

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

AUG - 1 2002

Subject: Anprolene AN-71
EPA Registration No. 69340-1
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. 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.
2. Under the "Directions for Use," add the statement "To be used only in Anprolene sterilizers, and only for hospital, medical, and veterinary sterilization."
3. According to Agency records, Anprolene AN 73 is an alternate brand name for Anprolene AN-71. The Agency does not stamp alternate brand name labels. However, it is evident that AN 71 and AN 73 are the same product which is sold in different container sizes. In order to consolidate the variation in the two labels, you will need to add AN-73's container sizes to AN-71's label.

Revise the package insert as follows:

1. On page 4, the statements, "Anprolene gas is extremely flammable. Do not use near fire, heated surface, or flame ~~or~~ ^{do not} smoke near the sterilizer while loading

SYMBOL								
SURNAME								
DATE								

or unloading it. Sterilize batteries wrapped individually and separately from their electrical instruments,' must appear under the "Physical or Chemical Hazards" section.

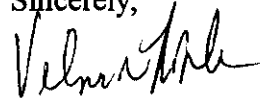
2. On page 4, The heading, "**Precautionary Statements**," followed by the subheading, "**Hazard to Humans and Domestic Animals**" must appear on the label above the "DANGER. Causes irreversible eye damage..... 29 CFR 1910.1047" statements.

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 71

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

ANGER

CAUSES IRREVERSIBLE EYE DAMAGE AND SKIN BURNS. HARMFUL IF INHALED. DO NOT BREATHE 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: 1-800-255-3824

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 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 2 glasses of water. Do not induce vomiting. Do not give anything by mouth to an unconscious victim. Call a physician.

NOTE TO PHYSICIAN

Ethylene oxide is a gas. Skin exposure from contact with fabric, rubber or plastic containing residual ethylene oxide will commonly result in skin 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.

KEEP OUT OF REACH OF CHILDREN • DANGER

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.

DIRECTIONS FOR USE

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

IMPORTANT: For Professional Use Only

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

**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 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.

Manufactured by:

ANDERSEN STERILIZERS, INC.
Health Science Park • 3154 Caroline Drive • Haw River, NC 27258 USA
336-376-8622

Distributed by:

ANDERSEN PRODUCTS, INC.
Health Science Park • 3202 Caroline Drive • Haw River, NC 27258 USA
1-800-523-1278 • 336-376-3000

European Distributor:

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

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

CE 0413

PN 671 043002

AN71 P/N671 043002

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. 69340-1

4/30/02, 12:18 PM

379

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-fusion 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
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.
69340-1

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.

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.

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 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.

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 AN72D: 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, 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 room temperature (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 according to 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 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 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 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.

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 & 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 EO Gas. 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 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.

DANGER

CAUSES IRREVERSIBLE EYE DAMAGE AND SKIN BURNS. HARMFUL IF INHALED. DO NOT BREATHE 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 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.

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 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 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 av. oz (4.5 g)

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.
AN79	Anprolene 20-Ampoule Refill Dispenser: use with AN74C/D/E/IX Anprolene Sterilizers.

- AN72C&D Ventilated and Purged Anprolene Tray Sterilizer with automatic cycle controls.
- AN74C/D/E Ventilated and Purged, High-Capacity Anprolene Sterilizer with automatic cycle controls.
- AN74//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' (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.
- AN1072 Humiditube (5 in a pack).

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

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

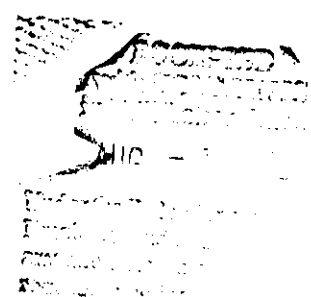


Manufactured by
Andersen Sterilizers, Inc.
Health Science Park
3154 Caroline Drive
Haw River, NC 27258-8710 U.S.A.

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

European Distributor:
H. W. Andersen Products, Ltd.
Davy Road • Gorse Estates Industrial Lane
Clacton-On-Sea • Essex C015 4XA U.K.

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



69340-1

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)

EOGas™ is a trademark and Dosimeter®, Humidichip®, and Steritest® are registered trademarks of Andersen Products, Inc., Haw River, NC 27258-9789

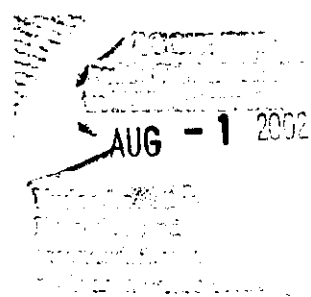
Humiditube™ is a trademark of Andersen Sterilizers, Inc., Haw River, NC 27258-9789

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

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

EPA REGISTRATION NO. 69340-2/5/6/?

EPA ESTABLISHMENT NO. 9417-NC-001



69340-1

Manufactured by:
Andersen Sterilizers, Inc.
 3154 Caroline Drive
 Haw River, NC 27258-9789 U. S. A.
 TEL 1-336-376-8622
 FAX 1-336-376-3088
 e-mail: melittel@earthlink.net

Validation services and contract sterilization available from:
Andersen Scientific, Inc.
 3220 Caroline Drive
 Haw River, NC 27258-9789 U. S. A.
 TEL 1-888-933-6427
 FAX 1-336-376-8153

Distributed by:
Andersen Products, Inc.
 32 Caroline Drive
 Haw River, NC 27258-9789 U. S. A.
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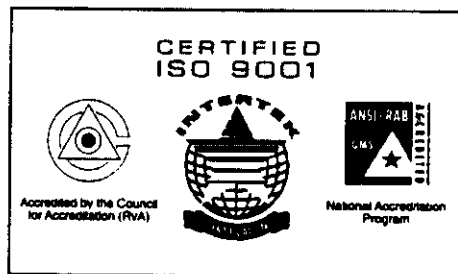
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