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	U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Antimicrobials Division (7510C)	EPA Reg. Number: 69340-8	Date of Issuance: FEB 2 0 2008	
, nitra	1200 Pennsylvania Avenue NW Washington, D.C. 20460		Term of Issuance: Conditional	
	NOTICE OF PESTICIDE: Registration Reregistration	Name of Pesti EOGas AN6		
(under FIFRA, as	amended)			
Andersen Steril 3154 Caroline I Haw River, NC	Drive	·		
Note: Changes in lab	eling differing in substance from that accepted in connection stration Division prior to use of the label in commerce. In an	with this registration must t	and the second	
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manner inconsistent with its labeling," to page 3 of the EOGas AN6006 "Directions For Use" insert."

3. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 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. If you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,

Velma Noble Product Manager 31 Regulatory Branch I Antimicrobials Division (7510P)

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Enclosure: (Stamped Label)

ACCEPTED with COMMENTS in EPA Letter Dated:

FEB 2 0 2008

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.

9340-8 6

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ONE KIT

Distributed by:

CONTENTS: 25 Cartridges, 26 Sterilization Bags, 25 Dosimeters®, 25 Humidichips®. Each AN6006 cartridge contains 0.37 av. oz. (10.5 g) EOGas sterilant.

ANDERSEN 🛠 STERILIZERS, INC.

Manufactured and Distributed by: ANDERSEN STERILIZERS, INC. 3154 Caroline Drive · Haw River, NC 27258 USA 336-376-8622



ANDERSEN PRODUCTS, INC. 3202 Caroline Drive - Haw River, NC 27258 USA 1-800-523-1276 • 336-376-3000 www.sterility.com • mailbox@anpro.com

European Distributor: H. W. ANDERSEN PRODUCTS, LTD. Clacton-On-Sea • Essex C015 4XA UK 44-1255-428328

0413

EPA Registration No. 69340-X EPA Establishment No. 69340-NC-001 PN2858_VN103007 **KEEP OUT OF REACH OF CHILDREN** DANGER

IMPORTANT: FOR PROFESSIONAL USE ONLY

Users must follow the requirements of the OSHA occupational exposure standard for Ethylene oxide (29 CFR 1910.1047).

Active ingredient: Ethylene oxide	98.06%
Other ingredient:	1.94%
Total:	100.0%

PRECAUTIONARY STATEMENTS Hazard to Humans and Domestic Animals.

DANGER

Causes irreversible eye damage and skin burns. Harmful if inhaled. Do not breath vapor. Do not get on eyes, skin, or clothing. Do not swallow. Cancer Hazard and Reproductive Hazard. May cause nervous system damage. Store and use with adequate ventilation in accordance with 29 CFR1910.1047

See user's manual for additional precautionary statements. Emergency Contact: 1-800-255-3924

FIRST AID STATEMENTS

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

IF IN EYES: Hold eyes open and rinse slowly and gently with water for 15 to 20 minutes. Remove contact lenses, if present, after the first 5 minutes then continue rinsing eye. Get medical treatment

IF INHALED: Get exposed person to fresh air. Keep warm. If not breathing call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible, If breathing is difficult, give oxygen. Call a physician even if no symptoms are present. Keep under medical observation. Symptoms may be delayed.



EOGas U.S. Pat. no. 4,937,046 and 5,160,700. Humidichip U.S. Pat. no. 5,082,636

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IF ON SKIN: Immediately wash skin with plenty of water while removing contaminated clothing and shoes. Call a physician. Aerate, wash, or clean contaminated clothing and discard leather goods.

IF SWALLOWED: Drink at least two glasses of water. Do not induce vomiting. Do not give anything by mouth to an unconscious victim. Call a physician.

NOTE TO PHYSICIAN

Ethylene oxide is a 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, incoordination, and cardiac irregularities. Treatment is symptomatic.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into takes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Discharge Pollution Elimination System (NDPES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sever systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

PHYSICAL OR CHEMICAL HAZARDS. DANGER. FLAMMABLE LIQUID AND GAS UNDER PRESSURE

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

Ethylene oxide gas is extremely flammable. Do not use near flame, electrical sparks, or hot surfaces. Ground all equipment to prevent static sparks.

DIRECTIONS FOR USE

To be used only in EOGas sterilizers, and only for hospital, medical and veterinary sterilization.

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. It is the responsibility of the employer of any person engaged in the handling or application of this product to follow the requirements of 29 CFR 1910.1047. Read package insert for complete sterilization instructions and additional precautions.

STORAGE AND DISPOSAL

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

STORAGE: Store in a cool place and out of direct sunlight.

PESTICIDE DISPOSAL: Unwanted or expired EOGas Contact Andersen Products, Inc. (tel. no. 336-376-3000) for instructions, If unwanted or expired EOGas cartridges cannot be disposed of according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for duidance.

CONTAINER, DISPOSAL: Do not reuse empty box, used sterilization bags in paper and discard in the trash. . . J. 000 ÷





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Gaseous Sterilant for 50°C Sterilization

ENGLISH: Directions for Use: EOGas Cartridges

Pages 3-7

FRANÇAIS: Instructions D' Utilisation De Cartouches EOGas

Pages 8-10

DEUTSCH: Anweisungen Für Die Benutzung Der EOGas Kartusche

Pages 11-14

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

Pages 15-18

ESPAÑOL: Instrucciones Para El Uso De Cartuchos EOGas

Pages 19-22

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

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

H.W. Andersen Products, Etd. Davy Road • Gorse Lane Industrial Estates Con-Clacton-on-Sea • Essex C015 AXA U.K.

Distributed in Asia by: ANDERSEN Medical (HK), Ltd. 2010 Unit 2, 18/F Westly Square, 40 Hoi Yuen Road Kwun Tong, Hong Kong Tel:2851-1655



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AN 6006 EOGas Cartridges

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. It is the responsibility of the employer of any person engaged in the handling or application of this product to follow the requirements of 29 CFR 1910.1047.

CAUTION:

Do not remove the trigger guard until just before you place the cartridge in the sterilization bag.

Typical Products which may Conveniently be Processed in an EOGas Sterilizer

Respirators, corrugated tubing

Bronchoscopes, gastroscopes, fiberscopes of all kinds Procedure Travs

Catheters - plastic, rubber, cloth

Tubing - plastic, rubber, metal, glass, cloth

Anesthesia equipment - endotracheal tubes, masks, rubber tubing

Adhesive tape

Bandages, dressing sets (reuse plastic forceps) Syringes - plastic, rubber, glass, bulb syringes Gloves - rubber, plastic, cloth Surgical instruments - steel, chrome plate, brass, plastic

Optical instruments - scopes, cameras, lenses, mirrors Ctrical equipment - whether autoclavable or not .nted equipment - metal, wood High speed steel - drills, burrs, chisels

Airways - plastic, rubber, metal Fabric - cloth, rubber, plastic, leather Electric wire - whether autoclavable or not Dry cell batteries, battery cases, bulbs Sutures - plastic, silk, cotton, stainless steel Tongue depressors, applicator sticks Rectal tubes, douche tubes - rubber, plastic Specula - plastic, metal

Preparation of Material for Sterilization

Material to be sterilized by EOGas must be meticulously clean and dry. Coatings of dry protein, like dry pus, blood or feces, protect microorganisms and slow the sterilization process. You must always be sure to take the following precautions before sterilizing with EOGas: 1. Disassemble and scrub all instruments in detergent and water to the most critical standard of cleanliness possible.

2. Be sure that items to be sterilized are physically dry before wrapping and processing. Towel drying or draining dry is sufficient. Water on instruments at the time of exposure to EOGas may react with the gas and reduce its effectiveness.

3. Although EOGas is a highly diffusible gaseous sterilant, nevertheless occlusive caps, plugs or stylets must be removed from instruments so that the gas can penetrate freely. Hollow bore needles and plastic or rubber tubing must be open and free from plugs. Syringes must be packaged disassembled with their plungers out of the barrels.

If the nature of the material to be sterilized is such that the water treatments specified above are harmful, then pretreatment in a sterilization bag having a saturated humidity will be necessary for an overall pretreatment routine of 8 hours. Use the following procedure:

To humidify the contents of the sterilization bag, wrap the items individually in paper or cloth in the usual manner. Place them in a sterilization bag along with a Humidichip[®], a Dosimeter[®] and card and a cartridge of EOGas from which the trigger guard has been removed. Heat shall the sterilization bag and place it in the EOGas^a steffilizer WITHOUT pressing the cartridge trigger.

After 4 hours, remove the sterilization from the EO-Gas sterilizer and leave it at root temperature for another 4 hours. Then, without opening the sterilization bug, grasp the cartridge of EOGas through the wall of the sterilization bag and press the trigger blitton firmly.

Put the sterilization bag with the activated cartridge back in the sterilizer cabinet for a normal length 16 hour sterilization cycle.

You must wrap all items individually in cloth or paper ir, the manner conventional for steam sterilization or in Andersen Seal and PeelTM Packaging.

Andersen Seal and Peel Packaging offers a see-through, peel open, extended shelf life package, proven and controlled to be compatible with the EOGas Sterilizing System. No other plastic film packaging material may be used with EOGas unless the user first carefully tests the material to be sure that EOGas can penetrate it in adequate concentration. Polyamide (Nylon) and polyester (Mylar) films are known to be inappropriate to use with EOGas. In as much as Seal and Peel is waterproof, you must include an AN1071 Humidichip RH Stabilizer in each Seal and Peel package.

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Do not pack the sterilization bag so tightly with cloth or gauze that gas diffusion may be slowed.

Sterilization Method with EOGas Sterilizer Cabinet

Be certain that all items have been prepared as described above.

Initiate the purge cycle (refer to the Owner's Manual for the specific instructions for the EOGas sterilizer cabinet you are using). The air in the cabinet will be purged by a high capacity blower, removing the residual sterilant from the air in the cabinet. This takes five minutes.

While the cabinet is being purged, remove one Dosimeter and card from the dispenser box. Write the date and time sterilization will begin and the date and time sterilization and aeration will be complete on the label. Attach the Dosimeter to its card, take one sterilization bag from the EOGas dispenser box and place the wrapped items to be sterilized into the sterilization bag along with one AN1071

Humidichip and the Dosimeter indicator card. Place the Dosimeter card so that it can be easily seen through the top of the sterilization bag. Place the Humidichip in the bottom of the sterilization bag so that it will be nearest to the metal shelf.

Select one EOGas cartridge from the dispenser box. Be certain that the number printed on the EOGas cartridge corresponds with the number printed on the sterilization bag you have chosen. Remove the cartridge trigger guard. Reace the EOGas cartridge into the sterilization bag. Press the excepts air off of the sterilization bag and heat seal it.

Gracp the cartridge through the heat sealed sterilization bag and press the trigger button firmly. Press it all the way so that the trigger reaches the cartridge wall. This action releases the gas instantly from the cartridge into the sterilization bag.

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When the purge is complete (refer to Owner's Manual for the EOGas sterilizer model you are using for specific instructions) on the front of the EOGas sterilizer indicating that the cabinet has been purged and the sterilizer door is unlocked, place the sterilization bag on a shelf in the sterilizer. Close the door securely. It will lock automatically in about two minutes. For EOGas sterilizer models with label printers see the Owner's Manual.

Leave the sterilization bag undisturbed in the sterilizer cabinet for 16 hours after which the sterilization bag may be removed, opened and its sterile contents used.

After the sterile material has been removed from the ster-

ilization bag, wrap the empty cartridge and sterilization bag in paper and discard in the trash. DO NOT REUSE EMPTY BOX, EMPTY CONTAINER, OR STERILI-ZATION BAGS. /11

Important - Variations from these Instructions

The user must not deviate from these instructions. EOGas cartridges are designed to be used only in the sterilization bags provided in the EOGas refill dispenser.

You may not reuse any EOGas sterilization bag. Any deviation from the procedures recommended in these instructions is made solely at the users' risk.

Technical description of the system

The EOGas Sterilizer cabinet is thermostatically trolled to assure an internal temperature of 50°C. provided with a dual-volume exhaust system: lowvolume during the sterilization cycle for economy and high-volume for purging just before opening the door. The purge cycle will lower the cabinet temperature for a few minutes, but it will return to 50°C shortly after the door locks.

The sterilization bag is a gas diffusion membrane retaining EOGas long enough to sterilize its contents and then allowing the gas to diffuse into the cabinet atmosphere from which it is vented harmlessly to the outside atmosphere.

The AN1071 Humidichip will help maintain adequate relative humidity in the sterilization bag during the cycle.

The EOGas cartridge will deliver a dose of at least 500 milligrams per liter hours to the contents of the sterilization bag. Tests in our laboratory confirm that this dose will kill the most resistant spores known at 50°C with the 16 hour cycle providing that the spores have it rehydrated according to our instructions.

The Dosimeter will indicate the actual dose of ethylene oxide delivered by the EOGas cartridge. A blue color change reaching the triangle on the Dosimeter scale indicates that a dose of ethylene oxide, usually adequate for sterilization, has been delivered.

Storage and Disposal

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

Storage: Store in a cool place out of direct sunlight.

Shelf Life: Each cartridge is marked with an expiration date.

Pesticide Disposal: Unwanted or expired EOGas cartridges should be returned to the manufacturer for disposal. Contact Andersen Products, Inc. (tel. no. 336-376-3000) for instructions. If unwanted or expired EOGas cartridges cannot be disposed of according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance, are display.

Container Disposal: Do not reuse empty box, used cartridge, or used sterilization bags. Wrap box, cartridge, and sterilization bags in paper and discard in ordinary trash.

Environmental Hazards

not discharge effluent containing this product into lakes, streams, ponds, estuaries, occans, or other water unless in accordance with the requirements of a National Discharge Eliminations System (NDPES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effuent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

PHYSICAL OR CHEMICAL HAZARDS DANGER. FLAMMABLE LIQUID AND GAS UN-DER PRESSURE

Ethylene Oxide gas is extremely flammable. Do not use near flame, electrical sparks, or hot surfaces. Ground all equipment to prevent static sparks.

Testing the Efficacy of the EOGas Sterilizer

itoring sterilization efficacy is extremely important. The EOGas AN1087 Dosimeter, placed in the most inaccessible part of the load, will verify whether or not the gaseous sterilant penetrated to the core of the load in adequate concentration to assure sterilization. In addition, an appropriate biological control, such as the EOGas AN1080 Steritest[®], should be used at least once per month to challenge the procedure.

Aeration: It is incumbent on the user to confirm that a gas absorbent item, sterilized in EOGas, has been adequately aired before it contacts living tissue. This is a particularly important warning to those using plastic or rubber items that directly contact tissue culture preparations, ova, semen or embryos.

Humidification: Vacuum dehydration, chemical desiccation or prolonged exposure to ambient relative humidity below 35% have been demonstrated to produce spores highly resistant to sterilization by EOGas. Rehydration of spores so changed, and hence reversion to normal sensitivity, does not seem to occur until they have been actually wetted or placed in a 100% relative humidity atmosphere. Do not attempt to sterilized materials which may be carrying dried spores without first washing the articles with water and detergents. If the nature of the material is such that the water treatments specified above are harmful, then pretreatment in a chamber having a saturated humidity at .50°C will be necessary for an overall pretreatment routine of at least 8 hours.

PRECAUTIONARY STATEMENTS

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Hazard to Humans and Domestic Animals

DANGER:

Causes irreversible eye damage and skin burns. Harmful if inhaled. Do not breath yapor. Do not get on eyes, skin, or clothing. Do not swallow. Cancer Hazard and Reproductive Hazard. May cause nervous system damage. Store and use with adequate ventilation in accordance with 29 CFR1910.1047

Emergency Contact: 1-800-255-3924

The EOGas Cartridges contain liquid and gas under pressure. Do not use near fire, heated surface, or flame. Do not smoke near the sterilizer while loading and unloading it.

Sterilize batteries wrapped individually and separately from their electrical instruments.

Avoid breathing EOGas vapor. Breathing EOGas vapor is harmful. If you can smell EOGas you are breathing toxic amounts. In concentrated amounts EOGas sterilizing gas is as irritating to the lungs and mucous membranes as is animonia gas.

As with other chemical vapors, there is a chance of an occasional allergic response to EOGas in a sensitive individual. Such individuals should not handle EOGas, and should neither breathe its vapors nor allow materials sterilized in it to come in contact with their skin or mucous membranes.

All users must avoid contact with skin, eyes and clothing. If contact with liquid EOGas occurs, users must immediately remove all contaminated clothing, including shoes. Flush skin or eyes with plenty of water for at least fifteen minutes. If liquid EOGas has gotten into your eyes, immediately see a physician for further treatment.

Effects of Overexposure to Ethylene Oxide: May be fatal if inhaled in high concentrations. May cause irritation

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of respiratory tract, chest tightness, headache, nausea, vomiting, diarrhea, light-headed feeling, dizziness, weakness, drowsiness, cyanosis, loss of

coordination, convulsions, 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 mutagency changes, and cancer.

PEL:	IPPM-TWA Ethylene Oxide
STEL:	(OSHA - 29 CFR 1910.1047) 5PPM-excursion limit, 15 minutes
ODOR:	Ether-like in high concentrations. Exposure to toxic levels may occur without warning or

detection by the user

See label or instructions for additional precautionary statements and statements of practical treatment.

Aeration: Failure to adequately air ethylene oxide absorbing materials may lead to contact chemical burns. The 16 hour sterilization cycle time at 50°C called for in these instructions includes an adequate amount of time to air most tubes, masks and the like. Large gas absorbent items like silicone breast implants and plastic extracorporeal blood filters may require additional aeration before they can be safely implanted or used. Aeration will progress more rapidly outside of the sterilization bag. Andersen Products for our customers. Call customer service at 336-376-3000 for more information.

FIRST AID STATEMENTS

Operator Exposure: Chronic exposure to concentrations of ethylene oxide (the active ingredient in EOGas) above 1 ppm may be dangerous to your health. All operators of ethylene oxide gas sterilizers must be tested for ethylene oxide exposure at frequent intervals.

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

If in Eyes: Hold eyes open and rinse slowly and gently with water for 15 to 20 minutes. Remove contact lenses, if present, after the first 5 minutes then continue rinsing eye. Get medical treatment.

If Inhaled: Get exposed person to fresh air. Keep warm. If not breathing call 911 or an ambulance, then give artificial respiration. preferably by mouth-to-mouth, if possible. If breathing is difficult, give oxygen. Call a physician even if no symptoms are present. Keep under medical observation. Symptoms may be delayed.

If on Skin: Immediately wash skin with plenty of water while removing contaminated clothing and shoes. Call a physician. Aerate, wash, or clean contaminated clothing and discard leather goods.

If Swallowed: Drink at least two glasses of water. Do not induce vomiting. Do not give anything by mouth to an unconscious victim. Call a physician.

See label or instructions for additional precautionary statements and statements of practical treatment.

Note to Physician: Ethylene Oxide is a gas. Skin exposure from contact with fabric, rubber or plastic contact residual ethylene oxide will commonly result in skintation with extensive blister formation. At high concentrations severe conjuctivitis can occur. Irritation of the respiratory tract may occur but without acute edema. Symptoms of systemic intoxication are headache, nausea, vomiting, incoordination 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 Discharge Eliminations System (NDPES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effuent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Content of Cartridges:

AN6006 EOGas Cartridge

Active ingredient ethylene oxide	
Other ingredients	1.94%
Total	
Net contents each cartridge 0.37 avoir, o	z. (10.5 g)

EOGas Modular Sterilizer Systems:

AN306 Microprocessor Controlled Sterilizer, Table-Top Cabinet 6 cubic foot, 168 liter capacity AN310 Microprocessor Controlled Sterilizer, Free Standing Cabinet 10 cubic foot, 280 liter capacity AN333 Microprocessor Controlled Sterilizer, High Capacity Cabinet 33 cubic foot, 913 liter capacity

EOGas Refill Kits:

AN6006 #6 Cartridge Refill Dispenser Kit

- 25 AN6006 (Large) EOGas Cartridges
 - 25 Humidichip Relative Humidity Stabilizer

- Chips
- 25 EOGas Dosimeters
- 26 EOGas 22" x 36" (56 cm x 92 cm) #6 Sterilization Bags

AN1090 EOGas Sterilization Bag Impulse Sealer

EOGas Sterilization Accessories

- AN1071 Humidichip RH Stabilizer Chips (25)
- AN1080 Steritest Biological and Chemical Controls (11)
- AN810 Steritest Incubator

AN1085 EOGas Exposure Indicator Strips (200)

Packaging Products For Use With EOGas Sterilizers AN820 2"x200' (5cm x 60m) Seal & Peel Packaging Roll Stock

- AN830 3"x200' (8cm x 60m) Seal & Peel Packaging Roll Stock
- 50 5"x200' (12cm x 60m) Seal & Peel Packaging Roll Stock
- AN870 7"x200' (18cm x 60m) Seal & Peel Packaging Roll Stock

EOGas[®]. Dosimeter[®], Humidichip[®], Seal and Peel[®], and Steritest[®] are registered trademarks of Andersen Sterilizers, Inc.

EOGas is protected by U.S. Patent 4,937,046 and 5,160,700

Humidichip is protected by U.S. Patent 5,082,636

EPA REGISTRATION NO. 69340-X EPA ESTABLISHMENT NO. 69340-NC-001

Manufactured and Distributed by: **ANDERSEN STERILIZERS, INC.** Health Science Park • 3154, 3170 & 3181 Caroline Drive Haw River, North Carolina 27258-9789 USA

Distributor:

ANDERSEN PRODUCTS, INC. Health Science Park • 3202 Caroline Drive Haw River, NC 27258 USA 1-800-523-1276 www.anpro.com

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