



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

September 12, 2022

Faith Rios
Director, Quality Assurance and Regulatory Affairs
Andersen Sterilizers, Inc.
Electronic Transmittal: faith.rios@sterility.com

Subject: Label Amendment – Updated label per ETO RED
Product Name: AN7916
EPA Registration Number: 69340-2
Received Date: August 3, 2022
Action Case Number: 00382797

Dear Faith Rios:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. The next label printing of this product must use this labeling unless subsequent changes have been approved. Pursuant to 40 CFR 156.10(a)(6) you must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the Agency. See FIFRA section 2(p)(2). If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process, FIFRA section 12(a)(1)(B). Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Assurance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

Page 2 of 2
EPA Reg. No. 69340-2
Action Case Number 00382797

with FIFRA section 6. If you have any questions, please contact Tara Flint Silva via email at flintsilva.tara@epa.gov.

Sincerely,

Tara M Flint Silva

Tara Flint Silva, Acting Product Manager 31
Regulatory Management Branch I
Antimicrobials Division
Office of Pesticide Programs

Enclosure: Stamped label

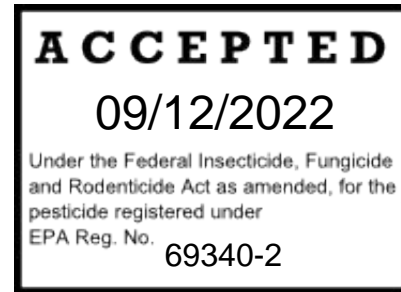
Primary Brand Name: AN7916

Master Label:

Note to Reviewer: In accordance with 40 CFR 156.68(d), all first aid statements, as prescribed, will appear on the front panel of the product label.

Anprolene® AN7916 Refill Kits:

AN7916 Anprolene® Refill Kit
CONTENTS: 14 Ampoules, 14 Liner Bags
Each ampoule contains 0.64 av. Oz.
(17.6 g) Ethylene Oxide
Active ingredient: Ethylene oxide 97.0%
Inert ingredient: 3.0%
Total: 100%



Manufactured by:
ANDERSEN STERILIZERS, INC.
3154 Caroline Drive • Haw River, NC 27258 USA

Distributed by:
ANDERSEN PRODUCTS, INC.
3202 Caroline Drive • Haw River, NC 27258 USA
1-800-523-1276 • 336-376-3000

Authorized UK Representative:
H. W. ANDERSEN PRODUCTS, LTD.
808 Fowler Clacton-On-Sea • Essex CO15 4AA UK
44-1255-428328

Authorized EU Representative:
H. W. ANDERSEN S.A.R.L.
12 Place Saint-Hubert • 59000 • Lille, France

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

Anprolene® is a registered trademark of Andersen Sterilizers, Inc.

AN736.00

Keep Out of Reach of Children

DANGER

PRECAUTIONARY STATEMENTS

Causes eye and skin burns. May be fatal if inhaled. Do not breathe vapor. Do not swallow. Do not get in eyes, on skin, or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Wear appropriate protective clothing.

USER SAFETY RECOMMENDATIONS

Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

OTHER POSSIBLE DELAYED HEALTH EFFECTS

Cancer and reproductive hazard. May cause nervous system damage, cataracts, adverse reproductive effects, chromosomal and mutagenic changes. May cause irritation of respiratory tract, chest tightness, headache, nausea, vomiting, diarrhea, light headed feeling, dizziness, weakness, drowsiness, cyanosis, loss of coordination, coma, delayed lung injury (fluid in lungs), immediate or delayed skin irritation and blisters, allergic skin.

PEL: 1 PPM-TWA Ethylene Oxide (OSHA-29CFR 1910.1047).

EL: 5 PPM-excursion limit, 15 minutes.

Store and use with adequate ventilation in accordance with 29 CFR1910.1047

FIRST AID

In all cases of exposure, get medical attention immediately. Take person to a doctor or emergency treatment facility at once.

Have the product container or label with you when calling the Emergency Contact number or doctor or going for treatment.

IF INHALED: Move exposed person to fresh air. Keep warm. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth method. If breathing is at all labored, give oxygen. Call a doctor even if no symptoms are present for further treatment advice. Keep under medical observation. Symptoms may be delayed.

IF IN EYES: Hold eyelids open and flush eyes with a steady, gentle stream of water for at least 15 to 20 minutes. Remove contact lenses, if present, after the first 5 minutes and then continue rinsing the eyes. Get immediate medical treatment.

IF ON SKIN: Immediately wash skin for 15-20 minutes with plenty of water while removing contaminated clothing and shoes. Call Emergency Contact number or a doctor for treatment advice. Aerate, wash, or clean contaminated clothing and discard leather goods.

IF SWALLOWED: Call the Emergency Contact number or a doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by an Emergency Contact responder or doctor. Do not give anything to an unconscious person.

NOTE TO PHYSICIAN

Ethylene oxide is a liquefied 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, lack of coordination, and cardiac irregularities. Treatment is symptomatic.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

A material that is chemical resistant to this product is butyl rubber.

All handlers must wear at a minimum:

- Long-sleeved shirt and long pants.
- Shoes plus socks.
- Chemical-resistant gloves and
- when the ambient ETO concentration is 1 to 50 ppm, full-facepiece respirator with ETO approved canister, front or back mounted,
- when the ambient ETO concentration is 50 to 2,000 ppm, (1) positive-pressure supplied-air respirator equipped with full-facepiece, hood, or helmet; or (2) continuous-flow supplied-air respirator (positive-pressure) equipped with hood, helmet, or suit,
- when the ambient ETO concentration is >2,000 ppm or unknown (e.g., emergency situations), (1) positive-pressure self-contained breathing apparatus equipped with full-facepiece; or (2) positive-pressure full facepiece supplied-air respirator equipped with an auxiliary positive-pressure self-contained breathing apparatus.

When handlers could have eye or skin contact with ETO or ETO solutions, such as during maintenance and repair, vessel cleaning, or cleaning up spills, they must wear:

- Chemical-resistant attire, such as an apron, protective suit, or footwear that protects the area of the body that might contact ETO or ETO solutions, and
- Face-sealing goggles, a full-face shield, or a full-face respirator.

USER SAFETY REQUIREMENTS

When wearing respirators:

1. Follow the respirator manufacturer's user's instructions for changing canisters.
2. Respirators must be fit-tested and fit-checked using a program that conforms to OSHA's requirements (see 29CFR Part 1910.134).
3. Respirator users must be trained using a program that confirms to OSHA's requirements (see 29CFR Part 1910.134).
4. Respirator users must be examined by a qualified medical practitioner to ensure physical ability to safely wear the style of respirator to be worn. A qualified medical practitioner is a physician or other licensed health care professional (PLHCP) who will evaluate the ability of a worker to wear a respirator. The initial evaluation consists of a questionnaire that asks about medical conditions (such as a heart condition) that would be problematic for respirator use. If concerns are identified, then additional evaluations, such as a physical exam, might be necessary. The initial evaluation must be done before respirator use begins. It does not need to be repeated unless the health status or respirator use conditions change (see 29CFR Part 1910.134).

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

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 Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Emergency Contact: 1-800-255-3924

PHYSICAL AND CHEMICAL HAZARDS

Ethylene oxide gas is extremely flammable. Do not use near flame, electrical sparks, hot surfaces, or allow sources of ignition near the sterilization area. Ground all equipment to prevent static sparks.

Contents under pressure. Do not puncture or incinerate container. Exposure to temperatures above 130 °F (54°C) may cause bursting.

ODOR: Ether-like in high concentrations. Exposure to toxic levels may occur without warning or detection by the user.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Employers in facilities that use ETO must comply with all requirements for ETO use specified in 29 CFR 1910.1047.

Employers in facilities that use ETO must comply with all of the requirements for ETO use specified in 29 CFR 1910.1047.

The AN7916 may be used only in Anprolene AN74 sterilizers, and only for hospital, medical, and veterinary sterilization.

In hospitals and healthcare facilities, and contract sterilization facilities treating medical equipment and supplies, sterilization/fumigation with ETO must be performed only in vacuum or gas tight chambers designed for use with ETO. After February 28, 2010, a single chamber process is required for ETO treatment (sterilization and aeration are to occur in the same chamber) in hospitals and healthcare facilities.

During the sterilization cycle, the sterilization bag may contain hazardous concentrations of ETO. Do not open the sterilization bag until the sterilization, ventilation, and aeration portions of the treatment cycle are complete.

Safety and awareness training is required for all employees including office staff. Information and training must be provided to all employees in the facility at the time of initial assignment and annually thereafter. The safety training must include, at a minimum, the following information: 1. the most recent monitored ambient levels of ETO in the facility; 2. the potential health effects from the levels of ETO in the facility; 3. the emergency response plan and how to respond in an emergency; 4. the availability of the Material Safety Data Sheet and other materials related to the health hazards of exposure to ETO. To reduce ambient levels of ETO, lengthy facility aeration is encouraged. Achieving an ambient level of 0.25 ppm (measured as a daily time-weighted average) greatly reduces potential long-term risks to employees not directly involved in the ETO applications. Air monitoring should include the entire facility including office space, break areas, and loading/unloading areas. Employers in facilities that use ETO must comply with all the requirements for ETO use specified in 29 CFR 1910.1047.

- Remove one sterilization bag from the dispenser box. Place wrapped devices to be sterilized inside the sterilization bag.
- Remove one ampoule from the AN7916 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. **DO NOT ACTIVATE AMPOULE.**
- Insert the purge probe into the sterilization bag. Gather the open end of the sterilization bag around the purge probe and wrap the hook and loop strap around both the sterilization bag opening and the purge probe, tightening it to completely seal the sterilization bag.
- Place the sealed sterilization bag inside the sterilizer. Connect the quick release connector on the purge probe to the purge probe tubing.
- Evacuate excess air from the sterilization bag using the initial bag purge, then follow the

- cycle selection and cycle verification prompts.
- Press the Purge button which will draw a vacuum on the sterilization bag for ninety seconds. At the end of ninety seconds, break the ampoule by manipulating the pre-scored neck of the ampoule through the wall of the sterilization bag.
 - Close the door to the sterilizer and start the sterilization cycle.
 - Always lock the door of the sterilizer to prevent unauthorized removal of devices during the sterilization and ventilation portions of the cycle.
 - After the sterile devices have been removed from the sterilization bag, discard the sterilization bag and empty cartridge according to disposal instructions. **DO NOT REUSE EMPTY BOX OR STERILIZATION BAGS.**

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool, well ventilated area away from heat and direct sunlight. Store in accordance with 29 CFR 1910.1047.

Pesticide Disposal: Pesticide wastes are toxic. Improper disposal of excess pesticides (unwanted or expired AN7916.00 Anprolene ampoules) is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact Andersen Products, Inc. (336-376-3000), or your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal: Do not puncture or incinerate unused ampoules. Aerate empty ampoules and used sterilization bags according to the complete Directions for Use. After aeration, dispose of in sanitary landfill.

AN7916



AN7916 Anprolene® Refill Kit

CONTENTS: 14 Ampoules, 14 Liner Bags,

Each ampoule contains	
0.64 av. oz. (17.6 g) Ethylene Oxide	
Active ingredient: Ethylene oxide	97.0%
Inert ingredient:	3.0%
Total:	100%

For use in the following Andersen Sterilizers
Ethylene Oxide Gas Sterilization Systems:
Anprolene AN74i/ix/j

Manufactured by:	Authorized UK Representative:
ANDERSEN STERILIZERS, INC.	H. W. ANDERSEN
3154 Caroline Drive	PRODUCTS, LTD.
Haw River, NC 27258 USA	808 Fowler Clacton-On-Sea
	Essex CO15 4AA UK
	44-1255-428328

Distributed by:	Authorized EU Representative:
ANDERSEN PRODUCTS, INC.	H.W. Andersen S.A.R.L.
3202 Caroline Drive	12 Place Saint-Hubert
Haw River, NC 27258 USA	59000 • Lille • France
1-800-523-1276	
336-376-3000	

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



AN736.00 Rev 1

Keep Out of Reach of Children DANGER

PRECAUTIONARY STATEMENTS

Causes eye and skin burns. May be fatal if inhaled. Do not breath vapor. Do not swallow. Do not get in eyes, on skin, or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Wear appropriate protective clothing.

USER SAFETY RECOMMENDATIONS

Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

OTHER POSSIBLE RELATED HEALTH

EFFECTS: Cancer and reproductive hazard. May cause nervous system damage, cataracts, adverse reproductive effects, chromosomal and mutagenic changes. May cause irritation of respiratory tract, chest tightness, headache, nausea, vomiting, diarrhea, light headed feeling, dizziness, weakness, drowsiness, cyanosis, loss of coordination, coma, delayed lung injury (fluid in lungs), immediate or delayed skin irritation and blisters, allergic skin.

PEL: 1 PPM-TWA Ethylene Oxide (OSHA-29 CFR 1910.1047).

EL: 5 PPM-excursion limit, 15 minutes.

Store and use with adequate ventilation in accordance with 29 CFR 1910.1047.

FIRST AID

In all cases of exposure, get medical attention immediately. Take person to a doctor or emergency treatment facility at once.

Have the product container or label with you when calling the Emergency Contact number or doctor, or going for treatment.

IF INHALED: Move exposed person to fresh air. Keep warm. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth to mouth method. If breathing is at all labored, give oxygen. Call a doctor even if no symptoms are present for further treatment advice. Keep under medical observation. Symptoms may be delayed.

IF IN EYES: Hold eyelids open and flush eyes with a steady, gentle stream of water for at least 15 to 20 minutes. Remove contact lenses, if present, after the first 5 minutes and then continue rinsing the eyes. Get immediate medical treatment.

IF ON SKIN: Immediately wash skin for 15-20 minutes with plenty of water while removing contaminated clothing and shoes. Call Emergency Contact number or a doctor for treatment advice. Aerate, wash, or clean contaminated clothing and discard leather goods.

IF SWALLOWED: Call the Emergency Contact number or a doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by an Emergency Contact responder or a doctor. Do not give anything to an unconscious person.

NOTE TO PHYSICIAN

Ethylene oxide is a liquefied 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, lack of coordination, and cardiac irregularities. Treatment is symptomatic.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

A material that is chemical resistant to this product is butyl rubber.

All handlers must wear at a minimum:

- Long-sleeved shirt and long pants.
- Shoes plus socks.
- Chemical-resistant gloves and
- when the ambient ETO concentration is 1 to 50 ppm, full-facepiece respirator with ETO approved canister, front or back mounted,
- when the ambient ETO concentration is 50 to 2,000 ppm, (1) positive-pressure supplied-air respirator equipped with full-facepiece, hood, or helmet; or (2) continuous-flow supplied-air respirator (positive- pressure) equipped with hood, helmet, or suit,
- when the ambient ETO concentration is >2,000 ppm or unknown (e.g., emergency situations), (1) positive-pressure self-contained breathing apparatus equipped with full-facepiece; or (2) positive-pressure full facepiece supplied-air respirator equipped with an auxiliary positive-pressure self-contained breathing apparatus.

When handlers could have eye or skin contact with ETO or ETO solutions, such as during maintenance and repair, vessel cleaning, or cleaning up spills, they must wear:

- Chemical-resistant attire, such as apron, protective suit, or footwear that protects the area of the body that might contact ETO or ETO solutions, and
- Face-sealing goggles, a full-face shield, or a full-face respirator.

USER SAFETY REQUIREMENTS

When wearing respirators:

1. Follow the respirator manufacturer's user's instructions for changing canisters.
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3. Respirator users must be trained using a program that confirms to OSHA's requirements (see 29CFR Part 1910.134).
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evaluate the ability of a worker to wear a respirator. The initial evaluation consists of a questionnaire that asks about medical conditions (such as a heart condition) that would be problematic for respirator use. If concerns are identified, then additional evaluations, such as a physical exam, might be necessary. The initial evaluation must be done before respirator use begins. It does not need to be repeated unless the health status or respirator use conditions change (see 29CFR Part 1910.134).

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

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 Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

EMERGENCY CONTACT: 1-800-255-3924 PHYSICAL AND CHEMICAL HAZARDS

Ethylene oxide gas is extremely flammable. Do not use near flame, electrical sparks, hot surfaces, or allow sources of ignition near the sterilization area. Ground all equipment to prevent static sparks.

Contents under pressure. Do not puncture or incinerate container. Exposure to temperatures above 130 °F (54°C) may cause bursting.

ODOR: Ether-like in high concentrations. Exposure to toxic levels may occur without warning or detection by the user.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Employees in facilities that use ETO must comply with all of the requirements for ETO use specified in 29CFR 1910.1047. The AN7916 may be used only in Anprolene AN74 sterilizers, and only for hospital, medical, and veterinary sterilization. In hospitals, healthcare facilities, and contract sterilization facilities treating medical equipment and supplies, sterilization/fumigation with ETO must be performed only in vacuum or gas tight chambers designed for use with ETO. After February 28, 2010, a single chamber process is

required (ETO treatment (sterilization and aeration are to occur in the same chamber) in hospitals and healthcare facilities.

During the sterilization cycle, the sterilization bag may contain hazardous concentrations of ETO. Do not open the sterilization bag until the sterilization, ventilation, and aeration portions of the treatment cycle are complete.

Safety and awareness training is required for all employees including office staff. Information and training must be provided to all employees in the facility at the time of initial assignment and annually thereafter. The safety training must include, at a minimum, the following information:

1. the most recent monitored ambient levels of ETO in the facility;
2. the potential health effects from the levels of ETO in the facility;
3. the emergency response plan and how to respond in an emergency;
4. the availability of the Material Safety Data Sheet and other materials related to the health hazards of exposure to ETO. To reduce ambient levels of ETO, lengthy facility aeration is encouraged. Achieving an ambient level of 0.25 ppm (measured as a daily time-weighted average) greatly reduces potential long-term risks to employees not directly involved in the ETO applications. Air monitoring should include the entire facility including office space, break areas, and loading/unloading areas. Employers in facilities that use ETO must comply with all the requirements for ETO use specified in 29 CFR 1910.1047.

Sterilization Process:

- Remove one sterilization bag from the dispenser box. Place wrapped devices to be sterilized inside the sterilization bag.
- Remove one ampoule from the AN7916 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. DO NOT ACTIVATE AMPOULE.
- Insert the purge probe into the sterilization bag. Gather the open end of the sterilization bag around the purge probe and wrap the hook and loop strap around both the sterilization bag opening and the purge probe, tightening it to completely seal the sterilization bag.
- Place the sealed sterilization bag inside the sterilizer. Connect the quick release connector on the purge probe to the purge probe tubing.
- Evacuate excess air from the sterilization bag using the initial bag purge, then follow the cycle selection and cycle verification prompts.

- Press the Purge button which will draw a vacuum on the sterilization bag for ninety seconds. At the end of ninety seconds, break the ampoule by manipulating the pre-scored neck of the ampoule through the wall of the sterilization bag.
- Close the door to the sterilizer and start the sterilization cycle.
- Always lock the door of the sterilizer to prevent unauthorized removal of devices during the sterilization and ventilation portions of the cycle.
- After the sterile devices have been removed from the sterilization bag, discard the sterilization bag and empty cartridge according to disposal instructions. DO NOT REUSE EMPTY BOX OR STERILIZATION BAGS.

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool, well ventilated area away from heat and direct sunlight. Store in accordance with 29 CFR 1910.1047.

Pesticide Disposal: Pesticide wastes are toxic. Improper disposal of excess pesticides (unwanted or expired AN7916.00 Anprolene ampoules) is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact Andersen Products, Inc. (336-376-3000), or your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal: Do not puncture or incinerate unused ampoules. Aerate empty ampoules and used sterilization bags according to the complete Directions for Use. After aeration, dispose of in sanitary landfill.



ANDERSEN
S T E R I L I Z E R S

DIRECTIONS FOR USE:

ANPROLENE AN7916

ETHYLENE OXIDE AMPOULES

For use in the following Andersen Sterilizers Ethylene Oxide Gas Sterilization Systems:

Anprolene AN74i/ix/j

Anprolene AN7916 Refill Kit contents:
14 Ampoules, 14 Liner Bags

Each Ampoule Contains 0.64 av. oz.
(17.6 g) Ethylene Oxide
Active ingredient: ethylene oxide 97.0%
Inert ingredient: 3.0%
Total: 100%

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

Anprolene® is a registered trademark of Andersen Sterilizers, Inc.

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

Distributed in the US by:
Andersen Products, Inc.
Health Science Park
3202 Caroline Drive
Haw River, NC 27258 U.S.A.
1.800.523.1276 • 336.376.3000

H.W. Andersen Products of California, Inc.
3151 Caroline Drive
Haw River, NC 27258 U.S.A.

Authorized UK Representative:
H.W. Andersen Products, Ltd.
808 Fowler Road
Clacton-on-Sea • Essex CO15 4AA U.K.

Authorized EU Representative:
H. W. ANDERSEN S.A.R.L.
12 Place Saint-Hubert • 59000 • Lille,
France

All other inquiries worldwide:
Andersen Products, Inc.
Health Science Park
3202 Caroline Drive
Haw River, NC 27258 USA

sterility.com

KEEP OUT OF REACH OF CHILDREN



DANGER

PRECAUTIONARY STATEMENTS

Causes eye and skin burns. May be fatal if inhaled. Do not breathe vapor. Do not swallow. Do not get in eyes, on skin, or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Wear appropriate protective clothing.

reproductive effects, chromosomal and mutagenic changes. May cause irritation of respiratory tract, chest tightness, headache, nausea, vomiting, diarrhea, light headed feeling, dizziness, weakness, drowsiness, cyanosis, loss of coordination, coma, delayed lung injury (fluid in lungs), immediate or delayed skin irritation and blisters, allergic skin.

PEL: 1 PPM-TWA Ethylene Oxide (OSHA-29CFR 1910.1047)
EL: 5 PPM-excursion limit, 15 minutes

Store and use with adequate ventilation in accordance with 29 CFR1910.1047

USER SAFETY RECOMMENDATIONS

Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

FIRST AID

In all cases of exposure, get medical attention immediately. Take person to a doctor or emergency treatment facility at once. Have the product container or label with you when calling the Emergency Contact number or doctor or going for treatment.

OTHER POSSIBLE DELAYED HEALTH EFFECTS

Cancer and reproductive hazard. May cause nervous system damage, cataracts, adverse

IF INHALED: Move exposed person to fresh air. Keep warm. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth method. If breathing is at all

labored, give oxygen. Call a doctor even if no symptoms are present for further treatment advice. Keep under medical observation. Symptoms may be delayed.

IF IN EYES: Hold eyelids open and flush eyes with a steady, gentle stream of water for at least 15 to 20 minutes. Remove contact lenses, if present, after the first 5 minutes and then continue rinsing the eyes. Get immediate medical treatment.

IF ON SKIN: Immediately wash skin for 15-20 minutes with plenty of water while removing contaminated clothing and shoes. Call Emergency Contact number or a doctor for treatment advice. Aerate, wash, or clean contaminated clothing and discard leather goods.

IF SWALLOWED: Call the Emergency Contact number or a doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by an Emergency Contact responder or doctor. Do not give anything to an unconscious person.

NOTE TO PHYSICIAN: Ethylene oxide is a liquefied 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, lack of coordination, and cardiac irregularities. Treatment is symptomatic.

PERSONAL PROTECTIVE EQUIPMENT (PPE): A material that is chemical resistant to this product is butyl rubber.

All handlers must wear at a minimum:

- Long-sleeved shirt and long pants.
- Shoes plus socks.
- Chemical-resistant gloves and
- When the ambient EO concentration is 1 to 50 ppm, full-facepiece respirator with EO approved canister, front or back mounted,
- When the ambient EO concentration is 50 to 2,000 ppm, (1) positive-pressure supplied-air respirator equipped with full-facepiece, hood, or helmet; or (2) continuous-flow supplied-air respirator (positive-pressure) equipped with hood, helmet, or suit,
- When the ambient EO concentration is >2,000 ppm or

unknown (e.g., emergency situations), (1) positive-pressure self-contained breathing apparatus equipped with full-facepiece; or (2) positive-pressure full facepiece supplied-air respirator equipped with an auxiliary positive-pressure self-contained breathing apparatus.

When handlers could have eye or skin contact with EO or EO solutions, such as during maintenance and repair, vessel cleaning, or cleaning up spills, they must wear:

- Chemical-resistant attire, such as an apron, protective suit, or footwear that protects the area of the body that might contact EO or EO solutions, and
- Face-sealing goggles, a full-face shield, or a full-face respirator.

USER SAFETY REQUIREMENTS

When wearing respirators:

1. Follow the respirator manufacturer's user's instructions for changing canisters.
2. Respirators must be fit-tested and fit-checked using a program that conforms to OSHA's requirements (see 29CFR Part 1910.134).
3. Respirator users must be trained using a program that confirms to OSHA's requirements (see 29CFR Part 1910.134).

4. Respirator users must be examined by a qualified medical practitioner to ensure physical ability to safely wear the style of respirator to be worn. A qualified medical practitioner is a physician or other licensed health care professional (PLHCP) who will evaluate the ability of a worker to wear a respirator. The initial evaluation consists of a questionnaire that asks about medical conditions (such as a heart condition) that would be problematic for respirator use. If concerns are identified, then additional evaluations, such as a physical exam, might be necessary. The initial evaluation must be done before respirator use begins. It does not need to be repeated unless the health status or respirator use conditions change (see 29CFR Part 1910.134).

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

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 Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

**EMERGENCY CONTACT:
1.800.255.3924**

PHYSICAL AND CHEMICAL HAZARDS

Ethylene oxide (EO) gas is extremely flammable. Do not use near flame, electrical sparks, hot surfaces, or allow sources of ignition near the sterilization area. Ground all equipment to prevent static sparks.

Contents under pressure. Do not puncture or incinerate container. Exposure to temperatures above 130°F (54°C) may cause bursting.

ODOR: Ether-like in high concentrations. Exposure to toxic

levels may occur without warning or detection by the user.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Employers in facilities that use EO must comply with all requirements for EO use specified in 29 CFR 1910.1047.

The AN7916 may be used only in Anprolene AN74 sterilizers, and only for hospital, medical, and veterinary sterilization. In hospitals, healthcare facilities, and contract sterilization facilities treating medical equipment and supplies, sterilization/fumigation with EO must be performed only in vacuum or gas tight chambers designed for use with EO. After February 28, 2010, a single chamber process is required for EO treatment (sterilization and aeration are to occur in the same chamber) in hospitals and healthcare facilities.

During the sterilization cycle, the sterilization bag may contain hazardous concentrations of EO. Do not open the sterilization bag until the sterilization, ventilation, and aeration portions of the treatment cycle are complete.

Safety and awareness training is required for all employees including office staff. Information and training must be provided to all employees in the facility at the time of initial assignment and annually thereafter. The safety training must include, at a minimum, the following information: 1. the most recent monitored ambient levels of EO in the facility; 2. the potential health effects from the levels of EO in the facility; 3. the emergency response plan and how to respond in an emergency; 4. the availability of the Material Safety Data Sheet and other materials related to the health hazards of exposure to EO. To reduce ambient levels of EO, lengthy facility aeration is encouraged. Achieving an ambient level of 0.25 ppm (measured as a daily time-weighted average) greatly reduces potential long-term risks to employees not directly involved in the EO applications. Air monitoring should include the entire facility including office space, break areas, and loading/unloading areas. Employers in facilities that use EO must comply with all the requirements for EO use specified in 29 CFR 1910.1047.

Sterilization Process:

- Remove one sterilization bag from the dispenser box. Place wrapped devices to be sterilized inside the sterilization bag.

- Remove one ampoule from the AN7916 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.

DO NOT ACTIVATE AMPOULE.

- Insert the purge probe into the sterilization bag. Gather the open end of the sterilization bag around the purge probe and wrap the hook and loop strap around both the sterilization bag opening and the purge probe, tightening it to completely seal the sterilization bag.
- Place the sealed sterilization bag inside the sterilizer. Connect the purge probe quick release connector to the purge probe tubing.
- Evacuate excess air from the sterilization bag using the initial bag purge, then follow the cycle selection and cycle verification prompts.
- Press the Purge button which will draw a vacuum on the liner bag for ninety seconds. At the end of ninety seconds, break the ampoule by manipulating the pre-scored neck of the ampoule through the wall of the liner bag.

- Close the door to the sterilizer and start the sterilization cycle.
- Always lock the door of the sterilizer to prevent unauthorized removal of devices during the sterilization and ventilation portions of the cycle.
- After the sterile devices have been removed from the sterilization bag, discard the sterilization bag and empty cartridge according to disposal instructions. **DO NOT REUSE EMPTY BOX, EMPTY CARTRIDGES, OR LINER BAGS.**

representative at the nearest EPA Regional Office for guidance.

Container Disposal: Do not puncture or incinerate unused ampoules. Aerate empty ampoules and used sterilization bags according to the complete Directions for Use. After aeration, dispose of in sanitary landfill.

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool, well ventilated area away from heat and direct sunlight. Store in accordance with 29 CFR 1910.1047.

Pesticide Disposal: Pesticide wastes are toxic. Improper disposal of excess pesticides (unwanted or expired AN7916.00 Anprolene ampoules) is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact Andersen Products, Inc. (336-376-3000), or your State Pesticide or Environmental Control Agency, or the Hazardous Waste