PM 32 69251-1 7/17/97 1/4

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (H7505C)
401 "M" St., S.W.
Washington, D.C. 20460

NOTICE OF PESTICIDE:
x Registration
____ Reregistration

(under FIFRA, as amended)

| EPA Reg. Number: | Date of Issuance: |
|---|---|
| 69251-1 | JUL 17 [illegible] |

Term of Issuance:
Time Limited - Expires July 17, 1999

Name of Pesticide Product:
ViraVac In-Line Disinfectant System

Name and Address of Registrant (include ZIP Code):
Viatro Corporation
6779 Engle Road
Cleveland, Ohio 44130

**Note:** Changes in labeling 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 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.

Registration is in no way to be construed as an endorsement or recommendation of this product by the 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 registered in accordance with FIFRA sec. 3(c)(5) and is subject to the following terms:

1. This registration shall expire on July 17, 1999 without opportunity for hearing.

2. EPA may, by order and without opportunity for hearing, cancel this registration prior to July 17, 1999 if the Agency determines, based upon comments submitted pursuant to section 3(c)(4) of FIFRA, or upon any other information, that this product no longer meets the requirements of section 3(c)(5).

3. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 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.

| Signature of Approving Official: | Date: |
|---|---|
| [signature] | 7/17/96 |

EPA Form 8570-6

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4. Labeling:

The Agency considers the label attached to the product, as the label of record. The circular has not been reviewed or accepted as part of the label.

a. Revise the EPA Registration Number to read, "EPA Reg. No. 69251-1".

b. The Agency does not allow disinfection claims for medical waste. Therefore, change the product name "ViraVac' In-Line Disinfection System" to read "Vira Vac' In-line Sanitization System" and also change "Disinfection to read "sanitization" wherever it appears on the label.

c. You must submit by December 17, 1997 the completed efficacy testing on the additional two batches. Studies must be conducted on two additional samples from two different batches one of which must be at least 60 days old (shelf-life) against each test organism. If the study can not be made acceptable for this product, then the product will need to be canceled under the conditions identified in item #2.

d. In the Ingredient statement align the decimal points so that the percentages add up to 100%.

| Active Ingredient(s) | |
|---|---|
| Name of the ingredient ..... | ___% |
| Inert Ingredients ..... | ___% |
| TOTAL | 100% |

e. Add the heading "Hazards to Humans and Domestic Animals" underneath the "Precautionary Statements".

f. Place the following statement on the attached label the "Environmental Hazards" Statement.

"This pesticide is toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA".

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5. Submit two copies of the revised final printed label for the record.

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.

Robert S. Brennis
Acting Product Manager (32)
Regulatory Management Branch II
Antimicrobials Division (7504C)

# Border for placement only

**PRECAUTIONS:**

- CORROSIVE: Causes eye damage and skin irritation. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Avoid contamination of food. Wear goggles and gloves when handling. Avoid breathing fumes or vapors. Wash thoroughly with soap and water after handling. Remove and wash contaminated clothing before reuse.
- WEAR HAND AND EYE PROTECTION WHEN HANDLING POTENTIALLY INFECTIOUS WASTE.
- NOT FOR INTERNAL USE.
- ENVIRONMENTAL HAZARDS: see attached circular.

**STORAGE AND DISPOSAL:**

Do not store below 0°F for extended periods. Do not contaminate water, food or feed by storage or disposal. Pesticide wastes are acutely hazardous. Improper disposal of excess pesticides, spray mixture or rinsate is a violation of Federal Law. If wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance. Triple rinse.

Lot No.

EPA Est. No. 69251 EPA Reg. No.

ViAtro

# ViraVac™

## In-line Disinfection System

Disinfect 6,000 cc

Active Ingredients:

| | |
|---|---|
| Iodine | 3.50% |
| Phosphoric Acid | 24.70% |
| Inert Ingredients | 71.80% |
| Total | 100.00% |

Net Contents 500 ml.

KEEP OUT OF REACH OF CHILDREN

# DANGER

**See side panel and attached circular for additional precautionary statements and direction for use.**

STATEMENT OF PRACTICAL TREATMENT:

**If swallowed:** drink large quantity of water promptly. No not induce vomiting. Avoid alcohol. Get medical attention.

**If in eyes:** flush with water for 15 minutes. Get medical attention.

**If on skin:** wash with soap and water. Get medical attention if irritation persists.

**Note to physician:** probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

**Distributed by: ViAtro, Corp.**
**6779 Engle Road, Cleveland, Ohio 44130**

**DIRECTIONS FOR USE:**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. **Read entire attached circular before assembly, application and disposal of the device.**

- For Institutional Healthcare use ONLY.
- This disinfectant must be used ONLY with ViraVac valve supplied in the package according to the attached instructions.
- DO NOT shake the bottle or turn upside down after the valve is installed.
- DO NOT remove valve after use.
- DO NOT attempt to reuse any part of the ViraVac System.

**GERMICIDAL:**

The ViraVac Germicide has been tested and is effective against Pseudomonas Aeruginosa, Streptococcus Feacalis, Staphylococcus Aureus and Escherichia Coli , and in whole blood when exposed to 1:12 disinfectant solution for 30 minutes at 20°C (68°F).

**VIRUCIDAL:**

The human HIV-1 virus (associated with AIDS) was completely inactivated when exposed to 1:12 disinfectant solution for 30 minutes at 20°C (68°F).

Patent #4,855,064

ACCEPTED
with COMMENT
In EPA Letter Date

JUL 17 1997

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

69251-1

RECD EPA/OPP/DPD1
'96 AUG 16 P2:39