

69340-7

1-5-2006

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U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs  
Antimicrobials Division (7510C)  
1200 Pennsylvania Ave, NW  
Washington, D.C. 20460

EPA Reg. Number:

Date of Issuance:

69340-7

JAN 5 2006

Term of Issuance:

Conditional

Name of Pesticide Product:

AN1004 EOGas 4

## NOTICE OF PESTICIDE:

Registration  
 Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Mr. John Lindley  
Andersen Sterilizers  
Health Science Park  
3154 Caroline Dr  
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. 69340-7".
  - b. Under the "Precautionary Statements," delete "may" from the first statement. It must read "Causes irreversible eye damage and skin burns."
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.

Signature of Approving Official:

*Velma Noble*  
Velma Noble

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

Date:

JAN 5 2006

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ACCEPTED WITH COMMENTS in EPA Letter Dated:

JAN 5 2006

Under the Federal Insecticide, Fungicide, and Rodenticide Act, registered under EPA Reg. No. 60740-7

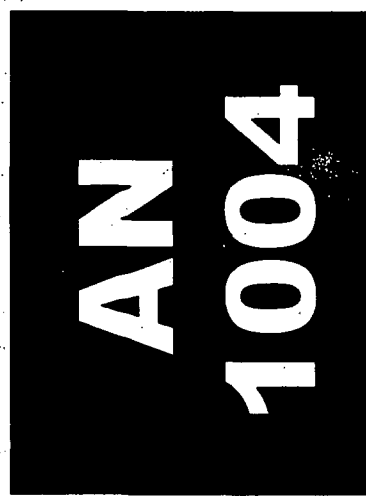
# EOGas 4® REFILL KIT

Dosimeters® and Humidichip® are trademarks of Andersen Products, Inc. EOGas 4® is a registered trademark of Andersen Sterilizers, Inc. EOGas U.S. Pat no. 4,837,048 and 5,160,700. Humidichip U.S. Pat no. 5,082,638

**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 ..... 97.0%  
Inert ingredient: ..... 3.0%



ONE EOGas 4 REFILL KIT

CONTENTS: 25 Cartridges, 25 Sterilization Bags, 25 Dosimeters®, 25 Humidichips®  
Each AN1004 cartridge contains 0.62 av. oz. (17.5 g) Ethylene oxide



Manufactured and Distributed by:  
**ANDERSEN STERILIZERS, INC.**  
3154 Caroline Drive • Haw River, NC 27258 USA  
338-378-8622

Distributed by:  
**ANDERSEN PRODUCTS, INC.**  
3202 Caroline Drive • Haw River, NC 27258 USA  
1-800-623-1276 • 338-378-3000  
www.enpro.com mailbox@enpro.com

European Distributor:  
**H. W. ANDERSEN PRODUCTS, LTD.**  
Clacton-On-Sea • Essex CO15 7AA UK  
+44-1255-42333

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**IF ON SKIN:** Immediately wash skin with plenty of water while removing contaminated clothing and shoes. Call a physician. Aerate, wash, or clean contaminated clothing and air leather goods for 24 hours at 20° C.

**IF SMALL SPILLS:** 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, lack of coordination, 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 Elimination System (NDES) 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.

**DANGER, FLAMMABLE LIQUID AND GAS UNDER PRESSURE**

Ethylene oxide gas is extremely flammable. Do not use near flames, electrical sparks, or hot surfaces. Ground all equipment to prevent static sparks.

To be used only in EOGas Series 4 sterilizers, and only for hospital, medical and veterinary sterilization.

**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. Read package insert for complete sterilization instructions and additional precautions.

**STORAGE AND DISPOSAL**

Do not concentrate water, food, or feed by storage or disposal. Store in a cool place and out of direct sunlight.

**PERIODE DISPOSAL:** Unvented or expired EOGas cartridges should be returned to the manufacturer for disposal. Contact Andersen Products, Inc. (tel. no. 338-378-3000) for instructions. If unvented 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:** Wrap box, cartridge, and liner bags in paper and discard with usual rubbish.

Version: 08/20/2005

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

JAN 5 2006  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No.

69346-7

REMOVE TAPE AND TRIGGER GUARD, IMMEDIATELY PLACE INSIDE STERILIZATION BAG

**AN1004**

Users must follow requirements of the OSHA Occupational Exposure Standard for Ethylene Oxide (29 CFR 1910.1047). Use only in an Andersen EDGas Series 4 Sterilizer with a EDGas 4B Liner Bag and according to the manufacturer's instructions. See outer box and package insert for additional precautions and sterilization instructions.

Active Ingredient: Ethylene Oxide.....97%  
Other Ingredient.....3%  
Net Contents: 0.39 av. oz. (11.5 g)

**DANGER**  
**KEEP OUT OF REACH OF CHILDREN**  
**CONTENTS FLAMMABLE**  
**DO NOT OPEN CARTRIDGE**

**DISPOSE OF EMPTY EDGAS CARTRIDGE IN ORDINARY TRASH**

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LOT NO.

USE  
BEFORE

Manufactured by: Andersen Sterilizers, Inc. • Health Science Park • New River, NC 27288 U.S.A.  
Distributed by: Andersen Products, Inc. • Health Science Park • New River, NC 27288 U.S.A.  
Distributed in Europe by: H. W. Andersen Products Ltd. • Clacton-On-Sea • Essex CO16 4JA U.K.  
EPA Registration No. 69340-6 • EPA Est. No. 69340-NC-001 • U.S. Patent No. 4,837,045 & 5,160,700

Version 091805

**NEVER PRESS BUTTON TO ACTIVATE CARTRIDGE OUTSIDE CLOSED STERILIZATION BAG**

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# Directions for Use: EOGas 4® Cartridges Catalog Number AN1004

**Emergency Contact: 1-800-255-3924**

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.

## CAUTION DANGER

**Do not remove the trigger guard until just before you place the cartridge in the sterilization liner bag.**

**Never depress button to activate cartridge outside sealed sterilization liner bag.**

To be used only in an EO Gas 4 Sterilizer for hospital, medical, and veterinary gas sterilization. Before using, read sterilizer Owner's Manual for complete sterilization instructions and additional precautions.

### Typical Products which may be Processed in an EO Gas 4 Sterilizer:

- Adhesive tape
- Airways - plastic, rubber, metal and separately wrapped to avoid a spark), battery cases, bulbs
- Anesthesia equipment - endotracheal tubes, masks, rubber tubing
- Bandages, dressing sets (reuse plastic forceps)
- Bronchoscopes, gastroscopes, fiberscopes of all kinds
- Catheters - plastic, rubber, cloth
- Dry cell batteries (must be removed from the instrument)
- Electric wire - whether autoclavable or not
- Electrical equipment - whether autoclavable or not
- Fabric - cloth, rubber, plastic, leather
- Gloves - rubber, plastic, cloth
- High speed steel - drills, burrs, chisels
- Optical instruments - scopes, cameras, lenses, mirrors
- Painted equipment - metal, wood
- Procedure Trays
- Rectal tubes, douché tubes - rubber, plastic
- Respirators, corrugated tubing
- Specula - plastic, metal
- Surgical instruments - steel, chrome plate, brass, plastic
- Sutures - plastic, silk, cotton, stainless steel
- Syringes - plastic, rubber, glass, bulb syringes
- Tongue depressors, applicator sticks
- Tubing - plastic, rubber, metal, glass, cloth

### Preparation of Material for Sterilization

Material to be sterilized by Ethylene Oxide must be meticulously cleaned and dried. Coatings of dry protein, like dry pus, blood or feces, protect microorganisms and slow the sterilization process. You must always be sure to take the following precautions before sterilizing with EO Gas 4®:

1. Disassemble and scrub all instruments in detergent and water to the most critical standard of cleanliness possible.
2. Be sure that items to be sterilized are physically dry before wrapping and processing. Towel drying or draining dry is sufficient. Water on instruments at the time of exposure to Ethylene Oxide may react with the gas and reduce its

effectiveness.

3. Although Ethylene Oxide is a highly diffusible gaseous sterilant, occlusive caps, plugs or stylets must be removed from instruments so that the gas can penetrate freely. Hollow bore needles and plastic or rubber tubing must be open and free from plugs. Syringes must be packaged disassembled with the plungers out of the barrels.

If the nature of the material to be sterilized is such that the water treatments specified above are harmful and there is doubt as to the level of humidity in which they have been stored (35% is the minimum acceptable storage humidity), then pretreatment in a sterilization liner bag having a saturated humidity will be necessary for an overall pretreatment routine of 12 hours. Use the following procedure:

**HUMIDICHIP®** - To humidify the contents of the sterilization liner bag, wrap the items individually in paper or cloth in the usual manner. Place them in a sterilization liner bag along with a Humidichip and an EOGas 4 cartridge. Do not activate the cartridge yet. Place the purge tube into the sterilization liner bag and, using the Velcro strap, close the neck of the bag securely around the purge bobbin. After 12 hours at a minimum temperature of 70°F (20°C), the sterilization cycle may be started normally.

You must wrap all items individually in cloth or paper in the manner conventional for steam sterilization or in ANPRO SEAL AND PEEL® Packaging.

ANPRO Seal and Peel Packaging offers a see-through, peel open, extended shelf life package, proven and designed to be compatible with the EOGas 4 Sterilization System. No other plastic film packaging material may be used with EOGas unless the user first carefully tests the material to be sure that Ethylene Oxide can penetrate the material adequately. Polyamide (Nylon) and polyester (Mylar) films and aluminum foil are known to be inappropriate to use with Ethylene Oxide.

Do not pack the sterilization liner bag so tightly that gas diffusion may be slowed. The gas must have unrestricted access to all areas of the load.

### **Sterilization Method with EOGas 4**

Be certain that all items have been prepared as described above.

Refer to the Owner's Manual for detailed operating instructions for the sterilizer.

Abbreviated operating instructions for EOGas 4 sterilizers:

Remove one **DOSIMETER®** and cycle card from the dispenser box. Write the date and time sterilization will begin and the date and time sterilization and aeration will be complete on the label. Attach the Dosimeter to its card. Take one sterilization liner bag from the EOGas 4 dispenser box. Use a new EOGas 4 sterilization liner bag for each cycle. Place the wrapped items to be sterilized into the sterilization liner bag along with one AN-1071 Humidichip and the Dosimeter indicator card. Place the Dosimeter card so that it can be easily seen through the top of the bag. Place the Humidichip in the bottom of the bag so that it will be nearest to the metal shelf.

Select one AN 1004 cartridge from the dispenser box. Remove the cartridge trigger guard. Place the EOGas cartridge into the sterilization liner bag. Securely attach the purge probe bobbin to the mouth of the sterilization liner bag using the Velcro strap provided. If the sterilizer is equipped with a label printer, attach the printed pre-cycle label to the external surface of the sterilization liner bag. If a multiple-bag sterilizer is being used and already has some loaded bags, purge the sterilizer prior to loading the bag. Open the door to the sterilizer, place the sterilization liner bag on the shelf and connect the purge probe to the purge tubing using the quick connect fitting provided.

Once the bag is connected, start the purge cycle. When the purge is complete as indicated by the display on the front of the sterilizer cabinet, grasp the cartridge through the sterilization liner bag and press the trigger button firmly. Press it all the way so that the head of the trigger reaches the cartridge wall. This action releases the gas from the cartridge into the sterilization liner bag. Close the door securely and select the cycle length. The door to the sterilizer will lock automatically.

Leave the sterilization liner bag undisturbed in the sterilizer cabinet for the sterilization and bag ventilation cycles, after which the sterilization liner bag may be removed and opened.

After the sterile material has been removed from the sterilization liner bag, wrap the empty cartridge and bag in paper and discard in the trash.

## Important - Variations from these instructions

Any deviation from the procedures recommended in these instructions is made solely at the users' risk. EOGas 4 cartridges are designed to be used only in the sterilization liner bags provided in the AN1004 EOGas 4 refill kit and should be used exclusively in a genuine EOGas 4 sterilizer. You may not reuse any EOGas sterilization liner bag.

## Technical description of the system

The EOGas Sterilizer cabinet is maintained at an internal temperature of 50°C. The machine may also be configured for a 'room temperature' 30°C cycle if needed.

The sterilization liner bag retains Ethylene Oxide until it is actively purged from the bag and vented to the outside atmosphere or absorbed in an Andersen Abator™, specifically designed to be compatible with an EOGas 4 sterilizer.

The AN1071 Humidichip will help maintain adequate relative humidity in the sterilization liner bag during the cycle.

The EOGas cartridge will deliver a dose of at least 500 milligrams per liter hours to the contents of the sterilization liner bag. Tests in our laboratory confirm that this dose will kill the most resistant spores known at 50°C within the sterilization cycle providing that the spores have not been dehydrated or have been rehydrated according to our instructions. The 3 hour sterilization cycle at 50°C is suitable for most loads. The 5 hour sterilization cycle is used for lumens narrower than 2 millimeters diameter or longer than 90cm (3 feet) or for loads with large quantities of gas absorbent items (such as plastic tubing or paper).

The Dosimeter will indicate the actual dose of Ethylene Oxide delivered by the EOGas cartridge. A blue color change reaching the triangle on the Dosimeter scale indicates that a dose of Ethylene Oxide, usually adequate for sterilization, has been delivered.

## Testing the Efficacy of the EOGas Sterilizer

Monitoring sterilization efficacy is extremely important. The EOGas AN-1087 Dosimeter, placed in the most inaccessible part of the load, will verify whether or not the gaseous sterilant penetrated to the core of the load in adequate concentration to assure sterilization. In addition, an appropriate biological control, such as the EOGas AN1080 **STERITEST**®, should be used at least once per month to challenge the procedure and any time packaging is changed.

**Humidification:** Vacuum dehydration, chemical desiccation or prolonged exposure to ambient relative humidity below 35% have been demonstrated to produce spores highly resistant to sterilization by Ethylene Oxide. Rehydration of spores so changed, and hence reversion to normal sensitivity, does not seem to occur until they have been actually wetted or placed in a 100% relative humidity atmosphere. Do not attempt to sterilize materials which may be carrying dried spores without first washing the articles with water and detergents. If the nature of the material is such that the water treatments specified above are harmful, then pretreatment in a chamber having a saturated humidity at 20°C will be necessary for an overall pretreatment routine of at least 12 hours.

**Aeration:** It is incumbent on the user to confirm that a gas absorbent item, sterilized in Ethylene Oxide, has been adequately aired before it contacts living tissue. This is a particularly important warning to those using plastic or rubber items that directly contact tissue culture preparations, ova, semen or embryos.

Failure to adequately air Ethylene Oxide absorbing materials may lead to contact chemical burns. The 3 hour sterilization cycle and 30 minute ventilation at 50°C called for in these instructions includes an adequate amount of time to air items that do not absorb Ethylene Oxide. This includes all glass and metal items such as instruments, glass syringes and needles. Many plastic items absorb Ethylene Oxide, such as plastic tubing and anesthesia masks. These items, as well as large gas absorbent items such as silicone breast implants and plastic extracorporeal blood filters will require additional aeration before they can be safely implanted or used.

Aeration may be accomplished inside or outside the sterilization liner bag. If the sterilization liner bag is left inside the sterilizer at the end of the ventilation cycle, the contents of the bag will continue to aerate. If gas absorbent items are removed from the bag they must be aerated in a dedicated area that is well-ventilated (at least 10 fresh air exchanges per hour). It is incumbent on the user to provide a safe aeration area if items from the sterilization liner bag are removed from the bag.

Andersen Products is prepared to determine product aeration times for our customers. Call customer service at 336-376-3000 for more information.

**Content of Cartridges: Content of Cartridges:**

**Catalog number AN-1004 EOGas 4 Cartridge**

Active ingredient Ethylene Oxide .....	97.0%
Inert ingredient .....	3.0%
Total .....	100.0%

Net contents each cartridge 0.39 avoird. oz. (17.5 g)

**Other EOGas Sterilizer Systems:**

- AN306** Microprocessor Controlled Sterilizer, Table-Top Cabinet 6 cubic foot, 168 liter capacity
- AN310** Microprocessor Controlled Sterilizer, Free Standing Cabinet 10 cubic foot, 280 liter capacity
- AN333** Microprocessor Controlled Sterilizer, High Capacity Cabinet 33 cubic foot, 913 liter capacity

**EOGas Sterilization Accessories:**

- AN1090** EOGas Liner Bag Impulse Sealer
- AN1071** Humidichip RH Stabilizer Chips (25)
- AN1080** Steritest Biological and Chemical Controls (11)
- AN810** Steritest Incubator
- AN1088** EOGas Exposure Indicator Strips (200)

**DOSIMETER® HUMIDICHIP®**, SEAL AND PEEL®, and **STERITEST®** are registered trademarks of Andersen Products, Inc.  
**EOGas 4®** is a registered trademark of Andersen Sterilizers, Inc.  
 EOGas U.S. Pat no: 4,937,046 and 5,160,700. Humidichip U.S. Pat no: 5,082,636

**Packaging Products For Use With EOGas Sterilizers:**

- AN820** 2"x200' (5cm x 60m) Seal & Peel Packaging Roll Stock
- AN830** 3"x200' (8cm x 60m) Seal & Peel Packaging Roll Stock
- AN850** 5"x200' (12cm x 60m) Seal & Peel Packaging Roll Stock
- AN870** 7"x200' (18cm x 60m) Seal & Peel Packaging Roll Stock

Patents are pending on EOGas in: Canada, France, Great Britain, Germany, Italy, Japan, Spain

EPA REGISTRATION NO. 69340-7  
 EPA ESTABLISHMENT NO. 69340-NC-001

**Manufactured by:**  
**ANDERSEN STERILIZERS, INC.**  
 Health Science Park 3154 & 3181 Caroline Drive  
 Haw River, North Carolina 27258-9789 USA

**U.S. Distribution:**  
**ANDERSEN PRODUCTS, INC.**  
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 1-800-523-1276 www.anpro.com

**European Distributor:**  
**H. W. ANDERSEN PRODUCTS LTD.**  
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