

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAY 10 2000

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

Subject: Anprolene AN-79
EPA Registration No. 69340-2

EOGas AN-1004/5/6
EPA Registration No. 69340-4

Amendment Date: 2/3/00
EPA Receive Date: 2/10/00

Attention: Mr. Juergen Ballo

The amendments, referenced above, submitted in connection with registration under FIFRA, as amended, to add new packaging configurations for EOGas Commercial Refill Packs are acceptable provided you address the following recommendations before you release this product for shipment.

Label Recommendations:

- a) Under the "Precautionary Statements," you will need to add the statements, "Do not breathe vapor. Do not swallow," after the "Harmful if inhaled" statement.
- b) The EPA Registration Number for this product must be on the label.

Manual Recommendation

The heading, "Instructions for Use," must be revised to state "Directions for Use."

Stamped labels are enclosed for your records. You must submit a final printed copy of the label and manual prior to the release of the products for shipment. If you have any questions regarding this letter, please contact Jacqueline Campbell at (703) 308-6416.

CONCURRENCES								
SYMBOL	7570C							
SURNAME	Campbell							
DATE	5/10/00							

Sincerely,

A handwritten signature in black ink, appearing to read "Velma Noble". The signature is written in a cursive style with a large initial "V".

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

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAY 10 2000

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 69340-2



ONE PACK

CONTENTS: 50 Cartridges. Each AN2018 cartridge contains 0.64 av. oz. (18.15 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. XXXXX-X
EPA Establishment No. 9417-NC-001



AN2018 Kit 012800

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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 97.0%
Inert ingredients: 3.0%
TOTAL 100.0%

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS.
DANGER! CANCER HAZARD AND REPRODUCTIVE HAZARD.
CAUSES 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.

See user's manual for additional precautionary statements.

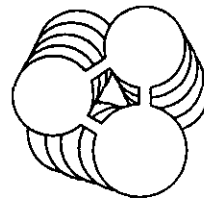
STATEMENT OF PRACTICAL TREATMENT

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

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

IF INHALED: Get exposed person to fresh air. Keep warm. Make sure person can breathe 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.



EOGas™

INDUSTRIAL REFILL PACK

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

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.

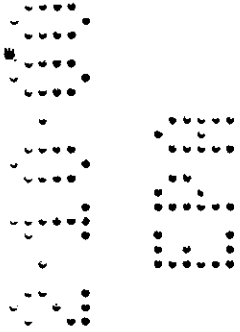
CONTAINER DISPOSAL: Do not reuse empty box, used cartridge, or used liner bags. Wrap box, cartridge, and liner bags in paper and discard in the trash.

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

P/N XXXX 012800

2/3/00, 11:29 AM

3/11



ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAY 10 2000

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. *69340-2*

REMOVE TAPE AND TRIGGER GUARD, PRESS BUTTON TO ACTIVATE CARTRIDGE

**AN
2018**



Use only in an Andersen EOGas Sterilizer and according to
manufacturer's instructions. See outer box and package insert for
precautions and sterilization instructions.

Active Ingredient: Ethylene Oxide	97%
Other Ingredient	3%
Total	100%

Net Contents: 0.64 av. oz. (18.15 g)

LOT NO.

USE
BEFORE

DANGER
KEEP OUT OF REACH OF CHILDREN
CONTENTS FLAMMABLE
DO NOT OPEN THIS PACKAGE
DISPOSE OF SPENT EOGas CARTRIDGE IN TRASH



Manufactured by: Andersen Sterilizers, Inc. • Health Science Park • Haw River, NC 27258 U.S.A.
Distributed by: Andersen Products, Inc. • Health Science Park • Haw River, NC 27258 U.S.A.
Distributed in Europe par: H. W. Andersen Products Ltd. • Clacton-On-Sea • Essex CO15 4XA U.K.
EPA Registration No. XXXX-X • EPA Est. No. 9417-NC-001 • U.S. Patent No. 4,937,046 & 5,160,700

PN XXXX 012800

REMOVE TAPE AND TRIGGER GUARD, PRESS BUTTON TO ACTIVATE CARTRIDGE

Industrial EOGas™ Cartridges
AN2003, AN2005, AN2011, AN2014, AN2018

MAY 10 2000

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

64340-2

██████████ for Use

DIRECTIONS

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 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 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.

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69340-2

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

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

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Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
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69340-2

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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.

11. Precautionary Statements

**DANGER: EXTREMELY FLAMMABLE
KEEP OUT OF REACH OF CHILDREN
DO NOT BREATHE EOGAS**

ACCEPTED
MAY 10 2000
69340-2

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 five 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 mutagenicity 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 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. Statements of Practical Treatment

If all cases of exposure, get medical attention immediately, take person to a doctor or emergency treatment facility.

If in Eyes: Hold eyelids open and flush with a steady gentle stream of water for at least 15 minutes.

If Inhaled: Get exposed person to fresh air. Keep warm. Make sure person can breathe 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, 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:

AN2003 EOGas Cartridge

Active ingredient Ethylene oxide	89.0%
Inert ingredients	11.0%
Total	100%
Net contents 0.09 avoird. oz. (3.0 g)	

AN2005 EOGas Cartridge

Active ingredient Ethylene oxide	90.0%
Inert Ingredients	10.0%
Total	100%
Net contents 0.18 avoird. oz. (5.0 g)	

AN2011 EOGas Cartridge

Active ingredient Ethylene oxide	96.0%
Inert Ingredients	4.0%
Total	100%
Net contents 0.38 avoird. oz. (11.0 g)	

AN2014 EOGas Cartridge

Active ingredient Ethylene oxide	96.0%
Inert Ingredients	4.0%
Total	100%
Net contents 0.49 avoird. oz. (14.0 g)	

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6/10/11

AN2018 EOGas Cartridge

Active ingredient Ethylene oxide 97.0%
Inert Ingredients 3.0%
Total 100%
Net contents 0.64 avoird. oz. (18.15 g)

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

AN2003 EOGas Cartridge

50 each EOGas 3.0g Cartridges (Total 150g)

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)

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EC  is™ 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. XXXXX-X
EPA ESTABLISHMENT NO. 9417-NC-001

Manufactured by:
Andersen Sterilizers, Inc.
3154 Caroline Drive
Haw River, NC 27258-9789 U. S. A.
TEL 1-336-376-8622
FAX 1-336-376-3088

Validation services and contract sterilization available from:
Andersen Scientific, Inc.

3220 Caroline Drive
Haw River, NC 27258-9789 U. S. A.
TEL 1-888-933-6427
FAX 1-336-376-8153

Distributed by:
Andersen Products, Inc.

3202 Caroline Drive
Haw River, NC 27258-9789 U. S. A.
TEL 1-800-523-1276
FAX 1-336-376-8153
www.anpro.com

Distributed in Europe, the Middle East and Africa by:
H. W. Andersen Products, Ltd.

Dartmouth Road
Clacton-on-Sea, Essex CO154XA
United Kingdom
TEL 1-255-428-328
FAX 1-255-222-987

H. W. Andersen, SARL
121 Rue Chanzy
59260 Hellemmes
France
TEL: 33-03-20-67-59-76

Distributed in Asia by:
Andersen Medical (HK), Ltd.
Floor 9/F Century Industrial Centre
33-35 Au Pui Wan Street
Fo Tan Shatin, Hong Kong
TEL: 852-2851-1655

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