

Mr. Jeurgen Ballo  
Andersen Sterilizers, Inc.  
3154 Caroline Drive  
Haw River, NC 27258

AUG - 1 2002

Subject: EOGas  
EPA Registration No. 69340-4  
Amendment Date: May 1, 2002  
EPA Receipt Date: May 6, 2002

Dear Mr. Ballo,

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with the conditions listed below.

- Update First Aid Statements
- Primary Brand Name Change to EOGas AN-2014

**Conditions**

Revise the label as follows:

The heading, "Precautionary Statements," followed by the subheading, "Hazard to Humans and Domestic Animals" must appear on the label above the "DANGER. Causes irreversible eye damage..... 29 CFR 1910.1047" statements.

Revise the package insert as follows:

1. On page 4, the statements, "The EOGas Cartridges contain liquid gas under pressure. Do not use near fire, heated surface, or flame. Do not smoke near the sterilizer while loading or unloading it. Sterilize batteries wrapped individually and separately from their electrical instruments," must appear under the "Physical or Chemical Hazards" section.
2. On page 4, The heading, "Precautionary Statements," followed by the subheading, "Hazard to Humans and Domestic Animals" must appear on the label above the "DANGER. Causes irreversible eye damage..... 29 CFR 1910.1047" statements.

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

**General Comments**

The proposed primary brand name, EOGas AN-2014, is acceptable.

A stamped copy of the labeling accepted with conditions is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

If you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,



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

# AN 2014

## ONE PACK

**CONTENTS: 50 Cartridges. Each AN2014 cartridge contains 0.49 av. oz. (14.0 g) EOGas sterilant.**

ANDERSEN  STERILIZERS, INC.

Manufactured and Distributed by:

**ANDERSEN STERILIZERS, INC.**

3154 Caroline Drive • Haw River, NC 27258 USA  
336-376-8622

Distributed by:

**ANDERSEN PRODUCTS, INC.**

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

European Distributor:

**H. W. ANDERSEN PRODUCTS, LTD.**  
Clacton-On-Sea • Essex CO15 4XA UK

EPA Registration No. 69340-4  
EPA Establishment No. 9417-NC-001



AN2014 Kit 042902

## 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 ..... 96.0%  
Inert ingredients: ..... 4.0%  
TOTAL ..... 100.0%

### 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 CFR 1910.1047**

See user's manual for additional precautionary statements.

**Emergency Contact: 1-800-255-3924**

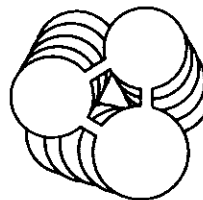
### FIRST AID STATEMENTS

In all cases of exposure, have the product container or label with you when you are going for treatment facility.

**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



# EOGas™

## INDUSTRIAL REFILL PACK

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 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 effluent 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 UNDER PRESSURE**

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

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. **To be used only in an EOGas sterilizer for hospital, medical, and veterinary sterilization.** 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 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.

**CONTAINER DISPOSAL:** Do not reuse empty box, used cartridge, or used liner bags. Wrap box, cartridge, and liner bags in paper and discard in the trash.

EOGas™ is a trademark of Andersen Products, Inc.  
EOGas U.S. Pat. no. 4,937,046 and 5,160,700

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4/29/02, 2:15 PM

ACCEPTED  
with COMMENTS  
11/21/02, 10:00 AM

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EOGas is a trademark of Andersen Products, Inc.  
registered under EPA Reg. No. 69340-4

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**Industrial EOGas™ Cartridges**  
**AN2005, AN2011, AN2014, AN2018**  
**Directions for Use**

ACCEPTED  
WITH COMMENTS  
in EPA Letter Dated:  
AUG - 1 2002

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Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
labeled on the pesticide  
registered under EPA Reg. No. 69340-11

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.

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

**CAUTION:**

**Do not remove the trigger guard until just before you place the cartridge in the sterilization bag.**  
**NEVER press the trigger outside of the sterilization bag.**

**1. Preparation of material for sterilization in EOGas.**

Items to be sterilized by EOGas Industrial Cartridges must have been stored at a relative humidity of more than 35% at a temperature of at least 20°C (68°F) for at least 24 hours immediately prior to sterilization. Storage must be in packaging materials that will permit water vapor to penetrate to the core of the load. All layers of packaging must be permeable to Ethylene oxide gas.

Although EOGas is a highly diffusible gaseous sterilant, occlusive caps, plugs or stylets must be removed from instruments or positioned so that the gas can penetrate the instrument freely. Glass or plastic syringes must be packaged disassembled with their plungers out of the barrels.

**2. Selection of packaging material**

All items to be sterilized by EOGas must be sealed in individual packages known to be permeable to Ethylene oxide. Paper and a combination of paper and plastic are ideal individual wrapping materials. Low density polyethylene film is very permeable to EOGas. Polyamide (Nylon) and polyester (Mylar) films are known to be relatively impermeable to Ethylene oxide gas and should not be used with EOGas.

Andersen Sterilizers, Inc. and Andersen Scientific, Inc. provide consultation and validation services to industrial customers regarding the appropriateness of packaging films for use with the EOGas system. See the final page of this brochure for telephone numbers and addresses for these companies.

**3. Selection of sterilization bags**

EOGas sterilization bags are not provided in the EOGas industrial cartridge refill packs. They may be obtained separately from Andersen Sterilizers, Inc. or one of its authorized distributors. Bag size and packaging materials are chosen during validation or the sterilization cycle.

The material selected for the outer bag must be permeable to Ethylene oxide, otherwise the post-sterilization aeration time will be inordinately long. It must also retain the Ethylene oxide gas long enough to assure an adequate dose of Ethylene oxide is delivered to the core of the load. The sterilization bag must have a relatively low permeability to water vapor so that the relative humidity in the bag is maintained above 35% during sterilization.

We recommend the use of a Humiditube™ and one or more Humidichip® relative humidity stabilizers in each sterilization bag as a proven method of assuring adequate levels of relative humidity during the sterilization cycle. Humidichips may be obtained from us directly or through any of our authorized distributors.

The film chosen for the sterilization bag must be pinhole free, which means that it must be extruded of virgin materials free from gels or coextruded in at least two layers.

The film chosen must have sufficient resistance to damage by abrasion that it will not develop holes when it is manipulated or when it is placed into the sterilizer cabinet.

**4. Selection of the EOGas cartridge size**

Cartridge size will be selected as part of the sterilization process design and validation. Once determined, only that size cartridge may be used in the sterilization process.

**5. Sterilization method**

Initiate the warmup or the purge cycle on your EOGas Sterilizer cabinet (For detailed instructions, see the instruction manual accompanying your EOGas cabinet).

Open one sterilization bag and load the packaged items for sterilization. Position one AN1071 Dosimeter® so that it may be easily seen through the wall of the bag. Add a Humiditube containing at least one Humidichip to the bag, and one or more biological indicators. The AN1080 Steritest® is a biological indicator that has been specifically designed for use with the EOGas system.

Finally, remove the trigger guard from the EOGas cartridge and place the cartridge into the sterilization bag, orienting the cartridge to make activation easy.

***Do not press the trigger yet.***

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 sterilizer 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.

Grasp the cartridge through the heat or vacuum sealed sterilizer 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 sterilizer bag.

Leave the sterilizer bag undisturbed in the sterilizer cabinet for 16 hours after which the sterilizer bag may be removed, opened and its sterile contents used. To minimize operator exposure to residual ethylene oxide, this must be done in a well ventilated room (10 air changes per hour) or in a fume hood. The EOGas cabinet also allows a repeat purge cycle (see the Owner's Manual provided with the sterilizer cabinet).

Do not distribute the product until you are sure the biological indicator is negative and any post-sterilization aeration is complete.

After the sterile material has been removed from the sterilizer bag, wrap the empty cartridge and bag in paper and discard in the trash. **DO NOT REUSE EMPTY BOX, EMPTY CONTAINER, OR LINER BAGS.**

**6. Technical description of the system**

The EOGas Sterilizer cabinet is thermostatically controlled to assure an internal temperature of 50°C. It is provided with a dual-volume exhaust system: low-volume 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.

ACCEPTED  
with COMMENTS  
in EPA Letter  
AUG 1 2002

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act,  
amended, for the pesticide,  
registered under EPA Reg. No. 69340-4

**7. Accessories for sterilization**

**AN1071 Humidichip®**

The Humidichip is designed to maintain the relative humidity in the sterilization bag during the sterilization cycle.

**AN1087 Dosimeter®**

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 attained.

**AN5024 Andersen Vacuum Sealer**

Vacuum sealing the sterilization bag reduces the air space in the bag. This increases the concentration of Ethylene oxide early in the cycle, speeds penetration of the gas into the load and also speeds the diffusion of Ethylene oxide out of the sterilization bag. At the end of the cycle, after the Ethylene oxide has diffused out of the bag, the vacuum tight appearance of the bag provides immediate visual assurance that there are no pinholes in the bag material.

**8. 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.

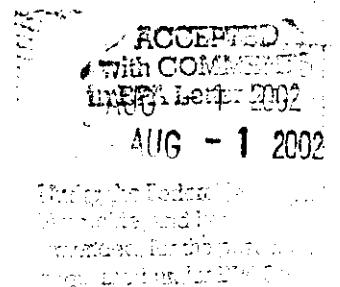
**Pesticide Disposal:** Unwanted or expired EOGas cartridges should be returned to the manufacturer for disposal. Contact Andersen Products, Inc. (tel. no. 336-376-3000) for instructions. If unwanted or expired EOGas cartridges cannot be disposed of according to label instructions, contact your State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

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

**9. Testing the Efficacy of the EOGas Sterilizer**

Monitoring sterilization parameters is the major focus of the validation that must be completed before distributing products sterilized in EOGas. Parameters for validation of an EOGas sterilization process include:

- Preconditioning
- Sterilization cycle temperature
- Sterilization cycle humidity
- Sterilization cycle Ethylene oxide dose
- Sterilization time
- Aeration time
- Ethylene oxide residuals
- Use of biological indicators
- Personnel and area monitoring



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Do not distribute or use products sterilized by EOGas without having completed this process under expert guidance.

Andersen Scientific, Inc. has the expertise to validate a sterilization cycle to United States and International standards.

**10. 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 effluent 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 UNDER PRESSURE**

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

**11. 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 CF 910.1047**

See user's manual for additional precautionary statements.

**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 ammonia 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 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 mutageny changes, and cancer.

**PEL:** 1PPM-TWA Ethylene Oxide (OSHA - 29 CFR1910.1047)

**STEL:** 5PPM-excursion limit, 15 minutes

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

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**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 sterilizer bag. Andersen Products and its authorized distributors are prepared to determine aeration times for unusual products for our customers. Call customer service at 336-376-3000 for more information.

**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.

**12. First Aid Statement**

**In all cases of exposure, have the product container or label with you when you are going for treatment facility.**

**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.

Keep under medical observation. Symptoms may be delayed. If breathing has stopped, give artificial respiration, preferably mouth-to-mouth. Do not give anything by mouth to an unconscious person.

**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 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 edema. Symptoms of systemic intoxication are headache, nausea, vomiting, incoordination and cardiac *arrhythmia*. Treatment is symptomatic and supportive.

**Contents of Cartridges:**

**AN2005 EOGas Cartridge**

Active ingredient Ethylene oxide	90.0%
Inert Ingredients	10.0%
Total	100%

Net contents 0.18 avoird. oz. (5.0 g)  
EPA Registration Number 69340-5

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**AN2011 EOGas Cartridge**

Active ingredient Ethylene oxide	96.0%
Inert Ingredients	4.0%
Total	100%

Net contents 0.38 avoird. oz. (11.0 g)  
EPA Registration Number 69340-6

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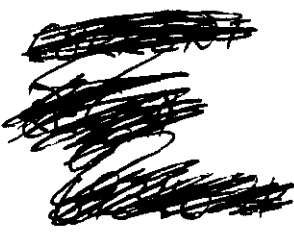
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**AN2014 EOGas Cartridge**

Active ingredient Ethylene oxide 96.0%  
Inert Ingredients 4.0%  
Total 100%

Net contents 0.49 avoir. oz. (14.0 g)

EPA Registration Number 69340-?



**AN2018 EOGas Cartridge**

Active ingredient Ethylene oxide 97.0%  
Inert Ingredients 3.0%  
Total 100%

Net contents 0.64 avoir. oz. (18.15 g)

EPA Registration Number 69340-2

The inert ingredients are non-volatile. They stay within the empty ampoule and cartridge and are not emitted into the sterilization bag.

**EOGas Commercial Refill Packs**

**AN2005 EOGas Cartridge**

50 each EOGas 5.0g Cartridges (Total 250g)

**AN2011 EOGas Cartridge**

50 each EOGas 11.0g Cartridges (Total 550g)

**AN2014 EOGas Cartridge**

50 each EOGas 14.0g Cartridges (Total 700g)

**AN2018 EOGas Cartridge**

50 each EOGas 18.15g Cartridges (Total 907.5g)

EOGas™ is a trademark and Dosimeter®, Humidichip®, and Steritest® are registered trademarks of Andersen Products, Inc., Haw River, NC 27258-9789

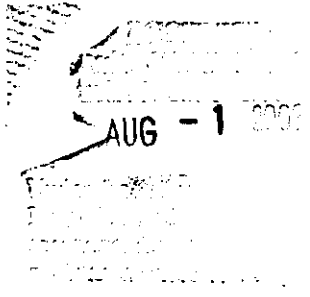
Humiditube™ is a trademark of Andersen Sterilizers, Inc., Haw River, NC 27258-9789

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. 69340-2/5/6/?

EPA ESTABLISHMENT NO. 9417-NC-001



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Manufactured by:  
**Andersen Sterilizers, Inc.**  
3154 Caroline Drive  
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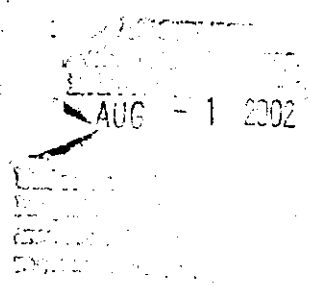
Validation services and contract sterilization available from:  
**Andersen Scientific, Inc.**  
3220 Caroline Drive  
Law River, NC 27258-9789 U. S. A.  
TEL 1-888-933-6427  
FAX 1-336-376-8153

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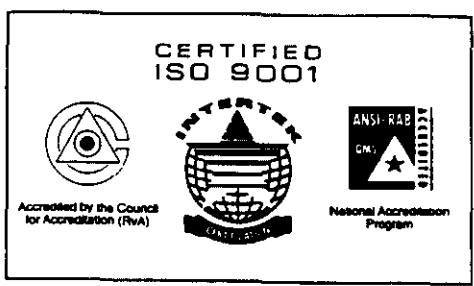
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Westly Square, 40 Hoi Yuen Road  
Kwun Tong, Hong Kong  
Tel: 2851-1655



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