



069340-00001-040999

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Systems Integration Group, Inc.

P/431

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

69340-1

4/9/99

1019

APR 09 1999

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

Subject: Anprolene AN-71/73
EPA Registration No. 69340-1
Your Amendment Dated: 1/07/99

Attention: Mr. Juergen Ballo,
QA Manager

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

Label Recommendations:

Label A

1. Place "IMPORTANT: For Professional Use Only" above the statement, "Users must follow (29 CFR 1910.1047)."
2. All section headings should be in the same font.
3. According to the Label Review Manual (2nd Edition) and Agency letter dated 10/15/98, the statement, "Keep out of Reach of Children," should precede the signal word.
4. The statement, "Do not contaminate water, food, or feed by storage or disposal," should immediately follow the "Storage and Disposal" heading.

CONCURRENCES							
SYMBOL	7510C						
SURNAME	Campbell						
DATE	4/9/99						

EPA Form 1320-1A (1/90)

Printed on Recycled Paper

OFFICIAL FILE COPY

5. The statement, "See user's manual for additional precautionary statements," should follow the "Precautionary Statements" section.
6. "Environmental Hazards" statements must be added to these labels according to PR Notice 95-1. (See Ethylene Oxide Label Template for guidance).

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Discharge Eliminations System (NDPES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

7. The "Physical/Chemical Hazards" section should be placed after the "Environmental Hazards" section.

Label B and C

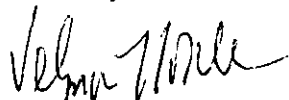
In addition to the 1-7 recommendations above, the label format should be revised by arranging the precautionary labeling in the following order: "Precautionary Statements, Practical Statements of Treatment, Note to Physician, Environmental Hazards, and Physical/Chemical Hazards". The "Directions for Use" and "Storage and Disposal" arrangement is correct.

Manual Recommendations:

On page 3, the statement, "Do not contaminate water, food, or feed by storage or disposal," should immediately follow the "Storage and Disposal" heading.

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

Sincerely,



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

Label A

AN
73

ONE BOX • CONTENTS: 60 AMPOULES • 60 LINER BAGS • 60 CLOSURES

ANPROLENE®

Manufactured by:
ANDERSEN STERILIZERS, INC.

ANDERSEN PRODUCTS Distributed by:
ANDERSEN PRODUCTS, INC.
Health Science Park • Haw River, NC 27258 USA

European Distributor:
H. W. ANDERSEN PRODUCTS LTD.
Davy Road • Clacton-on-Sea • Essex CO15 4XA UK

STERILIZING GAS AMPOULES

DANGER

KEEP OUT OF REACH OF CHILDREN

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

IMPORTANT: For Professional Use Only.

Active ingredient: Ethylene oxide 84.0%
Inert ingredients: 16.0%
Total: 100.0%
Net contents 60 ampoules, 0.16 av. oz. (4.5 g) each ampoule

EPA REGISTRATION NO. 69340-1 • EPA ESTABLISHMENT NO. 94171-MC-001

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 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.

STORAGE AND 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. 336-375-3000) 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, empty ampoules, or liner bags. Wrap box, ampoules, and bags in paper and discard in the trash.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS.
DANGER! CANCER HAZARD AND REPRODUCTIVE HAZARD.
MAY CAUSE IRREVERSIBLE EYE DAMAGE AND SKIN BURNS.
HARMFUL IF INHALED. MAY CAUSE NERVOUS SYSTEM DAMAGE. DO NOT GET IN EYES, SKIN, OR ON CLOTHING.
STORE AND USE WITH ADEQUATE VENTILATION.

PHYSICAL OR CHEMICAL HAZARDS

Ethylene oxide gas is **EXTREMELY FLAMMABLE LIQUID AND GAS UNDER PRESSURE**. Do not use near flame, electrical sparks, or hot surfaces. Ground all equipment to prevent static sparks.

STATEMENT OF PRACTICAL TREATMENT

IN ALL CASES OF EXPOSURE, GET MEDICAL ATTENTION IMMEDIATELY. TAKE PERSON TO A DOCTOR OR EMERGENCY TREATMENT FACILITY AT ONCE.

IF INHALED: Get exposed person to fresh air. Keep warm. Make sure person can breathe freely. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician even if no symptoms are present. Keep under medical observation. Symptoms may be delayed.

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for at least 15 minutes. Get medical attention immediately.

IF ON SKIN: Wash skin with plenty of water while removing contaminated clothing and shoes. Get medical attention immediately. 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.

See side panels and user's manual for additional precautionary statements.

CE 0413
P/N 6811231/98

P/N 681B&W 010699

1/06/99, 11:03 AM

00-21-1

0413

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

69340-1

369

Label B

**AN
73**

ONE BOX CONTENTS: 60 AMPOULES, 60 LINER BAGS, 60 CLOSURES

ANPROLENE®

STERILIZING GAS AMPOULES

Active ingredient: Ethylene oxide 84.0%
Inert ingredients: 16.0%
Total: 100.0%
Net contents 25 ampoules, 0.16 av. oz. (4.5 g) each ampoule

Manufactured by:
ANDERSEN STERILIZERS, INC.
Distributed by:
ANDERSEN PRODUCTS, INC.
Health Science Park • Haw River, NC 27258 USA
European Distributor:
H. W. ANDERSEN PRODUCTS LTD.
Davy Road • Clacton-on-Sea • Essex C015 4XA UK

**ANDERSEN
PRODUCTS**

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS.
DANGER! CANCER HAZARD AND REPRODUCTIVE
HAZARD. MAY CAUSE IRREVERSIBLE EYE DAMAGE
AND SKIN BURNS. HARMFUL IF INHALED. MAY
CAUSE NERVOUS SYSTEM DAMAGE. DO NOT GET IN
EYES, SKIN, OR ON CLOTHING. STORE AND USE
WITH ADEQUATE VENTILATION.

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 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.

EPA REGISTRATION NO. 69340-1
EPA ESTABLISHMENT NO. 9417 NC-001

STORAGE AND 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 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, empty ampoules, or liner bags. Wrap box, ampoules, and bags in paper and discard in the trash.

See side panels and user's manual for additional precautionary statements.

DANGER KEEP OUT OF REACH OF CHILDREN

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

PHYSICAL OR CHEMICAL HAZARDS

Ethylene oxide gas is **EXTREMELY FLAMMABLE LIQUID AND GAS UNDER PRESSURE**. Do not use near flame, electrical sparks, or hot surfaces. Ground all equipment to prevent static sparks.

STATEMENT OF PRACTICAL TREATMENT

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IF INHALED: Get exposed person to fresh air. Keep warm. Make sure person can breathe freely. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician even if no symptoms are present. Keep under medical observation. Symptoms may be delayed.

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NOTE TO PHYSICIAN

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CE 0413 P/N 683 123198

ACCEPTED
with COMMENTS
in EPA Letter Dated:

APR 9 1999

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

69340-1

P/N683 010699

1/06/99, 11:02 AM

AN 71

ONE BOX

CONTENTS: 25 AMPOULES, 25 LINER BAGS, 25 CLOSURES

ANPROLENE®

STERILIZING GAS AMPOULES

Active ingredient: Ethylene oxide 84.0%
 Inert ingredients: 16.0%
 Total: 100.0%
 Net contents 25 ampoules, 0.16 av. oz. (4.5 g) each ampoule

DANGER

KEEP OUT OF REACH OF CHILDREN

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS.
DANGER! CANCER HAZARD AND REPRODUCTIVE
HAZARD. MAY CAUSE IRREVERSIBLE EYE DAMAGE AND
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SKIN, OR ON CLOTHING. STORE AND USE WITH
ADEQUATE VENTILATION.

PHYSICAL OR CHEMICAL HAZARDS

Ethylene oxide gas is **EXTREMELY FLAMMABLE LIQUID AND GAS UNDER PRESSURE**. Do not use near flame, electrical sparks, or hot surfaces. Ground all equipment to prevent static sparks.



Manufactured by:
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 Davy Road • Clacton-on-Sea • Essex C015 4XA UK

EPA Registration No. 69340-1
 EPA Establishment No. 9417-NC-001

P/N 671 010699

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 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.

STORAGE AND DISPOSAL

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ACCEPTED
 With COMMENTS
 in EPA Letter Dated:

APR 9 1999

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

69340-1

1/06/99, 9:10 AM

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AN71•AN73

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-diffusion membrane of known permeability whose function it is to contain 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 CONVENIENTLY BE 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
Surgical instruments - steel, chrome plate, brass, plastic
Optical instruments - scopes, cameras, lenses, mirrors
Electrical equipment - whether autoclavable or not
Painted equipment - metal, wood high-speed steel - drills, burrs, chisels
Airways - plastic, rubber, metal
Fabric - cloth, rubber, plastic, leather
Electric wire - whether autoclavable or not
Dry-cell batteries, battery cases, bulbs
Sutures - plastic, silk, cotton, stainless steel
Thermometers, applicator sticks
Rectal tubes, douche tubes - rubber, plastic
Specula - plastic, metal

ACCEPTED
with COMMENTS
in EPA Letter Dated:

APR 9 1999

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

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® into 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.

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 gas-absorbent items for at least 24 hours prior to use (see: **Precautionary Statements**).

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

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STERILIZATION METHOD USING THE AN72C OR AN72D VENTILATED ANPROLENE STERILIZERS

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 AN71 or AN73 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 inside the liner bag.

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Remove one Anprolene ampoule from the AN71 or AN73 dispenser box. Do not open the plastic bag in which it is wrapped. Rather, unfold 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 tray. 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 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.

7 of 9

STERILIZATION METHOD WITH EARLIER ANPROLENE STERILIZERS AN70, AN72, AND VENTILATION HOOD MODEL AN77

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. Turn on the AN77 Ventilation Hood.

Remove one liner bag from the AN71 or AN73 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 inside the liner bag.

Remove one Anprolene ampoule from the AN71 or AN73 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 AN70 locks with the two mechanical locks on its cover, while the AN72 locks with a key. The key must be removed from the AN72 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 than 68°F (20°C).

At the end of the twelve-hour cycle, unlock the sterilizer. Remove the twist seal from the liner bag and open it. Leave the opened liner bag and wrapped items in the ventilation hood for an additional fifteen minutes before moving them. This procedure allows residual gas in the liner bag to dissipate before the products are handled.

AN72V: If you are using an AN72V sterilizer, be sure that the purge pump is turned off.

DO NOT OPERATE THE (AN72V) PURGE PUMP DURING THE TWELVE-HOUR STERILIZATION CYCLE. FAILURE TO HEED THIS WARNING WILL RESULT IN A NONSTERILE LOAD.

AN72C OR AN 72D: If you are using an AN72C & D sterilizer, press the CYCLE START button. 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 than 68°F (20°C) during the sterilization cycle.

At the end of the twelve-hour sterilization cycle, the AN72C or AN72D will automatically begin a two-hour purge cycle after which you may open the sterilizer and remove the load.

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 gas-absorbent items for at least 24 hours prior to use (see: **Precautionary Statements**).

After the sterile material has 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 AN70 or AN72 sterilizer in an AN77 Ventilation Hood, increase the cycle time to 24 hours. Be sure to permit residual sterilant gas to dissipate from the liner bag by opening the bag and leaving it in the chamber for fifteen minutes before removing the sterile items at the end of the cycle. If you are using an AN72V sterilizer, increase the cycle time to 24 hours, and purge the liner bag for two hours. With an AN72C, 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 a spark or open flame during the sterilization cycle. In the case of the AN72C, AN72D and AN72V sterilizers, the container also serves as a ventilation hood.

When using the AN70 and AN72 sterilizers, a separate AN77 Ventilation Hood is required. The liner bag, when properly closed with a tie, has a 7 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 rate slow enough to ensure that toxic levels are not reached in a properly ventilated room. Each AN71/73 ampoule releases approximately 4.0 grams of Anprolene at 68°F (20°C) and sea-level atmospheric pressure.

The AN71/AN73 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. **Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 69340-1**

STORAGE AND 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 material in 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, empty ampoules, or liner bags. Wrap box, ampoules, and bags in paper and discard in the trash.

TESTING THE EFFICACY 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 AN87 Dosimeter®, placed in the most inaccessible part of the load, will verify whether or not the gaseous sterilant penetrated to the core of the load in adequate concentration to assure sterilization. In addition, an appropriate biological control, such as the EOGas 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.

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

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

HUMIDIFICATION: Vacuum dehydration, chemical desiccation or prolonged exposure to ambient relative humidity below 30% have been demonstrated to produce spores highly resistant to sterilization by EOGas. Rehydration of spores so changed, and hence reversion to normal sensitivity, does not seem to occur until they have been actually wetted or placed in a 100% relative humidity atmosphere. Do not attempt to 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 in a chamber having a saturated humidity at 50°C will be necessary for an overall pretreatment routine of at least 8 hours.

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 and AN73 Anprolene ampoules are designed to be used only in the AN70, AN72, AN72C, and AN72V Anprolene Sterilizers with the liner bags and ties 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.

PRECAUTIONARY STATEMENTS:

DANGER: EXTREMELY FLAMMABLE. KEEP OUT OF REACH OF CHILDREN. DO NOT BREATHE.

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 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 clothing. Wear goggles or face-shield 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

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 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.

STATEMENT OF PRACTICAL TREATMENT

In 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 breath freely. If breathing is difficult, give oxygen. Call a physician even if no symptoms are present. Keep under medical observation. Symptoms may be delayed. If breathing has stopped, give artificial respiration. Do not give anything by mouth to an unconscious person.

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

IF SWALLOWED: Drink at least two glasses of water. Do not induce vomiting. Do not give anything by mouth to an unconscious victim. Call a physician.

See label 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 lung edema. Symptoms of systemic intoxication are headache, nausea, vomiting, incoordination and cardiac irregularities. Treatment is symptomatic.

Ampoule Fill Weights

Active ingredient: Ethylene oxide	84.0%
Inert Ingredients:	16.0%
Total:	100.0%
Net contents each ampoule	0.16 g (4.5 g)

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

69340-1

Anprolene Modular Sterilizing Systems and Refill Kits

- AN71 Anprolene 25 Ampoule Refill Dispenser: use with AN72C & D Anprolene Sterilizers.
- AN73 Anprolene 60-Ampoule Refill Dispenser: use with AN72C & D Anprolene Sterilizers.
- AN72C&D Ventilated and Purged Anprolene Tray Sterilizer with automatic cycle controls.
- AN79 Anprolene 20-Ampoule Refill Dispenser: use with AN74C/D/E Anprolene Sterilizers.
- AN74C/D/E 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' (12 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.

Anpro®, Anprolene®, Dosimeter®, Humidichip®, Seal and Peel® and Steritest® are trademarks of Andersen Products, Inc.

Humidichip U.S. patent No. 5,082,636

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Manufactured by
Andersen Steriliziers, Inc.
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European Distributor:
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EPA Registration No. 69340-1
EPA Establishment No. 9417 NC-001

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