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11/01/2012

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

NOV -1 2012

Bruce Fenn  
Andersen Sterilizer, Inc.  
3154 Caroline Drive  
Haw River, NC 27258

Subject: AN10004 EOGas 4  
EPA Registration Number 69340-7  
Application Dated: July 23, 2012  
Receipt Date: August 06, 2012

Dear Mr. Fenn:

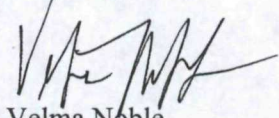
The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

- To update the instructions booklet

**General Comments**

A stamped copy of the accepted labeling is enclosed. Submit 1 copy of your final printed label before distributing or selling the product bearing the revised labeling. Should you have any questions concerning this letter, please contact Emilia Oiguenblik at (703) 347 0199 or Velma Noble at (703) 308-6233.

Sincerely,



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

**CONCURRENCES**

SYMBOL							
SURNAME							
DATE							



ACCEPTED  
with COMMENTS  
in Letter Dated:  
JUL 1 2014

Under **NEW** Fungicide and Rodenticide Act as amended, or the pesticide, registered under EPA Reg. No. **69340-7**

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# AN 1004

**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%  
Inert ingredient: ..... 3%  
Total: ..... 100%

### PRECAUTIONARY STATEMENTS

Hazard to Humans and Domestic Animals.

#### DANGER

Causes irreversible eye damage and skin burns. Harmful if inhaled. May cause respiratory irritation and damage to clothing. Do not swallow. Cancer Hazard and Reproductive Hazard. May cause nervous system damage. Store and use in accordance with ventilation in accordance with 29 CFR 1910.1047.

### PERSONAL PROTECTIVE EQUIPMENT (PPE):

A material that is chemical-resistant to this product is butyl rubber.

All handlers must wear at a minimum: Long-sleeved shirt and long pants, Chemical-resistant gloves, and The employer shall provide a respirator that is adequate to protect the user from the product and all other OSHA standard and regulatory requirements (see 29 CFR 1910.1047 and 29 CFR 1910.134).

When handlers could have eye or skin contact with ETO or ETO solutions, such as during maintenance and repair, vessel cleaning, or cleaning up spills, they must wear:

- Chemical-resistant attire, such as an apron, protective suit, or footwear that protects the area of the body that might contact ETO or ETO solutions, and
- Face-sealing goggles, a full face shield, or a full-face respirator.

**ONE EOGas 4 REFILL KIT  
CONTENTS: 16 Cartridges, 17 Sterilization Bags,  
16 Dosimeters<sup>®</sup>, 18 Humidichips<sup>®</sup>.**

Each AN1004 cartridge contains 0.62 oz. av. of (17.6 g) Ethylene Oxide

**ANDERSEN STERILIZERS, INC.**

Manufactured and Distributed by:

**ANDERSEN STERILIZERS, INC.**  
5194 Carolina Drive - York River, NC 27758 USA

Distributed by:  
**ANDERSEN PRODUCTS, INC.**  
1400 Doro Drive - York River, NC 27758 USA

1-800-523-1278 • 336-376-3000  
www.apro.com • customer.service@apro.com

Authorized EU Representative:  
**H. W. ANDERSEN PRODUCTS, LTD.**  
Clacton-On-Sea • Essex Q216 4XA UK  
44-1256-428328  
info@anderseneurope.com



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### IF SWALLOWED:

Drink at least two glasses of water. Do not induce vomiting. Call a physician.

### NOTE TO PHYSICIAN

Ethylene oxide is a gas. Skin exposure from contact with fabric, clothing, or equipment may result in skin irritation. At high concentrations severe conjunctivitis can occur. Irritation of the respiratory tract may occur, but without acute lung edema. Symptoms include coughing, wheezing, and chest tightness. 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 Pollution Discharge Elimination System (NPDES) permit and the applicable water quality standards. Do not discharge effluent containing this product to surface waters or to the ground. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewerage authority. For more information, contact your State Water Board or Regional Office of the EPA.

### PHYSICAL OR CHEMICAL HAZARDS, DANGERS, FLAMMABLE LIQUID AND GAS UNDER PRESSURE

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

### DIRECTIONS FOR USE

To be used only in EOGas Series 4 sterilizers, and only for hospital, medical and veterinary sterilization. It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

### Read package insert and sterilizer Owner's Manual for complete sterilization instructions and additional precautions.

In hospitals and healthcare facilities, sterilization/conditioning with ETO must be performed only in vacuum or gas tight chambers designed for use with ETO. After February 23, 2010, a single sterilization cycle (in the same chamber) in hospitals and healthcare facilities.

In sterilization facilities, facility, building, packed, shipment and supplies the following requirements must be met. Sterilization with ETO must be performed only in vacuum or gas tight chambers designed for use with ETO.

Safety and awareness training is required for all employees including office staff. Information and training must be provided to all employees in the facility. Employees must be trained in the use of ETO and the safe handling of ETO. Safety training must include, at a minimum, the following information:

1. the most recent monitored ambient levels of ETO in the facility,
2. the potential health effects from the levels of ETO in the facility,
3. the emergency response plan and how to respond in an emergency,
4. the availability of the Material Safety Data Sheet and other materials related to the health hazards of exposure to ETO.

In order to reduce ambient levels of ethylene oxide, lengthy facility cleaning and ventilation procedures must be implemented. Employees not directly involved in the ethylene oxide operations, Air monitoring should include the entire facility including office space, break areas, and landscaping areas.

Employees in facilities that use ETO must comply with all of the requirements for ETO use specified in 29 CFR 1910.1047.

### 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:** Unopened or opened EOGas cartridges should be returned to the manufacturer for disposal. Contact Andersen Products, Inc. (tel. no. 336-376-3000) for instructions. If unopened or partially used cartridges are returned to Andersen Products, Inc., they will be collected by 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 sterilization bag. Wrap box, cartridge, and sterilization bag in paper and discard with usual rubbish.

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# Directions for Use: AN 1004 EOGas 4 Ethylene Oxide Cartridges

Gaseous Sterilant for  
Sterilization at 30°C or 50°C  
In EOGas 4® Sterilization Systems

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:  
NOV 7 2012  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 69340-7

Manufactured by:  
**Andersen Sterilizers, Inc.**  
Health Science Park  
3154 Caroline Drive  
Haw River, NC 27258 U.S.A.

Distributed in the US by:  
**Andersen Products, Inc.**  
Health Science Park  
3202 Caroline Drive  
Haw River, NC 27258 U.S.A.

**H.W. Andersen Products of California, Inc.**  
3151 Caroline Drive  
Haw River, NC 27258 U.S.A.

Authorized EU Representative:  
**H.W. Andersen Products, Ltd.**  
Davy Road • Gorse Lane Industries Estates  
Clacton-on-Sea • Essex C015 4XA, U.K.

**For all other inquiries worldwide:**  
Andersen Products, Inc.  
Health Science Park  
3202 Caroline Drive  
Haw River, NC 27258 USA



## 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.

**Do not remove the trigger guard until just before you place the AN1004 EOgas 4 cartridge in the sterilization bag.**

**Never depress button to activate AN1004 EOgas 4 cartridge outside sealed sterilization bag.**

To be used only in an EOgas 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 EOgas 4 Sterilizer:

Adhesive tape  
Airways - plastic, rubber, metal  
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 and separately wrapped to avoid a spark), battery cases, bulbs  
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, burs, chisels  
Optical instruments - scopes, cameras  
Painted equipment - metal, wood  
Procedure trays  
Respirators, douche tubes - rubber, plastic  
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 AN1004 EOgas 4 cartridges:

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 styles 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.

4. Humidification: Vacuum dehydration, chemical desiccation or prolonged exposure to ambient relative humidity below 35% has been demonstrated to produce spores highly resistant to sterilization by Ethylene Oxide. Re-hydration of spores so changed, and hence reversion to normal sensitivity, does not 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 detergent.

5. 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 bag having a saturated humidity will be

necessary for an overall pretreatment routine of 4 hours. Use the following procedure for pre-humidification using an EOgas 4 sterilization bag:

- Make sure the sterilizer is switched on so that it heats to 50 °C (122 °F).
- Prepare the items in the load for sterilization.
- Place the prepared items along with a Humidichip® inside a sterilization bag. Using the Velcro® strap, securely close the neck of the sterilization bag around the purge bobbin. It is not necessary to attach the purge probe to the purge tube at this time.
- Place the sterilization bag in the heated sterilizer for 2 hours, then remove the sterilization bag from the sterilizer for an additional 2 hours to allow for cooling. **DO NOT ACTIVATE THE CARTRIDGE AT ELEVATED TEMPERATURE.**

After the 2 hours of cooling, the sterilization bag may be placed in the sterilizer, attached to the purge tube and the cycle started normally.

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

Andersen Seal and Peel Packaging offers a second through, peel open, extended shelf life package, proven to be compatible with the EOgas 4 Sterilizing System. No other plastic film packaging material may be used with AN1004 EOgas 4 cartridges unless the user first carefully tests the material to be sure that Ethylene Oxide can penetrate it in adequate concentration. Polyamide (Nylon) and polyester (Mylar) films are known to be inappropriate for use with Ethylene Oxide.

Since Seal and Peel is waterproof, you must include an AN1071 Humidichip RH Stabilizer in each Seal and Peel package if the product being sterilized has not been properly hydrated prior to sealing.

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

### Sterilization Method with AN1004 EOgas 4 Cartridges

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

Refer to the Owner's Manual for detailed operating instructions for the EOgas 4 sterilizer.

### Abbreviated operating instructions for EOgas 4 sterilizer cabinets:

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 bag from the AN1004 EOgas 4 dispenser box. Use a new AN1004 EOgas 4 sterilization bag for each cycle. Place the wrapped items to be sterilized into the sterilization bag along with one AN1071 Humidichip and one AN1087 Dosimeter. Place the Dosimeter in the center of the load. Place the Humidichip in the bottom of the sterilization bag so that it will be nearest to the metal shelf.

Select one AN1004 EOgas 4 cartridge from the dispenser box. Remove the cartridge trigger guard. Place the AN1004 EOgas 4 cartridge into the sterilization bag on top of the load where it is accessible. Securely attach the purge probe bobbin to the mouth of the sterilization 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 bag. If a multiple bag EOgas 4 sterilizer is being used and already has some bags loaded, purge the sterilizer prior to loading the sterilization bag. Open the door to the EOgas 4 sterilizer, place the sterilization bag on the shelf and connect the purge probe to the purge tubing using the quick connect fitting provided.

Once the sterilization 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 AN1004 EOgas 4 cartridge through the sterilization 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 bag. Close the door securely and select the cycle length. The door to the sterilizer will lock automatically.

Leave the sterilization bag undisturbed in the EOgas 4 sterilizer cabinet for the sterilization and bag ventilation cycles, after which the sterilization bag may be removed and opened.

Fungicide, and Rodenticide Act as registered under EPA Reg. No. 30090-1

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After the sterile material has been removed from the sterilization bag, wrap the empty cartridge and sterilization 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. AN1004 EOGas 4 cartridges are designed to be used only in the sterilization bags provided in the AN1004 EOGas 4 refill kit and must be used exclusively in a genuine EOGas 4 sterilizer. You may not reuse any EOGas 4 sterilization bag.

#### Technical Description of The System

The EOGas 4 sterilizer cabinet is maintained at an internal temperature of 50°C (122°F). The machine may also be configured for a 'room temperature' 30°C (86°F) cycle if needed.

The EOGas 4 sterilization bag retains Ethylene Oxide until it is actively purged from the sterilization 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 bag during the cycle.

The AN1004 EOGas 4 cartridge will deliver a dose of at least 500 milligrams per liter hours to the contents of the sterilization 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 re-hydrated 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) 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 AN1004 EOGas 4 cartridge. A color change reaching the ring on the Dosimeter scale indicates that a dose for the EOGas 4 sterilization cycle has been delivered.

#### Storage and Disposal

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

**Storage:** Store in a cool place out of direct sunlight.  
**Shelf Life:** Each AN1004 EOGas 4 cartridge is marked with an expiration date.

**Pesticide Disposal:** Unwanted or expired AN1004 EOGas 4 cartridges should be returned to the manufacturer for disposal. Contact Andersen Products, Inc. (tel. no. 336-376-3000) for instructions. If unwanted or expired AN1004 EOGas 4 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 ordinary trash.

#### Environmental Hazards

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other water unless in accordance with the requirements of a National Discharge Eliminations System 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 DANGER. FLAMMABLE LIQUID AND GAS UNDER PRESSURE

Ethylene Oxide gas is extremely flammable. Do not store near flame, electrical sparks, or hot surfaces. And all equipment to prevent static sparks.

Cartridges wrapped individually and separately from their electrical instruments to avoid any electrical spark and ignition.

#### Testing the Efficacy of the EOGas Sterilizer

Monitoring sterilization efficacy is extremely important. The EOGas AN1087 Dosimeter, placed in the most inaccessible part of the load, will verify whether or not the gaseous Ethylene Oxide penetrated to the core of the load in adequate concentration to assure sterilization. In addition, an appropriate biological control, such as the AN1080 STERITEST®, should be used at least once per month to challenge the procedure and any time packaging or loading configuration is changed.

**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 bag. If the sterilization bag is left inside the sterilizer at the end of the ventilation cycle, the contents of the sterilization bag will continue to aerate. If gas absorbent items are removed from the sterilization 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 bag are removed from the sterilization bag.

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

#### PRECAUTIONARY STATEMENTS with COMMENTS KEEP OUT OF REACH OF CHILDREN

Hazard to Humans and Domestic Animals.  
Under Federal Pesticide Act as  
**DANGER:** Irritant to the eyes.  
**Causes irreversible eye burning and tearing. Harmful if inhaled. Do not breathe 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**

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

The AN1004 EOGas 4 Cartridges contain liquid and gaseous Ethylene Oxide under pressure. Do not use near fire, heated surface, or flame. Do not smoke near the sterilizer while loading and unloading it.

Avoid breathing Ethylene Oxide vapor. Breathing Ethylene Oxide vapor is harmful. If you can smell Ethylene Oxide you are breathing toxic amounts. In concentrated amounts Ethylene Oxide sterilizing gas is as irritating to the lungs and mucous membranes as is ammonia gas.

As with other chemical vapors, there is a chance of an occasional allergic response to Ethylene Oxide in a sensitive individual. Such individuals should not handle Ethylene Oxide, and should neither breathe its vapors nor allow materials sterilized in it to come in contact with their skin or mucous membranes.

All users must avoid contact with skin, eyes and clothing. If contact with liquid Ethylene Oxide occurs, users must immediately remove all contaminated clothing, including shoes. Flush skin, or eyes with plenty of water for at least fifteen minutes. If liquid Ethylene Oxide has gotten into your eyes, immediately see a physician for further treatment.

**Effects of Overexposure to Ethylene Oxide:** May be fatal if inhaled in high concentrations. May cause irritation of respiratory tract, chest tightness, headache, nausea, vomiting, diarrhea, light-headed feeling, dizziness, weakness, drowsiness, cyanosis, loss of coordination, convulsions, coma, delayed

lung injury (fluid in lungs), immediate or delayed skin irritation and blisters, allergic skin.

**Other Possible Delayed Health Effects:** May cause nervous system injury, cataracts, adverse reproductive effects, chromosomal and mutageny changes, and cancer.

**PEL:** 1PPM-TWA Ethylene Oxide (OSHA - 29 CFR 1910.1047)

**STEL:** 5PPM-excision limit, 15 minutes  
**ODOR:** Ether-like in high concentrations. Exposure to toxic levels may occur without warning or detection by the user

See label or instructions for additional precautionary statements and statements of practical treatment.

#### FIRST AID STATEMENTS

**Operator Exposure:** Chronic exposure to concentrations of ethylene oxide (the active ingredient in EOGas) above 1 ppm may be dangerous to your health. All operators of ethylene oxide gas sterilizers must be tested for ethylene oxide exposure at frequent intervals.

In all cases of exposure, get medical attention immediately. Take person to a doctor or emergency treatment facility. Have the product container or label with you when going for treatment.

**If in Eyes:** Hold eyes open and rinse slowly and gently with water for 15 to 20 minutes. Remove contact lenses, if present, after the first 5 minutes then continue rinsing eye. Get medical treatment.

**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.

**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 discard leather goods.

**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.

See label or instructions for additional precautionary statements and statements of practical treatment.

**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 edema. Symptoms of systemic intoxication are headache, nausea, vomiting, incoordination, and irregularities. Treatment is symptomatic. **COMMENTS:** See label or instructions for additional precautionary statements and statements of practical treatment.

#### Content of Cartridges:

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, EOGas 4 is a Sterilizer. Active ingredients are listed on the label. Inert ingredients registered under EPA Reg. No. 93-40-7 Total ..... 100.0% Net contents each cartridge 0.64 avoird. oz. (18.2 g)

EPA Registration No. 69340-7  
EPA Establishment No. 69340-NC-001

#### EOGas 4 Sterilization System Accessories

- AN1071 Humidichip RH Stabilizer Chips (25)
- AN1080 Steritest Biological and Chemical Controls (11)
- AN810 Steritest Incubator
- AN85 EOGas Exposure Indicator Labels (200)
- AN86 EOGas Exposure Indicator Tape (200)

#### Packaging Products For Use With EOGas 4 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

#### IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Preparation of Material for Sterilization, Abbreviated Operating Instructions, Testing the Efficacy of the EOGas Sterilizer and Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

It is imperative that the user/reader be familiar with and adhere to OSHA regulations which are specific to Ethylene Oxide (29 CFR 1910.1047) as well as any other applicable Federal, State, or local government regulations.

By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

**CONDITIONS:** The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Non-sterile product, contact chemical burns, ignition of flammable gas, operator exposure or other unintended consequences may result because of the user or buyer's failure to carefully follow the Instructions for Use and Operating Instructions in the EOGas 4 Sterilizer Owner's Manual which is beyond the control of Andersen Sterilizers, Inc. All such risks shall be assumed by the user or buyer.

**DISCLAIMER OF WARRANTIES:** To the extent consistent with applicable law, Andersen Sterilizers, Inc. makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of Andersen Sterilizers, Inc. is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Andersen Sterilizers, Inc. disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

**LIMITATIONS OF LIABILITY:** To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at Andersen Sterilizers, Inc. election, the replacement of product.



Manufactured by:  
**Andersen Sterilizers, Inc.** 0413  
Health Science Park  
3154 Caroline Drive  
Haw River, NC 27258 U.S.A.

Distributed by:  
**Andersen Products, Inc.** with COMMENTS  
Health Science Park in EPA Letter Dated:  
3202 Caroline Drive  
Haw River, NC 27258 U.S.A.

1-800-523-1276  
www.ampro.com  
customerservice@ampro.com  
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, EOGas 4 is a Sterilizer, registered under EPA Reg. No. 93-40-7.

**H.W. Andersen Products, Inc.**  
Health Science Park  
3151 Caroline Drive  
Haw River, NC 27258 U.S.A.  
Tel: 1-800-524-3455  
Fax: 336-376-3088  
www.amandcal.com

Authorized EU Representative:  
**H. W. Andersen Products, Ltd.**  
Davy Road • Clacton-on-Sea  
Essex CO15 4XA U.K.  
Tel: 44-1-255-428-328  
Fax: 44-1-255-222-987  
info@andersen-europe.com

**For all other inquiries worldwide:**  
Andersen Products, Inc.  
Health Science Park  
3202 Caroline Drive  
Haw River, NC 27258 USA  
E-mail: customerservice@ampro.com  
Tel: +1 336 376-3000  
Fax: +1 336 376-8153

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