UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

July 26, 2021

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

Subject: Label Amendment – Updating kit label language to align with ETO RED
Product Name: EOGas AN1006
EPA Registration Number: 69340-6
Application Date: May 8, 2020
Decision Number: 00309661

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 contact Tara Flint via email at flint.tara@epa.gov.

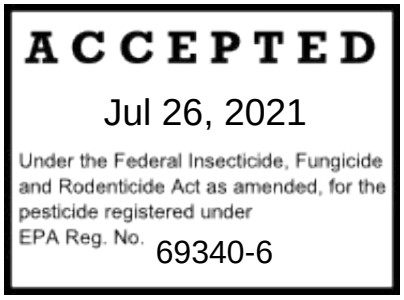
Sincerely,

Aline Heffernan
Acting Product Manager Team 31
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: Stamped 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.

EOGAS AN1006
Kit CONTENTS: 23 Cartridges, 25 Liner Bags, 25 Dosimeters, 25 Humidichips
Each AN1006 cartridge contains 0.39 av. Oz.
(10.5 g) Ethylene Oxide
Active ingredient: Ethylene oxide 96%
Inert ingredient: 4%
Total: 100%



EOGAS AN2011
Kit CONTENTS: 50 Cartridges
Each AN2011 cartridge contains 0.39 av. Oz.
(10.5 g) Ethylene Oxide
Active ingredient: Ethylene oxide 96%
Inert ingredient: 4%
Total: 100%

AN 2011 cartridges are for industrial use in a fully validated sterilization system only. It is incumbent on the user to determine the definition of a fully validated sterilization system.

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 S.A.R.L.
12 Place Saint Hubert
69000 Lille, France
Tel: 33-0359-560614

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

EPA Registration No. 69340-6
EPA Establishment No. 69340-NC-001

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

AN2852.00 Rev 1 (AN1006.00 and AN2011.00)

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, lightheaded 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 in EOGas® 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 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. Prepare items to be sterilized. Remove one Dosimeter® and card from the dispenser box. Write the date and time sterilization will begin and the date and time sterilization and aeration will be complete on the label. Attach the Dosimeter® to its card. Take one sterilizer bag from the EOGas dispenser box and place the wrapped items to be sterilized into the sterilizer bag.
2. Place the Dosimeter® in the core of the load. Place the Humidichip® inside the HumidiTube and place the HumidiTube in the sterilization bag. Select one EOGas cartridge from the dispenser box. Confirm

that the number printed on the EOGas cartridge corresponds with the number printed on the sterilizer bag. Remove the cartridge trigger guard (secured with green tape). And place the cartridge on top of the devices near the open end of the sterilization bag, but do not activate the cartridge at this time.

3. Remove excess air with a vacuum sealer or press the excess air out of the sterilization bag and heat seal the open end of the sterilization bag. Initiate the sterilization cycle by pressing the LOAD key on the front of the EOGas sterilizer cabinet and follow the directions for loading.
4. After the cabinet has purged for 5 minutes, "DOOR UNLOCKED" will be displayed and door will unlock. Place the sterilization bag on a shelf in the sterilizer.
5. Without opening the sterilization bag, grasp the EOGas cartridge through the wall of the sterilization bag and press the plunger (trigger button) firmly to activate the cartridge. Press it all the way so that the trigger reaches the cartridge wall. This action releases the gas instantly from the cartridge into the sterilizer bag.
6. Close the sterilizer door securely. It will lock automatically at the end of the 3-minute countdown displayed on the screen. Leave the sterilizer bag undisturbed in the sterilizer cabinet for 16 hours, the sterilizer bag may then be removed. To accomplish this, initiate a 5-minute purge cycle by pressing the UNLOAD button. The sterilizer will begin purging (high volume ventilation to remove any residual EO from the cabinet). At the end of the 5-minute purge cycle, the sterilizer will unlock the door for 10 minutes. The door may be opened at any time during this 10-minute window. Once the door is opened the operator has a 3-minute window to remove sterilization bags.
7. When unloading multiple sterilization bags or loads which absorb a large amount of EO, some operators prefer to cut open the end of the sterilization bag while it is still in the cabinet, then shut the door and repeat the PURGE cycle. This minimizes the chance of exposure to residual EO within the sterilization bag.
8. After the sterile material has been removed from the sterilizer bag, wrap the empty cartridge and bag in paper and discard according to disposal instructions. DO NOT REUSE EMPTY BOX, EMPTY CONTAINERS (Cartridges), OR LINER 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 AN71.00 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 cartridges. Aerate empty cartridges and used sterilization bags according to the complete Directions for Use. After aeration, dispose of in sanitary landfill.

AN1005 • AN1006 • AN2011

Gaseous Sterilant for
50°C Sterilization

ENGLISH:
Directions for Use: EOGas Cartridges

Pages 3-7

FRANÇAIS:
Instructions D' Utilisation De Cartouches EOGas

Pages 8-10

DEUTSCH:
Anweisungen Für Die Benutzung Der EOGas Kartusche

Pages 11-14

ITALIANO:
Manuale D'istruzioni Per L'uso Del Sistema

Pages 15-19

ESPAÑOL:
Instrucciones Para El Uso De Cartuchos EOGas

Pages 20-23

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

AN4649.00 Rev 0

AN1005 • AN1006 • AN2011

EOGas®

Brand Gaseous Sterilant for 50°C Sterilization
Use in EOGas 3 Sterilizers Only

EOGAS AN1005

Kit CONTENTS: 25 Cartridges, 26 Sterilization Bags, 25 AN1087 Dosimeters®, and 25 Humidichips

Each AN1005 cartridge contains 0.18 av. Oz. (4.5 g) Ethylene Oxide

Active ingredient: Ethylene oxide 90%
Inert ingredient: 10%
Total: 100%

EOGAS AN1006
Kit CONTENTS: 23 Cartridges, 25 Sterilization Bags, 25 AN1087 Dosimeters®, and 25 Humidichips

EOGAS AN2011
Kit CONTENTS: 50 Cartridges

AN 2011 cartridges are for industrial use in a fully validated sterilization system only. It is incumbent on the user to determine the definition of a fully validated sterilization system..

Each AN1006 or AN2011 cartridge contains 0.39 av. Oz. (10.5 g) Ethylene Oxide

Active ingredient: Ethylene oxide 96%
Inert ingredient: 4%
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

EPA Registration No. AN1005: 69340-5
EPA Registration No. 69340-6 (AN1006 and AN2011)
EPA Establishment No. 69340-NC-001

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.
- 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 in EOGas® 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 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. Prepare items to be sterilized. Remove one Dosimeter® and card from the dispenser box. Write the date and time sterilization will begin and the date and time sterilization and aeration will be complete on the label. Attach the Dosimeter® to its card. Take one sterilizer bag from the EOGas dispenser box and place the wrapped items to be sterilized into the sterilizer bag.
2. Place the Dosimeter® in the core of the load. Place the Humidichip® inside the HumidiTube and place the HumidiTube in the sterilization bag. Select one EOGas cartridge from the dispenser box. Confirm that the number printed on the EOGas cartridge corresponds with the number printed on the sterilizer bag. Remove the cartridge trigger guard (secured with green tape). And place the cartridge on top of the devices near the open end of the sterilization bag, but do not activate the cartridge at this time.
3. Remove excess air with a vacuum sealer or press the excess air out of the sterilization bag and heat seal the open end of the sterilization bag. Initiate the sterilization cycle by pressing the LOAD key on the front of the EOGas sterilizer cabinet and follow the directions for loading.
4. After the cabinet has purged for 5 minutes, “DOOR UNLOCKED” will be displayed and door will unlock. Place the sterilization bag on a shelf in the sterilizer.
5. Without opening the sterilization bag, grasp the EOGas cartridge through the wall of the sterilization bag and press the plunger (trigger button) firmly to activate the cartridge. Press it all the way so that the trigger reaches the cartridge wall. This action releases the gas instantly from the cartridge into the sterilizer bag.
6. Close the sterilizer door securely. It will lock automatically at the end of the 3-minute countdown displayed on the screen. Leave the sterilizer bag undisturbed in the sterilizer cabinet for 16 hours, the sterilizer bag may then be removed. To accomplish this, initiate a 5-minute purge cycle by pressing the UNLOAD button. The sterilizer will begin purging (high volume ventilation to remove any residual EO from the cabinet). At the end of the 5-minute purge cycle, the sterilizer will unlock the door for 10 minutes. The door may be opened at any time during this 10-minute window. Once the door is opened the operator has a 3-minute window to remove sterilization bags.
7. When unloading multiple sterilization bags or loads which absorb a large amount of EO, some operators prefer to cut open the end of the sterilization bag while it is still in the cabinet, then shut the door and repeat the PURGE cycle. This minimizes the chance of exposure to residual EO within the sterilization bag.
8. After the sterile material has been removed from the sterilizer bag, wrap the empty cartridge and bag in paper and discard according to disposal instructions. DO NOT REUSE EMPTY BOX, EMPTY CONTAINERS (Cartridges), OR LINER 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 EOGas cartridge) 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.

Distributed by:
Andersen Products, Inc.
Health Science Park
3202 Caroline Drive
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sterility.com
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E-mail: customerservice@anpro.com
Tel: +1 336 376-3000
Fax: +1 336 376-8153

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AN1006
AN2011 EOGas®

EO GAS AN1006
Kit **CONTENTS**: 23 Cartridges, 25 liner Bags, 25 Dosimeters, 25 Humidichips

REF

EO GAS AN2011
Kit **CONTENTS**: 50 Cartridges

Each AN1006 / 2011 cartridge contains 0.39 av. Oz. (10.5 g) Ethylene Oxide

Active ingredient: Ethylene oxide	96%
Inert ingredient:	4%
Total:	100%

AN 2011 cartridges are for industrial use in a fully validated sterilization system only. It is incumbent on the user to determine the definition of a fully validated sterilization system.

US

Manufactured by:
ANDERSEN STERILIZERS, INC.
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Haw River, NC 27258 USA

Distributed by:
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EPA Registration No. 69340-6.
EPA Establishment No. 69340-NC-001

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

CE 0413

AN2852.00.00 Rev 1 (AN1006.00 and AN2011)

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 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).

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(postive- 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 in EOGas® 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 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. Prepare items to be sterilized. Remove one Dosimeter® and card from the dispenser box. Write the date and time sterilization will begin and the date and time sterilization and aeration will be complete on the label. Attach the Dosimeter® to its card. Take one sterilizer bag from the EOGas dispenser box and place the wrapped items to be sterilized into the sterilizer bag.
2. Place the Dosimeter® in the core of the load. Place the Humidichip® inside the HumidiTube and place the HumidiTube in the sterilization bag. Select one EOGas cartridge from the dispenser box. Confirm that the number printed on the EOGas cartridge corresponds with the number printed on the sterilizer bag. Remove the cartridge trigger guard (secured with green tape) and place the cartridge on top of the devices near the open end of the sterilization bag, but do not activate the cartridge at this time.
3. Remove excess air with a vacuum sealer or press the excess air out of the sterilization bag and heat seal the open end of the sterilization bag. Initiate the sterilization cycle by pressing the LOAD key on the front of the EOGas sterilizer cabinet and follow the directions for loading.
4. After the cabinet has purged for 5 minutes, "DOOR UNLOCKED" will be displayed and door will unlock. Place the sterilization bag on a shelf in the sterilizer.
5. Without opening the sterilization bag, grasp the EOGas cartridge through the wall of the sterilization bag and press the plunger (trigger button) firmly to activate the cartridge. Press it all the way so that the trigger reaches the cartridge wall. This action releases the gas instantly from the cartridge into the sterilizer bag.
6. Close the sterilizer door securely. It will lock automatically at the end of the 3-minute countdown displayed on the screen. Leave the sterilizer bag undisturbed in the sterilizer cabinet for 16 hours, the sterilizer bag may then be removed. To accomplish this, initiate a 5-minute purge cycle by pressing the UNLOAD button. The sterilizer will begin purging (high volume ventilation to remove any residual EO from the cabinet). At the end of the 5-minute purge cycle, the sterilizer will unlock the door for 10 minutes. The door may be opened at any time during this 10-minute window. Once the door is opened the operator has a 3-minute window to remove sterilization bags.
7. When unloading multiple sterilization bags or loads which absorb a large amount of EO, some operators prefer to cut open the end of the sterilization bag while it is still in the cabinet, then shut the door and repeat the PURGE cycle. This minimizes the chance of exposure to residual EO within the sterilization bag.
8. After the sterile material has been removed from the sterilizer bag, wrap the empty cartridge and bag in paper and discard according to disposal instructions. DO NOT REUSE EMPTY BOX, EMPTY CONTAINERS (Cartridges), OR LINER 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 EOGas 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.

AN 1006

EOGas®

Active Ingredient: Ethylene Oxide…96.0%
Other Ingredients:……....4.0%
Total: ...……....100.0%
Net Contents: 0.39 av. oz. (11.0 g)

REMOVE TAPE AND TRIGGER GUARD, IMMEDIATELY PLACE INSIDE STERILIZATION BAG

Users must follow requirements of the OSHA Occupational Exposure Standard for Ethylene oxide (29 CFR 1910.1047). Use only in an Andersen EOGas Sterilizer with a #6 Diffusion Bag and according to manufacturer's instructions. See outer box and package insert for precautions and sterilization instructions.

DANGER
KEEP OUT OF REACH OF CHILDREN
CONTENTS FLAMMABLE
DO NOT OPEN THIS PACKAGE
DISPOSE OF EMPTY EOGas CARTRIDGE IN TRASH

CE 0413

Manufactured by: Andersen Sterilizers, Inc • Health Science Park • Haw River, NC 27258 U.S.A.
Distributed by: Andersen Products, Inc. • Health Science Park • Haw River, NC 27258 U.S.A.

EPA Registration No. 69340-6 • EPA Est. No. 69340-NC-001 • U.S. Patent No. 4,937,046 & 5,160,700

REMOVE TAPE AND TRIGGER GUARD, PRESS BUTTON TO ACTIVATE CARTRIDGE

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