U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

NOTICE OF PESTICIDE:
_X_ Registration
___ Reregistration
(under FIFRA, as amended)

EPA Reg. Number:	**Date of Issuance:**
69340-9	1/10/17

Term of Issuance:
Conditional

Name of Pesticide Product:
AN7514

Name and Address of Registrant (include ZIP Code):

Dale Pfeifer
Operations Manager
Andersen Sterilizers
3154 Caroline Drive
Haw River, NC 27258

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:	**Date:**
E. Miederhoff Eric Miederhoff, Product Manager 31 Regulatory Management Branch I Antimicrobials Division (7510P)	1/10/17

EPA Form 8570-6

2. You are required to comply with the data requirements described in the DCI identified below:

    a. Ethylene oxide GDCI-042301-1428

    You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Reevaluation Team Leader (Team 36): http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division

3. Make the following label changes before you release the product for shipment:

    - Revise the EPA Registration Number to read, "EPA Reg. No. 69340-9."

4. Submit one copy of the final printed label for the record before you release the product for shipment.

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.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 06/16/2016

If you have any questions, you may contact Joe Daniels at (703) 347-8669 or via email at daniels.joseph@epa.gov.

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-#.
EPA Establishment No. 69340-NC-001

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

AN7514.20_VN2016-05-24AN7514

ANPROLENE Keep Out of Reach of Children
DANGER
Causes eye and skin burns. Harmful if inhaled. May cause nervous system damage. Cancer Hazard and reproductive hazard.
PRECAUTIONARY STATEMENTS
EFFECT OF OVEREXPOSURE: May be fatal if inhaled in high concentrations. 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.

OTHER POSSIBLE DELAYED HEALTH EFFECTS: May cause nervous system injury, cataracts, adverse reproductive effects, chromosomal and mutagenic changes, and cancer.

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

EL: 5 PPM-excursion limit, 15 minutes.

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

May cause nervous system damage.

PRECAUTIONS: Do not breathe vapor. Do not swallow. Do not get in eyes, on skin or on clothing Store and use with adequate ventilation in accordance with 29 CFR1910.1047

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.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

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

All handlers must wear at a minimum:

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

The employer shall provide a respirator that is adequate to protect the health of the employee and ensure compliance with all other OSHA statutory and regulatory requirements (see 29 CFR 1910.1047 and 29 CFR 1910.134)

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

- Chemical-resistant attire, such as an apron, protective suit, or footwear that protects the area of the body that might contact ETO, and

- Face-sealing goggles, a full-face shield, or a full-face respirator.

When wearing respirators:

1. Follow the respirator manufacturer's user's instructions for changing canisters.

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

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

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

User Safety Recommendations

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

Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

Emergency Contact: 1-800-255-3924

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.

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 Instructions for Use. After aeration, dispose of in sanitary landfill.