UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 27, 2019

Faith Rios
Director, QRA
Andersen Sterilizers, Inc.
3154 Caroline Drive
Haw River, NC 27258

Subject: Label Amendment – Agency-initiated label revisions to align with current guidelines for ETO products
Product Name: AN7514
EPA Registration Number: 69340-9
Application Date: August 23, 2019
Decision Number: 554682

Dear Ms. Rios:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, 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. 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 the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. 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) list 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. 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 Compliance.

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 with FIFRA section 6. If you have any questions, please Tara Flint email at flint.tara@epa.gov or Eric Miederhoff at Miederhoff.eric@epa.gov.

Sincerely,

Eric Miederhoff
Product Manager 31
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure

One AN7514 Anprolene® Refill Kit
CONTENTS: 14 Cartridges, 15 Sterilization Bags, and 14 AN87 Dosimeters®
Each AN7514 cartridge contains 0.62 av. Oz.
(17.6 g) Ethylene Oxide
Active ingredient: Ethylene oxide 97%
Inert ingredient: 3%
Total: 100%

ACCEPTED
08/27/2019
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under
EPA Reg. No. 69340-9

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

EPA Registration No. 69340-9
EPA Establishment No. 69340-NC-001

Anprolene® and Dosimeter® are registered trademarks of Andersen Sterilizers, Inc.

AN7514.20 Rev 0

ANPROLENE 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 of the requirements for ETO use specified in 29 CFR 1910.1047.

This product may be used only for ETO sterilization of medical devices in an AN75 Anprolene sterilizer.

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 treatment 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. In order 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 of the requirements for ETO use specified in 29 CFR 1910.1047.

1. Press the START button on the touchscreen of the Anprolene AN75 sterilizer to initiate a cycle.

2. After the self-test is complete, the Load Sterilizer screen prompts the operator to load the sterilization bag. Always use a new sterilization bag for each cycle. Load the wrapped devices into the sterilization bag.

3. Insert an AN87 Dosimeter into the core of the load in the sterilization bag.

4. Insert an AN2203 Biological Indicator (BI) into the Anprolene Process Challenge Device (PCD) in the purge probe and tighten the cap.

5. Remove one Anprolene ETO cartridge from the AN7514 Refill Kit. Remove the adhesive tape, then remove the trigger guard. Place the cartridge on top of the wrapped items near the open end of the bag where it is accessible for cartridge activation. Do not activate the cartridge at this time.

6. Insert the purge probe into the sterilization bag. Gather the open end of the sterilization bag around the purge probe and wrap the Velcro strap around both the sterilization bag opening and the purge probe, tightening it to completely seal the sterilization bag.

7. Place the sealed sterilization bag inside the sterilizer and connect the quick release connector on the purge probe to the purge probe hose.

8. Press the PURGE button on the touchscreen to evacuate excess air from the sterilization bag, then follow the Cycle Selection and Cycle Verification prompts.

9. At the Start Cycle screen the sterilizer prompts the operator to activate the cartridge. Grasp the cartridge through the wall of the sterilization bag and fully depress the trigger button on the side of the cartridge to release ETO into the bag.

10. Close the door and press the START button on the touchscreen.

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

12. At the end of the cycle, follow the prompts on the Cycle Data and Unload touchscreens. Unload the sterilizer, evaluate the AN87 Dosimeter and process the AN2203 BI.

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 AN7514 Anprolene cartridges) 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 cartridges. Aerate empty cartridges and used sterilization bags according to the complete Directions for Use. After aeration, dispose of in sanitary landfill.

AN7514

ANPROLENE®

ENGLISH:

BRAND GASEOUS STERILANT FOR ROOM TEMPERATURE, ATMOSPHERIC PRESSURE STERILIZATION

Instructions for use Anprolene AN7514

Pages 3-5

ESPAÑOL:

ESTERILIZANTE GASEOSO PARA USO A TEMPERATURA AMBIENTE, PRESIÓN ATMOSFERICA

Instrucciones para uso Anprolene AN7514

Pagina 6-10

ITALIANO:

STERILIZZANTE GASSOSO PER STERILIZZAZIONE A TEMPERATURA E PRESSIONE ATMOSFERICA AMBIENTALI

Instruzioni per l'uso Anprolene AN7514

Pagine 11-14

FRANÇAIS:

AGENT STÉRILISANT GAZEUX POUR UNE STÉRILISATION À TEMPÉRATURE AMBIANTE, PRESSION ATMOSPHÉRIQUE

Mode d'emploi Anprolene AN7514

Pages 15-19

DEUTSCH:

GASFÖRMIGES MARKEN-STERILISATIONSMITTEL ZUR VERWENDUNG BEI RAUMTEMPERATUR, STERILISATION BEI ATMOSPHÄRISCHEM DRUCK

Gebrauchsanweisung Anprolene AN7514

die Seiten 20-24

Manufactured by:
Andersen Sterilizers, Inc. CE 0413
Health Science park
3154 Caroline Drive
Haw River, NC 27258 U.S.A.

Distributed 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.
Health Science Park
3151 Caroline Drive
Haw River, NC 27258 U.S.A.
1-800-524-3455 • 336-376-3000

EC REP
Authorized EU Representative:
H.W. Andersen Products, Ltd.
808 Fowler Road
Clacton-on-Sea • Essex C015 4AA U.K.
44-1255-428328

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

AN7577.00_R0

AN7514

ANPROLENE®

Brand Gaseous Sterilant for Room Temperature,
Atmospheric Pressure Sterilization
Use in Ventilated Anprolene AN75 Sterilizers Only

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

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ANDERSEN PRODUCTS, INC.
3202 Caroline Drive • Haw River, NC 27258 USA
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44-1255-428328

EPA Registration No. 69340-9
EPA Establishment No. 69340-NC-001

Anprolene® and Dosimeter® are registered trademarks of Andersen Sterilizers, Inc.

Keep Out of Reach of Children

DANGER

PRECAUTIONARY STATEMENTS

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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:
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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.

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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.
- 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:

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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.

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During the treatment 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. In order to reduce ambient levels of ethylene oxide, 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 of the requirements for ETO use specified in 29 CFR 1910.1047.

1. Press the START button on the touchscreen of the Anprolene AN75 sterilizer to initiate a cycle.

2. After the self-test is complete, the Load Sterilizer screen prompts the operator to load the sterilization bag. Always use a new sterilization bag for each cycle. Load the wrapped devices into the sterilization bag.

3. Insert an AN87 Dosimeter into the core of the load in the sterilization bag.

4. Insert an AN2203 Biological Indicator (BI) into the Anprolene Process Challenge Device (PCD) in the purge probe and tighten the cap.

5. Remove one Anprolene ETO cartridge from the AN7514 Refill Kit. Remove the adhesive tape, then remove the trigger guard. Place the cartridge on top of the wrapped items near the open end of the bag where it is accessible for cartridge activation. Do not activate the cartridge at this time.

6. Insert the purge probe into the sterilization bag. Gather the open end of the sterilization bag around the purge probe and wrap the Velcro strap around both the sterilization bag opening and the purge probe, tightening it to completely seal the sterilization bag.

7. Place the sealed sterilization bag inside the sterilizer and connect the quick release connector on the purge probe to the purge probe hose.

8. Press the PURGE button on the touchscreen to evacuate excess air from the sterilization bag, then follow the Cycle Selection and Cycle Verification prompts.

9. At the Start Cycle screen the sterilizer prompts the operator to activate the cartridge. Grasp the cartridge through the wall of the sterilization bag and fully depress the trigger button on the side of the cartridge to release ETO into the bag.

10. Close the door and press the START button on the touchscreen.

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

12. At the end of the cycle, follow the prompts on the Cycle Data and Unload touchscreens. Unload the sterilizer, evaluate the AN87 Dosimeter and process the AN2203 BI.

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 AN7514 Anprolene cartridges) 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 cartridges. Aerate empty cartridges and used sterilization bags according to the complete Directions for Use. After aeration, dispose of in sanitary landfill.

ADDITIONAL CONTACT INFORMATION

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

CE 0413

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

AN7514 ANPROLENE

One AN7514 Anprolene® Refill Kit REF

CONTENTS: 14 Cartridges, 15 Sterilization Bags, and 14 AN87 Dosimeters®

Each AN7514 cartridge contains 0.62 av. Oz. (17.6 g) Ethylene Oxide

Active ingredient: Ethylene oxide 97%
Inert ingredient: 3%
Total: 100%

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CE 0413

AN7514.20 Rev 0

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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-29 CFR 1910.1047).

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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.

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.

Employees in facilities that use ETO must comply with all of the requirements for ETO use specified in 29CFR 1910.1047. This product may be used only for ETO sterilization of medical devices in an AN75 Anprolene sterilizer.

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 treatment 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. In order to reduce ambient levels of ethylene oxide, 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 of the requirements for ETO use specified in 29 CFR 1910.1047.

1. Press the START button on the touchscreen of the Anprolene AN75 sterilizer to initiate a cycle.
2. After the self-test is complete, the Load Sterilizer screen prompts the operator to load the sterilization bag. Always use a new sterilization bag for each cycle. Load the wrapped devices into the sterilization bag.
3. Insert an AN87 Dosimeter into the core of the load in the sterilization bag.
4. Insert an AN2203 Biological Indicator (BI) into the Anprolene Process Challenge Device (PCD) in the purge probe and tighten the cap.
5. Remove one Anprolene ETO cartridge from the AN7514 Refill Kit. Remove the adhesive tape, then remove the trigger guard. Place the cartridge on top of the wrapped items near the open end of the bag where it is accessible for cartridge activation. Do not activate the cartridge at this time.
6. Insert the purge probe into the sterilization bag. Gather the open end of the sterilization bag around the purge probe and wrap the velcro strap around both the sterilization bag opening and the purge probe, tightening it to completely seal the sterilization bag.
7. Place the sealed sterilization bag inside the sterilizer and connect the quick release connector on the purge probe to the purge probe hose.
8. Press the PURGE button on the touchscreen to evacuate excess air from the sterilization bag, then follow the Cycle Selection and Cycle Verification prompts.
9. At the Start Cycle screen the sterilizer prompts the operator to activate the cartridge. Grasp the cartridge through the wall of the sterilization bag and fully depress the trigger button on the side of the cartridge to release ETO into the bag.
10. Close the door and press the START button on the touchscreen.
11. During the cycle, the sterilization bag contains hazardous concentrations of ETO. Do not open the sterilization bag until the sterilization, ventilation, and aeration portions of the cycle are complete.
12. At the end of the cycle, follow the prompts on the Cycle Data and Unload touchscreens. Unload the sterilizer, evaluate the AN87 Dosimeter and process the AN2203 BI.

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 AN7514 Anprolene cartridges) 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 cartridges. Aerate empty cartridges and used sterilization bags according to the complete Directions for Use. After aeration, dispose of in sanitary landfill.

AN7514
ANPROLENE

REF

KEEP OUT OF REACH OF CHILDREN

DANGER

CONTENTS EXTREMELY FLAMMABLE
DO NOT OPEN THIS CARTRIDGE

Users must follow the requirements of the OSHA Occupational Exposure Standard for Ethylene Oxide (29 CFR 1910.1047). See box label for precautions. Use only in an Andersen AN75 Anprolene® Sterilizer with an AN7514 Sterilization Bag and according to manufacturer's instructions. For complete instructions for use, refer to Andersen Sterilizers AN75 Ethylene Oxide sterilizer User's Manual.

REMOVE TAPE AND TRIGGER GUARD, IMMEDIATELY PLACE INSIDE STERILIZATION BAG. SEAL BAG, PURGE, THEN PRESS BUTTON TO ACTIVATE CARTRIDGE. DISPOSE OF USED BAG AND EMPTY CARTRIDGE IN TRASH.

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2018-01-01

LOT

Active Ingredient: Ethylene Oxide.. 97%
Other Ingredients:..... 3%
Total: 100%

Net Contents: 0.64 av. oz. (18.2 g)

Manufactured by:
Andersen Sterilizers, Inc.
Haw River, NC 27258 U.S.A.

Distributed by: Andersen Products, Inc.
Haw River, NC 27258 U.S.A.

EC REP Authorized EC Representative:
H. W. Andersen Products Ltd.
Clacton-On-Sea • Essex CO15 4AA U.K.

EPA Reg. No. 69340-X
EPA Est. No. 69340-NC-001

CE 0413

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