UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG - 1 2002

Mr. Jeurgen Ballo
Andersen Sterilizers, Inc.
3154 Caroline Drive
Haw River, NC 27258

Subject: Anprolene AN-79
EPA Registration No. 69340-2
Amendment Date: May 1, 2002
EPA Receipt Date: May 6, 2002

Dear Mr. Ballo,

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

- Update First Aid Statements

Conditions

Revise the label as follows:

1. According to Agency records, EOGas AN-2018 is an alternate brand name for Anprolene AN-79. The Agency does not stamp alternate brand name labels. However, it is evident that AN 79 and AN-2018 are the same product which is sold in different containers In order to consolidate the variation in the two labels, you will need to add additional label language separating the two types of container to the AN-79's label.

   For example: You would distinguish under the label's "Directions for Use" by adding following statement according to sterilizer type.

   Anprolene AN79: To be used only in Anprolene sterilizers, and only for hospital, medical, and veterinary sterilization."

   EOGas AN2018: To be used only inEOGas sterilizers, and only for hospital, medical, and veterinary sterilization."

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

2. The heading, "**Precautionary Statements,**" followed by the subheading, "**Hazard to Humans and Domestic Animals**" must appear on the label above the "DANGER. Causes irreversible eye damage..... 29 CFR 1910.1047" statements.

Revise the package inserts as follows:

1. The package inserts are already distinguished by sterilizer type; however, the following change must be made.

   AN 79: On page 4, the statements, "Anprolene gas is extremely flammable. Do not use near fire, heated surface, or flame. Do not smoke near the sterilizer while loading or unloading it. Sterilize batteries wrapped individually and separately from their electrical instruments,' must appear under the "Physical or Chemical Hazards" section.

   AN 2018: On page 4, the statements, "The EOGas Cartridges contain liquid gas under pressure. Do not use near fire, heated surface, or flame. Do not smoke near the sterilizer while loading or unloading it. Sterilize batteries wrapped individually and separately from their electrical instruments,' must appear under the "Physical or Chemical Hazards" section.

2. On page 4, The heading, "**Precautionary Statements,**" followed by the subheading, "**Hazard to Humans and Domestic Animals**" must appear on the label above the "DANGER. Causes irreversible eye damage..... 29 CFR 1910.1047" statements.

General Comments

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

If you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,

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

AN 79

ONE BOX CONTENTS: 20 AMPOULES, 20 LINER BAGS, 20 CLOSURES

ANPROLENE®

STERILIZING GAS AMPOULES

Active Ingredient: Ethylene oxide 97.0%
Inert ingredients: 3.0%
Total: 100.0%
Net contents 20 ampoules, 0.64 av. oz. (18.15 g) each ampoule

Manufactured by:
Andersen Sterilizers, Inc.
3154 Caroline Dr.
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

European Distributor:
H. W. Andersen Products, Ltd.
Davy Road • Clacton-on-Sea
Essex C015 4XA UK

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 CFR 1910.1047

See user's manual for additional precautionary statements.
Emergency Contact Number: 1-800-255-3924

FIRST AID STATEMENTS

In all cases of exposure, have the product container or label with you when you are going for treatment facility.

IF IN EYES: Hold eyes open and rinse slowly and gently with water for 15 - 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 amubulance, then give artificial respiration, preferrably 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: *Immediatly* 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 2 glasses of water. Do not induce vomiting. Do not give anything by mouth to an unconscious victim. Get *medical* attention.

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 burns with extensive blister formation. At high concentrations severe conjunctivitis can occur. Respiratory tract irritation may occur, but without acute lung *edema. Symptoms* of *systemic intoxication* are *headache*, nausea, vomiting, incoordination, and cardiac irregularities. Treatment is symptomatic.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Discharge 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.

KEEP OUT OF REACH OF CHILDREN • DANGER

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.

IMPORTANT: For Professional Use Only

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

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. **To be used only in Anprolene sterilizers, and only for hospital, medical, and veterinary sterilization.** It is the responsibility of the employer of any person engaged in the handling or application of this product to follow the *requirements* of 29 CFR 1910.1047. Read package insert for complete sterilization instructions and *additional precautions*.

FOR USE IN ANPROLENE STERILIZERS ONLY

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 ampoules* should be returned to the manufacturer for disposal. Contact Andersen Products, Inc. (tel. no. 336-376-3000) for instructions. If unwanted or expired ampoules cannot be disposed of according to Control Agency, or the Hazardous Waste Representative at the *nearest* EPA Regional *Office* for *guidance*.

CONTAINER DISPOSAL: Do not *reuse* empty box, empty ampoules, or liner bags. Wrap box, ampoules, and bags in paper and discard in the trash.

CE 0413

EPA Registration No. 69340-2
EPA Establishment No. 9417-NC-001

P/N 735 043002

ACCEPTED
with COMMENTS
In EPA Letter Dated:
AUG - 1 2002

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registe under EPA Reg. No. 69340-2

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AN79

ANPROLENE®

Brand Gaseous Sterilant for Room Temperature,
Atmospheric Pressure Sterilization
Use in Ventilated Anprolene Sterilizers Only

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. It is the responsibility of the employer of any person engaged in the handling or application of this product to follow the requirements of 29 CFR 1910.1047.

Do not open the plastic bag in which each individual Anprolene ampoule is sealed

Each ampoule of Anprolene is surrounded by a plastic break shield. The ampoule and shield are sealed in a plastic bag. The plastic bag is a gas "fusion membrane of known permeability whose function is to ıtain the gas given off by the ampoule and to release it at a controlled rate during the sterilization cycle. The plastic shield around the ampoule prevents the broken glass of the opened ampoule from puncturing the gas-release bag.

Typical products which may be conveniently processed in Anprolene sterilizers

Respirators, corrugated tubing
Bronchoscopes, gastroscopes, fiberscopes of all kinds
Procedure trays
Catheters - 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
gical 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
Thermometers, applicator sticks
Rectal tubes, douche tubes - rubber plastic
Specula - plastic, metal

ACCEPTED
with COMMENTS
In EPA Letter Dated:
AUG 1 2002
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 69340-2

Preparation of materials for sterilization

Materials to be sterilized by Anprolene must first be meticulously cleaned and towel-dried. Coating of dry protein, such as dry pus, blood, or feces, protect microorganisms and slow the sterilization process. To prevent this possibility, and to be certain that your system meets the highest standard of sterilization, you must:

1. Disassemble and scrub all instruments in detergent and water to the most critical standard of cleanliness possible.
   If an item cannot be washed in detergent and water, then presterilization humidification is required. This pretreatment must be done in a chamber having 100% relative humidity at a temperature of at least 68°F (20°C) for at least four hours. Such a chamber may be made by placing an AN1071 Humidichip® in a liner bag with the item and closing the bag with a twist-tie.
2. Water on instruments at the time of exposure to Anprolene may react with the gas and reduce its effectiveness. Be sure that items to be sterilized are dry before wrapping and processing. Drain or towel-dry instruments. Do not dry them in a hot-air oven.
3. 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 at both ends and free from plugs. Syringes must be packaged disassembled, with the plunger removed from the barrel.
4. You must wrap all items individually, in cloth or paper, in a manner conventional for steam sterilization, or in Anpro® Seal and Peel® Packaging. Anpro Seal and Peel is a transparent, peel-open, extended shelf-life packaging, proven to be compatible with the Anprolene Sterilizing System. Do not pack the liner bag so tightly with cloth or gauze that gas diffusion is slowed.

Sterilization method using AN74A, AN74C/D/E, AN74V AND AN74I/IX

Be certain that all items have been prepared as described above. The ambient relative humidity must be at least 30% for Anprolene processing. The user must verify that this minimum exists before processing begins. Remove one liner bag from the AN79 dispenser box. Prepare the bag to receive the wrapped items to be sterilized by opening it and placing it into the sterilizer container, open end out. Put the wrapped items to be sterilized into the liner bag.

Remove one Anprolene ampoule from the AN79 dispenser box. Do not open the plastic bag in which it is wrapped. Rather, unroll the plastic bag. Push the ampoule gently to the center of the gas-release bag. Place the ampoule, still sealed in its plastic bag, inside the liner bag along with the material to be sterilized. Press out any excess air before closing the mouth of the liner bag. Locate the flexible, plastic purge tube that protrudes into the interior of the sterilizer. Place the purge tube into the mouth of the liner bag. Using one of the closures provided in the Anprolene kit, tie the liner bag around the purge tube. Grasp the ampoule through the bag and protective shield and snap the top of the ampoule. Each ampoule is prescored around its neck to facilitate this action. Snapping off the top of the ampoule activates it, i.e., releases the sterilant gas within the gas-release bag. Close and lock the sterilizer. The AN74 key must be removed from the sterilizer and remain in the possession of a supervisor to prevent unauthorized removal of goods during the sterilization cycle.

AN74C/D/E/I/IX: Close sterilizer and lock the door. The AN74 key must be removed from the sterilizer and remain in the possession of a supervisor to prevent unauthorized removal of goods during the sterilization cycle. The sterilizer must be located in a clean, well-ventilated area, away from sparks or flame. The temperature of the room must be maintained at no less that 68°F (20°C).

At the end of the fourteen-hour cycle, unlock the sterilizer. Remove the seal from the liner bag and open it. Leave the opened liner bag and the wrapped items in the sterilizer for an additional fifteen minutes before removing them.

AN74A or AN74V: Turn the ventilation on if you are using an AN74V sterilizer, make sure that the purge pump is turned off. If you are using an AN74A sterilizer, press the CYCLE START button.

At the end of the twelve-hour sterilization cycle, the AN74A will automatically begin a two-hour purge cycle and a green light will signal when you

may open the sterilizer remove the load. If you are using an AN74V, turn the purge pump on and purge the liner bag for two hours before opening the sterilizer and removing the sterile items.

CAUTION: FAILURE TO OBSERVE THE ABOVE INSTRUCTIONS MAY EXPOSE THE STERILIZER OPERATOR TO MORE THAN 0.5 PPM ETHYLENE OXIDE

(The OSHA Established Action Level Measured as an Eight-Hour Time Weighted Average).

Aerate the gas-absorbent items for at least 24 hours before use (see: **Precautionary Statements**).

After the sterile materials have been removed from the liner bag, the exhausted and empty gas-release ampoule and its bag may be disposed of in ordinary rubbish.

Special processes

When sterilizing long lengths of plastic or rubber tubing, such as ureteral catheters, heart catheters, and coils of drainage tubing, use two ampoules and double the cycle time.

If you are using an AN74 series sterilizer, increase the cycle time to 24 hours. If you are using an AN74V sterilizer, increase the cycle time to 24 hours, and purge the liner bag for two hours. With an AN74C/D/E/I/IX, load the sterilizer with the items for sterilization and the two activated gas-release bags, but then wait twelve hours before pushing the START button. Before loading the sterilizer, be sure that the ventilator is running. The ventilator must continue to run during the entire augmented cycle.

Technical description of the system

The Anprolene Sterilizer container serves as a guard against inadvertent ignition of the contents by spark or open flame during the sterilization cycle. In the case of the AN74C, AN74D, AN74E, and AN74I/IX sterilizers, the container also serves as a ventilation hood.

The liner bag, when properly closed with a tie, has a 35 liter capacity. It is a second gas-diffusion membrane that serves to retain Anprolene long enough to sterilize its contents and releases it into the surrounding vent hood at a slow enough rate to insure that toxic levels are not reached in a properly ventilated room. Each ampoule releases approximately 17.6 grams of Anprolene at room temperature (68°F/20°C) and sea-level atmospheric pressure.

The AN79 ampoule produces a minimum peak concentration within the liner bag of 500 mg/1000 cc. Tests in our laboratory confirm that this dose will kill the most resistant spores known within the twelve-hour cycle, providing they have been rehydrated according to our instructions (see: **Preparation of Materials for Sterilization**).

Storage and disposal

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

STORAGE: Anprolene must be stored in a cool place out of direct sunlight. Under normal conditions its shelf life will exceed one year. As long as the content of the ampoule is liquid at 68°F (20°C), it is sufficiently potent to use.

PESTICIDE DISPOSAL: Unwanted or expired ampoules should be returned to the manufacturer for disposal. Contact Andersen Products Inc. (tel. no. 336-376-3000) for instructions. If unwanted or expired ampoules 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 ampoules, or liner bags. Wrap box, ampoules, and liner bags in paper and discard in the trash.

Testing the efficiency of the Anprolene Sterilizer

Monitoring sterilization efficacy is extremely important. It is strongly recommended that the user establish a routine for monitoring each cycle. A color-change chemical indicator, such as the AN87 Dosimeter®, placed in the most inaccessible part of the load, will indicate 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 AN80 Steritest®, should be used at least once per month to challenge the procedure. The AN80 Steritest is sensitive to the gas concentration, cycle time, and average cycle temperature.

AERATION: It is incumbent on the user to confirm that gas-absorbent items, sterilized in Anprolene, have been adequately aired before they contact 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.

Nylon and polyester films are virtually impervious to ethylene oxide. The only other plastic, water proof wrapping material proven compatible with Anprolene is our Seal and Peel brand roll stock. Do not use any other plastic film to wrap items to be sterilized in Anprolene.

Vacuum dehydration, chemical desiccation or prolonged exposure to ambient relative humidity below 30% has been demonstrated to produce spores highly resistant to sterilization by Anprolene. Rehydration of spores so changed, and hence reversion to normal sensitivity, does not seem to occur until they have been actually wetted or placed in a 100% relative humidity atmosphere. Do not attempt to sterilize materials which may be carrying dried spores without first washing the articles with water and detergents. If the nature of the material is such that the water treatments specified above are harmful, then pretreatment must be done in a chamber having 100% relative humidity at a temperature of at least 68°F (20°C) for at least four hours. Such a chamber may be made by placing an AN1071 Humidichip® in a liner bag with the item and closing the bag with a twist-tie.

IMPORTANT - THE USER MUST NOT DEVIATE FROM THESE INSTRUCTIONS

Do not be fooled by the apparent simplicity of the Anprolene Sterilizing System. Its reliable use depends upon precise adherence to these instructions. AN71 an AN73 Anprolene ampoules are designed to be used only in the AN72C, AN72D, and AN72V Anprolene Sterilizers with the liner bags and twist seals supplied in the refill dispenser. No other container may be used, no matter how similar it seems. Liner bags must not be reused; use only a genuine, fresh Anprolene liner bag with each load.

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 CFR 1910.1047

See user's manual for additional precautionary statements.
Emergency Contact Number: 1-800-255-3924

Anprolene gas is extremely flammable. Do not use it near fire, heated surfaces, or flame. Do not smoke near the container while loading and unloading it. When sterilizing battery-operated instruments, remove the

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batteries and wrap them separately to avoid the possibility of an electrical spark igniting the gas during the sterilization cycle.

Never open the sterilizer during the sterilization cycle. Avoid breathing Anprolene vapor.

Exposure to liquid or gas can cause severe eye damage. Intimate skin contact with fabric, rubber, or plastics containing residual Ethylene oxide can cause damage to the skin, or on clothing. Wear goggles or faceshield when handling. May be fatal if swallowed. Do not breathe vapor. Extremely hazardous liquid and gas under pressure. Inhalation may be fatal. Ethylene oxide gas can be odorless at toxic levels; therefore, exposure to toxic levels may occur without warning or capability of detection by user.

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

y cause nervous system injury, cataracts, adverse reproductive effects, chromosomal and mutagenic 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 for additional precautionary statements and statements of practical treatment.

AERATION: Failure to adequately air gas-absorbing materials may lead to contact chemical burns. All items that may contact living tissues must be aired for at least 24 hours, at a minimum temperature of 68°F (20°C), prior to use. Items such as plastic instruments, foam rubber, plastic foams, vinyl tubing, rubber tubing, plastic items, rubber items, and sealed air-cushioned devices (for instance, anesthesia masks), must be aired. Instruments need not be removed from cloth or paper wrappings to obtain adequate diffusion of the residual Anprolene vapors.

OPERATOR EXPOSURE: It is absolutely essential that reliable forced ventilation be employed in the room where the Anprolene Sterilizer is used. This system must be capable of ten air changes per hour, so that operator exposure remains within U.S. government permissible exposure limits.

FIRST AID STATEMENTS

In all cases of exposure, have the product container or label with you when you are going for treatment facility.

IF IN EYES: Hold eyes open and rinse slowly and gently with water for 15 - 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 amubulance, then give artificial respiration, preferrably 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: Immediatly 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 burns with extensive blister formation. At high concentrations severe conjunctivitis can occur. Respiratory tract irritation may occur, but without acute lung edema. Symptoms of systemic intoxication are headache, nausea, vomiting, incoordination, and cardiac irregularities. Treatment is symptomatic.

Ampoule Fill Weights

Active ingredient: Ethylene oxide	97.0%
Inert Ingredients:	3.0%
Total:	100.0%
Net contents each ampoule	0.64 av. oz (18.15 g)

Anprolene Modular Sterilizing System

AN71	Anprolene 25 Ampoule Refill Dispenser: use with AN72C & D Anprolene Sterilizers.
AN73	Anprolene 60-Ampoule Refill Dispenser: use with AN72C & D Anprolene Sterilizers.
AN79	Anprolene 20-Ampoule Refill Dispenser: use with AN74C/D/E/I/IX Anprolene Sterilizers.
AN72C & D	Ventilated and Purged Anprolene Tray Steril izer with automatic cycle controls.
AN74C/D/E	Ventilated and Purged, High-Capacity Anprolene Sterilizer with automatic cycle controls.
AN74I/IX	Ventilated and Purged, High-Capacity Anprolene Sterilizer with automatic cycle controls.

Anprolene Sterilizing Accessories

AN80	Steritest biological and chemical controls.
AN85	Anprolene Exposure Indicator Strips.
AN87	Anprolene Dosimeter.
AN90	Seal and Peel Electric Impulse Sealer.
AN820	2" x 200' (5 cm x 60 m) Seal and Peel Roll Stock.
AN830	3" x 200' (8 cm x 60 m) Seal and Peel Roll Stock.
AN850	5" x 200' (13 cm x 60 m) Seal and Peel Roll Stock.
AN870	7" x 200' (18 cm x 60 m) Seal and Peel Roll Stock.
AN1071	Humidichip (2" x 2" / 5 cm x 5 cm) humidity stabilizing chips.
AN1072	Humiditube (5 in a pack).

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ANPRO ANDERSEN PRODUCTS

Manufactured by:
Andersen Sterilizers, Inc.
Health Science Park
3154 Caroline Drive
Haw River, NC 27258-8710 U.S.A.
Tel: 336-376-8622
Fax: 336-376-3088

Distributed by:
Andersen Products, Inc.
Health Science Park
3202 Caroline Drive
Haw River, NC 27258-8710 U.S.A.
1-800-523-1276
www.anpro.com
mailbox@anpro.com

Validation services and contract sterilization available from:
Andersen Scientific, Inc.
3220 Caroline Drive
Haw River, NC 27258-9789 U.S.A.
Tel: 888-933-6427
Fax: 336-376-8153

Distributed in Europe, the Middle East and Africa by:
H. W. Andersen Products, Ltd.
Davy Road • Clacton-on-Sea, Essex
Essex C015 4XA U.K.
Tel: 44-1-255-428-328
Fax: 44-1-255-222-987

Distributed in France by:
H.W. Andersen , SARL
Batiment A - RDC - Parc d' Activities de l' Epi de Soll
55 rue Salvador Allende
59120 LOOS, France
Tel: 33-03-20-97-05-25
Fax: 33-03-20-97-61-77

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

EPA Registration No.69340-2
EPA Establishment No. 9417-NC-001

CERTIFIED ISO 9001 EN 46001 SEMKO

CE 0413

P/N862 050102

ACCEPTED
WITH COMMENTS
IN EPA Letter Dated
AUG - 1 2002

... for
...gistered under ... 69340-2

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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.

12. 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 S llowed: 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 conjuctivitis can occur. Irritation of the respiratory tract may occur but without acute edema. Symptoms of systemic intoxication are headache, nausea, vomiting, incoordination and cardiac *arrhythmia.* Treatment is symptomatic *and supportive.*

ACCEPTED
with COMMENTS
in EPA Letter Dated:

AUG 1 2002

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 69340-2

Contents of Cartridges:

AN2003 EOGas Cartridge

Active ingredient Ethylene oxide	89.0%
Ine. ngredients	11.0%
Total	100%

Net contents 0.09 avoir. oz. (3.0 g)

AN2005 EOGas Cartridge

Active ingredient Ethylene oxide	90.0%
Inert Ingredients	10.0%
Total	100%

Net contents 0.18 avoir. oz. (5.0 g)

AN2011 EOGas Cartridge

Active ingredient Ethylene oxide	96.0%
Inert Ingredients	4.0%
Total	100%

Net contents 0.38 avoir. oz. (11.0 g)

AN2014 EOGas Cartridge

Active ingredient Ethylene oxide	96.0%
Inert Ingredients	4.0%
Total	100%

Net contents 0.49 avoir. oz. (14.0 g)

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ACCEPTED
with COMMENTS
In EPA Letter Dated:
AUG - 1 2002
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended for the pesticide registered under EPA Reg. No. 6973-40-2

Industrial EOGas™ Cartridges
AN2005, AN2011, AN2014, AN2018
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.

These cartridges are for industrial use in a fully validated sterilization system only.
It is incumbent on the user to determine the definition of a fully validated sterilization system.

CAUTION:
Do not remove the trigger guard until just before you place the cartridge in the sterilization bag.
NEVER press the trigger outside of the sterilization bag.

1. Preparation of material for sterilization in EOGas.
Items to be sterilized by EOGas Industrial Cartridges must have been stored at a relative humidity of more than 35% at a temperature of at least 20°C (68°F) for at least 24 hours immediately prior to sterilization. Storage must be in packaging materials that will permit water vapor to penetrate to the core of the load. All layers of packaging must be permeable to Ethylene oxide gas.

Although EOGas is a highly diffusible gaseous sterilant, occlusive caps, plugs or stylets must be removed from instruments or positioned so that the gas can penetrate the instrument freely. Glass or plastic syringes must be packaged disassembled with their plungers out of the barrels.

2. Selection of packaging material
All items to be sterilized by EOGas must be sealed in individual packages known to be permeable to Ethylene oxide. Paper and a combination of paper and plastic are ideal individual wrapping materials. Low density polyethylene film is very permeable to EOGas. Polyamide (Nylon) and polyester (Mylar) films are known to be relatively impermeable to Ethylene oxide gas and should not be used with EOGas.

Andersen Sterilizers, Inc. and Andersen Scientific, Inc. provide consultation and validation services to industrial customers regarding the appropriateness of packaging films for use with the EOGas system. See the final page of this brochure for telephone numbers and addresses for these companies.

3. Selection of sterilization bags
EOGas sterilization bags are not provided in the EOGas industrial cartridge refill packs. They may be obtained separately from Andersen Sterilizers, Inc. or one of its authorized distributors. Bag size and packaging materials are chosen during validation or the sterilization cycle.

The material selected for the outer bag must be permeable to Ethylene oxide, otherwise the post-sterilization aeration time will be inordinately long. It must also retain the Ethylene oxide gas long enough to assure an adequate dose of Ethylene oxide is delivered to the core of the load. The sterilization bag must have a relatively low permeability to water vapor so that the relative humidity in the bag is maintained above 35% during sterilization.

We recommend the use of a Humiditube™ and one or more Humidichip® relative humidity stabilizers in each sterilization bag as a proven method of assuring adequate levels of relative humidity during the sterilization cycle. Humidichips may be obtained from us directly of through any of our authorized distributors.

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The film chosen for the sterilization bag must be pinhole free, which means that it must be extruded of virgin materials free from gels or coextruded in at least two layers.

The film chosen must have sufficient resistance to damage by abrasion that it will not develop holes when is manipulated or when it is placed into the sterilizer cabinet.

4. Selection of the EOGas cartridge size

Cartridge size will be selected as part of the sterilization process design and validation. Once determined, only that size cartridge may be used in the sterilization process.

5. Sterilization method

Initiate the warmup or the purge cycle on your EOGas Sterilizer cabinet (For detailed instructions, see the instruction manual accompanying your EOGas cabinet).

Open one sterilization bag and load the packaged items for sterilization. Position one AN1071 Dosimeter® so that it may be easily seen through the wall of the bag. Add a Humiditube containing at least one Humidichip to the bag, and one or more biological indicators. The AN1080 Steritest® is a biological indicator that has been specifically designed for use with the EOGas system.

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In EPA Letter Dated:
AUG 1 2002
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 49340-2

Finally, remove the trigger guard from the EOGas cartridge and place the cartridge into the sterilization bag, orienting the cartridge to make activation easy.

Do not press the trigger yet.

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.

Grasp the cartridge through the heat or vacuum 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.

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. To minimize operator exposure to residual ethylene oxide, this must be done in a well ventilated room (10 air changes per hour) or in a fume hood. The EOGas cabinet also allows a repeat purge cycle (see the Owner's Manual provided with the sterilizer cabinet).

Do not distribute the product until you are sure the biological indicator is negative and any post-sterilization aeration is complete.

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 BAGS.

6. 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.

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7. Accessories for sterilization

AN1071 Humidichip®

The Humidichip is designed to maintain the relative humidity in the sterilization bag during the sterilization cycle.

AN1087 Dosimeter®

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 attained.

AN5024 Andersen Vacuum Sealer

Vacuum sealing the sterilization bag reduces the air space in the bag. This increases the concentration of Ethylene oxide early in the cycle, speeds penetration of the gas into the load and also speeds the diffusion of Ethylene oxide out of the sterilization bag. At the end of the cycle, after the Ethylene oxide has diffused out of the bag, the vacuum tight appearance of the bag provides immediate visual assurance that there are no pinholes in the bag material.

8. 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 cartridge is marked with an expiration date.

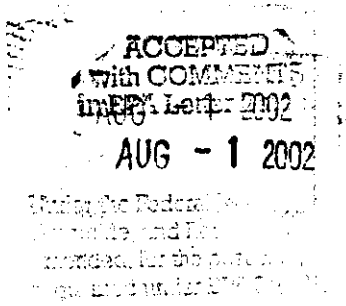
Pesticide Disposal: Unwanted or expired EOGas cartridges should be returned to the manufacturer for disposal. Contact Andersen Products, Inc. (tel. no. 336-376-3000) for instructions. If unwanted or expired EOGas cartridges cannot be disposed of according to label instructions, contact your State Pesticide 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 liner bags. Wrap box, cartridge, and liner bags in paper and discard in ordinary trash.

9. Testing the Efficacy of the EOGas Sterilizer

Monitoring sterilization parameters is the major focus of the validation that must be completed before distributing products sterilized in EOGas. Parameters for validation of an EOGas sterilization process include:

Preconditioning
Sterilization cycle temperature
Sterilization cycle humidity
Sterilization cycle Ethylene oxide dose
Sterilization time
Aeration time
Ethylene oxide residuals
Use of biological indicators
Personnel and area monitoring



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Do not distribute or use products sterilized by EOGas without having completed this process under expert guidance.

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Andersen Scientific, Inc. has the expertise to validate a sterilization cycle to United States and International standards.

10. Environmental Hazards

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Discharge 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.

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.

11. 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 CF. .910.1047

See user's manual for additional precautionary statements.

Emergency Contact: 1-800-255-3924

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 ster' 'ed 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 mutagency changes, and cancer.

PEL: 1PPM-TWA Ethylene Oxide (OSHA - 29 CFR1910.1047
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

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

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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 *and its authorized distributors are* 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.

12. First Aid Statement

In all cases of exposure, have the product container or label with you when you are going for treatment facility.

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 phy ·ian even if no symptoms are present. Keep under medical observation. Symptoms may be delayed.

Kee$_p$ 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 conjuctivitis can occur. Irritation of the respiratory tract may occur but without acute edema. Symptoms of systemic intoxication are headache, nausea, vomiting, incoordination and cardiac *arrhythmia.* Treatment is symptomatic *and supportive.*

Contents of Cartridges:

AN2005 EOGas Cartridge

Active ingredient Ethylene oxide	90.0%
Inert Ingredients	10.0%
Total	100%

Net contents 0.18 avoir. oz. (5.0 g)
EPA Registration Number 69340-5

AN2011 EOGas Cartridge

Active ingredient Ethylene oxide	96.0%
Inert Ingredients	4.0%
Total	100%

Net contents 0.38 avoir. oz. (11.0 g)
EPA Registration Number 69340-6

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AN2014 EOGas Cartridge

Active ingredient Ethylene oxide	96.0%
Inert Ingredients	4.0%
Total	100%

Net contents 0.49 avoir. oz. (14.0 g)
EPA Registration Number 69340-?

AN2018 EOGas Cartridge

Active ingredient Ethylene oxide	97.0%
Inert Ingredients	3.0%
Total	100%

Net contents 0.64 avoir. oz. (18.15 g)
EPA Registration Number 69340-2

The inert ingredients are non-volatile. They stay within the empty ampoule and cartridge and are not emitted into the sterilization bag.

EOGas Commercial Refill Packs

AN2005 EOGas Cartridge
50 each EOGas 5.0g Cartridges (Total 250g)

AN2011 EOGas Cartridge
50 each EOGas 11.0g Cartridges (Total 550g)

AN2014 EOGas Cartridge
50 each EOGas 14.0g Cartridges (Total 700g)

AN2018 EOGas Cartridge
50 each EOGas 18.15g Cartridges (Total 907.5g)

EPA REGISTRATION NO. 69340-2/5/6/?
EPA ESTABLISHMENT NO. 9417-NC-001

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