

69340-6

4-17-2002

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

EPA Reg. Number:

Date of Issuance:

69340-6

APR 17 2002

Term of Issuance:

Conditional

Name of Pesticide Product:

EOGas AN-1006

NOTICE OF PESTICIDE:

- Registration
 Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Andersen Sterilizers, Inc.
3154 Caroline Drive
Haw River, NC 27258

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 conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. 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.
2. Make the following label changes:
 - a. Revise the EPA Registration Number to read, "EPA Reg. No. 69340-~~6~~".
 - b. Revise the "Statements of Practical Treatment" to comply with PR Notice 2001-1 to state the following:
 1. Revise the heading "Statements of Practical Treatment to read "First Aid Statements."
 2. The statement, "Have the product container or label with you when going for treatment," must be added after the "In all cases of exposurefacility" statements.
 3. IF IN EYES: Hold eyes open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes then continue rinsing eye. Get medical treatment.

Signature of Approving Official:

Velma Noble
Velma Noble

Product Manager 31
Regulatory Management Branch I
Antimicrobials Division (7510C)

Date:

APR 17 2002

4. IF INHALED: Get exposed person to fresh air. Keep warm. *If not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.* If breathing is difficult, give oxygen. Call a physician even if no symptoms are present. Keep under medical observation. Symptoms may be delayed.

5. All product labels are required to list a hot line number that consumers may call for additional emergency advice. It should appear either immediately after or before the "first aid statements."

c. Revise the "Precautionary Labeling" to read "DANGER. Causes irreversible eye damage and skin burns. Harmful if inhaled. Do not breath vapor. Do not get on eyes, skin, or clothing. Do not swallow. Cancer Hazard and Reproductive Hazard. May cause nervous system damage. Store and use with adequate ventilation in accordance with 29 CFR 1910.1047."

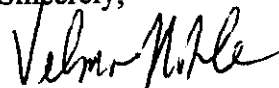
d. Under "Physical/Chemical Hazards," add the following in all capital letters, "DANGER. FLAMMABLE LIQUID AND GAS UNDER PRESSURE."

3. Submit two (2) 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 this product constitutes acceptance of these conditions.

A stamped label is enclosed for your records. If you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510C)

AN 1006

ONE KIT

CONTENTS: 25 Cartridges, 25 Liner Bags, 25 Dosimeters®, 25 Humidichips®. Each AN1006 cartridge contains 0.39 av. oz. (11.00 g) EOGas sterilant.

ANDERSEN Ⓢ STERILIZERS, INC.

Manufactured and Distributed by:

ANDERSEN STERILIZERS, INC.
3154 Caroline Drive • Haw River, NC 27258 USA
336-376-8622

Distributed by:

ANDERSEN PRODUCTS, INC.
3202 Caroline Drive • Haw River, NC 27258 USA
1-800-523-1276 • 336-376-3000
www.anpro.com • mailbox@anpro.com

European Distributor:

H. W. ANDERSEN PRODUCTS, LTD.
Clacton-On-Sea • Essex CO15 4XA UK

EPA Registration No. 69340-4
EPA Establishment No. 9417-NC-001



CE 0413

KEEP OUT OF REACH OF CHILDREN DANGER

IMPORTANT: FOR PROFESSIONAL USE ONLY

Users must follow the requirements of the OSHA occupational exposure standard for Ethylene oxide (29 CFR 1910.1047).

Active ingredient: Ethylene oxide 96.0%
Inert ingredient: 4.0%
Total: 100.0%

PRECAUTIONARY STATEMENTS

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS.
DANGER! CANCER HAZARD AND REPRODUCTIVE HAZARD.
CAUSES IRREVERSIBLE EYE DAMAGE AND SKIN BURNS.
HARMFUL IF INHALED. MAY CAUSE NERVOUS SYSTEM
DAMAGE. DO NOT GET IN EYES, SKIN, OR ON CLOTHING.
STORE AND USE WITH ADEQUATE VENTILATION.**

See user's manual for additional precautionary statements.

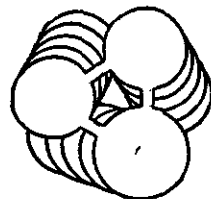
STATEMENT OF PRACTICAL TREATMENT

In all cases of exposure, get medical attention immediately. Take person to a doctor or emergency treatment facility.

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for at least 15 minutes.

IF INHALED: Get exposed person to fresh air. Keep warm. Make sure person can breathe freely. If breathing is difficult, give oxygen. Call a physician even if no symptoms are present. Keep under medical observation. Symptoms may be delayed. If breathing has stopped, give artificial respiration. Do not give anything by mouth to an unconscious person.

IF ON SKIN: Immediately wash skin with plenty of water while removing contaminated clothing and shoes. Call a physician. Aerate, wash, and discard contaminated clothing and discard leather goods.



EOGas

Dosimeter®, EOGas®, and Humidichip® are trademarks of Andersen Products, Inc.
EOGas U.S. Pat. no. 4,937,046 and 5,160,700. Humidichip U.S. Pat. no. 5,082,638

ACCEPTED
with COMMENTS TM
in EPA Letter Dated:
APR 17 2002
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.
69340-4

IF SWALLOWED: Drink at least two glasses of water. Do not induce vomiting. Do not give anything by mouth to an unconscious victim. Call a physician.

NOTE TO PHYSICIAN

Ethylene oxide is a gas. Skin exposure from contact with fabric, rubber or plastic containing residual ethylene oxide will commonly result in skin irritation with extensive blister formation. At high concentrations severe conjunctivitis can occur. Irritation of the respiratory tract may occur, but without acute lung edema. Symptoms of systemic intoxication are headache, nausea, vomiting, incoordination, and cardiac irregularities. Treatment is symptomatic.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Discharge Eliminations System (NDPES) 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 local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

PHYSICAL OR CHEMICAL HAZARDS

Ethylene oxide gas is extremely flammable. Do not use near flame, electrical sparks, or hot surfaces. Ground and bond to prevent static sparks.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. It is the responsibility of the employer of any person engaged in the handling or application of this product to follow the requirements of 29 CFR 1910.1047. To be used only in an EOGas sterilizer for hospital, medical, and veterinary sterilization. Read package insert for complete sterilization instructions and additional precautions.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

STORAGE: Store in a cool place and out of direct sunlight.

PESTICIDE DISPOSAL: Unwanted or expired EOGas cartridges should be returned to the manufacturer for disposal. Contact Andersen Products, Inc. (tel. no. 336-376-3000) for instructions. If unwanted or expired EOGas cartridges cannot be disposed of 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.

CONTAINER DISPOSAL: Do not reuse empty box, used cartridge, or used liner bags. Wrap box, cartridge, and liner bags in paper and discard in the trash.

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