

069340-00002-040999

Printed: 13:05:35 Friday, 07 May, 1999 # 74 / 2788

Systems Integration Group, Inc.

APR 0 S 1999

Andersen Sterilizers, Inc 3154 Caroline Dr. Haw River, NC 27258

Subject:

Anprolene AN-79

EPA Registration No. 69340-2 Your Amendment Dated: 1/07/99

Attention:

Mr. Juergen Ballo,

OA Manager

The amendment referenced above submitted in connection with registration under FIFRA, as amended, to update the product label is acceptable provided the following recommendations are addressed before you release the product for shipment.

Label Recommendations:

- a) The label format should be revised by arranging the precautionary labeling in the following order: "Precautionary Statements, Practical Statements of Treatment, Note to Physician, Environmental Hazards, and Physical/Chemical Hazards Physical/Chemical Hazards". The "Directions for Use" and "Storage and Disposal" arrangement is correct.
- You should add the text, "IMPORTANT: For Professional Use Only," above the b) statement, "Users must followoxide (29 CFR 1910.1047).
- c) All section headings should be in the same font.
- According to the Label Review Manual (2nd Edition) and Agency letter dated 10/15/98, d) the statement, "Keep out of Reach of Children," should precede the signal word.

e) The statement, "I	On not contaminate ONCHERER	958. or feed by stor	age or disposal.	'should
SYMBOL 7570C	,		1	
SURNAME (a) ohll				
DATE \$ 4/9/99			***************************************	
EPA Form 1320-1A (1/90)		·		

immediately follow the "Storage and Disposal" heading.

- f) The statement, "See user's manual for additional precautionary statements," should follow the "Precautionary Statements" section.
- g) "Environmental Hazards" statements must be added to these labels according to PR Notice 95-1. (See Ethylene Oxide Label Template for guidance).

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.

h) The "Physical/Chemical Hazards" section should be placed after the "Environmental Hazards" section.

Manual Recommendations:

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On page 3, the statement, "Do not contaminate water, food, or feed by storage or disposal," should immediately follow the "Storage and Disposal" heading.

A stamped copy of the label and manual is enclosed for your records. Submit one (1) final printed label prior to the release of the product for shipment. If you have any questions regarding this letter, please contact Jacqueline Campbell at (703) 308-6416.

Sincerely,

Velma Noble

Product Manager (31)

Regulatory Management Branch I Antimicrobials Division (7510C)







ONE BOX

CONTENTS: 20 AMPOULES, 20 LINER BAGS, 20 CLOSURES

STERILIZING GAS AMPOULES

Active ingredient: Ethylene oxide	97.0%
Inert ingredients:	
Total:	100.0%
Net contents 20 ampoules, 0.64 av. oz. (18.15 g) each	ampoule

Manufactured by: Andersen Sterilizers, Inc.

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

Europen Distributor: H. WAndersen Products, Ltd. Davy Road · Clacton-on-Sea Éssex C015 4XA UK



PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS.

DANGER! CANCER HAZARD AND REPRODUC-TIVE HAZARD, MAY CAUSE IRREVERSIBLE EYE DAMAGE AND SKIN BURNS. HARMFUL IF INHALED, MAY CAUSE NERVOUS SYSTEM DAMAGE, DO NOT GET IN EYES, SKIN, OR ON CLOTHING, STORE AND USE WITH ADEQUATE VENTILATION.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. To be used only in Anprolene sterilizers only for hospital, medical, and veterinary sterifization. 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.

EPA REGISTRATION NO. 69340-2 EPA ESTABLISHMENT NO. 9417-NC-001

STORAGE AND DISPOSAL

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

PESTICIDE DISPOSAL: Unwanted or expired ampoules should be returned to the manufacturer for disposal Contact Andersen Products, Inc. (tel. no. 336-376-3000) for instructions. If unwanted or expired ampoules 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, empty ampoules, or liner bags. Wrap box, ampoules, and bags in paper and discard in the trash.

FOR USE IN ANPROLENE STERILIZERS. **AN74 SERIES ONLY**

DANGER KEEP OUT OF REACH OF CHILDREN

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

PHYSICAL OR CHEMICAL HAZARDS

Ethylene oxide gas is EXTREMELY FLAMMABLE LIQUID AND GAS UNDER PRESSURE. Do not use near flame. electrical sparks, or hot surfaces. Ground all equipment to prevent static sparks.

STATEMENT OF PRACTICAL TREATMENT

IN ALL CASES OF EXPOSURE, GET MEDICAL ATTEN-TION IMMEDIATELY, TAKE PERSON TO A DOCTOR OR EMERGENCY TREATMENT FACILITY AT ONCE.

IF INHALED: Get exposed person to fresh air. Keep warm. Make sure person can breathe freely. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician even if no symptoms are present. Keep under medical observation. Symptoms may be delayed.

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for at least 15 minutes. Get medical attention immediately.

IF ON SKIN: Wash skin with plenty of water while removing contaminated clothing and shoes. Get medical attention immediately. Aerate, wash, or clean contaminated clothing and discard leather goods.

tF SWALLOWED: Drink at least 2 glasses of water. Do not induce vomiting. Do not give anything by mouth to an unconscious victim. Get medical atten-

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 burns with extensive blister formation. At high concentrations severe conjunctivitis can occur. Respiratory tract irritation may occur, but without acute lung edema. Symptoms of systemic intoxication are headache, nausea, vomiting, incoordination, and cardiac irregularities. Treatment is symptomatic.

See side panels and user's manual for additional precautionary statements.

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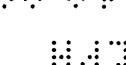
1/06/99, 11:35 AM

ACCEPTED with COMMENTS in EPA Letter Dated:

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

69340.2

P/N 735 010699









Brand Gaseous Sterilant for Room Temperature, Atmospheric Pressure Sterilization Use in Ventilated Anprolene Sterilizers Only

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.

DO NOT OPEN THE PLASTIC BAG IN WHICH EACH INDIVIDUAL ANPROLENE AMPOULE IS SEALED

Each ampoule of Anprolene is surrounded by a plastic break shield. The ampoule and shield are sealed in a plastic bag. The plastic bag is a gas diffusion membrane of known permeability whose function is to contain

3 gas given off by the ampoule and to release it at a controlled rate ring the sterilization cycle. The plastic shield around the ampoule prevents the broken glass of the opened ampoule from puncturing the gas-release bag.

TYPICAL PRODUCTS WHICH MAY BE CONVENIENTLY PROCESSED IN ANPROLENE STERILIZERS

Respirators, corrugated tubing

Bronchoscopes, gastroscopes, fiberscopes of all kinds

Procedure travs

Catheters - 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

Electrical equipment - whether autoclavable or not

Painted 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

Thermometers, applicator sticks

Rectal tubes, douche tubes - rubber plastinder the Federal Insecticide,

ACCEPTED

with COMMENTS

in EPA Letter Dated:

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Materials to be sterilized by Approlene must first be meticulously cleaned and towel-dried. Coating of dry protein, such as dry pus, blood, or feces, protect microorganisms and slow the sterilization process. To prevent this possibility, and to be certain that your system meets the highest standard of sterilization, you must:

1. Disassemble and scrub all instruments in detergent and water to the most critical standard of cleanliness possible.

If an item cannot be washed in detergent and water, then presterilization humidification is required. This pretreatment must be done in a chamber having 100% relative humidity at a temperature of at least 68°F (20°C) for at least four hours. Such a chamber may be made by placing an AN1071 Humidichip® in a liner bag with the item and closing the bag with a twist-tie.

- 2. Water on instruments at the time of exposure to Anprolene may react with the gas and reduce its effectiveness. Be sure that items to be sterilized are dry before wrapping and processing. Drain or towel-dry instruments. Do not dry them in a hot-air oven.
- 3. 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 at both ends and free from plugs. Syringes must be packaged disassembled, with the plunger removed from the barrel.
- 4. You must wrap all items individually, in cloth or paper, in a manner conventional for steam sterilization, or in Anpro® Seal and Peel® Packaging. Anpro Seal and Peel is a transparent, peel-open, extended shelf-life packaging, proven to be compatible with the Anprolene Sterilizing System. Do not pack the liner bag so tightly with cloth or gauze that gas diffusion is slowed.

STERILIZATION METHOD USING AN74A, AN74C/D/E AND AN74V

Be certain that all items have been prepared as described above. The ambient relative humidity must be at least 30% for Approlene processing. The user must verify that this minimum exists before processing begins. Remove one liner bag from the AN79 dispenser box. Prepare the bag to receive the wrapped items to be sterilized by opening it and placing it into the sterilizer container, open end out. Put the wrapped items to be sterilized into the liner bag.

Remove one Anprolene ampoule from the AN79 dispenser box. Do not open the plastic bag in which it is wrapped. Rather, unroll the plastic bag, Push the ampoule gently to the center of the gas-release bag. Place the ampoule, still sealed in its plastic bag, inside the liner bag along with the material to be sterilized. Press out any excess air before closing the mouth of the liner bag. Locate the flexible, plastic purge tube that protrudes into the interior of the sterilizer. Place the purge tube into the mouth of the liner bag, Using one of the closures provided in the Anprolene kit, tie the liner bag around the purge tube. Grasp the ampoule through the bag and protective shield and snap the top of the ampoule. Each ampoule is prescored around its neck. to facilitate this action. Snapping off the top of the ampoule activates it, i.e. releases the sterilant gas within the gas-release bag. Close and lock the sterilizer. The AN74 key must be removed from the sterilizer and remain in the possession of a supervisor to prevent unauthorized removal of goods during the sterilization cycle.

AN74C/D/E: Close sterilizer and lock the door. The AN74 key must be removed from the sterilizer and remain in the possession of a supervisor to prevent unauthorized removal of goods during the sterilization cycle. The sterilizer must be located in a clean, well-ventilated area, away from sparks Fungicide, and Rodenficide Actorilame. The temperature of the room must be maintained at no less that

PREPARATION OF MATERIALS FOR STERRIZATION

Pangicide, and rode in 168° F (20° S).

An interior of the fourteen-hour cycle, unlock the sterilizer. Remove the seal from the liner bag and open it. Leave the opened liner bag and the wrapped items in the sterilizer for an additional fifteen minutes before removing them.

> AN74A or AN74V: Turn the ventilation on if you are using an AN74V sterilizer, make sure that the purge pump is turned off. If you are using an AN74A sterilizer, press the CYCLE START button.

> At the end of the twelve-hour sterilization cycle, the AN74A will automatically begin a two-hour purge cycle and a green light will signal when you may

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open the sterilizer remove the load. If you are using an AN74V, turn the purge pump on and purge the liner bag for two hours before opening the sterilizer and removing the sterile items.

CAUTION: FAILURE TO OBSERVE THE ABOVE INSTRUCTIONS MAY EXPOSE THE STERILIZER OPERATOR TO MORE THAN 0.5 PPM ETHYLENE OXIDE

(The OSHA Established Action Level Measured as an Eight-Hour Time Weighted Average).

Aerate the gas-absorbent items for at leaACCEPITED fore use (see: Precautionary Statements). with COMMENTS

After the sterile materials have been removed from the liner bag, the exhausted and empty gas-release ampound and its bag may be disposed of in ordinary rubbish.

SPECIAL PROCESSES

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide,

When sterilizing long lengths of predictor-tubble tubble tubbles. We ureteral catheters, heart catheters, and coils of drainage tubing, use two ampoules and double the cycle time.

If you are using an AN74 series sterilizer, increase the cycle time to 24 hours. If you are using an AN74V sterilizer, increase the cycle time to 24 hours, and purge the liner bag for two hours. With an AN74C/D/E, load the sterilizer with the items for sterilization and the two activated gas-release bags, but then wait twelve hours before pushing the START button. Before loading the sterilizer, be sure that the ventilator is running. The ventilator must continue to run during the entire augmented cycle.

TECHNICAL DESCRIPTION OF THE SYSTEM

The Anprolene Sterilizer container serves as a guard against inadvertent ignition of the contents by spark or open flame during the sterilization cycle. In the case of the ANT4C, ANT4D, ANT4E sterilizers, the container also serves as a ventilation hood.

The liner bag, when properly closed with a tie, has a 35 liter capacity. It is a second gas-diffusion membrane that serves to retain Anprolene long enough to sterilize its contents and releases it into the surrounding vent hood at a slow enough rate to insure that toxic levels are not reached in a properly ventilated room. Each ampoule releases approximately 17.6 grams of Anprolene at room temperature (68°F/20°C) and sea-level atmospheric pressure.

The AN79 ampoule produces a minimum peak concentration within the liner bag of 500 mg/1000 cc. Tests in our laboratory confirm that this dose will kill the most resistant spores known within the twelve-hour cycle, providing they have been rehydrated according to our instructions (see: **Preparation of Materials for Sterilization**).

STORAGE AND DISPOSAL

STORAGE: An prolene must be stored in a cool place out of direct sunlight. Under normal conditions its shelf life will exceed one year. As long as the content of the ampoule is liquid at 68°F (20°C), it is sufficiently potent to use.

PESTICIDE DISPOSAL: Unwanted or expired ampoules should be returned to the manufacturer for disposal. Contact Andersen Products, Inc. (tel. no. 336-376-3000) for instructions. If unwanted or expired ampoules 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 ampoules, or liner bags. Wrap box, ampoules, and liner bags in paper and discard in the trash.

TESTING THE EFFICACY OF THE ANPROLENE STERILIZER

Monitoring sterilization efficacy is extremely important. It is strongly recommended that the user establish a routine for monitoring each cycle. A color-change chemical indicator, such as the Anpro AN87 Dosimeter[©], placed in the most inaccessible part of the load, will indicate 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 Anpro AN80 Steritest[©], should be used at least once per month to challenge the procedure. The AN80 Steritest is sensitive to the gas concentration, cycle time, and average cycle temperature.

AERATION: It is incumbent on the user to confirm that a gas-absorbent item, sterilized in Anprolene, 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.

Nylon and polyester films are virtually impervious to ethylene oxide. The only all plastic, water proof wrapping material proven compatible with Anprolene is our Seal and Peel brand roll stock. Do not use any other plastic film to wrap items to be sterilized in Anprolene.

Vacuum dehydration, chemical desiccation or prolonged exposure to ambient relative humidity below 30% have been demonstrated to produce spores highly resistant to sterilization by Anprolene. 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 sterilize 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.

IMPORTANT - THE USER MUST NOT DEVIATE FROM THESE INSTRUCTIONS

Do not be fooled by the apparent simplicity of the Anprolene Sterilizing System. Its reliable use depends upon precise adherence to these instructions. AN71 an AN73 Anprolene ampoules are designed to be used only in the AN70, AN72, AN72C, AN72D, and AN72V Anprolene Sterilizers with the liner bags and twist seals supplied in the refill dispenser. No other container may be used, no matter how similar it seems. Liner bags must not be reused; use only a genuine, fresh Anprolene liner bag with each load.

PRECAUTIONARY STATEMENTS DANGER: EXTREMELY FLAMMABLE. KEEP OUT OF REACH OF CHILDREN. DO NOT BREATH.

Anprolene gas is extremely flammable. Do not use it near fire, heated surfaces, or flame. Do not smoke near the container while loading and unloading it. When sterilizing battery-operated instruments, remove the batteries and wrap them separately to avoid the possibility of an electrical spark igniting the gas during the sterilization cycle.

Never open the sterilizer during the sterilization cycle. Avoid breathing Approlene vapor.

Exposure to liquid or gas can cause severe eye damage. Intimate skin contact with fabric, rubber, or plastics containing residual Ethylene oxide can cause damage to the skin, or on clothing. Wear goggles or faceshield

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when handling. May be fatal if swallowed. Do not breathe vapor. Extremely hazardous liquid and gas under pressure. Inhalation may be fatal. Ethylene oxide gas can be odorless at toxic levels; therefore, exposure to toxic levels may occur without warning or capability of detection by user.

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 mutagenic changes, and cancer.

PEL: 1PPM-TWA Ethylene Oxide (OSHA - 29 CFR 1910.1047)

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.

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

FRATION: Failure to adequately air gas-absorbing materials may lead to htact chemical burns. All items that may contact living tissues must be aired for at least 24 hours, at a minimum temperature of 68°F (20°C), prior to use. Items such as plastic instruments, foam rubber, plastic foams, vinyl tubing, rubber tubing, plastic items, rubber items, and sealed air-cushioned devices (for instance, anesthesia masks), must be aired. Instruments need not be removed from cloth or paper wrappings to obtain adequate diffusion of the residual Anprolene vapors.

OPERATOR EXPOSURE: It is absolutely essential that reliable forced ventilation be employed in the room where the Anprolene Sterilizer is used. This system must be capable of ten air changes per hour, so that operator exposure remains within U.S. government permissible exposure limits.

STATEMENT OF PRACTICAL TREATMENT

In cases of exposure, get medical attention immediately. Take person to a doctor or emergency treatment facility.

FINEYES: Hold eyelids open and flush with a steady gentle stream of water at least 15 minutes.

IF INHALED: Get exposed person to fresh air. Keep warm Make sure person can breath freely. If breathing is difficult, give oxygen. Call a physician even if no symptoms are present. Keep under medical observation. Symptoms may be delayed. If breathing has stopped give artificial respiration. 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 lung edema. Symptoms of systemic intoxication are headache, nausea, vomiting, incoordination and cardiac irregularities. Treatment is symptomatic.

Ampoule Fill Weights

Active ingredient: Ethylene oxide	97.0%
Inert Ingredients:	
Total:	
Net contents each ampoule	0.64 av. oz (18.15 g)

Anprolene Modular Sterilizing System

AN71 Anprolene 25 Ampoule Refill Dispenser: use with

AN72C & D Anprolene Sterilizers.

AN73 Anprolene 60-Ampoule Refill Dispenser: use with

AN72C & D Anprolene Sterilizers.

AN72C & D Ventilated and Purged Anprolene Tray Sterilizer

with automatic cycle controls.

AN79 Anprolene 20-Ampoule Refill Dispenser: use with

AN74C/D/E Anprolene Sterilizers.

AN74C/D/E Ventilated and Purged, High-Capacity Anprolene

Sterilizer with automatic cycle controls.

Anprolene Sterilizing Accessories

AN80	Steritest biological and chemical controls.
AN85	Anprolene Exposure Indicator Strips.
AN87	Anprolene Dosimeter.
AN90	Seal and Peel Electric Impulse Sealer.
AN820	2" x 200' (5 cm x 60 m) Seal and Peel Roll Stock.
AN830	3" x 200' (8 cm x 60 m) Seal and Peel-Rell Stock.
AN850	5" x 200' (13 cm x 60 m) Seal and Peel Roll Stock.
AN870	7" x 200' (18 cm x 60 m) Seal and Peel Roll Stock.
AN1071	Humidichip (2" x 2" / 5 cm x 5 cm) humidity
	stabilizing chips

Anpro®, Anprolene®, Dosimeter®, Humidichip®, Seal and Peel® and Stefficst® are trademarks of Andersen Products, Inc.

Humidichip U.S. patent No. 5,082,636

ACCEPTED with COMMENTS in EPA Letter Dated:

APR 9 1999

Under the Federal Insecticide,
Pangicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.
(09340-2)



Manufactured by Andersen Sterilizers, Inc. Health Science Park 3154 Caroline Drive Haw River, NC 27258-8710 U.S.A.

Distributed by Andersen Products, Inc. Health Science Park 3202 Caroline Drive Haw River, NC 27258-8710 U.S.A.

European Distributor: H. W. Andersen Products Ltd. Davy Road • Gorse Lane Industrial Estates Clacton-on-Sea • Essex C015 4XA U.K.

EPA Registration No.69340-2 EPA Establishment No. 9417-NC-001

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in Figure Dated:

APR 9 1999

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

69340-2