

NOTICE OF PESTICIDE: REGISTRATION
 REREGISTRATION
(Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended)

TERM OF ISSUANCE

NAME OF PESTICIDE PRODUCT

Renalin™ Dialyzer Reprocessing
Concentrate

NAME AND ADDRESS OF REGISTRANT (Include ZIP code)

Renal Systems, Inc.
14905 28th Avenue North
Minneapolis, MN 55441

Attn: LeRoy J. Fishbach

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 with EPA, sec. 3(c)(5) provided that you:

1. Submit to EPA, within 90 days, all data required for registration/reregistration of your product under EPA sec. 3(c)(5) when the Agency receives all registrations of similar products to permit comparison.

2. Make the labeling changes listed below before you release the product for shipment:

a. Add the phrase "EPA Registration No. 52252-1" to your label before you release the product for shipment.

b. The required front panel precautionary labeling is "DANGER - Keep Out of Reach of Children". See other precautionary labeling on side panel.

BEST AVAILABLE COPY

ATTACHMENT IS APPLICABLE

SIGNATURE OF APPROVING OFFICIAL

DATE

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 (TS-767)

Enclosure

BEST AVAILABLE COPY

Label

Renalin™
Concentrate

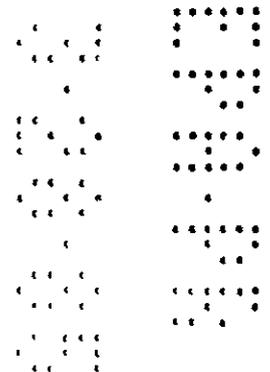
2.5 gallon container

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



11/21 # 52252-1 PN 31
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)

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

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)

5225-1-1131

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.

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.

5225-1

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

- | | |
|--|---|
| <ol style="list-style-type: none"> 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 | <ol style="list-style-type: none"> 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 diluted 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 burned, stay clear of the smoke.

BEST AVAILABLE COPY

11 #58-2-1 FM 31

203.0 a (2)

Shipping Carton
Label

Renalin™
Concentrate

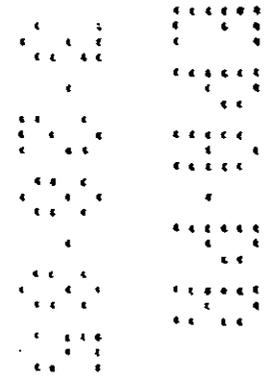
Twin Pack
(2 - 2-1/2 gallon containers)

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.

57252-1



1- # 52252-1 PM/31

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

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|--|--|
| 1. Renalin™ is a strong oxidizer. | Such contamination may cause rapid decomposition, generation of large quantities of oxygen gas and high pressures. |
| 2. Store in shipping carton. | |
| 3. Do not expose to direct sunlight. | |
| 4. Maintain temperature below 75°F (24°C). | 8. Store in original closed container— NEVER TAMPER WITH VENT. |
| 5. Avoid contact with skin and eyes. Wear rubber gloves and goggles. | 9. If spilled, flush away with large quantities of water. |
| 6. Avoid contact with combustible materials. | |
| 7. Avoid contamination from any source, including metals, dust, etc. | 10. Use AAMI quality water in all dialyzer reprocessing steps when using Renalin.™ |

DISPOSAL

- Do not contaminate water, food or feed by storage or disposal.
- Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.
- 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%

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JUL 10 1985

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

NET CONTENTS: 1.06 gal (4 liter)

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

52252-1

LOT NO. _____

CONCENTRATE
EXPIRATION DATE _____

For chemical emergency, spill, leak, fire, exposure and accident, call Chemtrec, day or night

(800) 424-9300.

In District of Columbia or Outside Continental U.S.A. Call:
(202) 462-7618



renal systems inc.
1905 28th Avenue North
Minneapolis, Minnesota 55441 U.S.A.
Telephone (612) 553-3300 Toll Free (800) 328-5340
Telex 29-0625 RENAPLS PLOH

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.

52252-1

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COLD STERILANT FOR DIALYZER REPROCESSING

renalin™

DIALYZER REPROCESSING CONCENTRATE

Bottle contains 180 milliliters of Renalin™ Concentrate.
These contents must be diluted with AAMI water prior to use.

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.

STORAGE

1. Do not expose to direct sunlight.
2. Maintain temperature below 75°F (24°C).
3. Avoid contact with skin and eyes. Wear rubber gloves and goggles when handling.
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 shipping carton and in original closed container — Never Pump! With Vent!
7. If spilled, flush away with large quantities of water.
8. Use AAMI quality water in all dialyzer reprocessing steps when using Renalin™.
9. If concentrated Renalin™ in unopened bottle is not within 1/8 inch of concentrate line shown below, DO NOT USE.
10. For chemical emergency, spill, leak, fire, exposure and medical, call Chemtrec, day or night (800) 424-9300. IN DISTRICT OF COLUMBIA AND OUTSIDE CONTINENTAL U.S.A. (202) 462-7614.

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

Active Ingredients	
Hydrogen peroxide....	24.0%
Peroxyacetic acid....	4.0%
Inert ingredients.....	72.0%
Total	100%

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: 6 fl oz (177.4 ml)



renal systems inc.

14995 20th Avenue N. W.
Minneapolis, Minnesota 55411 (754)
Telephone (612) 553-3700 Fax (612) 553-3340

INSTRUCTIONS FOR USE

1. Use only with the HPR™ Dialyzer Reprocessor which is labeled for use with Renalin™.
2. Prior to dilution, ensure that the concentrate level is within 1/8 inch of the "concentrate" label.
3. Dilute Renalin™ concentrate by filling the "W" line with AAMI quality water. Fill to expiration date in the indicated space of the dilution. The diluted expiration date is either concentrate's expiration date or seven days dilution, whichever is sooner.
4. Connect to HPR™ uptake hose and follow instructions.

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 burned, stay clear of the smoke.

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REGISTERED
with COMMENTS
to EPA Letter Dated:

JUL 10 1985

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

52252-1

renalin

DIALYZER REPROCESSING CONCENTRATE

COLD STERILANT FOR DIALYZER REPROCESSING
FOR USE WITH HPR™ 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
6. Store in shipping carton and in original closed container —
Never Tamper With Vent.
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%

NET CONTENTS: 72 fl oz (2.13 liter)

Lot No. _____
Expiration Date _____



renal systems inc.

14915 29th Avenue North
Minneapolis, Minnesota 55441 USA
Telephone (612) 553 3300 Tele Fax (800) 328 3340

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

For chemical emergency spill
leak, fire, exposure and information
call Chemtrec, day or night
(800) 424-9300.
IN DISTRICT OF COLUMBIA AND
OUTSIDE CONTINENTAL U S A
(202) 462 7010

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in EPA L

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Under the F
Fungicide, an
as amended,
registered use

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