



069340-00004-040999

Printed: 13:30:27 Friday, 14 May, 1999 # 29 / 2818

Systems Integration Group, Inc.

PM 31

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

69340-4

4/9/99

1 of 10

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

APR 09 1999

Subject: EOGas AN-1004/5/6
EPA Registration No. 69340-4
Your Amendment Dated: 1/07/99

Attention: Mr. Juergen Ballo,
QA Manager

The amendment referenced above submitted in connection with registration under FIFRA, as amended, to update the product label is acceptable provided the following recommendations are addressed before you release the product for shipment.

Label Recommendations:

- a) You should add the text, "IMPORTANT: For Professional Use Only," above the statement, "Users must follow ...oxide (29 CFR 1910.1047).
- b) All section headings should be in the same font.
- c) According to the Label Review Manual (2nd Edition) and Agency letter dated 10/15/98, the statement, "Keep out of Reach of Children," should precede the signal word.
- d) The statement, "Do not contaminate water, food, or feed by storage or disposal," should immediately follow the "Storage and Disposal" heading.
- e) The statement, "See user's manual for additional precautionary statements," should follow the "Precautionary Statements" section.

CONCURRENCES

SYMBOL	7510C						
SURNAME	Campbell						
DATE	4/9/99						

- f) "Environmental Hazards" statements must be added to these labels according to PR Notice 95-1. (See Ethylene Oxide Label Template for guidance).

"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.

- g) The "Physical/Chemical Hazards" section should be placed after the "Environmental Hazards" section.

Manual Recommendations:

- 1) On page 4, the "Container Disposal" section is not necessary since the text could be incorporated into the last paragraph. It could be revised to reflect the following:


After the sterile material has been removed from the sterilizer bag, wrap the empty cartridge and bag in paper and discard in the trash. DO NOT REUSE EMPTY BOX, EMPTY CONTAINER, OR LINER BAG.

- 2) On page 5, the statement, "Do not contaminate water, food, or feed by storage or disposal," should immediately follow the "Storage and Disposal" heading. Also, the "Shelf life" information should be included in the "Storage and Disposal" section.

- 3) "Environmental Hazards" statements must be added to the manual according to PR Notice 95-1.

A stamped copy of the label and manual is enclosed for your records. Submit one (1) final printed label prior to the release of the product for shipment. If you have any questions regarding this letter, please contact Jacqueline Campbell at (703) 308-6416.

Sincerely,



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

**AN
1004**

ONE KIT

(CONTENTS: 25 Cartridges, 25 Liner Bags, 25 Dosimeters[®], 25 Humidchips[®]. Each AN1004 cartridge contains 0.09 av. oz. (3.0 g) EOGas sterilant.)



**ANDERSEN
PRODUCTS**

Manufactured by: **ANDERSEN STERILIZERS, INC.**

Distributed by:
ANDERSEN PRODUCTS, INC.

Health Science Park • Haw River, NC 27258-9789 USA

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



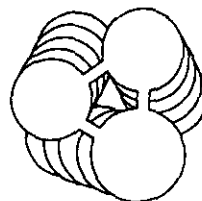
P/N 2848 123198

DANGER

KEEP OUT OF REACH OF CHILDREN

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

Active ingredient: Ethylene oxide 89.0%
Inert ingredients: 11.0%
TOTAL 100.0%



EOGas™

Dosimeter[®], EOGas[®], and Humidchip[®] are trademarks of Andersen Products, Inc.
EOGas U.S. Pat. no. 4,937,046 and 5,160,700. Humidchip U.S. Pat. no. 5,082,636

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

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 trash.

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.

PHYSICAL OR CHEMICAL HAZARDS

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

STATEMENT OF PRACTICAL TREATMENT

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

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.

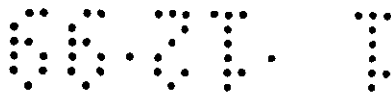
IF ON SKIN: Immediately wash skin with plenty of water while removing contaminated clothing and shoes. Call a physician. Aerate, wash, or clean contaminated clothing and discard leather goods.

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 user's manual for additional precautionary statements.

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.



1/06/99, 12:19 PM

**ACCEPTED
with COMMENTS
in EPA Letter Dated:**

APR 9 1999

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

69340-4

30410

P/N 2848 120198

AN 1005

ONE KIT

(CONTENTS: 25 Cartridges, 25 Liner Bags, 25 Dosimeters[®], 25 Humidchips[®]. Each AN1005 cartridge contains 0.18 av. oz. (5.0 g) EOGas sterilant.)



Manufactured by: ANDERSEN STERILIZERS, INC.

Distributed by:

ANDERSEN PRODUCTS, INC.

Health Science Park • Haw River, NC 27258 USA

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



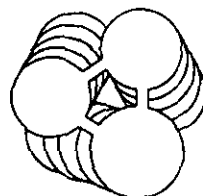
P/N 2849 123198

DANGER

KEEP OUT OF REACH OF CHILDREN

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

Active ingredient: Ethylene oxide 90.0%
Inert ingredient: 10.0%
Total: 100.0%



EOGasTM

Dosimeter[®], EOGas[®], and Humidchip[®] are trademarks of Andersen Products, Inc.
EOGas U.S. Pat. no. 4,937,046 and 5,160,700. Humidchip U.S. Pat. no. 5,082,636

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

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.

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.

PHYSICAL OR CHEMICAL HAZARDS

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

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, 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.

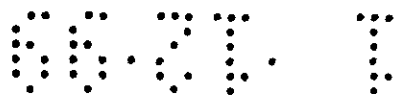
See user's manual for additional precautionary statements.

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.

P/N 2849 123198

1/06/99, 12:35 PM



ACCEPTED
with COMMENTS
in EPA Letter Dated:
APR 9 1999
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.

69340-4

4/8/10

**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
PRODUCTS**

Manufactured by: **ANDERSEN STERILIZERS, INC.**
3154 Caroline Drive • Haw River, NC 27258 U.S.A.

Distributed by:

ANDERSEN PRODUCTS, INC.

3202 Caroline Drive • Haw River, NC 27258 U.S.A.

European Distributor:

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

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

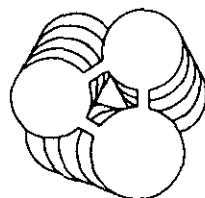


DANGER

KEEP OUT OF REACH OF CHILDREN

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%



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. 5,082,636

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

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.

PRECAUTIONARY STATEMENTS

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DO NOT GET IN EYES, SKIN, OR ON CLOTHING. STORE AND USE WITH ADEQUATE VENTILATION.

PHYSICAL OR CHEMICAL HAZARDS

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STATEMENT OF PRACTICAL TREATMENT

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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, 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 user's manual for additional precautionary statements.

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.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

APR 9 1999

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

69340-4

5 of 10



Gaseous Sterilant for
50°C Sterilization

Directions for Use: EOGas Cartridges

ACCEPTED
with COMMENTS
in EPA Letter Dated:

APR 9 1999

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

69340-4

Distributed by:



CE 0413

AN1004 • AN1005 • AN1006

Directions for Use

EOGas Cartridges

AN1004 • AN1005 • AN1006

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:

Do not remove the trigger guard until just before you place the cartridge in the sterilizer bag.

To be used only in an EOGas Sterilizer for hospital, medical, and veterinary sterilization. Before using read package insert for complete sterilization instructions and additional precautions.

Typical Products which may Conveniently be Processed in an EOGas Sterilizer

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

Preparation of Material for Sterilization

Material to be sterilized by EOGas must be meticulously clean and dry. 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 EOGas:

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 EOGas may react with the gas and reduce its effectiveness.
3. Although EOGas is a highly diffusible gaseous sterilant, nevertheless 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 plungers out of the barrels.

ACCEPTED
with COMMENTS
in EPA Letter Dated: 3/2/79

If the nature of the material to be sterilized is such that the water treatments specified above are harmful, then pretreatment in a sterilizer bag may be necessary for an over a 16 hour routine of 8 hours. Use the following procedure.

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 69340-4

To humidify the contents of the sterilizer bag, wrap the items individually in paper or cloth in the usual manner. Place them in a sterilizer bag along with a Humidichip[®], a Dosimeter³ and card and a cartridge of EOGas from which the trigger guard has been removed. Heat seal the sterilizer bag and place it in the EOGas sterilizer WITHOUT pressing the cartridge trigger. After 4 hours, remove the bag from the EOGas sterilizer and leave it at room temperature for another 4 hours. Then, without opening the sterilizer bag, grasp the cartridge of EOGas through the wall of the sterilizer bag and press the trigger button firmly. Put the sterilizer bag with the activated cartridge back in the sterilizer cabinet for a normal length 16 hour sterilization cycle.

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 controlled to be compatible with the EOGas Sterilizing System. No other plastic film packaging material may be used with EOGas unless the user first carefully tests the material to be sure that EOGas can penetrate it in adequate concentration. Polyamide (Nylon) and polyester (Mylar) films are known to be inappropriate to use with EOGas. In as much as Seal and Peel is waterproof, you must include an AN1071 Humidichip RH Stabilizer in each Seal and Peel package.

Do not pack the sterilizer bag so tightly with cloth or gauze that gas diffusion may be slowed.

Sterilization Method with EOGas Sterilizer Cabinet

Be certain that all items have been prepared as described in paragraph 2 above.

Initiate the purge cycle (refer to the Owner's Manual for the specific instructions for the EOGas sterilizer cabinet you are using). The air in the cabinet will be purged by a high capacity blower, removing the residual sterilant from the air in the cabinet. This takes five minutes.

While the cabinet is being purged, remove one Dosimeter and 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 sterilizer bag from the EOGas dispenser box and place the wrapped items to be sterilized into the sterilizer bag along with one AN1071 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 EOGas cartridge from the dispenser box. Be certain that the number printed on the EOGas cartridge corresponds with the number printed on the sterilizer bag you have chosen. Remove the cartridge trigger guard. Place the EOGas cartridge into the sterilizer bag. Press the excess air out of the sterilizer bag and heat seal it.

Grasp the cartridge through the heat sealed sterilizer bag and press the trigger button firmly. Press it all the way so that the trigger reaches the cartridge wall. This action releases the gas instantly from the cartridge into the sterilizer bag.

When the purge is complete (refer to Owner's Manual for the EOGas sterilizer model you are using for specific instructions) on the front of the EOGas sterilizer indicating that the cabinet has been purged and the sterilizer door is unlocked, place the sterilizer bag on a shelf in the sterilizer. Close the door securely. It will lock automatically in about two minutes. For EOGas sterilizer models with label printers see the Owner's Manual.

Leave the sterilizer bag undisturbed in the sterilizer cabinet for 16 hours after which the sterilizer bag may be removed, opened and its sterile contents used.

Container Disposal

Do not reuse empty box, empty cartridges or liner bags. Wrap box, cartridge and bags in paper and discard in trash.

Important - Variations from these Instructions

The user must not deviate from these instructions. EOGas cartridges are designed to be used only in the sterilizer bags provided in the EOGas refill dispenser.

You may not reuse any EOGas sterilizer bag. Any deviation from the procedures recommended in these instructions is made solely at the users' risk.

Technical description of the system

The EOGas Sterilizer cabinet is thermostatically controlled to assure an internal temperature of 50°C. It is provided with a dual-volume exhaust system: low-volume during the sterilization cycle for economy and high-volume for purging just before opening the door. The purge cycle will lower the cabinet temperature for a few minutes, but it will return to 50°C shortly after the door locks.

The sterilizer bag is a gas diffusion membrane retaining EOGas long enough to sterilize its contents and then allowing the gas to diffuse into the cabinet atmosphere from which it is vented harmlessly to the outside atmosphere.

The AN1071 Humidichip will maintain the contents of the sterilizer bag at a relative humidity of greater than 30% at 50°C.

The EOGas cartridge will deliver a dose of at least 500 milligrams per liter hours to the contents of the sterilizer bag. Tests in our laboratory confirm that this dose will kill the most resistant spores known at 50°C within the 1 hour cycle providing that the spores have been rehydrated according to our instructions.

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.

Shelf Life

Each cartridge is marked with an expiration date.

Storage and Disposal

Storage: Store in a cool place 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 ordinary trash.

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 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.

Aeration: It is incumbent on the user to confirm that a gas absorbent item, sterilized in EOGas, 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.

Humidification: Vacuum dehydration, chemical desiccation or prolonged exposure to ambient relative humidity below 30% have been demonstrated to produce spores highly resistant to sterilization by EOGas. 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 sterilized 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 saturated humidity at 50°C will be necessary. overall pretreatment routine of at least 8 hours.

Precautionary Statements

Danger: Extremely Flammable
Keep Out of Reach of Children.
Do Not Breathe EOGas.

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

69340-4

The EOGas Cartridges contain liquid and gas under pressure. Do not use near fire, heated surface, or flame. Do not smoke near the sterilizer while loading and unloading it. Sterilize batteries wrapped individually and separately from their electrical instruments.

Avoid breathing EOGas vapor. Breathing EOGas vapor is harmful. If you can smell EOGas you are breathing toxic amounts. In concentrated amounts EOGas

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 EOGas in a sensitive individual. Such individuals should not handle EOGas, 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 EOGas 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 EOGas 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 mutagenicity changes, and cancer.

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

STEL: 5PPM-excursion 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.

Aeration: Failure to adequately air ethylene oxide absorbing materials may lead to contact chemical burns. The 16 hour sterilization cycle time at 50°C called for in these instructions includes an adequate amount of time to air most tubes, masks and the like. Large gas absorbent items like silicone breast implants and plastic extracorporeal blood filters may require additional aeration before they can be safely implanted or used. Aeration will progress more rapidly outside of the sterilizer bag. Andersen Products is prepared to determine aeration times for unusual products for our customers. Call customer service at 336-376-3000 for more information.

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.

Statements of Practical Treatment

If 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, preferably mouth-to-mouth. 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, 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 poisoning are headache, nausea, vomiting, incoordination, cardiac irregularities. Treatment is symptomatic.

ACCEPTED with COMMENTS in EPA Letter Dated: APR 9 1999

Content of Cartridges: Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 693404

#4 EOGas Cartridge	Active ingredient ethylene oxide	100.0%
	Inert ingredient	0.0%
	Total	100.0%
	Net contents each cartridge	0.09 avoird. oz. (3.0 g)

#5 EOGas Cartridge	Active ingredient ethylene oxide	90.0%
	Inert ingredient	10.0%
	Total	100.0%
	Net contents each cartridge	0.18 avoird. oz. (5.0 g)

#6 EOGas Cartridge	Active ingredient ethylene oxide	96.0%
	Inert ingredient	4.0%
	Total	100.0%
	Net contents each cartridge	0.38 avoird. oz. (11.0 g)

EOGas Modular Sterilizer Systems:

- AN1120** Sterilizer, Table-Top Cabinet 4.3 cubic foot, 127 liter capacity
- AN1220** Sterilizer, Free-Standing Cabinet 8.6 cubic foot, 247 liter capacity
- 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
- AN324** Microprocessor Controlled Sterilizer, High Capacity Cabinet 24 cubic foot, 672 liter capacity
- AN333** Microprocessor Controlled Sterilizer, High Capacity Cabinet 33 cubic foot, 913 liter capacity

EOGas Refill Kits:

- AN1004** #4 Cartridge Refill Dispenser Kit
 - 25 #4 (Small) EOGas Cartridges
 - 25 Humidichip Relative Humidity Stabilizer Chips
 - 25 EOGas Dosimeters
 - 25 EOGas 12" x 24" (31cm x 61cm) #4 Liner Bags
- AN1005** #5 Cartridge Refill Dispenser Kit
 - 25 #5 (Medium) EOGas Cartridges
 - 25 Humidichip Relative Humidity Stabilizer Chips
 - 25 EOGas Dosimeters
 - 25 EOGas 18" x 24" (45 cm x 61 cm) #5 Liner Bags
- AN1006** #6 Cartridge Refill Dispenser Kit
 - 25 #6 (Large) EOGas Cartridges
 - 25 Humidichip Relative Humidity Stabilizer Chips
 - 25 EOGas Dosimeters
 - 25 EOGas 22" x 36" (56 cm x 92 cm) #6 Liner Bags
- AN1090** EOGas Liner Bag Impulse Sealer

EOGas Sterilization Accessories

- AN1071** Humidichip RH Stabilizer Chips (25)
- AN1080** Steritest Biological and Chemical Controls (11)
- AN810** Steritest Incubator
- AN1085** EOGas Exposure Indicator Strips (200)

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

Dosimeter[®], Humidichip[®], Seal and Peel[®], and Steritest[®] are registered trademarks of Andersen Products, Inc.

EOGas[™] is a trademark of Andersen Products, Inc.

EOGas is protected by U.S. Patent 4,937,046 and 5,160,700

Humidichip is protected by U.S. Patent 5,082,636

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

EPA REGISTRATION NO. 69340-4

EPA ESTABLISHMENT NO. 9417-NC-001

Manufactured by:
ANDERSEN STERILIZERS, INC.

Distributed by:
ANDERSEN PRODUCTS, INC.
Health Science Park
Haw River, North Carolina 27258-8710 U.S.A.
336-376-3000

European Distributor:
H. W. ANDERSEN PRODUCTS LTD.
Clacton-On-Sea • Essex C015 4XA U.K.

ACCEPTED
with COMMENTS
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Fungicide, and Rodenticide Act as
amended, for the pesticide,
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69340-4