

FEB 04 1988

H.W. Andersen Products, Inc.  
45 East Main Street  
Oyster Bay, NY 11771

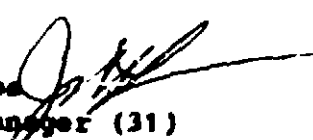
Attention: Lauren Andersen

Gentlemen:

Subject: Anprolene AN-79  
EPA Registration No. 9417-3  
Your Amendment Application Dated January 5, 1988

The modernization and improvement pamphlet for the product and EPA  
Registration Number referred to above, submitted in connection with  
registration under the Federal Insecticide, Fungicide, and Rodenticide  
Act, as amended, is acceptable. A stamped copy is enclosed for your records.

Sincerely yours,

  
John H. Lee  
Product Manager (31)  
Disinfectants Branch  
Registration Division (TS-767C)

Enclosure

10876: L: Lee: L-3: KENCO: 2/2/88: 2/11/88: CONCURRENCE: An:

SYMBOL	ORIGINATOR							
SURNAME								
DATE								

OFFICIAL FILE COPY

ACCEPTED  
in EPA Letter Dated:

FEB 04 1988

Product Name: ANPROLENE  
EPA Reg. No.:  
EPA Approval No.:  
EPA Test Report No.:

9917-3

AN-79

ANPRO

**ANPROLENE<sup>R</sup>**

**BRAND GASEOUS STERILANT FOR ROOM TEMPERATURE,  
ATMOSPHERIC PRESSURE STERILIZATION.**

**Instructions for using Anprolene gas ampules**

1. Do not open the plastic bag in which each individual Anprolene ampule is sealed.

Each ampule of Anprolene has a fabric shield surrounding the ampule. The ampule and shield are sealed in a plastic bag. The plastic bag is a gas diffusion membrane of known permeability whose function is to contain the gas given off by the ampule and release it at a controlled rate during the sterilization cycle. The fabric shield around the ampule prevents the broken glass of the opened ampule from puncturing the gas release bag.

2. Typical products which may conveniently be processed in the AN-74 Anprolene Sterilizer.

Respirators, corrugated tubing

Bronchoscopes, gastroscopes, fiberscopes of all kinds...

Procedure trays

Catheters - plastic, rubber, cloth

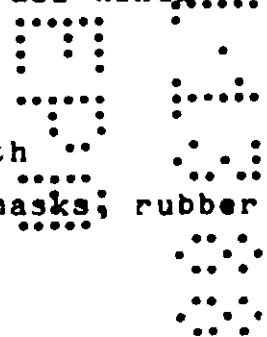
Tubing - plastic, rubber, metal, glass, cloth

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 autoclaveable or not
- Painted equipment - metal, wood
- High speed steel - drills, burrs, chisels
- Airways - plastic, rubber, metal
- Fabric - cloth, rubber, plastic, leather
- Electric wire - whether autoclaveable 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

3. Preparation of material for sterilization.

Material to be sterilized by Anprolene must first be meticulously cleaned and then towel dried. Coatings of dry protein, like 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 take four precautions:

A. Disassemble and then scrub all instruments in detergent and water to the most critical standard of cleanliness possible.

If an item to be sterilized cannot be washed in detergent and water, then presterilization humidification is required. That 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 a wet surgical sponge in a liner bag with the item and twist tying the bag.

B. 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.

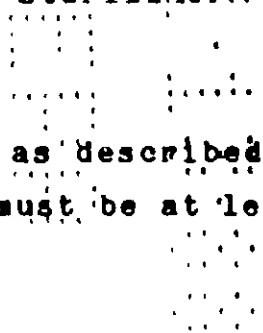
C. Occlusive caps, plugs or stylets must be removed from instruments so that the gas can penetrate freely. Hollow bore needles and plastic or rubber tubing must be open at both ends and free from plugs. Syringes must be packaged disassembled, with the plunger out of the barrel.

D. You must wrap all items individually, in cloth or paper, in the manner conventional for steam sterilization, or in Anpro Seal and Peel<sup>R</sup> Packaging. Anpro Seal and Peel Packaging offers a see-through, peel open, extended shelf-life package, 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.

4. Sterilization method with AN-74 Anprolene Sterilizer, and AN-77 Ventilated Hood.

Be certain that all items have been prepared as described in paragraph 3 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 gusseted liner bag from the AN-79 dispenser box. Prepare the bag to receive the wrapped items to be sterilized by opening it and placing it in the sterilizer container with the open end out. Put the wrapped items to be sterilized inside the liner bag.

**TURN ON THE AN-77 VENTILATED HOOD.**

Remove one large size Anprolene ampule from the AN-79 dispenser box. Do not open the plastic bag in which it is wrapped. Rather, unroll the plastic bag. Each ampule is prescored around its neck to facilitate releasing the gas. Push the ampule gently to the center of the gas release bag. Grasp the ampule through the bag and protective shield and snap the top of the ampule. This action releases the gas within the gas release bag. Place the activated ampule, still sealed in its plastic bag, inside the liner bag with the material to be sterilized. After loading the liner bag with the gas release bag and the materials to be sterilized, press out any excess air before closing the mouth of the liner bag. If you fail to do this, you may experience difficulty in closing the sterilizer due to "pillowing" of the liner bag. Twist the liner bag shut and hold it firmly shut with one of the white twist seal wire closures which are provided in the kit.

Close the door of the AN-74 Sterilizer and lock it with the key provided. The key should be removed from the Sterilizer and remain in the possession of a supervisor. This prevents unauthorized removal of goods from the Sterilizer.

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The AN-74 Sterilizer must be located in a clean, well-ventilated area, away from flame or spark. An AN-77 Anprolene Ventilating Hood or other appropriate ventilating hood, properly connected to the outside, must be used. The temperature of the room must be maintained at no less than 68°F. (20°C).

At the end of the twelve-hour cycle, open the AN-74 Sterilizer with the supervisor's key. Remove the twist seal from the liner bag and open it. Allow fifteen minutes for the diffusion of any residual free gas and then remove the sterilized materials.

FAILURE TO OBSERVE THE ABOVE INSTRUCTIONS MAY EXPOSE THE STERILIZER OPERATOR TO MORE THAN 0.5 PPM ETHYLENE OXIDE (8 HOUR Time-Weighted Average).

Aerate the gas absorbent items for at least 24 hours before use (see paragraph 7: Precautions)

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

5. Sterilization method with AN-74V and AN-74A Ventilated Anprolene Sterilizers.

Be certain that all items have been prepared as described in paragraph 3 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 gusseted liner bag from the AN-79 Dispenser box.

Prepare the bag to receive the wrapped items to be sterilized by opening it and placing it in the sterilizer container with the open end out. Put the wrapped items to be sterilized inside the liner bag.

TURN ON THE VENTILATOR. If you are using the AN-74V sterilizer, be sure the purge pump is turned off.

Remove one large size Anprolene ampule from the AN-79 dispenser box. Do not open the plastic bag in which it is wrapped. Rather, unroll the plastic bag. Each ampule is prescored around its neck to facilitate releasing the gas. Push the ampule gently to the center of the gas release bag. Grasp the ampule through the bag and protective shield and snap the top of the ampule. This action releases the gas within the gas release bag. Place the activated ampule, still sealed in its plastic bag, inside the liner bag with the material to be sterilized. After loading the liner bag with the gas release bag and the materials to be sterilized, press out any excess air before closing the mouth of the liner bag. If you fail to do this, you may experience difficulty in closing the sterilizer due to "pillowing" of the liner bag. Put the small plastic purge tube into the mouth of the liner bag. Twist the liner bag shut around the the purge tube. Hold it firmly closed with one of the white twist seal wire closures which are provided in the kit.

Close the door of the AN-74 Sterilizer and lock it with the key provided. The key should be removed from the Sterilizer and remain in the possession of a supervisor. This prevents unauthorized removal of goods from the Sterilizer. If you are using the AN-74A sterilizer, press the cycle start button.

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DO NOT OPERATE THE PURGE PUMP DURING THE 12 HOUR STERILIZATION CYCLE. FAILURE TO HEED THIS WARNING WILL RESULT IN AN UNSTERILE LOAD.

The AN-74 Sterilizer must be located in a clean, well-ventilated area, away from flame or spark. The temperature of the room must be maintained at no less than 68°F, (20°C).

If you are using the AN-74V sterilizer, at the end of the twelve-hour cycle, turn the purge pump on. Leave the ventilator on. Purge the liner bag for 2 hours before opening the sterilizer and removing the sterile items. If you are using the AN-74A sterilizer, the purge cycle starts automatically. A green indicator tells when the sterilizer may be opened.

FAILURE TO OBSERVE THE ABOVE INSTRUCTIONS MAY EXPOSE THE STERILIZER OPERATOR TO MORE THAN 0.5 PPM ETHYLENE OXIDE (8 HOUR Time-Weighted Average).

Aerate the gas absorbent items for at least 24 hours before use (see paragraph 7: Precautions)

#### 7. PRECAUTIONS.

DANGER: EXTREMELY FLAMMABLE  
KEEP OUT OF REACH OF CHILDREN.

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. Remove batteries from electrical instruments being sterilized in Anprolene and wrap them separately to avoid the possibility of an electrical spark igniting the gas during the sterilization cycle.



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Never open the container during the sterilization cycle. Avoid breathing Anprolene vapor. Breathing Anprolene vapor is harmful. Anprolene sterilizing gas, in concentrated amounts, is as irritating to the lungs and mucous membranes as is ammonia gas. Like many other chemical vapors, Anprolene has the potential to cause an allergic response in a sensitive individual. Such individuals should not handle Anprolene, and should neither breathe its vapors nor allow materials sterilized in it to come in contact with their skin or mucous membranes.

All users must avoid contact of Anprolene with skin, eyes and clothing. If contact with liquid Anprolene 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 Anprolene has come in contact with your eyes, see a physician immediately for further treatment.

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

It is incumbent on the user to determine appropriate abnaction parameters for gas absorbent items intended to contact tissue culture, microbial cell culture, spermatocytes, oocytes, embryonic tissue, or the like.

To minimize operator exposure to ethylene oxide vapors and to shorten the above quoted aeration times, use a heated aerator. H. W. Andersen Products, Inc. offers the AN-78 Anprolene Aerator to speed aeration. For appropriate aeration times using a heated aerator, consult the manual accompanying the aerator.

Microorganisms and spores which are vacuum dehydrated, crystallized in salt, chemically desiccated, or dried by prolonged exposure to ambient relative humidity below 30% may become highly resistant to sterilization by Anprolene. Rehydration of organisms so changed, and hence reversion to normal sensitivity, occurs only when they have been actually wetted or placed in a 100% relative humidity atmosphere. Do not attempt to sterilize materials which may be carrying dried microorganisms without first scrubbing the articles with water and soap or detergents. If the nature of the material is such that immersion in water is harmful, then pre-treatment in a chamber having a saturated humidity and a temperature of at least 68° F. (20° C.) is required for at least four hours.

Anprolene is a potent polymerizing agent. It must not be used for sterilizing food-stuffs or drugs because it may chemically change them in an detrimental manner.

It is absolutely essential that reliable forced ventilation be employed in the room in which 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.

Ventilation hoods and ventilated sterilizers must be tested for efficacy, and serviced at the sterilizer site at least once a

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year. If you cannot arrange for this locally, you may contact H. W. Andersen Products, Inc. at 1-800-523-1276 for advice regarding testing and service.

8. IMPORTANT - The user must not deviate from these instructions.

Do not be fooled by the Anprolene Sterilizing System's apparent simplicity. Its reliable use depends on your adhering precisely to these instructions. AN-79 Anprolene ampules are designed to be used only in the AN-74, AN-74V and AN-74A 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. You must use a genuine, fresh Anprolene liner bag with each load.

8. 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. The liner bag, when properly twist closed, has a 35 liter capacity. It serves as a second gas diffusion membrane, retaining Anprolene long enough to sterilize its contents and then diffusing 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 ampule releases approximately 17 grams of Anprolene at room temperature (68°F., 20°C.) and sea level atmospheric pressure. The AN-79 ampule produces a minimum peak concentration within the liner bag of 500 µgm/1,000 cc. Tests in our laboratory confirm that this configuration will kill

the most resistant spores known within the 12 hour cycle providing they have been been rehydrated according to our instructions.

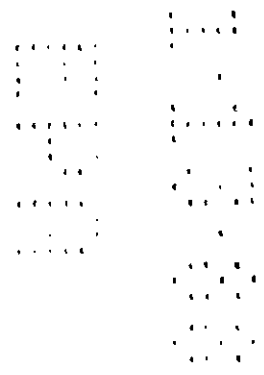
9. Storage - Shelf Life.

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

10. 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, such as the ANPRO AN-87 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 ANPRO AN-80 Steritest, should be used at least once per month to challenge the procedure. It is sensitive to the gas concentration, cycle time and average cycle temperature.

Net contents each ampule .....0.64 av. oz.  
Active ingredient ethylene oxide ..... 97%  
Inert ingredients .....3%



Anprolene<sup>R</sup> Modular Sterilizing System

- AN-71 Anprolene 25 Ampule Refill Dispenser: use with AN-70, or AN-72 Sterilizers (includes 25 ampules of Anprolene Sterilizing Gas)
- AN-72 Anprolene Tray Kit (Includes 1 AN-73)
- AN-72V Ventilated Anprolene Tray Kit with manual cycle controls (Includes 1 AN-71)
- AN-73 Anprolene 60 Ampule Refill Dispenser: use with AN-70, or AN-72 Sterilizers (includes 60 ampules of Anprolene Sterilizing Gas)
- AN-74 Anprolene High Capacity Sterilizer (Includes 1 AN-79)
- AN-74A Anprolene High Capacity Sterilizer - ventilated sterilizer with automatic cycle timer (Includes 1 AN-79)
- AN-74V Anprolene High Capacity Sterilizer - ventilated sterilizer with manual controls (Includes 1 AN-79)
- AN-77 Anprolene Ventilated Hood
- AN-78 Anprolene Aerator Cabinet
- AN-79 Anprolene 20 cc. Ampule Refill Dispenser: Use with AN-74 Sterilizer only (includes 20 ampules of Anprolene Sterilizing Gas)
- AN-80 Steritest<sup>R</sup> biological and chemical controls
- AN-85 Anprolene Exposure Indicator Strips
- AN-87 Anprolene Dosimeter<sup>R</sup>
- AN-90 Seal and Peel Electric Impulse Sealer
- AN-820 2" by 200' Seal and Peel<sup>R</sup> Roll Stock
- AN-830 3" by 200' Seal and Peel Roll Stock
- AN-850 5" by 200' Seal and Peel Roll Stock
- AN-870 7" by 200' Seal and Peel Roll Stock

Anprolene<sup>R</sup>, Steritest<sup>R</sup>, Dosimeter<sup>R</sup> and Seal and Peel<sup>R</sup> are registered trademarks of H.W. Andersen Products, Inc.

Anprolene is patented in

Argentina 167,959	
Australia 414,088	Mexico 104,930
Canada 791,915	New Zealand 144,583
France 1,475,399	Pakistan 117,277
Great Britain 1,138,512	U.S.A. 3,476,506, 3,505,775,
& 1,138,513	3,552,083
Italy 800,099	West Germany 17,92,771 & 16,17,957
India 1620	South Africa 1692/66
Japan 830.237	Sweden 337,282

Other Patents Pending

Manufactured By  
H.W. ANDERSEN PRODUCTS, INC.  
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EPA REGISTRATION NO. 9417-3  
EPA ESTABLISHMENT NO. 9417-NYOI

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