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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 NO. | DATE OF ISSUANCE |
|---|---|
| 59665-1 | JUN 17 1994 |
| TERM OF ISSUANCE | JUN 17 1994 |

NAME OF PESTICIDE PRODUCT

Puristeril 340 Concentrate

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

Fresenius USA Inc
2637 Shadelands Dr
Walnut Creek, CA 94598

**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/cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

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

a. Add the phrase "EPA Registration No. 59665-1".

b. Place the signal word: Danger to appear directly below and centered under the heading: Keep Out of Reach of Children.

c. Include the appropriate EPA Est No.

d. Include the full company name on the label.

e. Include the correct full address as above onto the label.

[X] ATTACHMENT IS APPLICABLE

| SIGNATURE OF APPROVING OFFICIAL | DATE |
|---|---|
| | |

EPA Form 8570-6 (Rev. 5-76) PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



f. Revise the statement: "...read instructions for use before using..." to read: "...Read Directions for use before using..."

g. A statement in the Manual Sterilization section states: "...clean and rinse the dialyzer as described in Point 3 above... ". This reference should be corrected to identify the correct location of these cleaning/rinsing instructions.

h. Clearly indicate the major areas in which the product is recommended for use: eg. Hospitals.

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,

Marshall Swindell
Acting Product Manager (31)
Antimicrobial Program Branch
Registration Division (H7505C)

| | CONCURRENCES | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| SYMBOL | | | | | | | | |
| SURNAME | | | | | | | | |
| DATE | | | | | | | | |



*U.S. Government Printing Office: 1992 — 820-856/40672

# PURISTERIL™ 340 CONCENTRATE

## COLD STERILANT FOR DIALYZER REPROCESSING

**IMPORTANT: READ INSTRUCTIONS FOR USE BEFORE USING THIS PRODUCT**

This concentrated product must be diluted with water that meets AAMI standards for Reuse (1986) and Hemodialysis (RD5).

| ACTIVE INGREDIENTS | |
|---|---|
| Peroxyacetic acid | 3.5% |
| Hydrogen peroxide | 26.0% |
| INERT INGREDIENTS | 70.5% |
| Total | 100.0% |

NET CONTENTS 11.023 POUNDS (5kg)
EPA Reg. No.:
EPA Est. No.:
Lot No.:
Exp. Date:

**DANGER** **KEEP OUT OF REACH OF CHILDREN**

**PELIGRO** PRECAUCION AL USARIO: SI usted no lee ingles, no use este producto hasta que le etiqueta haya sido explicado ampliamente.

**STATEMENT OF PRACTICAL TREATMENT** If swallowed, drink water immediately to dilute; do not attempt to cause vomiting. Call physician immediately. 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. See back panel for additional precautionary statements.

**NOTE TO PHYSICIAN** Probable mucosal damage may contraindicate the use of gastric lavage.

**FRESENIUS**
4090 Pike Lane
Concord, California 94520

Telephone (510) 676-1600
Telefax (510) 686-3579

FRONT LABEL

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JUN 17 1994

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 59665-1

# STORAGE AND DISPOSAL

## STORAGE

1. Store Puristeril™ 340 in shipping carton and keep sealed in original containers. **NEVER TAMPER WITH VENT.**
2. Store in upright position.
3. Do not expose to direct sunlight.
4. Store in cool, well-ventilated rooms.
5. Maintain temperature below 75°F (24°C), but do not freeze.
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 pressure.
8. The expiration date of AAMI quality water diluted Puristeril™ 340 is eight (8) days after dilution.
9. Expiration date of Puristeril™ 340 concentrate: see front panel.
10. For chemical emergency, spill, leak, fire, exposure and accident, call Chemtrec, day or night (800) 424-9300. In the District of Columbia or outside the continental US, call (202) 483-7616.

## DISPOSAL

**Pesticide 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.

**Container Disposal**

1. Triple rinse empty container with water. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning.
2. If container is burned, stay out of smoke.

**FRESENIUS**
4090 Pike Lane
Concord, California 94520
Telephone (510) 676-1600
Telefax (510) 686-3579

ACCEPTED
with COMMENTS
In EPA Letter Dated:
JUN 17 1994
Under the Pesticide Registration

SIDE LABEL

S9665-1

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## PURISTERIL™ 340 CONCENTRATE
## PRECAUTIONARY STATEMENTS - HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER CORROSIVE. KEEP OUT OF REACH OF CHILDREN. Causes eye and skin damage. Do not get in eyes, on skin or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. Avoid contamination of food. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. Always dilute spilled Puristeril™ 340 with water. Mop up with cleaning cloth and rinse under running water. Do not mop up residues with paper or cellulose tissues or other combustible materials. Do not heat Puristeril™ 340.

## DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.
Read Instructions for Use before using this product.
For use with dialyzer reprocessing machines intended for use with peroxyacetic acid as the cleaner and/or sterilant.
Also for sanitization and cleaning of dialysate delivery systems.
Dissolves bicarbonate precipitation.
Clinical use of reprocessed dialyzers is the sole responsibility of the attending physician.
Puristeril™ 340 concentrate must be diluted with water that meets AAMI standards for reuse and dialysis prior to use.
Do not reuse solution. Discard unused, diluted Puristeril™ 340 solution after eight (8) days.
Do not return used fluid or concentrate from other containers into the Puristeril™ 340 container.
For all cleaning procedures, consult the manufacturer of dialyzer reprocessing machines and dialysate delivery equipment for material compatibility with peroxyacetic acid, hydrogen peroxide, and acetic acid.

**Sterilization of Hemodialyzers with Reprocessing Machines**
For sterilization of dialyzers with reprocessing machines, follow the machine instructions of the respective manufacturer. Clean the dialyzer and rinse any cleaning agent thoroughly. Do not reuse dialyzers with less than 80% of the original total blood volume (TBV). Fill the dialyzer completely with machine diluted 3% Puristeril™ 340 (filled dialyzer must contain 0.1% peroxyacetic acid). Total dilution is 4 oz. (117 cc) of Puristeril™ 340 with 1 gallon of water. Recommended minimum contact time is ten (10) hours. Test the dialyzer for presence of germicide solution before rinsing it. Puristeril™ 340 solution must be rinsed from the blood side of the dialyzer with sterile saline prior to initiating dialysis. Rinse the dialysate side by connecting dialyzer to the dialysate delivery machine. Using aseptic technique, test a small sample of liquid from the venous side with Puristeril™ 340 residual test strips to determine if sterilant residual less than 3 ppm (discoloration indicates presence of Puristeril™ 340).

**Manual Sterilization of Hemodialyzers**
For sterilization of dialyzers using a manual reprocessing system, produce a 4% Puristeril™ 340 solution (e.g. 5.3 oz. or 160 cc Puristeril™ 340 concentrate well mixed with 1 gallon of water that meets AAMI standards). Clean and rinse the dialyzer as described in Point 3 above. Fill both blood and dialysate sides of the dialyzer completely, allowing for dilution of the sterilant during filling. Follow the remaining instructions as described above.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JUN 17 1994

Under the [illegible]
registered under [illegible]

S9665-1

BACK LABEL

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