

69340-7

07/25/2007

1/6

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUL 25 2007

Ms. Melanie Anderson
Andersen Sterlizers, Inc
Health Science Park
3154 Caroline Drive
Haw River, NC 27258-9789

Subject: AN1004 EOGas 4
EPA Registration No.: 69340-7
Amendment Date: June 6, 2007
EPA Receipt Date: June 6, 2007

Dear Ms. Anderson,

The amendment submitted in connection with registration under FIFRA, as amended, is acceptable with the conditions listed below.

- Revised AN1004 EOGas 4 Insert

Conditions

Revise the label as follows:

- 1) On page 2, delete the phrase, "Misuse Statement," and state "*Directions for Use.*"
- 2) On page 2, delete the term, "Precaution."

General Comments

A stamped copy of the label accepted with conditions is enclosed. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

CONCURRENCES

| | | | | | | | | |
|---------|--|--|--|--|--|--|--|--|
| SYMBOL | | | | | | | | |
| SURNAME | | | | | | | | |
| DATE | | | | | | | | |

2/6

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Should you have any questions or comments concerning this letter, please contact
Jacqueline McFarlane at (703) 308-6416.

Sincerely,

Tracy Zark
for

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

Enclosure: Stamped Insert

CONCURRENCES

| CONCURRENCES | | | | | | | |
|--------------|--|--|--|--|--|--|--|
| SYMBOL | | | | | | | |
| SURNAME | | | | | | | |
| DATE | | | | | | | |

**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

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.

Distributed in Europe by:
H.W. Andersen Products, Ltd.
Davy Road • Gorse Lane Industries Esta
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

ACCEPTED
with COMMENTS
in EPA Letter Dated
JUL 25 2007

Underwritten with all the
Fungicide and bactericide
demanded for the product
registered under EPA no. 1004

69340-7

CE 0413
PN14037_VN060607

3/6

MISUSE STATEMENT

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.

PRECAUTION

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

Never depress button to activate AN1004 EOGas 4 cartridge outside sealed sterilization liner 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, burrs, chisels
Optical instruments - scopes, cameras, lenses, mirrors
Painted equipment - metal, wood
Procedure trays
Rectal tubes, douche tubes - rubber, plastic
Respirators, corrugated tubing
Specula - plastic, metal
Surgical instruments - steel, chrome plate, brass,

plastic
Sutures - plastic, silk, cotton, stainless steel
Syringes - plastic, rubber, glass, bulb syringes
Tongue depressors, applicator sticks
Tubing - plastic, rubber, metal, glass, cloth

Preparation of Material for Sterilization

Material to be sterilized by Ethylene Oxide must be meticulously cleaned and dried. Coatings of dry protein, like dry pus, blood or feces, protect microorganisms and slow the sterilization process. You must always be sure to take the following precautions before sterilizing with 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 treatments specified above are harmful and there is doubt as to the level of humidity in which they have been stored (35% is the minimum acceptable storage humidity), then pretreatment in a sterilization liner bag having a saturated humidity will be necessary for an overall pretreatment routine

Content of Cartridges:

Catalog number AN1004 EOGas 4 Cartridge
Active ingredient Ethylene Oxide97.0%
Inert ingredient3.0%
Total100.0%
Net contents each cartridge 0.62 avoird. oz. (17.6 g)

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

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



DOSEMETER®, **HUMIDICHIP**®, **SEAL AND PEEL**®, **STERITEST**® and **EOGas 4**® are registered trademarks of Andersen Sterilizers, Inc.
Velcro® is a registered trademark of Velcro Industries B.V. Ltd Liab. Co.
Humidichip U.S. Pat no. 5,082,636

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.

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.

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 cardiac irregularities. Treatment is symptomatic.

of 4 hours. Use the following procedure for pre-humidification using an EOGas 4 sterilization liner 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 liner bag. Using the Velcro® strap, securely close the neck of the bag around the purge bobbin. It is not necessary to attach the purge probe to the purge tube at this time.

d. Place the bag in the heated sterilizer for 2 hours, then remove the bag from the sterilizer for an additional 2 hours to allow for cooling. **DO NOT ACTIVATE THE CARTRIDGE AT ELEVATED TEMPERATURE.**

e. After the 2 hours of cooling, the 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 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.

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

Sterilization Method with 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 liner bag from the AN1004 EOGas 4 dispenser box. Use a new AN1004 EOGas 4 sterilization liner bag for each cycle. Place the wrapped items to be sterilized into the sterilization liner 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 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 liner bag on top of the load where it is accessible. Securely attach the purge probe bobbin to the mouth of the sterilization liner bag using the Velcro strap provided. If the sterilizer is equipped with a label printer, attach the printed pre-cycle label to the external surface of the sterilization liner bag. If a multiple-bag EOGas 4 sterilizer is being used and already has some bags loaded, purge the sterilizer prior to loading the bag. Open the door to the EOGas 4 sterilizer, place the sterilization liner bag on the shelf and connect the purge probe to the purge tubing using the quick connect fitting provided.

Once the bag is connected, start the purge cycle. When the purge is complete as indicated on the display on the front of the sterilizer cabinet, insert the AN1004 EOGas 4 cartridge through the sterilization liner bag and press the trigger button firmly. Press it all the way so that the head of the trigger reaches the cartridge wall. This action releases the gas from the cartridge into the sterilization liner bag. Close the door securely and select the cycle length. The door to the sterilizer will lock automatically.

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

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

Important - Variations from These Instructions

Any deviation from the procedures recommended in these instructions is made solely at the users' risk. AN1004 EOGas 4 cartridges are designed to be used only in the sterilization liner 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 liner 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 liner bag retains Ethylene Oxide until it is actively purged from the bag and vented to the outside atmosphere or absorbed in an Andersen Abator[®], specifically designed to be compatible with an EOGas 4 sterilizer.

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

The AN1004 EOGas 4 cartridge will deliver a dose of at least 500 milligrams per liter hours to the contents of the sterilization liner bag. Tests in our laboratory confirm that this dose will kill the most resistant spores known at 50°C within the sterilization cycle providing that the spores have not been dehydrated or have been 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) 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.

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

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

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

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

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.

6/6