69340-7 3/3/2010 UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 1 of 7

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

MAR 3 2010

SUBJECT: AN10004 EOGas 4
EPA Registration Number: 69340-7
Application Date: December 2, 2009
Receipt Date: December 3, 2009

Dear Mr. Fenn:

This letter acknowledges receipt of the amendment identified above submitted under the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended is acceptable, subject to the conditions listed below.

- Add Language per the 2008 Reregistration Eligibility Document (RED) for Ethylene Oxide.
- Submit revised alternate formulation

The revised alternate formulation dated 2/4/10 is acceptable and will be made part of the record for this file.

Conditions:

1) Revise the labeling for the EO Gas 4 Refill Kit (PN14036_VN120109) and the AN 1004 EO Gas 4 Directions for Use Label (PN14037_VN020310) to include mandatory language as per PR Notice 2000-5. Revise the heading "User Safety Recommendations" to read "User Safety Requirements". Revise the statements in this section to include mandatory language as follows:

"Users *must* wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
Users *must* remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
Users *must* remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."

CONCURRENCES								
SYMBOL	7510P							
SURNAME	S. Funk							
DATE	3/2/2010							

2) Add the following language to the Precautionary Statements (Personal Protective Equipment section, page 4) of the AN 1004 EO Gas 4 Directions for Use Label:

- Insert the following language required on page 50 in the RED,

> *when the ambient ETO concentration is 1 to 50 ppm, full-facepiece respirator with ETO approved canister, front or back mounted,*
> *when the ambient ETO concentration is 50 to 2,000 ppm, (1) positive-pressure supplied-air respirator equipped with full-facepiece, hood, or helmet; or (2) continuous-flow supplied-air respirator (positive-pressure) equipped with hood, helmet, or suit,*
> *when the ambient ETO concentration is >2,000 ppm or unknown (e.g., emergency situations), (1) positive-pressure self-contained breathing apparatus equipped with full-facepiece; or (2) positive-pressure fullfacepiece supplied-air respirator equipped with an auxiliary positive-pressure self-contained breathing apparatus.*

General Comments

A stamped copy of the accepted labeling is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling. Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,

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

7510P:T.Lantz:3/2/10:69340-7 RED amend CSF

	CONCURRENCES							
SYMBOL								
SURNAME								
DATE								

ACCEPTED
with COMMENTS
in EPA Letter Dated:
MAR 13 2010
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.
69340-7

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	97.0%
Inert ingredient	3.0%
Total:	100.0%

EOGas 4® REFILL KIT

Dosimeter® and Humidichip® are trademarks of Andersen Sterilizers, 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
EPA Registration No. 69340-7. EPA Establishment No. 69340-NC-001

ONE EOGas 4 REFILL KIT
CONTENTS: 16 Cartridges, 17 Sterilization Bags, 16 Dosimeters®, 16 Humidichips®.

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

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 • www.sterility.com • mailbox@anpro.com

Authorized EU Representative:
H. W. ANDERSEN PRODUCTS, LTD.
Clacton-On-Sea • Essex C015 4XA UK
44-17[illegible]328

CE 0413

PN14036_VN120109

PRECAUTIONARY STATEMENTS

Hazard to Humans and Domestic Animals.

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 CFR1910.1047

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 plants,
Shoes plus socks,
Chemical-resistant gloves, and
The employer shall provide a respirator that is adequate to protect the health of the employee and ensure compliance with all other OSHA statutory 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.

When wearing respirators:

1. *Follow the respirator manufacturer's user's instructions for* changing canisters.

2. Respirators must be fit-tested and fit-checked using a program that conforms to OSHA's requirements (see 29CFR Part 1910.134).

3. Respirator users must be trained using a program that conforms to OSHA's requirements (see 29CFR Part 1910.134).

4. Respirator users must be examined by a qualified medical practitioner to ensure physical ability to safely wear the style of respirator to be worn. A qualified medical practitioner is a physician or other licensed health care professional (PLHCP) who will evaluate the ability of a worker to wear a respirator. The initial evaluation consists of a questionnaire that asks about medical conditions (such as a heart condition) that would be problematic for respirator use. If concerns are identified, then additional evaluations, such as a physical exam, might be necessary. The initial evaluation must be done before respirator use begins. It does not need to be repeated unless the health status of respirator use conditions change (see 29CFR Part 1910.134).

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

See User's Manual for additional precautionary statements.

Emergency Contact: 1-800-255-3924

User Safety Recommendations

Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

FIRST AID STATEMENTS

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 immediate 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 method.* If breathing is at all labored, 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.

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 Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the 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 use near flame, electrical 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 for complete sterilization instructions and additional precautions.

In hospitals and healthcare facilities, Sterilization/fumigation with ETO must be performed only in vacuum or gas tight chambers designed for use with ETO. After February 28, 2010, a single chamber process is required for ETO treatment (sterilization and aeration are to occur in the same chamber) in hospitals and healthcare facilities.*

*In contract sterilization facilities treating medical equipment and supplies the following requirements must be followed: Sterilization/fumigation 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 at the time of initial assignment and annually thereafter. The 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 aeration is encouraged. It can reduce potential long-term risks to employees not directly involved in the ethylene oxide applications.

Air monitoring should include the entire facility including office space, break areas, and loading/unloading areas.

Employers 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: 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 sterilization bag. Wrap box, cartridge, and sterilization bag in paper and discard with usual rubbish.

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Content of Cartridges:

Catalog number AN1004 EOGas 4 Cartridge
Active ingredient Ethylene Oxide 97%
Inert ingredient 3%
Total 100%
Net contents each cartridge 0.64 avoir. oz. (18.2 g)

EOGas 4 Sterilization System Accessories

AN85	EOGas Exposure Indicator Labels (200)
AN86	EOGas Exposure Indicator Tape (200)
AN87	Dosimeter Chemical Integrator for 30C cycle (16)
AN1087	Dosimeter Chemical Integrator for 50C cycle (16)
AN1071	Humidichip RH Stabilizer Chips (16)
AN80	Steritest Biological and Chemical Controls for 30C cycle (11)
AN1080	Steritest Biological and Chemical Controls for 50C cycle (11)
AN810	Steritest Incubator

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

CE 0413

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

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

Disclaimer

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.

Any warranty (either express or implied) of merchantability or fitness for a particular purpose with respect to the product or its use is expressly denied.

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:
MAR 3 2010
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended for the pesticide, registered under EPA Reg. No.
69340-7

EOGas 4 REFILL KIT CONTENTS:

16 Cartridges, 17 Sterilization Bags, 16 Dosimeters and 16 Humidichips.

Each AN1004 EOGas 4 cartridge contains 0.62 av. oz., (17.6 g) Ethylene Oxide

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

CE 0413

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.

Distributed in Asia by:
ANDERSEN Medical (HK), Ltd.
Unit 2, 18/F
Westly Square, 40 Hoi Yuen Road
Kwun Tong, Hong Kong

PN14037_VN020310

1 of 4

DIRECTIONS FOR USE

To be used only in EOGas 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. Before using, read sterilizer Owner's Manual for complete sterilization instructions and additional precautions.

In hospitals and healthcare facilities, Sterilization/ fumigation with ETO must be performed only in vacuum or gas tight chambers designed for use with ETO. After February 28, 2010, a single chamber process is required for ETO treatment (sterilization and aeration are to occur in the same chamber) in hospitals and healthcare facilities.

In contract sterilization facilities treating medical equipment and supplies the following requirements must be followed: Sterilization/fumigation with ETO must be performed only in vacuum or gas tight chambers designed for use with ETO.

In hospitals and healthcare facilities, aeration in the EOGas 4 sterilizer is accomplished by leaving the contents inside the sterilization liner bag at the end of the ventilation cycle. The contents of the sterilization bag will continue to aerate until removed from the sterilizer.

In contract sterilization facilities, if gas absorbent items are removed from the sterilization bag immediately following sterilization and ventilation *and* they require additional aeration before use, 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 for items processed in this manner.

Safety and awareness training is required for all employees including office staff. Information and training must be provided to all employees in the facility at the time of initial assignment and annually thereafter. The 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 aeration is encouraged. It can reduce potential long-term risks to employees not directly involved in the ethylene oxide applications.

Air monitoring should include the entire facility including office space, break areas, and loading/ unloading areas.

Employers in facilities that use ETO must comply with all of the requirements for ETO use specified in 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.

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, burrs, chisels
Optical instruments - scopes, cameras, lenses, mirrors

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

FIRST AID STATEMENTS

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 immediate 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 method.* If breathing is at all labored, 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.

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 Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

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.

SHELF LIFE: Each AN1004 EOGas 4 cartridge is marked with an expiration date.

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 sterilization bag. Wrap box, cartridge, and sterilization bag in paper and discard with usual rubbish.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAR 3 2010

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

69340-7

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7. 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.

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 three 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 AN1004 EOGas 4 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.

PHYSICAL OR CHEMICAL HAZARDS DANGER. FLAMMABLE LIQUID AND GAS UNDER PRESSURE

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

Sterilize batteries wrapped individually and separately from their electrical instruments to avoid the possibility 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 three (3) hour sterilization cycle and thirty (30) minute ventilation at 50°C called for in these instructions includes an adequate amount of time to

All items that do not absorb Ethylene Oxide. This includes all glass and metal items such as 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.

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

PRECAUTIONARY STATEMENTS

KEEP OUT OF REACH OF CHILDREN

Hazard to Humans and Domestic Animals.

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 CFR1910.1047

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 plants,
Shoes plus socks,
Chemical-resistant gloves, and
The employer shall provide a respirator that is adequate to protect the health of the employee and ensure compliance with all other OSHA statutory 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.

When wearing respirators:

1. Follow the respirator manufacturer's user's instructions for changing canisters.

2. Respirators must be fit-tested and fit-checked using a program that conforms to OSHA's requirements (see 29CFR Part 1910.134).

3. Respirator users must be trained using a program that conforms to OSHA's requirements (see 29CFR Part 1910.134).

4. Respirator users must be examined by a qualified medical practitioner to ensure physical ability to safely wear the style of respirator to be worn. A qualified medical practitioner is a physician or other licensed health care professional (PLHCP) who will evaluate the ability of a worker to wear a respirator. The initial evaluation consists of a questionnaire that asks about medical conditions (such as a heart condition) that would be problematic for respirator use. If concerns are identified, then additional evaluations, such as a physical exam, might be necessary. The initial evaluation must be done before respirator use begins. It does not need to be repeated unless the health status of respirator use conditions change (see 29CFR Part 1910.134).

Follow manufacturer's instructions for cleaning/ maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

See User's Manual for additional precautionary statements.

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 mutagency 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

Painted equipment - metal, wood
Procedure trays
Rectal tubes, douche tubes - rubber, plastic
Respirators, corrugated tubing
Specula - plastic, metal
Surgical instruments - steel, chrome plated, 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 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.

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 detergents.

5. If the nature of the material to be sterilized is such that the water treatment 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:
   a. Make sure the sterilizer is switched on so that it heats to 50 °C (122 °F).
   b. Prepare the items in the load for sterilization.
   c. 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.
   d. Place the sterilization bag in the heated sterilizer for two (2) hours, then remove the sterilization bag from the sterilizer for an additional two (2) hours to allow for cooling. DO NOT ACTIVATE THE CARTRIDGE AT ELEVATED TEMPERATURE.
   e. After the two (2) hours of cooling, the sterilization bag may be placed in the sterilizer, attached to the purge tube and the cycle started normally.

6. 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 see-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.