UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 6, 2019

Faith Rios
Director, Quality and Regulatory Affairs
Andersen Sterilizers
3154 Caroline Drive
Haw River, NC 27258

Subject: Label Amendment – Agency-requested revision to precautionary language on outer box label
Product Name: AN7514
EPA Registration Number: 69340-9
Application Date: May 13, 2019
Decision Number: 551696

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 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%

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

AN7514.20_VN2016-05-24AN7514

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. Remove and wash contaminated clothing before reuse.

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-@(CFR 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)

All handlers must wear at a minimum:

- Long-sleeved shirt and long pants.
- Shoes plus socks.
- Chemical-resistant gloves.

When handlers could have direct contact with ETO due to a leak or spill, they must wear:

1. a NIOSH approved self-contained breathing apparatus (SCBA) with a full facepiece operated in pressure demand mode, chemically resistant attire such as an apron, protective suit, or footwear that protects the area of the body that might contact ETO
2. Chemically resistant gloves

When wearing respirators:

1. Respirators must be fit-tested and fit-checked using a program that conforms to OSHA's requirements (see 29CFR Part 1910.134).

2. Respirator users must be trained using a program that confirms to OSHA's requirements (see 29CFR Part 1910.134).

3. 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).

User Safety Recommendations

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.

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.

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.

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, sterilization with ETO must be performed only in vacuum or gas tight chambers designed for use with ETO. 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. It can reduce potential long-term risks to employees not directly involved in the ethylene oxide applications.

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.

ANPROLENE®

EO-FCT ETHYLENE OXIDE FLEXIBLE CHAMBER TECHNOLOGY

ENGLISH

KEEP OUT OF REACH OF CHILDREN

DANGER

Ethylene Oxide (ETO) is Extremely Flammable – Do not use near flame, sparks, heated surfaces, or other sources of ignition.

CANCER HAZARD AND REPRODUCTIVE HAZARD

Users must follow the requirements of OSHA Occupational Exposure Standard for ETO (29 CFR 1910.1047), or their applicable national standard.

This product may be used only for ETO sterilization of medical devices in an Andersen AN75 Anprolene Sterilizer with an AN7514 Anprolene Cartridge. Use only after reading Instructions for Use. Complete Instructions for Use are contained in the AN75 Anprolene Sterilizer User's Manual.

In hospital and health care facilities, sterilization with ETO must be performed only in vacuum or gas tight chambers designed for use with ETO, and a single chamber process is required for ETO treatment (sterilization and aeration must occur in the same chamber). Do not open this bag until the sterilization, ventilation, and aeration portions of the cycle are complete. Shortening the sterilization and ventilation cycles may result in non-sterile devices, unacceptable operator exposure to ETO, and/or chemical burns due to inadequate aeration of residual ETO. It is a violation of federal law to use this product in a manner inconsistent with its labeling.

FRANÇAIS

TENIR HORS DE PORTÉE DES ENFANTS

DANGER

L'oxyde d'éthylène (EtO) est extrêmement inflammable - Ne pas utiliser à proximité d'une flamme, d'étincelles, de surfaces chauffées, ou d'autres sources d'inflammation.

RISQUE DE CANCER ET DANGER POUR LA REPRODUCTION

Les utilisateurs doivent respecter les exigences de la norme OSHA sur l'exposition professionnelle à l'EtO (29 CFR 1910.1047), ou leur norme nationale applicable.

Ce produit ne peut être utilisé que pour la stérilisation à l'EtO de dispositifs médicaux dans un stérilisateur Anprolene AN75 d'Andersen avec une cartouche d'Anprolene AN7514. Utiliser seulement après avoir lu les instructions d'utilisation. Les instructions complètes d'utilisation sont contenues dans le manuel d'utilisation du stérilisateur Anprolene AN75.

Dans les hôpitaux et les établissements de santé, la stérilisation à l'EtO doit être effectuée uniquement dans des chambres sous vide ou étanches au gaz conçues pour l'EtO, et un traitement en chambre unique est nécessaire pour le traitement à l'EtO (stérilisation et aération dans la même chambre). Ne pas ouvrir cette poche avant que les étapes de stérilisation, de ventilation et d'aération du cycle ne soient terminées. Un raccourcissement des cycles de stérilisation et de ventilation peut entraîner des dispositifs non stériles, une exposition inacceptable de l'opérateur à l'EtO et/ou des brûlures chimiques dues à une aération inadéquate de l'EtO résiduel. L'utilisation de ce produit d'une manière incompatible avec son étiquetage constitue une violation de la loi fédérale.

DEUTSCH

FÜR KINDER UNZUGÄNGLICH AUFBEWAHREN


GEFAHR

Ethylenoxid (ETO) ist hochentzündlich - Nicht neben offenem Feuer, Funken, erhitzten Oberflächen, oder anderen Zündquellen benutzen.

GEFAHR VON KREBSERKRANKUNGEN UND FORTPFLANZUNGSDEFEKTEN

Benutzer müssen die Vorschriften der OSHA Standards für berufsbedingte Exposition bei ETO (29 CFR 1910.1047) oder die geltenden nationalen Standards befolgen.

Dieses Produkt darf nur zur Sterilisation von Medizinprodukten mit ETO in einem Andersen AN75 Anprolene Sterilisator mit einer AN7514 Anprolene Kartusche verwendet werden. Vor Benutzung sind die Gebrauchshinweise zu lesen. Die vollständigen Gebrauchshinweise befinden sich in der Bedienungsanleitung für den AN75 Anprolene Sterilisator.

In Krankenhäusern und medizinischen Einrichtungen darf die Sterilisation mit ETO nur in Vakuumkammern oder gasdichten Kammern durchgeführt werden, die für den Einsatz von ETO entwickelt wurden. Die Behandlung mit ETO muss in einem Einkammer-Verfahren erfolgen (Sterilisation und Entlüftung müssen in der gleichen Kammer vorgenommen werden). Dieser Beutel darf nicht geöffnet werden, bis die Sterilisations-, Belüftungs- und Entlüftungsschritte des Zyklus abgeschlossen sind. Das Verkürzen der Sterilisations- und Belüftungszyklen kann zu unsterilen Produkten, unannehmbarer ETO-Exposition des Benutzers und/oder chemischen Verbrennungen aufgrund unzureichender Entlüftung des noch vorhandenen ETOs führen. Der unzulässige Gebrauch des Produkts verstößt gegen das Bundesgesetz.

ITALIANO

TENERE LONTANO DALLA PORTATA DEI BAMBINI

PERICOLOSITÀ

L'ossido di etilene (ETO) è estremamente infiammabile – non usare in prossimità di fiamme, scintille, superfici calde, o altre fonti di ignizione.

RISCHIO DI CANCRO E RISCHIO PER LA RIPRODUZIONE

Gli utilizzatori devono seguire le disposizioni dello Standard per l'esposizione professionale dell'OSHA [Agenzia per la sicurezza e la salute sul lavoro degli Stati Uniti] (Codice dei Regolamenti Federali 1910.1047 titolo 29) oppure gli standard nazionali vigenti.

Il presente prodotto può essere utilizzato soltanto per la sterilizzazione a ossido di etilene (ETO) di dispositivi medici, in uno sterilizzatore Andersen AN75 Anprolene dotato di cartuccia AN7514 Anprolene. Utilizzare esclusivamente dopo aver letto le istruzioni per l'uso. Le istruzioni per l'uso complete sono contenute nel manuale dell'utente dello sterilizzatore AN75 Anprolene.

Negli ospedali e nelle strutture sanitarie, la sterilizzazione all'ossido di etilene deve essere eseguita soltanto in camere a vuoto o a tenuta stagna antigas progettate per l'uso di ossido di etilene, e il processo per il trattamento all'ossido di etilene deve essere realizzato in un'unica camera (sterilizzazione e aerazione devono aver luogo nella stessa camera). Non aprire questo contenitore fino a quando le fasi di sterilizzazione, ventilazione e aerazione non saranno completate. La riduzione dei cicli di sterilizzazione e ventilazione può risultare in dispositivi non sterili, inaccettabile esposizione dell'operatore all'ossido di etilene e/o ustioni chimiche dovute all'aerazione inadeguata di residui di ossido di etilene. L'utilizzo del presente prodotto secondo modalità non conformi a quanto indicato sull'etichetta costituisce una violazione della legge federale.

ESPAÑOL

MANTENER ALEJADO DEL ALCANCE DE LOS NIÑOS

PELIGRO

El Óxido de Etileno (ETO) es Extremadamente Inflamable. No usar cerca de llamas, chispas, superficies calientes, u otras fuentes de ignición.

PELIGRO DE CÁNCER Y RIESGO REPRODUCTIVO

Los usuarios deben respetar los requisitos de la OSHA (Administración de Seguridad y Salud Ocupacional) sobre la Norma de Exposición Ocupacional al ETO (29 CFR [Código de Regulaciones Federales] 1910.1047), o su norma nacional aplicable.

Este producto solo se puede utilizar para la esterilización con ETO de dispositivos médicos en un Esterilizador Andersen AN75 Anprolene con un Cartucho AN7514 Anprolene. Usar únicamente luego de leer las Instrucciones de Uso. Puede acceder a estas Instrucciones de Uso completas en el Manual de Usuario del Esterilizador AN75 Anprolene.

En hospitales y centros de atención médica, la esterilización con ETO se debe realizar únicamente en cámaras herméticas al vacío o a gas diseñadas para uso con ETO, y también se requiere de un proceso único de cámara para el tratamiento con ETO (la esterilización y aireación se deben realizar en la misma cámara). No abra esta bolsa hasta que las etapas de esterilización, ventilación y aireación del ciclo estén completas. Reducir los ciclos de esterilización y/o ventilación puede producir que los dispositivos no sean estériles, causar una exposición inaceptable del operador al ETO, o quemaduras químicas a causa de una aireación inadecuada del ETO residual. El uso de este producto en forma incongruente con su etiquetado constituye una violación a la ley federal.

EPA Registration No. 69340-9

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

EPA Est. No. 69340-NC-001

Bag Manufacture Date: yyyy-mm-dd

Bag Expiration Date: yyyy-mm-dd

LOT M. P. O. No. 123456

REF PN750003_R0_VN2016-05-24

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

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

CE 0413

AN7514
ANPROLENE

REF

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

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.

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

CE 0413

AN4792.00_VN2016-05-24

LOT 160001

2018-01-01

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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44-1255-428328

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

CE 0413

AN7514.20 Rev 0

Keep Out of Reach of Children

DANGER

PRECAUTIONARY STATEMENTS

Causes eye and skin burns. May be fatal is 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. Remove and wash contaminated clothing before use.

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 respiritory 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-@(CFR 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 tratment advice. Keep under medical observation. Symptoms may be delayed.

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

IF ON SKIIN: 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 liquified 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 respiritory tract may occur, but without acute lung adema. Symptoms of systemic intoxication are headache, nausea, vomiting, lack of coordination, and cardiac irregularities. Treatment is symptomatic.

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All handlers must wear at a minimum:

- Long-sleeved shirt and long pants.
- Shoes plus socks.
- Chemical-resistant gloves.

When handlers could have direct contact with ETO due to a leak or spill, they must wear:

1. A NIOSH approved self-contained breathing apparatus (SCBA) with a full facepiece operated in pressure demand mode, chemically resistant attire such as an apron, protective suit, or footwear that protects the area of the body that might contact ETO.

2. Chemically resistant gloves.

When wearing respirators:
1. Respirators must be fit-tested and fit-checked using a program that conforms to OSHA's requirements (see 29CFR Part 1910.134).

2. Respirator users must be trained using a program that conforms to OSHA's requirements (see 29CFR Part 1910.;134).

3. Repirator 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 askes 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).

USER SAFETY RECOMMENDATIONS

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.

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 oncentrations. Exposure to toxic levels may occur without warning or detection by the user.

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.

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Employers 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, sterilization 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. It can reduce potential long-term risks to employees not directly involved in the ethylene oxide applications.

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. After aeration, dispose of in sanitary landfill.

NOTE TO PHYSICIAN

ylene oxide is a liquified gas. Skin exposure from contact
ı fabric, rubber, or plastic containing residual ethylene
le will commonly result in skin irritation with extensive
:er formation. At high concentrations severe conjunctivitis
occur. Irritation of the respiritory tract may occur, but
ıout acute lung adema. Symptoms of systemic
xication are headache, nausea, vomiting, lack of
rdination, and cardiac irregularities. Treatment is
ptomatic.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

ıandlers must wear at a minimum:

- Long-sleeved shirt and long pants.
- Shoes plus socks.
- Chemical-resistant gloves.

en handlers could have direct contact with ETO due to a
. or spill, they must wear:

. NIOSH approved self-contained breathing apparatus
3A) with a full facepiece operated in pressure demand
de, chemically resistant attire such as an apron, protective
. or footwear that protects the area of the body that might
tact ETO.

Chemically resistant gloves.

en wearing respirators:
Respirators must be fit-tested and fit-checked using a
gram that conforms to OSHA's requirements (see 29CFR
1910.134).

Respirator users must be trained using a program that
forms to OSHA's requirements (see 29CFR Part 1910.;134).

Repirator users must be examined by a qualified medical
:titioner to ensure physical ability to safely wear the style
espirator to be worn. A qualified medical practitioner is a
sician or other licensed health care professional (PLHCP)
ı will evaluate the ability of a worker to wear a respirator.
initial evaluation consists of a questionnaire that askes
ut medical conditions (such as a heart condition) that
ıld be problematic for respirator use. If concerns are
ıtified, then additional evaluations, such as a physical
ın might be necessary. The initial evaluation must be done
ore respirator use begins. It does not need to be repeated
ess the health status or respirator use conditions change
29CFR Part 1910.134).

R SAFETY RECOMMENDATIONS

rs should remove PPE immediately after handling this
duct. Wash the outside of gloves before removing. As
ı as possible, wash thoroughly and change into clean
hing.

NOTE TO PHYSICIAN

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R SAFETY RECOMMENDATIONS

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duct. Wash the outside of gloves before removing. As
n as possible, wash thoroughly and change into clean
hing.

Emergency Contact: 1-800-255-3924

PHYSICAL AND CHEMICAL HAZARDS

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Keep Out of Reach of Children

DANGER

PRECAUTIONARY STATEMENTS

auses eye and skin burns. May be fatal is inhaled.. Do not eathe vapor. Do not swallow. Do not get in eyes, on skin, or n clothing. Wash thoroughly with soap and water after andling and before eating, drinking, chewing gum, using bacco, or using the toilet. Wear appropriate protective othing. Remove and wash contaminated clothing before se.

THER POSSIBLE DELAYED HEALTH EFFECTS: Cancer and productive hazard. May cause nervous system damage, taracts, adverse reproductive effects, chromosomal and utagenic changes. May cause irritation of respiritory tract, iest tightness, headache, nausea, vomiting, diarrhea, light eaded feeling, dizziness, weakness, drowsiness, cyanosis, ss of coordination, coma, delayed lung injury (fluid in ngs), immediate or delayed skin irritation and blisters, lergic skin.

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

ore and use with adequate ventilation in accordance with) CFR1910.1047

FIRST AID

all cases of exposure, get medical attention immediately. ke person to a doctor or emergency treatment facility at nce.
ave the product container or label with you when calling e Emergency Contact number or doctor or going for eatment.

INHALED: Move exposed person to fresh air. Keep warm. If erson is not breathing, call 911 or an ambulance, then give tificial respiration, preferably by mouth to mouth method. If eathing is at all labored, give oxygen. Call a doctor even if symptoms are present for further tratment advice. Keep nder medical observation. Symptoms may be delayed.

IN EYES: Hold eyelids openand flush eyes with a steady, entle stream of water for at least 15 to 20 minutes. Remove ntact lenses, if present, fter the first 5 minutes and then ntinue rinsing the eyes. Get immediate medical treatment.

ON SKIIN: Immediately wash skin for 15-20 minutes with enty of water while removing contaminated clothing and oes. Call Emergency Contact number or a doctor for eatment advice. Aerate, wash, or clean contaminated othing and discard leather goods.

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

uld be problematic for respirator use. If concerns are
ntified, then additional evaluations, such as a physical
m might be necessary. The initial evaluation must be done
ore respirator use begins. It does not need to be repeated
ess the health status or respirator use conditions change
e 29CFR Part 1910.134).

ER SAFETY RECOMMENDATIONS

ers should remove PPE immediately after handling this
duct. Wash the outside of gloves before removing. As

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.

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

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

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

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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

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

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. Remove and wash contaminated clothing before reuse.

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-@ CFR 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)

All handlers must wear at a minimum:

- Long-sleeved shirt and long pants.
- Shoes plus socks.
- Chemical-resistant gloves.

When handlers could have direct contact with ETO due to a leak or spill, they must wear:

- a NIOSH approved self-contained breathing apparatus (SCBA) with a full facepiece operated in pressure demand mode, chemically resistant attire such as an apron, protective suit, or footwear that protects the area of the body that might contact ETO
- Chemically resistant gloves

When wearing respirators:

1. Respirators must be fit-tested and fit-checked using a program that conforms to OSHA's requirements (see 29CFR Part 1910.134).
2. Respirator users must be trained using a program that confirms to OSHA's requirements (see 29CFR Part 1910.134).
3. 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).

USER SAFETY RECOMMENDATIONS

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.

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.

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.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

In hospitals and healthcare facilities, sterilization with ETO must be performed only in vacuum or gas tight chambers designed for use with ETO. A single chamber process is required for ETO treatment (sterilization and aeration are to occur in the same chamber) in hospitals and healthcare facilities.

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.

This product may be used only by trained sterilizer operators, and only for the sterilization of reusable medical devices in an Anprolene AN75 ethylene oxide gas sterilizer.

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.

Distributed by:
Andersen Products, Inc.
Health Science Park
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www.andcal.com

Authorized EU Representative:
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info@anderseneurope.com

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3202 Caroline Drive
Haw River, NC 27258 USA
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Tel: +1 336 376-3000
Fax: +1 336 376-8153

AN7514

ANPROLENE®

Esterilizante Gaseoso Para Uso A Temperatura Ambiente, Presión Atmosferica. Para Uso Unicamente en Esterilizadores Ventilados De Anprolene AN75.

Un Kit de Recarga de Anprolene®AN7514
CONTENIDOS: 14 Cartuchos, 15 Bolsas de Esterilización y 14 Dosímetros® AN87
Cada cartucho AN7514 contiene 0,62 av. Oz. (17,6 g) de Óxido de Etileno (ETO)
Ingrediente Activo: Óxido de etileno 97%
Ingrediente Inerte: 3%
Total: 100%

Fabricado por:
ANDERSEN STERILIZERS, INC.
3154 Caroline Drive • Haw River, NC 27258 USA

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

Representante Autorizado en la UE (Unión Europea):
H. W. ANDERSEN PRODUCTS, LTD.
808 Fowler Clacton-On-Sea • Essex CO15 4AA UK
44-1255-428328

Nº de Inscripción en la EPA (Agencia de Protección Ambiental): 69340-9
Nº de Establecimiento EPA: 69340-NC-001

Anprolene® y Dosimeter® son marcas registradas de Andersen Sterilizers, Inc.

Mantener Alejado del Alcance de los Niños.

PELIGRO

Produce quemaduras en los ojos y en la piel. Es dañino si se inhala. Puede causar daños al sistema nervioso. Peligro de cáncer y riesgo reproductivo.

DECLARACIONES DE PREVENCIÓN

EFECTO DE LA SOBREEXPOSICIÓN: Puede ser fatal si se inhala en concentraciones altas. Puede causar irritación del tracto respiratorio, opresión torácica, dolor de cabeza, náuseas, vómitos, diarrea, aturdimiento, mareos, adormecimiento, cianosis, pérdida de coordinación, coma, lesión pulmonar tardía (fluido en los pulmones), irritación inmediata o tardía en la piel, ampollas y reacciones alérgicas en la piel.

OTROS EFECTOS TARDÍOS POSIBLES EN LA SALUD: Puede causar lesiones en el sistema nervioso, cataratas, efectos reproductivos adversos, cambios cromosómicos y mutagénicos, y cáncer.

Limitaciones de exposición de la Administración de Seguridad y Salud Ocupacional de los EE. UU. (OSHA):

PEL (Límite de Exposición Permitido): Límite 1 PPM-TWA (partes por millón-media ponderada en el tiempo), 8 horas, Óxido de Etileno.
EL (Límite de Excursión): Límite de excursión de 5 PPM, 15 minutos.

OLOR: Similar al éter en altas concentraciones. La exposición a niveles tóxicos puede producirse sin advertencia o detección por parte del usuario. Puede causar daños al sistema nervioso.

PRECAUCIONES: No respire vapor. No trague. No entre en contacto con el producto en los ojos, la piel o la ropa. Guarde y úselo con la ventilación adecuada de acuerdo con la reglamentación nacional y local aplicable.

RIESGOS FÍSICOS Y QUÍMICOS

El gas de óxido de etileno es extremadamente inflamable. No lo utilice cerca de llamas, chispas eléctricas, superficies calientes, ni permita que se aproxime a fuentes de ignición cerca del área de esterilización.

Conecte a tierra todo el equipo para prevenir chispas por estática. Los contenidos están bajo presión. No perfore ni queme el recipiente. La exposición a temperaturas superiores a 130º F (54º C) puede provocar estallidos.

EQUIPO DE PROTECCIÓN PERSONAL (EPP)

El caucho butílico es un material resistente a este producto químico.

Toda persona que lo manipule debe vestir, como mínimo:

- Playera manga larga y pantalones largos.
- Calzado con calcetines.
- Guantes resistentes a los químicos.

El empleador debe proporcionar un respirador que sea adecuado para proteger la salud del empleado y garantizar el cumplimiento con la reglamentación nacional y local aplicable.

Cuando el ETO entra en contacto con los ojos o la piel de la persona que lo manipula, tal como durante tareas de reparación y mantenimiento, limpieza de recipientes o derrames, debe vestir lo siguiente:

- Ropa resistente a los químicos, como un delantal, un traje protector, o calzado que proteja la parte del cuerpo que podría entrar en contacto con el ETO.

• Gafas de protección facial, un protector de cara o una mascarilla de respiración completa.

Cuando se utilicen mascarillas:

1. Seguir las instrucciones para el usuario del fabricante de la mascarilla de respiración para cambiar los cartuchos.
2. Las mascarillas de respiración deben someterse a una prueba y verificación de ajuste utilizando un programa que cumpla con la reglamentación nacional y local aplicable.
3. Las personas que usen las mascarillas de respiración se deben entrenar por medio de un programa que cumpla con la reglamentación nacional y local aplicable.
4. Las personas que usen las mascarillas de respiración deben someterse a una revisación médica profesional para garantizar su aptitud física para utilizar con seguridad el tipo de mascarilla respiratoria a utilizar. Se considera "médico profesional" a un doctor u otro profesional de la salud matriculado (PLHCP, por sus siglas en inglés), quien evaluará la capacidad de un trabajador para usar una mascarilla de respiración. El proceso inicial de evaluación consta de un cuestionario sobre las condiciones médicas (como una condición cardíaca) que puede ser problemática a la hora de usar una mascarilla. Si se detectan problemas, puede que sea necesario someterse a exámenes físicos. La evaluación inicial se debe realizar antes de comenzar a utilizar la mascarilla. No debe repetirse, salvo que el estado de salud o las condiciones del uso de la mascarilla cambien. (vea 29CFR Part 1910.134).

RECOMENDACIONES DE SEGURIDAD PARA EL USUARIO:

Siga las instrucciones del fabricante para la limpieza o el mantenimiento del EPP. Si no existen dichas instrucciones para prendas lavables, use detergente y agua caliente. Conserve y lave el EPP separado de otras prendas.

Los usuarios deben lavarse las manos antes de comer, beber, mascar goma, consumir tabaco o ir al baño.

Los usuarios deben quitarse la ropa/EPP de inmediato si se ve penetrada por pesticida. Posteriormente, lavar por completo y ponerse ropa limpia.

Los usuarios deben quitarse el EPP de inmediato luego de manipular este producto. Limpie la parte exterior de los guantes antes de quitárselos. Limpie por completo y cambie su ropa por prendas limpias lo antes posible.

CONTACTO DE EMERGENCIA: 1-800-255-3924

PRIMEROS AUXILIOS

En todos los casos de exposición, obtenga atención médica de inmediato. Lleve a la persona al médico o a una sala de emergencia enseguida. Tenga consigo el recipiente o la etiqueta del producto cuando llame al número de Contacto de Emergencia o al doctor, o cuando vaya a recibir tratamiento.

EN CASO DE INHALACIÓN: Mueva a la persona expuesta a un lugar donde circule aire fresco y manténgala abrigada. Si la persona no respira, llame al número de emergencia municipal o nacional aplicable o una ambulancia, luego ejerza respiración artificial, preferentemente el método de boca a boca. Si la respiración es en lo más mínimo dificultosa, administre oxígeno. Llame a un doctor incluso si no hay presencia de síntomas para que reciba una recomendación de tratamiento. Mantenga a la persona bajo observación médica. Los síntomas pueden retrasarse.

EN CASO DE CONTACTO CON LOS OJOS: Mantenga los párpados abiertos y remoje los ojos con un flujo firme y suave de agua por lo menos de 15 a 20 minutos. Quite los lentes de contacto, si están colocados, luego de los primeros cinco minutos y luego continúe enjuagando los ojos. Consiga tratamiento médico inmediato.

EN CASO DE CONTACTO CON LA PIEL: Lave la piel de inmediato durante 15 a 20 minutos con abundante agua mientras se quita las prendas y el calzado contaminados. Llame al número de Contacto de Emergencia o a un doctor para recibir una recomendación de tratamiento. Airee, lave o limpie las prendas contaminadas y deseche los artículos de cuero.

SI TRAGÓ EL QUÍMICO: Llame al número de Contacto de Emergencia o a un doctor de inmediato para recibir una recomendación de tratamiento. Procure que la persona tome un vaso de agua a sorbos si puede tragar. No provoque vómitos a menos que así lo indique el Contacto de Emergencia o doctor asignados. No le dé nada a una persona inconsciente.

NOTA PARA EL MÉDICO

El óxido de etileno es un gas licuado. La exposición de la piel por el contacto con la tela, goma o plástico que contengan óxido de etileno residual normalmente produce una irritación en la piel con una gran formación de ampollas. En altas concentraciones, puede contraerse una conjuntivitis grave. Asimismo, puede generarse una irritación en el tracto respiratorio, pero sin edema pulmonar agudo. Los síntomas de intoxicación sistémica son dolor de cabeza, náuseas, vómitos, falta de coordinación y anomalías cardíacas. El tratamiento es sintomático.

RIESGOS AMBIENTALES

No vierta los efluentes que contienen este producto en lagos, arroyos, estanques, estuarios, océanos u otras aguas, salvo que, de conformidad con los requisitos del permiso aplicable "Sistema de Eliminación de Emisión de Contaminación Nacional" (NPDES, por sus siglas en inglés) y la autoridad correspondiente haya sido

notificada por escrito previo a la emisión. No vierta los efluentes que contienen este producto en sistemas de alcantarillado sin notificar previamente a la planta autorizada para el tratamiento de aguas residuales. Si necesita orientación, contacte a su oficina de protección ambiental nacional o regional.

INSTRUCCIONES DE USO
No use este producto de manera incongruente con su etiquetado.

En hospitales y centros de atención médica, la esterilización con ETO se debe realizar únicamente en cámaras herméticas al vacío o a gas diseñadas para uso con ETO. Se requiere de un proceso de cámara única para el tratamiento con ETO (la esterilización y aireación se deben realizar en la misma cámara) en hospitales y centros de salud. La capacitación de seguridad y conocimiento es obligatoria para todos los empleados, incluyendo al personal administrativo.

La información y la capacitación se deben proporcionar a todos los empleados en el establecimiento al momento de la asignación inicial y, a partir de entonces, de forma anual. La capacitación de seguridad debe incluir, como mínimo, la siguiente información: (1) los niveles ambientales más recientemente supervisados de ETO en el establecimiento; (2) los efectos potenciales sobre la salud por los niveles de ETO en el establecimiento; (3) el plan de respuesta ante emergencias y cómo responder en dicha situación; (4) la disponibilidad de la ficha informativa de seguridad y otros materiales asociados con los riesgos contra la salud por exposición al ETO.

Solo los operadores esterilizadores calificados pueden utilizar este producto, con el único fin de esterilizar dispositivos médicos reutilizables en un esterilizador a gas de óxido de etileno Anprolene AN75.

1. Presione el botón COMENZAR en la pantalla táctil del esterilizador Anprolene AN75 para iniciar un ciclo.

2. Luego de que la autoprueba finalice, la pantalla de Carga del Esterilizador le solicita al operador que cargue la bolsa de esterilización. Siempre utilice una bolsa de esterilización nueva para cada ciclo. Cargue los dispositivos envueltos en la bolsa de esterilización.

3. Inserte un Dosímetro AN87 en el centro de la carga en la bolsa de esterilización.

4. Inserte un Indicador Biológico (BI, por sus siglas en inglés) AN2203 en el Dispositivo de Prueba de Procesos (PCD, por sus siglas en inglés) Anprolene en la sonda de purga y ajuste la tapa.

5. Quite un cartucho de ETO Anprolene del Kit de Recarga AN7514. Remueva la cinta adhesiva y luego la protección del gatillo. Coloque el cartucho sobre los artículos envueltos cerca del extremo abierto de la bolsa desde donde la activación del cartucho es accesible. No active el cartucho todavía.

6. Inserte la sonda de purga en la bolsa de esterilización. Rodee el extremo abierto de la bolsa de esterilización alrededor de la sonda de purga y envuelva la correa de Velcro alrededor de tanto la abertura de la bolsa de esterilización como la sonda de purga, y ajústela para sellar por completo la bolsa de esterilización.

7. Coloque la bolsa de esterilización sellada dentro del esterilizador y conecte el conector de liberación rápida en la sonda de purga a la manguera de la sonda de purga.

8. Presione el botón PURGAR en la pantalla táctil para expulsar el aire en exceso de la bolsa de esterilización. Luego, siga las instrucciones de Selección de Ciclo y Verificación de Ciclo.

9. En la pantalla de Comenzar Ciclo, el esterilizador solicita al operador que active el cartucho. Tome el cartucho a través del lado lateral de la bolsa de esterilización y apriete por completo el botón de gatillo en el costado del cartucho para introducir el ETO en la bolsa.

10. Cierre la puerta y presione el botón COMENZAR en la pantalla táctil.

11. Durante el ciclo, la bolsa de esterilización contiene concentraciones peligrosas de ETO. No abra la bolsa de esterilización hasta que los pasos de esterilización, ventilación y aireación del ciclo hayan sido completados.

12. Al final del ciclo, siga las indicaciones en las pantallas táctiles de Datos del Ciclo y Descarga. Descargue el esterilizador, evalúe el Dosímetro AN87 y procese el BI AN2203.

ALMACENAMIENTO Y DESECHO
No contamine el agua, la comida o la alimentación al almacenar y desechar el producto.

Almacenamiento de Pesticida: Guardar en lugar fresco y bien ventilado, alejado del calor y la luz solar directa. Almacenar de acuerdo con la reglamentación nacional y local aplicable.

Desecho de Pesticida: Los desechos de pesticidas son tóxicos. El desecho incorrecto de pesticidas excedentes (cartuchos Anprolene AN7514 indeseados o vencidos) puede infringir la reglamentación nacional o local. Si estos residuos no se pueden desechar mediante el uso de acuerdo con las instrucciones de la etiqueta, contacte a su distribuidor local, Andersen Products, Inc. (00-1-336-376 -3000), o a su oficina de protección ambiental o de pesticidas nacional o local para recibir orientación.

Desecho del Recipiente: No perfore ni queme los cartuchos no usados. Airee los cartuchos vacíos y las bolsas de esterilización usadas según las Instrucciones de

Uso completas. Luego de la aireación, deseche en un vertedero sanitario.

INFORMACIÓN DE CONTACTO ADICIONAL

Fabricado por:
Andersen Sterilizers, Inc.
Health Science Park
3154 Caroline Drive
Haw River, NC 27258 USA

CE 0413

Distribuido por:
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Health Science Park
3202 Caroline Drive
Haw River, NC 27258 USA
1-800-523-1276
www.anpro.com
customerservice@anpro.com

Representante EU Autorizado:
H.W. Andersen Products, Ltd.
808 Fowler Road, Clacton-on-Sea
Essex C015 4AA U.K.
Tel: 44-1-255-428-328
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info@anderseneurope.com

Para todas las otras indagaciones mundiales:
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Tel: +1 336 376-3000
Fax: +1 336 376-8153

AN7514

ANPROLENE®

Sterilizzante gassoso per sterilizzazione a temperatura e pressione atmosferica ambientali
Utilizzare unicamente in sterilizzatori ventilati Anprolene AN75

Kit di Ricarica Anprolene®AN7514
CONTENUTO: 14 Cartucce, 15 Sacchetti per la Sterilizzazione e 14 Dosimetri AN87®
Ogni cartuccia AN7514 contiene in media 0,62 once (17,6 g) di Ossido di Etilene
Principio attivo: Ossido di Etilene 97%
Ingrediente inerte: 3%
Totale: 100%

Fabbricato da:
ANDERSEN STERILIZERS, INC.
3154 Caroline Drive • Haw River, NC 27258 USA

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

Distribuito da:
Rappresentante autorizzato per la UE:
Authorized EU Representative:
H. W. ANDERSEN PRODUCTS, LTD.
808 Fowler Clacton-On-Sea • Essex CO15 4AA UK
44-1255-428328

Nr. di registrazione EPA [Agenzia per la protezione dell'ambiente]: 69340-9

Nr. di stabilimento EPA: 69340-NC-001

Anprolene® e Dosimetro® sono marchi registrati di Andersen Sterilizers, Inc.

Tenere lontano dalla portata dei bambini

PERICOLO

Provoca ustioni cutanee e oculari. Dannoso se inalato. Può causare danni al sistema nervoso. Rischio di cancro e rischio per la riproduzione.

INDICAZIONI PRECAUZIONALI

EFFETTI DELL'ESPOSIZIONE ECCESSIVA: può essere mortale se inalato in elevate concentrazioni. Può causare irritazione alle vie respiratorie, costrizione toracica, cefalea, nausea, vomito, diarrea, sensazione di vertigine, capogiri, debolezza, sonnolenza, cianosi, perdita di coordinazione dei movimenti, coma, lesioni polmonari ritardate (liquido nei polmoni), irritazione cutanea immediata o ritardata, vesciche e reazioni cutanee di tipo allergico.

ALTRI POSSIBILI EFFETTI RITARDATI SULLA SALUTE: può causare lesioni al sistema nervoso, cataratta, effetti avversi per la riproduzione, alterazioni cromosomiche e mutageniche, e cancro.

Limiti all'esposizione stabiliti dalla Occupational Safety and Health Administration:
LEP: limite MPT per 1 PPM, 8 ore, Ossido di Etilene
LE: limite di escursione per 5 PPM, 15 minuti.
Gli utilizzatori devono osservare le prescrizioni normative locali e nazionali vigenti.

ODORE: simile all'Etere in elevate concentrazioni.
L'esposizione a livelli tossici può aver luogo senza avviso o rilevamento da parte dell'utilizzatore. Può causare danni al sistema nervoso.

PRECAUZIONI: non respirare il vapore. Non ingerire. Tenere lontano da occhi, pelle e indumenti. Conservare e utilizzare in presenza di ventilazione adeguata secondo le prescrizioni normative nazionali e locali vigenti.

RISCHI FISICI E CHIMICI

L'Ossido di Etilene è un gas estremamente infiammabile. Non utilizzare in prossimità di fiamme, scintille elettriche, superfici calde né consentire la presenza di fonti di ignizione in prossimità dell'area di sterilizzazione. Mettere a terra tutte le attrezzature per impedire la formazione di scintille statiche.

Contenuto sotto pressione. Non forare o incenerire il sacchetto. L'esposizione a temperature superiori a 130°F (54°C) potrebbe provocare esplosioni.

DISPOSITIVI DI PROTEZIONE INDIVIDUALE (DPI)

Un materiale resistente agli agenti chimici di questo prodotto è la gomma butilica.
Tutti gli addetti alla manipolazione devono indossare almeno:
- camicia a maniche lunghe e pantaloni lunghi
- scarpe e calze
- guanti resistenti agli agenti chimici.

Il datore di lavoro è tenuto a fornire un respiratore che sia adatto a proteggere la salute del dipendente e assicurare il rispetto delle prescrizioni normative nazionali e locali vigenti.

Qualora la cute e gli occhi degli addetti alla manipolazione vengano in contatto con l'ETO, ad esempio durante le operazioni di manutenzione e riparazione, la pulizia delle navi o qualora si verifichi una perdita di prodotto durante la pulizia, è necessario indossare:
- Abbigliamento resistente agli agenti chimici, come grembiule, tuta protettiva o calzature, che proteggano la parte del corpo che potrebbe venire in contatto con l'ETO, e
- Occhiali di protezione, visiera protettiva completa o respiratore completo.

Quando si indossano i respiratori:
1. Seguire le istruzioni d'uso del fabbricante del respiratore per cambiare le bombole.
2. L'idoneità dei respiratori deve essere testata e controllata utilizzando un programma che rispetti le prescrizioni normative nazionali e locali vigenti.
3. Gli utilizzatori del respiratore devono essere formati utilizzando un programma che rispetti le prescrizioni normative

nazionali e locali vigenti.

4. Gli utilizzatori del respiratore devono essere visitati da un operatore sanitario qualificato perché venga assicurata la loro capacità fisica di indossare in sicurezza il respiratore. Un operatore sanitario qualificato è un dottore o altro operatore sanitario abilitato che valuterà la capacità del lavoratore di indossare un respiratore. La valutazione iniziale è costituita da un questionario sulla presenza di eventuali patologie (ad es. cardiache) che renderebbero problematico l'uso di un respiratore. In caso di perplessità, potrebbero essere necessarie ulteriori valutazioni, ad esempio l'esame obiettivo. La valutazione iniziale deve essere eseguita prima di utilizzare il respiratore. Non è necessario ripeterla a meno che non cambino lo stato di salute o le condizioni d'uso del respiratore.

RACCOMANDAZIONI DI SICUREZZA PER L'UTILIZZATORE:

Seguire le istruzioni del fabbricante per pulire/mantenere i DPI. Se non sono previste le istruzioni per i capi lavabili, usare detergente e acqua calda. Conservare e lavare i DPI separatamente.

Gli utilizzatori dovrebbero lavarsi le mani prima di mangiare, bere, masticare gomme, far uso di tabacco o della toilette.

Gli utilizzatori dovrebbero levarsi gli indumenti/DPI immediatamente in caso di penetrazione del pesticida, lavarsi accuratamente e indossare indumenti puliti.

Gli utilizzatori dovrebbero levarsi i DPI immediatamente dopo aver maneggiato questo prodotto. Lavare esternamente i guanti prima di toglierli. Appena possibile, lavarsi accuratamente e indossare indumenti puliti.

NUMERO DI EMERGENZA: 1-800-255-3924

PRONTO SOCCORSO

In tutti i casi di esposizione, rivolgersi a un medico. Portare immediatamente l'infortunato dal dottore o in una struttura di emergenza.

Al momento di richiedere assistenza medica urgente, sia per via telefonica che personalmente, assicurarsi di essere in possesso della confezione del prodotto o dell'etichetta.

INALAZIONE: Trasferire l'infortunato all'aperto. Tenerlo al caldo. In assenza di respirazione, chiamare il numero di emergenza locale o nazionale o chiamare un'ambulanza, quindi provvedere alla respirazione artificiale, preferibilmente bocca a bocca. In caso di continua difficoltà di respirazione, somministrare ossigeno. Chiamare un medico anche se non sono presenti sintomi che richiederebbero un'ulteriore consulenza terapeutica. Tenere sotto osservazione medica. I sintomi potrebbero verificarsi in ritardo.

CONTATTO OCULARE: Tenere le palpebre aperte e risciacquare gli occhi con un flusso costante, leggero di acqua per almeno 15-20 minuti.
Rimuovere le lenti a contatto, se presenti, dopo i primi 5 minuti e poi continuare a lavare gli occhi. Consultare immediatamente un medico.

CONTATTO CUTANEO: Lavare immediatamente la pelle per 15-20 minuti con abbondante acqua, togliendo nello stesso tempo gli indumenti e le scarpe contaminate. Chiamare il numero d'emergenza o consultare un medico. Esporre all'aria, lavare o pulire gli indumenti contaminati e disfarsi degli oggetti in pelle.

INGESTIONE. Chiamare immediatamente il numero di emergenza o consultare un medico. Somministrare all'infortunato un bicchiere d'acqua, se è in grado di ingerire. Non indurre il vomito salvo su consiglio di un operatore dei servizi di emergenza o di un medico. Non somministrare nulla in caso di incoscienza dell'infortunato.

NOTA PER IL MEDICO

L'Ossido di Etilene è un gas liquefatto. L'esposizione cutanea mediante contatto con tessuti, gomma o plastica contenenti residui di ossido di etilene provoca generalmente irritazione cutanea con formazione estesa di vesciche. A elevate concentrazioni possono verificarsi gravi congiuntiviti. Può verificarsi un'irritazione delle vie respiratorie, ma senza edemi polmonari acuti. I sintomi dell'intossicazione sistemica sono mal di testa, nausea, vomito, perdita di coordinazione dei movimenti e scompensi cardiaci. Il trattamento è sintomatico.

RISCHI PER L'AMBIENTE

Non disperdere i liquidi di scarico contenenti questo prodotto in laghi, ruscelli, stagni, estuari, oceani o altri bacini d'acqua se non nel rispetto dei requisiti di cui al National Pollution Discharge Elimination System (NPDES) [Sistema Nazionale di Eliminazione degli Scarichi Inquinanti] e previa autorizzazione dell'autorità preposta che sarà stata preventivamente avvisata per iscritto. Non disperdere i liquidi di scarico contenenti questo prodotto nei sistemi fognari senza aver precedentemente informato l'autorità locale competente. Per indicazioni, contattare l'ufficio regionale o nazionale per la tutela ambientale.

INDICAZIONI PER L'USO

Non utilizzare questo prodotto secondo modalità non conformi a quanto indicato sull'etichetta.
Negli ospedali e nelle strutture sanitarie, la sterilizzazione all'ETO deve essere eseguita soltanto in camere a vuoto o a tenuta stagna antigas progettate per l'uso di ETO. Il trattamento con ETO deve essere eseguito in un'unica camera (sterilizzazione e aerazione devono aver luogo nella stessa camera) negli ospedali e strutture sanitarie.

Tutti i dipendenti, compreso il personale d'ufficio, devono essere formati alla sicurezza e alla sensibilizzazione. L'informazione e la formazione devono essere offerte a tutti i dipendenti della struttura al momento del conferimento dell'incarico e, successivamente, una volta all'anno. La formazione in materia di sicurezza deve comprendere le seguenti informazioni minime: (1) gli ultimi livelli ambientali di ETO riscontrati nella struttura; (2) i potenziali effetti sulla salute derivanti dai livelli di ETO nella struttura; (3) il piano d'emergenza e le modalità di reazione in caso di emergenza; (4) la disponibilità della Scheda sui Dati di Sicurezza e altri materiali relativi ai rischi per la salute dell'esposizione all'ETO.

Questo prodotto può essere utilizzato soltanto da addetti alla sterilizzazione che siano formati in merito, e soltanto per la sterilizzazione di dispositivi medici riutilizzabili in uno sterilizzatore a gas di ossido di etilene Anprolene AN75.
1. Premere il tasto AVVIO sul touch screen dello sterilizzatore Anprolene AN75

2. Dopo il completamento dell'autotest, la schermata "Carica Sterilizzatore" indica all'operatore di caricare il sacchetto per la sterilizzazione. Utilizzare sempre un nuovo sacchetto per ogni ciclo. Caricare i dispositivi avvolti nel sacchetto per la sterilizzazione.
3. Inserire un Dosimetro AN87 nel centro della parte caricata nel sacchetto per la sterilizzazione.
4. Inserire un Indicatore Biologico (IB) AN2203 nel Dispositivo per le Prove di Prestazione (DPP) Anprolene nel sondino di depurazione e chiudere saldamente il tappo.
5. Prendere una cartuccia di ETO Anprolene dal Kit di Ricarica AN7514. Rimuovere il nastro adesivo, poi rimuovere la sicura. Porre la cartuccia in cima agli articoli avvolti accanto all'estremità aperta del sacchetto accessibile per l'attivazione della cartuccia. Non attivare la cartuccia in questo momento.
6. Inserire il sondino di depurazione nel sacchetto per la sterilizzazione. Applicare l'estremità aperta del sacchetto attorno alla sondina di depurazione e avvolgere il cinturino in velcro attorno all'apertura del sacchetto e il sondino di depurazione, facendoli ben aderire per sigillare accuratamente il sacchetto.
7. Porre il sacchetto per la sterilizzazione sigillato nello sterilizzatore e collegare il connettore a sgancio rapido del sondino di depurazione alla manichetta dello stesso.
8. Premere il tasto DEPURARE sul touch screen per far uscire l'aria in eccesso dal sacchetto, poi seguire le indicazioni relative alla Selezione Ciclo e Verifica Ciclo.
9. Con la schermata "Inizia ciclo" lo sterilizzatore chiede all'operatore di attivare la cartuccia. Afferrare la cartuccia attraverso la parete del sacchetto e abbassare completamente il tasto di innesco sul lato della cartuccia per dispensare l'ETO nel contenitore.
10. Chiudere il portello e premere il tasto AVVIO sul touch screen.
11. Durante il ciclo, il sacchetto per la sterilizzazione contiene concentrazioni pericolose di ETO. Non aprire il sacchetto fino a quando le fasi di sterilizzazione, ventilazione e aerazione non saranno completate.
12. Al termine del ciclo, seguire le indicazioni sul touch screen relativi ai "Dati Ciclo" e "Scarico". Scaricare lo sterilizzatore, osservare il Dosimetro AN87 e trattare l'IB AN2203.

CONSERVAZIONE E SMALTIMENTO

Non contaminare acqua, cibo o mangime attraverso la conservazione e lo smaltimento.
Conservazione dei pesticidi: Conservare in un ambiente fresco, ben ventilato lontano da calore e luce solare diretta. Conservare secondo le norme locali e nazionali.

Smaltimento dei pesticidi: I rifiuti dei pesticidi sono tossici. Uno scorretto smaltimento dei pesticidi in eccesso (cartucce Anprolene AN7514 non utilizzate o scadute) può rappresentare una violazione delle normative locali e nazionali. Se tali rifiuti non possono essere smaltiti con l'uso in conformità con la loro etichetta, contattare il distributore locale, Andersen Products, Inc. (00-1-336-376-3000), l'agenzia di tutela ambientale o antipesticida locale o nazionale per ricevere indicazioni.

Smaltimento del contenitore: non forare o incenerire le cartucce inutilizzate. Arieggiare le cartucce vuote e utilizzare i sacchetti per la sterilizzazione secondo le Istruzioni d'Uso complete. Dopo l'aerazione, smaltirli in discariche controllate.

ULTERIORI INFORMAZIONI DI CONTATTO

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

CE 0413

Distribuito da:
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info@anderseneurope.com

Per tutte le altre domande mondiali:
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3202 Caroline Drive
Haw River, NC 27258 USA
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AN7514

ANPROLENE®

Agent Stérilisant Gazeux pour une Stérilisation à Température ambiante, Pression Atmosphérique A n'utiliser qu'avec les Stérilisateurs Ventilés Anprolene AN75.

Un kit de recharge Anprolene® AN7514
CONTENU : 14 cartouches, 15 poches de stérilisation et 14 AN87 Dosimeters®
Chaque cartouche AN7514 contient en moy. 0,62 Oz. (17,6 g) d'oxyde d'éthylène
Composants actifs : Oxyde d'éthylène ..... 97 %
Ingrédient inerte : ..... 3 %
Total : ..... 100 %

Fabriqué par :
ANDERSEN STERILIZERS, INC.
3154 Caroline Drive • Haw River, NC 27258 USA

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

Représentant autorisé en Europe :
H. W. ANDERSEN PRODUCTS, LTD.
808 Fowler Clacton-On-Sea • Essex CO15 4AA UK
44-1255-428328

N° d'enregistrement EPA 69340-9
N° d'établissement EPA 69340-NC-001

Anprolene® et Dosimeter® sont des marques déposées d'Andersen Sterilizers, Inc.

Tenir hors de portée des enfants.

DANGER

Provoque des brûlures aux yeux et à la peau. Nocif par inhalation. Peut causer des dommages au système nerveux. Peut être cancérigène et présenter des risques pour la reproduction.

DÉCLARATIONS DE PRÉCAUTION

EFFETS DE SUREXPOSITION : Peut être mortel si inhalé à des concentrations élevées. Peut causer une irritation des voies respiratoires, de l'oppression thoracique, des maux de tête, des nausées, des vomissements, de la diarrhée, des sensations d'étourdissement, des vertiges, de la faiblesse, de la somnolence, de la cyanose, une perte de coordination, un coma, des lésions pulmonaires retardées (liquide dans les poumons), une irritation de la peau immédiate ou retardée, des cloques et une réaction cutanée allergique.

AUTRES EFFETS RETARDÉS POSSIBLES SUR LA SANTÉ : Peut causer des lésions du système nerveux, des cataractes, des effets nocifs sur la reproduction, des changements chromosomiques et mutagènes et un cancer. Limites d'exposition selon le ministère américain de la santé et sécurisation professionnelle :

VLEP : Limite de 1 PPM-VEMP en 8 heures d'oxyde d'éthylène
VLCT : Limite d'exposition de 5 PPM en 15 minutes.
Les utilisateurs doivent se conformer aux exigences réglementaires nationales et locales applicables.

ODEUR : Semblable à l'éther à haute concentration. L'exposition à des niveaux toxiques peut se produire sans avertissement ou détection de la part de l'utilisateur. Peut causer des dommages au système nerveux.

PRÉCAUTIONS : Ne pas respirer les vapeurs. Ne pas avaler. Éviter tout contact avec les yeux, la peau ou les vêtements. Stocker et utiliser avec une ventilation adéquate conformément aux exigences réglementaires nationales et locales applicables.

DANGERS PHYSICO-CHIMIQUES

Le gaz d'oxyde d'éthylène est extrêmement inflammable. Ne pas utiliser à proximité d'une flamme, d'étincelles électriques, de surfaces chaudes. Ne pas permettre de sources d'inflammation près de la zone de stérilisation. Mettre tous les équipements à la masse pour éviter les étincelles statiques. Contenu sous pression. Ne pas percer ou incinérer le conteneur. L'exposition à des températures supérieures à 54 °C (130 °F) peut provoquer un éclatement.

ÉQUIPEMENT DE PROTECTION INDIVIDUELLE (EPI)

Le caoutchouc butyle est un matériau qui résiste aux produits chimiques de ce produit.
Tous les manutentionnaires doivent porter au minimum :

- Une chemise à manches longues et un pantalon long.
- Des chaussures et chaussettes.
- Des gants résistant aux produits chimiques.

L'employeur doit fournir un respirateur adéquat pour protéger la santé de l'employé et assurer la conformité aux exigences réglementaires nationales et locales applicables.

Lorsque les yeux ou la peau des manutentionnaires pourraient entrer en contact avec de l'EtO, comme lors d'un entretien et d'une réparation, du nettoyage du conteneur ou de déversements, ceux-ci doivent porter :

- Une tenue vestimentaire résistante aux produits chimiques, telle qu'un tablier, une combinaison de protection ou des chaussures qui protègent la zone du corps pouvant entrer en contact avec l'EtO, et
- Des lunettes étanches au visage, un écran facial

intégral ou un respirateur complet.

Lors du port de respirateurs :

1. Suivre les instructions du fabricant du respirateur pour changer les cartouches.
2. Les respirateurs doivent être soumis à un test d'ajustement et l'ajustement doit être vérifié à l'aide d'un programme conforme aux exigences réglementaires nationales et locales applicables.
3. Les utilisateurs de respirateurs doivent être formés à l'aide d'un programme qui confirme les exigences réglementaires nationales et locales applicables.
4. Les utilisateurs de respirateurs doivent être examinés par un médecin qualifié pour assurer la capacité physique de porter en toute sécurité le style de respirateur à porter. Un médecin qualifié est un médecin ou autre professionnel de la santé agréé (PLHCP, en anglais) qui évaluera la capacité d'un travailleur à porter un respirateur.

L'évaluation initiale consiste en un questionnaire portant sur des conditions médicales (telles que des problèmes cardiaques) qui seraient problématiques pour l'utilisation d'un respirateur. Si des problèmes sont identifiés, des évaluations supplémentaires, telles qu'un examen physique, peuvent être nécessaires. L'évaluation initiale doit être faite avant le début de l'utilisation du respirateur. Elle ne doit pas être répétée à moins que l'état de santé ou les conditions d'utilisation du respirateur changent.

RECOMMANDATIONS DE SÉCURITÉ POUR L'UTILISATEUR :

Suivre les instructions du fabricant pour le nettoyage et l'entretien de l'EPI. Si ces instructions ne sont pas disponibles, utiliser un détergent et de l'eau chaude.

Garder et laver l'EPI séparément des autres vêtements. Les utilisateurs doivent se laver les mains avant de manger, boire, mâcher de la gomme, fumer ou aller aux toilettes.
Les utilisateurs doivent enlever immédiatement les vêtements/EPI si le pesticide y a pénétré. Ils doivent ensuite se laver soigneusement et mettre des vêtements propres.
Les utilisateurs doivent retirer l'EPI immédiatement après avoir manipulé ce produit. Laver l'extérieur des gants avant de les enlever. Dès que possible, se laver soigneusement et mettre des vêtements propres.

Personne à contacter en cas d'urgence : 1 800 255-3924

PREMIERS SOINS

Dans tous les cas d'exposition, consulter un médecin immédiatement.

Emmener immédiatement la personne chez un médecin ou à un centre de traitement d'urgence. Avoir le contenant ou l'étiquette du produit avec soi au moment d'appeler le numéro de téléphone d'urgence ou un médecin, ou d'aller le consulter.

EN CAS D'INHALATION : Déplacer immédiatement la personne vers une source d'air frais. La garder au chaud. Si la personne ne respire pas, appeler le numéro d'urgence local ou national applicable ou une ambulance, puis administrer la respiration artificielle, de préférence par bouche-à-bouche. Si la respiration est difficile, donner de l'oxygène. Appeler un médecin même si aucun symptôme n'est présent pour d'autres conseils de traitement. Garder la personne en observation médicale. Les effets peuvent être différés.

EN CAS DE CONTACT AVEC LES YEUX : Tenir les paupières ouvertes et rincer les yeux avec un jet d'eau doux et constant pendant au moins 15 à 20 minutes. Si présentes, enlever les lentilles de contact après les 5 premières minutes, puis continuer à rincer les yeux. Obtenir immédiatement des soins médicaux.

EN CAS DE CONTACT AVEC LA PEAU : Laver immédiatement la peau pendant 15 à 20 minutes avec beaucoup d'eau tout en retirant les vêtements et les chaussures contaminés. Appeler le numéro de contact d'urgence ou un médecin pour obtenir des conseils sur le traitement. Aérer, laver ou nettoyer les vêtements contaminés et jeter les articles en cuir.

EN CAS D'INGESTION : Appeler immédiatement le numéro de contact d'urgence ou un médecin pour obtenir des conseils sur le traitement. Faire boire un verre d'eau à la personne si elle est capable d'avaler. Ne pas faire vomir à moins qu'un médecin ou un répondant des urgences ne l'indique. Ne rien faire prendre à une personne inconsciente.

NOTE POUR LE MÉDECIN

L'oxyde d'éthylène est un gaz liquéfié. L'exposition de la peau par contact avec un tissu, un caoutchouc ou un plastique contenant de l'oxyde d'éthylène résiduel entraîne généralement une irritation de la peau accompagnée d'une formation importante de cloques. À concentrations élevées, une conjonctivite sévère peut survenir. Une irritation des voies respiratoires peut survenir, mais sans œdème pulmonaire aigu. Les symptômes d'intoxication systémique sont des maux de tête, des nausées, des vomissements, un manque de coordination et des troubles du rythme cardiaque. Le traitement est symptomatique.

RISQUES POUR L'ENVIRONNEMENT

Ne pas déverser d'effluents contenant ce produit dans les lacs, cours d'eau, étangs, estuaires, océans ou autres eaux à moins d'être en conformité avec les exigences du permis national d'élimination des rejets de pollution (NPDES en anglais) et d'avoir avisé les autorités ad hoc par écrit. Ne pas déverser d'effluents contenant ce produit dans les égouts sans en aviser préalablement l'autorité

locale de traitement des eaux usées. Pour obtenir des conseils, contacter le bureau national ou régional de protection de l'environnement.

MODE D'EMPLOI

Ne pas utiliser ce produit d'une manière incompatible avec son étiquetage.

Dans les hôpitaux et les établissements de santé, la stérilisation à l'EtO ne doit être effectuée que dans des chambres sous vide ou étanches au gaz, conçues pour être utilisées avec l'EtO. Un processus à chambre unique est nécessaire pour le traitement par EtO (la stérilisation et l'aération doivent avoir lieu dans la même chambre) dans les hôpitaux et les établissements de santé.

Une formation sur la sécurité et de sensibilisation est requise pour tous les employés, y compris le personnel de bureau. Des informations et une formation doivent être fournies à tous les employés de l'établissement au moment de l'affectation initiale et chaque année par la suite. La formation sur la sécurité doit inclure au minimum les informations suivantes : (1) les plus récents niveaux ambiants d'EtO contrôlés dans l'établissement ; (2) les effets potentiels sur la santé des niveaux d'EtO dans l'établissement ; (3) le plan d'intervention d'urgence et la façon de réagir en cas d'urgence ; (4) la disponibilité de la fiche de données de sécurité et d'autres matériels liés aux dangers pour la santé de l'exposition à l'EtO.

Ce produit ne peut être utilisé que par des opérateurs formés pour les stérilisateurs, et uniquement pour la stérilisation de dispositifs médicaux réutilisables dans un stérilisateur à gaz d'oxyde d'éthylène Anprolene AN75.

1. Appuyer sur le bouton START de l'écran tactile du stérilisateur Anprolene AN75 pour lancer un cycle.
2. Une fois l'autotest terminé, l'écran 'Charger le stérilisateur' invite l'opérateur à charger la poche de stérilisation. Toujours utiliser une nouvelle poche de stérilisation pour chaque cycle. Charger les appareils emballés dans la poche de stérilisation.
3. Insérer un dosimètre AN87 au milieu de la charge dans la poche de stérilisation.
4. Insérer un indicateur biologique (BI) AN2203 dans le dispositif de défi de procédé (PCD, Process Challenge Device, en anglais) de l'Anprolene dans la sonde de purge et serrer le bouchon.
5. Retirer une cartouche EtO Anprolene du kit de recharge AN7514. Retirer le ruban adhésif, puis le pontet. Placer la cartouche au-dessus des articles emballés près de l'extrémité ouverte de la poche où elle sera accessible pour activation. Ne pas activer la cartouche à ce stade.
6. Insérer la sonde de purge dans la poche de stérilisation. Rassembler l'extrémité ouverte de la poche de stérilisation autour de la sonde de purge et enrouler la bande Velcro autour de l'ouverture de la poche de stérilisation et de la sonde de purge, en la serrant pour sceller complètement la poche de stérilisation.
7. Placer la poche de stérilisation scellée à l'intérieur du stérilisateur et connecter le connecteur à dégagement rapide sur la sonde de purge au tuyau de la sonde de purge.
8. Appuyer sur le bouton PURGE sur l'écran tactile pour évacuer l'excès d'air de la poche de stérilisation, puis suivre les instructions de sélection du cycle et les invites de vérification du cycle.
9. Sur l'écran de démarrage du cycle, le stérilisateur invite l'opérateur à activer la cartouche. Saisir la cartouche à travers la paroi de la poche de stérilisation et enfoncer complètement le bouton de déclenchement sur le côté de la cartouche pour libérer l'EtO dans la poche.
10. Fermer la porte et appuyer sur le bouton START sur l'écran tactile.
11. Pendant le cycle, la poche de stérilisation contient des concentrations dangereuses d'EtO. Ne pas ouvrir la poche de stérilisation avant que les étapes de stérilisation, de ventilation et d'aération du cycle ne soient terminées.
12. À la fin du cycle, suivre les invites sur les écrans tactiles Cycle Data (données de cycle) et Unload (décharger). Décharger le stérilisateur, évaluer le dosimètre AN87 et traiter le BI AN2203.

STOCKAGE ET ÉLIMINATION

Ne pas contaminer l'eau, les aliments ou les aliments pour animaux lors du stockage et de l'élimination.

Stockage du pesticide : Le conserver dans un endroit frais et bien ventilé, loin de la chaleur et de la lumière directe du soleil. Stocker conformément aux exigences réglementaires nationales et locales applicables.

Élimination du pesticide : Les déchets de pesticides sont toxiques. L'élimination inadéquate des pesticides en excès (cartouches Anprolene AN7514 non désirées ou périmées) peut enfreindre les exigences réglementaires nationales et locales applicables. Si ces déchets ne peuvent pas être éliminés conformément aux instructions de l'étiquette, contacter le distributeur local, Andersen Products, Inc. (+1-336-376-3000), votre organisme local ou national des pesticides ou de protection de l'environnement.

Élimination du conteneur : Ne pas percer ou incinérer les cartouches inutilisées. Aérer les cartouches vides et les poches de stérilisation usagées conformément aux instructions d'utilisation complètes. Après aération, les jeter dans un site d'enfouissement sanitaire.

INFORMATIONS DE CONTACT SUPPLÉMENTAIRES

Fabriqué par :
Andersen Sterilizers, Inc. CE 0413
Health Science Park
3154 Caroline Drive
Haw River, NC 27258 U.S.A.

Distribué par :
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Pour toutes les autres enquêtes mondiales:
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Haw River, NC 27258 USA
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Tel: +1 336 376-3000
Fax: +1 336 376-8153

AN7514

ANPROLENE®

Gasförmiges Marken-Sterilisationsmittel zur Verwendung bei Raumtemperatur, Sterilisation bei atmosphärischem Druck Nur zur Verwendung in belüfteten Anprolene-Sterilisatoren AN75

Eine Anprolene ®AN7514 Nachfüllpackung
INHALT: 14 Ampullen, 15 Sterilisationsbeutel und 14 AN87 Dosimeter®
Jede AN7514 Ampulle enthält 0,62 av.Oz. (17,6 g) Ethylenoxid
Aktiver Wirkstoff: Ethylenoxid.....97%
Inerter Wirkstoff:.....3%
Gesamtmenge:.....100%

Hergestellt durch:
ANDERSEN STERILIZERS, INC.
3154 Caroline Drive • Haw River, NC 27258 USA

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

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

EPA-Registrierungs-Nr. 69340-9
EPA-Erzeuger-Nr. 69340-NC-001

Anprolene® und Dosimeter® sind eingetragene Warenzeichen der Andersen Sterilizers, Inc.

Für Kinder unzugänglich aufbewahren

GEFAHR

Verursacht Augen- und Hautverätzungen. Gesundheitsschädlich beim Einatmen. Kann das Nervensystem schädigen. Gefahr von Krebserkrankungen und Fortpflanzungsdefekten.

SICHERHEITSHINWEISE

AUSWIRKUNGEN BEI ZU LANGEM KONTAKT: Kann bei Einatmen hoher Dosen tödlich sein. Kann zu Reizungen der Atemwege, Engegefühl in der Brust, Kopfschmerzen, , Übelkeit, Erbrechen, Durchfall, Benommenheit, Schwindel, Schwächegefühl, Schläfrigkeit, Blaufärbung der Haut, Koordinationsstörungen, Koma, Lungenschädigung (Flüssigkeit in der Lunge), unmittelbar oder später auftretende Hautreizungen, Blasen und allergischen Hautreaktionen führen.

WEITERE MÖGLICHE, SPÄTERE AUSWIRKUNGEN AUF DIE GESUNDHEIT: Kann zur Schädigung des Nervensystems, Katarakt, Reproduktionsdefekten, Chromosomen -und Erbgutveränderungen und Krebs führen.

Maximale Kontaktdauer gemäß :
PEL: 1 ppm-TWA Grenzwert, 8 Stunden, Ethylenoxid
EL: 5 ppm-Exkursions-Grenzwert, 15 Minuten.
Die Benutzer müssen die geltenden landesweiten und örtlichen Bestimmungen einhalten.

GERUCH: wie Äther bei hohen Konzentrationen. Eine toxische Exposition kann ohne Vorwarnung oder ohne Wahrnehmung des Anwenders auftreten. Kann das Nervensystem schädigen

SICHERHEITSHINWEISE: Dämpfe nicht einatmen. Nicht schlucken. Kontakt mit den Augen, der Haut oder der Kleidung vermeiden. Ausreichend belüftet entsprechend den geltenden landesweiten und örtlichen Bestimmungen aufbewahren und anwenden.

PHYSIKALISCHE UND CHEMISCHE RISIKEN

Ethylenoxidgas ist extrem entzündlich. Nicht neben offenem Feuer, elektrischen Funkenquellen, heißen Oberflächen verwenden und Zündquellen neben dem Sterilisationsbereich vermeiden. Erden Sie alle elektrischen Geräte, um elektrostatische Funken zu vermeiden.

Inhalt steht unter Druck. Den Container nicht durchstechen oder verbrennen. Bei Temperaturen über 130° F (54° C) besteht Explosionsgefahr.

PERSÖNLICHE SCHUTZAUSRÜSTUNG (PSA)

Butylkautschuk ist ein chemisch resistentes Material.
Alle Benutzer müssen mindestens tragen:
- Shirt mit langen Ärmeln und lange Hosen.
- Schuhe und Strümpfe.
- Chemisch resistente Handschuhe.

Der Arbeitgeber soll eine geeignete, den geltenden landesweiten und örtlichen Bestimmungen entsprechende Atemschutzmaske zum Schutz der Arbeitnehmer zur Verfügung stellen.

Da während der Wartungs- und Reparaturarbeiten, der Reinigung des Behälters oder der Entfernung von Spritzern ETO in die Augen oder auf die Haut der Benutzer gelangen kann, ist von den Benutzern zu tragen:
- Chemisch-resistente Kleidung, wie z.B. eine Schürze, einen Schutzanzug oder Schuhe, die den Körperbereich schützen, der mit ETO in Kontakt kommen könnte und
- eine dicht abschließende Schutzbrille, Gesichtsmaske

oder ein Atemschutzgerät.

Beim Tragen eines Atemschutzgeräts ist zu beachten:
1. Befolgen Sie die Herstellerhinweise beim Austauschen des Filters.
2. Der Sitz des Atemschutzgeräts ist anhand eines Programms zu überprüfen, das den geltenden landesweiten und örtlichen Bestimmungen entspricht.
3. Die Träger von Atemschutzgeräten sind anhand eines Programms zu schulen, das den geltenden landesweiten und örtlichen Bestimmungen entspricht.
4. Die Träger von Atemschutzgeräten sind von einem qualifizierten praktischen Arzt zu untersuchen, um die körperliche Eignung für das sichere Tragen des erforderlichen Atemschutzgeräts sicherzustellen. Als qualifiziert gilt ein praktischer Arzt oder ein anderer approbierter Mediziner (PLHCP), der die Eignung eines Arbeiters zum Tragen eines Atemschutzgeräts beurteilt. Bei der ersten Untersuchung ist ein Fragebogen zu bestehenden Krankheiten (wie z.B. Herzleiden) zu beantworten, die problematisch für das Tragen eines Atemschutzgerätes wären. Wenn Beschwerden festgestellt werden, sind eventuell weitere, körperliche, Untersuchungen erforderlich. Die erste Untersuchung muss noch vor dem ersten Tragen des Atemschutzgeräts erfolgen. Diese muss nicht wiederholt werden, außer wenn sich der Gesundheitszustand oder die Umstände beim Tragen des Atemschutzgeräts ändern.

SICHERHEITSEMPFEHLUNGEN FÜR DIE BENUTZER:

Befolgen Sie die Herstellerhinweise zu Reinigung/Pflege der PSA. Wenn Hinweise dazu fehlen, verwenden Sie Waschmittel und heißes Wasser. Waschen Sie die persönliche Schutzkleidung separat und bewahren Sie diese getrennt von der anderen Wäsche auf.

Die Benutzer sollten sich vor dem Essen, Trinken, Kaugummikauen, Rauchen oder Benutzen der Toilette die Hände waschen.
Die Benutzer sollten die Kleidung/Schutzkleidung sofort ausziehen, wenn Pestizid nach innen gelangt ist. Danach waschen Sie sich gründlich und ziehen saubere Kleidung an.
Benutzer sollten die Schutzkleidung sofort ausziehen, wenn sie dieses Produkt verwendet haben. Waschen Sie die Handschuhe außen ab, bevor Sie diese ausziehen. Waschen Sie sich sobald wie möglich gründlich und ziehen Sie saubere Kleidung an.

NOTFALLTELEFON: 1-800-255-3924

ERSTE HILFE

Bei jedem Kontakt mit dem Schadstoff ist umgehend ein Arzt aufzusuchen.

Bringen Sie die betreffende Person zu einem Arzt oder in eine notärztliche Einrichtung. Halten Sie den Behälter oder das Etikett bereit, wenn Sie die Notrufnummer oder den Arzt anrufen oder in die notärztliche Einrichtung fahren.

NACH EINATMEN: Bringen Sie die betreffende Person an die frische Luft. Halten Sie sie warm. Bei Atemstillstand rufen Sie die örtliche oder landesweit geltende Notfallnummer oder eine Ambulanz an, dann führen Sie eine künstliche Beatmung, vorzugsweise Mund-zu-Mund-Beatmung, durch. Wenn das Atmen nur unter Anstrengung möglich ist, führen Sie Sauerstoff zu. Konsultieren Sie auch beim Fehlen von Symptomen einen Arzt zur Abklärung einer weiteren Behandlung. Sorgen Sie für eine medizinische Überwachung. Symptome können auch verspätet auftreten.

BEI AUGENKONTAKT: Halten Sie die Augen offen und spülen Sie die Augen mit einem konstanten, sanften Wasserstrahl mindestens 15-20 Minuten lang. Entfernen Sie gegebenenfalls Kontaktlinsen nach den ersten 5 Minuten und spülen Sie die Augen weiterhin aus. Begeben Sie sich sofort in medizinische Behandlung.

BEI HAUTKONTAKT: Reinigen Sie die Haut sofort 15-20 Minuten lang mit reichlich Wasser und ziehen Sie die kontaminierte Kleidung und Schuhe aus. Rufen Sie den Notdienst oder einen Arzt an und besprechen Sie die weitere Behandlung. Lüften, waschen oder reinigen Sie die kontaminierte Kleidung und werfen Sie Lederwaren weg.

BEI VERSCHLUCKEN: Rufen Sie sofort den Notdienst oder einen Arzt und besprechen Sie die weitere Behandlung. Lassen Sie die betreffende Person, wenn möglich, ein Glas Wasser trinken. Lösen Sie nur bei Anweisung (medizinischen Personals) Erbrechen aus. Einer bewusstlosen Person ist kein Wasser zu reichen.

HINWEIS FÜR DEN ARZT

Ethylenoxid ist ein Flüssiggas. Wenn die Haut mit einem Stoff, Gummi oder Kunststoff mit Ethylenoxidresten in Berührung gekommen ist, führt dies gewöhnlich zu einer Hautreizung mit ausgeprägter Blasenbildung. Bei hohen Dosen kann eine schwere Konjunktivitis ausgelöst werden. Die Atemwege können gereizt werden, jedoch ohne akutes Lungenödem. Die Symptome einer systemischen Intoxikation sind Kopfschmerzen, Übelkeit, Erbrechen, Koordinationsprobleme und Herzrhythmusstörungen. Die Behandlung erfolgt symptomatisch.

UMWELTGEFÄHRDUNG

Entsorgen Sie kein Abwasser mit diesem Produkt in Seen, Bäche, Teiche, Flussmündungen, Meere oder andere Gewässer, außer wenn dies aufgrund der geltenden Bestimmungen der nationalen Schadstoffentsorgung (NPDES) zulässig ist und die Genehmigungsbehörde vor der Entsorgung schriftlich darüber in Kenntnis gesetzt wurde. Entsorgen Sie kein Abwasser mit diesem Produkt in die Kanalisation, ohne vorher die für die kommunale Kläranlage zuständige

Behörde zu informieren. Für weitere Auskünfte kontaktieren Sie bitte die nationale oder regionale Umweltschutzbehörde.

GEBRAUCHSHINWEISE

Verwenden Sie dieses Produkt nur bestimmungsgemäß.

In Krankenhäusern und medizinischen Einrichtungen darf eine Sterilisation mit ETO nur in Vakuumkammern oder gasdichten Kammern durchgeführt werden, die für den Einsatz von ETO entwickelt wurden. Die Behandlung mit ETO in Krankenhäusern und medizinischen

Einrichtungen erfordert ein Einkammer-Verfahren (Sterilisation und Entlüftung müssen in der gleichen Kammer ablaufen). Das gesamte Personal einschließlich der Büroangestellten muss an Schulungen zur Sicherheit und Sicherheitsbewusstsein teilnehmen.

Alle Angestellten der Einrichtung müssen beim ersten Einsatz Informationen und eine Schulung erhalten, die jährlich wiederholt wird. Das Sicherheitstraining muss mindestens folgende Themen behandeln: (1) die zuletzt in der Einrichtung gemessenen ETO-Werte; (2) die möglichen Gesundheitsrisiken aufgrund der gemessenen ETO-Werte in der Einrichtung; (3) den Notfallplan und Vorgehensweise bei einem Notfall; (4) das Sicherheitsdatenblatt und andere Unterlagen bezüglich der Gesundheitsrisiken bei ETO-Exposition.

Dieses Produkt darf nur von Personen, die im Umgang mit einem Sterilisator geschult sind und für die Sterilisation von wiederverwendbaren medizinischen Produkten in einem Anprolene AN75 Ethylenoxidgas-Sterilisator verwendet werden.

1. Drücken Sie den START Knopf auf dem Touchscreen-Bildschirm des Anprolene AN75 Sterilisators, um den Zyklus zu starten.
2. Sobald der Selbsttest abgeschlossen ist, wird dem Bedienpersonal auf dem Bildschirm angezeigt, den Sterilisationsbeutel einzulegen. Benutzen Sie für jeden Zyklus einen neuen Beutel. Geben Sie die eingewickelten Produkte in den Sterilisationsbeutel.
3. Legen Sie ein AN87 Dosimeter in die Mitte des Sterilisationsbeutels.
4. Stecken Sie einen AN2203 Bioindikator (BI) in den Anprolene Prüfkörper (PCD) in der Sonde und verschliessen Sie die Kappe.
5.Nehmen Sie eine Anprolene ETO-Ampulle aus der AN7514 Nachfüllpackung. Entfernen Sie den Klebstreifen und danach den Aktivierungsriegel. Legen Sie die Ampulle an der offenen Seite des Beutels auf die eingewickelten Produkte, damit diese später aktiviert werden kann. Aktivieren Sie die Ampulle zu diesem Zeitpunkt noch nicht.
Geben Sie die Sonde in den Sterilisationsbeutel. Raffen Sie den Sterilisationsbeutel am offenen Ende um die Sonde zusammen und umwickeln Sie den Sterilisationsbeutel und die Sonde dann fest mit dem Klettband, damit der Sterilisationsbeutel komplett dicht verschlossen ist.
7. Geben Sie den verschlossenen Sterilisationsbeutel in den Sterilisator und verbinden Sie den Schnellanschluss auf der Sonde mit dem Sondenschlauch.
8. Drücken Sie auf den ABSAUG-Knopf auf dem Bildschirm, um überschüssige Luft aus dem Sterilisationsbeutel zu entfernen, danach befolgen Sie die Anzeigen zur Zykluswahl und Zyklusverifizierung.
9. Bei Programmbeginn erscheint die Anzeige, dass die Ampulle aktiviert werden soll. Nehmen Sie die im Sterilisationsbeutel befindliche Ampulle und drücken Sie fest auf den Aktivierungsknopf, der sich seitlich an der Ampulle befindet, um das ETO im Beutel freizusetzen.
10. Schließen Sie die Tür und drücken Sie den START-Knopf auf dem Bildschirm.
11. Während dem Zyklus enthält der Sterilisationsbeutel ETO in einer gefährlichen Konzentrationsmenge. Öffnen Sie den Sterilisationsbeutel nicht, bevor die Sterilisations-, Belüftungs- und Entlüftungszyklen abgeschlossen sind.
12. Bei Programmende befolgen Sie die Bildschirmanzeigen zu Zyklusdaten und Entnahme. Entleeren Sie den Sterilisator, überprüfen Sie den AN87 Dosimeter und entwickeln Sie den AN2203 Bioindikator.

AUFBEWAHRUNG UND ENTSORGUNG

Verunreinigen Sie kein Wasser, Nahrungsmittel oder Futter durch Aufbewahrung und Entsorgung des Produkts.

Pestizidaufbewahrung: Bewahren Sie dieses an einem kühlen, gut belüfteten Ort, geschützt vor Wärme und direkter Sonneneinstrahlung und gemäß der geltenden nationalen und örtlichen Bestimmungen auf.

Pestizidentsorgung: Pestizidabfälle sind toxisch. Eine unsachgemäße Entsorgung überschüssiger Pestizide (nicht benötigte oder abgelaufene Anprolene AN7514 Ampullen) kann gegen geltende nationale und örtliche Bestimmungen verstoßen. Wenn diese Abfälle nicht wie auf dem Etikett angegeben entsorgt werden können, kontaktieren Sie bitte Ihren örtlichen Händler, Andersen Products, Inc. (00-1-336-376-3000) oder Ihre örtliche oder nationale Umweltschutzbehörde für weitere Informationen.

Containerentsorgung: Stechen Sie nicht in unbenutzte Ampullen und verbrennen Sie diese nicht. Entlüften Sie leere Ampullen und gebrauchte Sterilisationsbeutel entsprechend der vollständigen Gebrauchshinweise und entsorgen diese anschließend auf der Mülldeponie.

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