use the labeling changes shown below before you release the product for shipment:

- Add the phrase "EPA Registration No. 52257-1" to your label before you release the product for shipment.

The required front panel precautionary labeling is "MAINTAIN OUT OF REACH OF CHILDREN." See other required precautionary labeling on front panel.

BEST AVAILABLE COPY

[Signature]

[Date]

PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED.
c. The precautionary section must contain the following statements:

"Danger - Corrosive. Cause eye damage and skin irritation. Do not get in eyes, or skin or on clothing. Wear safety glasses and rubber gloves when handling. Harmful if swallowed. Wash thoroughly after handling.

d. On the front panel delete "Caution: Federal (USA) Law restricts this device to use by or on the order of a physician".

e. Directly under "Instructions for Use", on the label add the following misuse statement "It is a violation of Federal Law to use this product in a manner inconsistent with its labeling".

f. For proper format and type size see the enclosure titled, "THE LABEL".

3. 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.

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

Enclosure
Label

Renalin™
Concentrate

2.5 gallon container

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JUL 10 1985
Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
52252-1
COLD STERILANT FOR DIALYZER REPROCESSING

RENALIN™

DIALYZER REPROCESSING CONCENTRATE

READ RENALIN™ INSTRUCTIONS FOR USE AND TECHNICAL NOTES BEFORE USING PRODUCT.

Active Ingredients

- Hydrogen peroxide: 24.0%
- Peroxyacetic acid: 4.0%
- Inert ingredients: 72.0%

Total: 100.0%

Note: This product must be diluted with AAMI water prior to use.

Caution: Federal (USA) law restricts this device to use by or on the order of a physician.

DILUTED EXPIRATION DATE

Lot No. ________

Concentrate
Expiration Date ________

NET CONTENTS: 0.53 gallons (2 liters)

In case of contact with skin or eyes, flush with large amounts of water for at least fifteen (15) minutes. For eyes, get prompt medical attention.

If swallowed, drink water immediately to dilute, do not attempt to cause vomiting. Call physician immediately.

See Renalin™ Instructions for Use and Technical Notes (PN 50058-000) as well as side panel for additional precautionary statements.

renal systems, Inc.
14905 28th Avenue North
Minneapolis, Minnesota 55441 USA
Telephone (612) 553-3300, Toll Free (800) 328-3340
Telex 29-0825 RSIMPLS PLOH

Establishment No. (to be included upon assignment by EPA)
EPA Registration No. (to be included upon assignment by EPA)
PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

DANGER

Renalin™ is a strong oxidizer.
Avoid contact with skin and eyes.
Wear rubber gloves and goggles when handling this product.

ACCIDENTAL INHALATION

Renalin™ is a strong oxidizer.
If inhaled, get fresh air immediately.
Call a doctor.

ACCEPTED
with COMMENTS
by EPA Letter Date:

JUL 10 1985

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.

INSTRUCTIONS FOR USE

1. Read Renalin™ instructions for use and technical notes before using this product.
2. Use only with the Renatron Dialyzer Reprocessing System, which has been modified
   for use with Renalin™.
3. Dilute Renalin™ concentrate by filling original container to the shoulder with
   AAMI quality water.
4. Connect to Renatron uptake hose and follow machine instructions.

STORAGE

1. Store in shipping carton.
2. Do not expose to direct sunlight.
3. Maintain temperature below 75°F (24°C).
4. Avoid contact with combustible materials.
5. Avoid contamination from any source, including metals, dust, etc. Such
   contamination may cause rapid decomposition, generation of large quantities of oxygen
   gas and high pressures.
6. Store in original closed container—NEVER
   TAMPER WITH VENT

7. Use AAMI quality water in all
   dialyzer reprocessing steps
   when using Renalin™.
8. After dilution, the resultant
   solution must be used within seven
   (7) days. Fill in the expiration
   date of dilution solution at time
   of dilution in the space provided
   on this label. The expiration date
   of the diluted Renalin™ is seven
   days after dilution.
9. For chemical emergency, spill, leak, fire, exposure and accident, call Chemtrec, day
   or night (800) 424-9300, (202) 483-7616

DISPOSAL

1. Do not contaminate water, food or feed by storage or disposal.
2. Wastes resulting from the use of this product may be disposed of on-site
   or at an approved waste disposal facility.
3. Triple rinse empty container with water. Then offer for recycling or
   reconditioning; or puncture and dispose of in a sanitary landfill; incinerate;
   or if allowed by state and local authorities dispose of by burning. If buried,
   stay clear of the smoke.

BEST AVAILABLE COPY
Shipping Carton Label

Renalin™ Concentrate
Twin Pack
(2 - 2-1/2 gallon containers)

JUL 10 1985

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 522-352-1
renalin™

DIALYZER REPROCESSING CONCENTRATE

COLD STERILANT FOR DIALYZER REPROCESSING

NOTE: READ RENALIN INSTRUCTIONS FOR USE AND TECHNICAL NOTES BEFORE USING THIS PRODUCT

These contents must be diluted with AAMI water prior to use.

Contains two containers. Each of the two containers has two liters of Renalin™ Concentrate

STORAGE

1. Renalin™ is a strong oxidizer.
2. Store in shipping carton.
3. Do not expose to direct sunlight.
4. Maintain temperature below 75°F (24°C).
5. Avoid contact with skin and eyes. Wear rubber gloves and goggles.
6. Avoid contact with combustible materials.
7. Avoid contamination from any source, including metals, dust, etc.

Such contamination may cause rapid decomposition, generation of large quantities of oxygen gas and high pressures.
8. Store in original closed container—NEVER TAMPER WITH VENT.
9. If spilled, flush away with large quantities of water.
10. Use AAMI quality water in all dialyzer reprocessing steps when using Renalin™

DISPOSAL

1. Do not contaminate water, food or feed by storage or disposal.
2. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.
3. Triple rinse empty container with water. Then offer container for recycling or reconditioning; or puncture and dispose of in a sanitary landfill; incinerate; or if allowed by state and local authorities, dispose of by burning. If burned, stay clear of the smoke.

Active ingredients

Hydrogen peroxide...24.0%
Peroxyacetic acid...4.0%
Inert ingredients.....72.0%
Total...100.0%

NET CONTENTS: 1.0 gal (4 liter)

CAUTION: Federal (U.S.A.) law restricts this device to use by or on the order of a physician.

LOT NO. ____________________________

CONCENTRATE

EXPIRATION DATE _____________________

/net contents/ 1.0 gal (4 liter)

For chemical emergency, spill, leak, fire, exposure and accident, call Chemtrec, day or night
(800) 424-9300.

Renal Systems Inc.

11925 38th Avenue North
Minneapolis, Minnesota 55441 U.S.A.
Telephone (612) 933-3300 Toll Free (800) 326-3340
Telex 29-0625 Renewable PLOCH

31/08/85
Label

Renalin™
Concentrate
For Use with HPR™ Machine
32 oz. container

Note: This product is for household use.

ACCEPTED
with COMMENTS
in EPA Letter Dated

JUL 10 1985
Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.

5280-8
COLD STERILANT FOR DIALYZER REPROCESSING

renalin™

DIALYZER REPROCESSING CONCENTRATE

Bottle contains 100 ml/8 fl oz. of Renalin™ Concentrate. These contents must be diluted with AMW water prior to use.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

READ PRECAUTIONARY STATEMENTS FOR USE AND TECHNICAL NOTES BEFORE USING THIS PRODUCT

DANGER

Renalin™ is a strong oxidizer. Avoid contact with skin and eyes. Wear rubber gloves and goggles when handling this product.

ACTIVE INGREDIENTS

Hydrogen peroxide .... 24.0%
Peroxycetic acid .... 4.0%
Inert ingredients .... 72.0%
Total .... 100%

Note: This product must be diluted with AMW water prior to use.

Caution: Federal (USA) law restricts this device to use by or on the order of a physician.

STORAGE

- Do not expose to direct sunlight.
- Maintain temperature below 75°F (24°C).
- Avoid contact with skin and eyes. Wear rubber gloves and goggles when handling.
- Do not use for reprocessing.
- Avoid contact with combustible materials.
- Avoid contamination from any source, including metals, dust, etc. Such contamination may cause rapid decomposition, generation of large quantities of oxygen gas and high pressures.
- Store in shipping carton and in original closed container - Never Tamper With Carton
- Ship only fresh with large quantities of water
- Use AMW quality water in all dialyzer reprocessing steps when using Renalin™.
- If concentrated Renalin™ in unitized bottle is not within % of concentrate as shown below DO NOT USE.

INSTRUCTIONS FOR USE

1. Use only with the HPM™ Dialyzer Reprocessor which is labeled for use with Renalin™.
2. Prior to dilution, ensure that the concentration level is within % each of the "Concentrable Range."
3. Dilute Renalin™ concentrate by filling dialyzer TM with AMW quality water. For information data in the indicated range of dilution. The diluted solution data is valid concentrate a specification date or seven (7) days, whichever is sooner.
4. Connect to HPM™ unit and follow instructions.

DISPOSAL

1. Do not contaminate water, food or feed by storage or disposal.
2. Wastes resulting from this use this product may be disposed of on-site or at an approved waste disposal facility.
3. Triple rinse empty container with water, then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, incinerator, or as allowed by state and local authorities dispose of by burning. If burned, stay clear of the smoke.

NET CONTENTS: 6 fl oz (177.4 ml)

renal systems inc.

1954 e 50th avenue f. m.
hamilton, ontario l8l 3h1

519.689.200

4707 0085

JUL 10 1985

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide approval under EPA Reg No.

192532-1

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide approval under EPA Reg No.

192532-1
Shipping Carton
Label

Renalin™
Concentrate
For Use with HPR™ Machine
32 oz. container
12 units per case

Note: This product is for household use.
COLD STERILANT FOR DIALYZER REPROCESSING SYSTEM ONLY.

READ RENALIN INSTRUCTIONS FOR USE AND TECHNICAL NOTES BEFORE USING THIS PRODUCT.

Case contains 12 bottles. Each bottle contains 180 milliliters of Renalin concentrate. These contents must be diluted with AAMI water prior to use.

STORAGE

1. Renalin" is a strong oxidizer.
2. Do not expose to direct sunlight.
3. Maintain temperature below 75°F (24°C).
4. Avoid contact with skin and eyes. Wear rubber gloves and goggles when handling either concentrated or diluted Renalin.
5. Avoid contact with combustible materials.

7. Avoid contamination from any source, including metals, dust, etc. Such contamination may cause rapid decomposition, generation of large quantities of oxygen gas and high pressures.
8. If spilled, flush away with large quantities of water.
9. Use AAMI quality water in all dialyzer reprocessing steps when using Renalin.

DISPOSAL

1. Do not reuse container.
2. Rinse thoroughly with water before discarding in the trash.
3. Securely wrap original container in several layers of newspaper and discard in trash.

Active ingredients
- Hydrogen peroxide...24.0%
- Peroxyacetic acid...4.0%
- Inert ingredients...72.0%
Total 100.0%

CAUTION: Federal (U.S.A) law restricts this device to use by or on the order of a physician.

Renal Systems Inc.
14955 29th Avenue North
Minneapolis, Minnesota 55441 USA
Telephone (612) 333-3300
Toll-Free (800) 328-3340

JUL 1
Under the Fe Pugicide, and
as amended.
reprinted and
1989

Active ingredient:
- Hydrogen peroxide...24.0%
- Peroxyacetic acid...4.0%
- Inert ingredients...72.0%
Total 100.0%

CAUTION: Federal (U.S.A) law restricts this device to use by or on the order of a physician.

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