

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DEC 19 1996

ARC Chemical Division Balchem Corporation
P.O. Box 180
Slate Hill, NY 10973

Attention: Diane Powers
Vice President

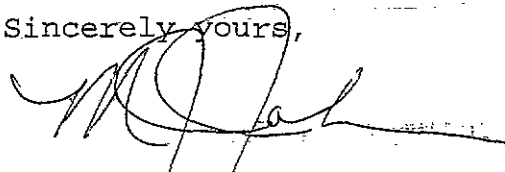
Subject: Sterilizing Gas 8
EPA Registration Number 36736-7
Your Submission Dated May 15, 1996

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to update your label is unacceptable. Five (5) copies of draft labeling revised in accordance with the label change listed below must be submitted before further consideration can be given to this amendment.

1. Under the "Statement of Practical Treatment" add the statement "In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Call a physician. Aerate, wash or clean contaminated clothing and discard leather goods.
2. Under the heading "Storage and Disposal" augment the standard storage and disposal statements with specific information regarding shelf-life and conditions which cause ETO to polymerize and possibly become less efficacious.

If you have any questions concerning this letter, please contact Velma Noble at (703) 305-7441.

Sincerely yours,



Marion J. Johnson, Jr.
Product Manager (31)
Antimicrobial Program Branch
Registration Division (7505C)

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS

DANGER! CAUSES EYE AND SKIN BURNS. HARMFUL IF INHALED. MAY CAUSE NERVOUS SYSTEM DAMAGE.

DANGER! CANCER HAZARD AND REPRODUCTIVE HAZARD.

EFFECTS OF OVEREXPOSURE: May be fatal if inhaled in high concentrations. May cause irritation of the 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 the lungs), immediate or delayed skin irritation or blisters, allergic skin reaction.

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

PEL: 1 PPM TWA (as per the Ethylene Oxide Standard 29CFR1910.1047).

EL: 5 PPM - excursion limit 15 minutes

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

PRECAUTIONS - Do not breathe vapor. Do not swallow. Do not get in eyes, on skin, or on clothing. Store and use with adequate ventilation in accordance with the Ethylene Oxide Standard (29 CFR 1910.1047).

PHYSICAL OR CHEMICAL HAZARDS: DANGER! - NONFLAMMABLE LIQUID AND GAS UNDER PRESSURE.

Contents under pressure. Do not use near flame, sparks, hot surfaces, or allow sources of ignition near the sterilization/fumigation area. Ground all equipment (including this container) to prevent sparks.

LEAK - In case of leak evacuate area and keep personnel upwind. Shut off all sources of ignition. Use self-contained breathing apparatus and protective clothing, and shut off leak if without risk.

FIRE - In case of fire move container away from fire if without risk. Use water spray or fog nozzle to keep container cool.

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 Pollutant Discharge Effluent System (NPDES) 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.

It is imperative that users of this material be familiar with ARC Chemical's Material Safety Data Sheet for Sterilizing Gas 8, which accompanies this shipment, the label and valve tag attached to this drum.

EPA Registration No. 36736-7
EPA Establishment No. 36736-NY-01
 36736-SC-02
 35084-TX-1
 35084-PA-2

STERILIZING GAS 8

STERILANT/FUMIGANT

ACTIVE INGREDIENTS:

- ETHYLENE OXIDE 8.5% BY WEIGHT (CAS REGISTRY NUMBER 75-21-8)
- CARBON DIOXIDE 91.5% BY WEIGHT (CAS REGISTRY NUMBER 124-38-9)

KEEP OUT OF REACH OF CHILDREN

DANGER PELIGRO

PRECAUTION AL USARIO: Si usted no lee ingles, no use este producto hasta que la etiqueta le haya sido explicada ampliamente.

Users must follow requirements of the OSHA Occupational Exposure Standard for ethylene oxide (29CFR1910.1047).

STATEMENT OF PRACTICAL TREATMENT

IN ALL CASES OF OVEREXPOSURE GET MEDICAL ATTENTION IMMEDIATELY. TAKE PERSON TO A DOCTOR OR EMERGENCY TREATMENT FACILITY AT ONCE.

IF INHALED - Remove exposed person to fresh air. Keep warm. If breathing has stopped, administer artificial respiration or oxygen. Do not give anything by mouth to an unconscious person. Call a physician even if no symptoms are present. Keep under medical observation. Symptoms may be delayed.

IF ON SKIN - Immediately remove contaminated clothing and shoes. Wash contaminated area thoroughly with soap and water. Call a physician. Aerate, wash or clean contaminated clothing and discard leather goods.

IF SWALLOWED - Give at least two glasses of water. Do not induce vomiting. Do not give anything by mouth to an unconscious person. Call a physician.

IF IN EYES - Hold eyelid open and flush with a steady, gentle stream of water for at least 15 minutes. Call a physician.

NOTE TO PHYSICIAN - Skin exposure to Sterilizing Gas 8 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. Refer to ARC Chemical Sterilizing Gas 8 MSDS, Section 8, Health Hazard Data. A Material Safety Data Sheet for Sterilizing Gas 8 is sent with each shipment. If unable to locate MSDS for this product, please call ARC Chemical at the telephone number below and request that one be sent immediately.

Distributed By:
ARC Chemical Division
Balchem Corporation
P.O. Box 180
Slate Hill, NY 10973
Tel: 914-355-5300
Fax: 914-355-6314

DO NOT REMOVE THIS LABEL.

RECD EPA/OP/DPD2
Net Contents: _____ lbs.

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DIRECTIONS FOR USE
It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. It is the employer's responsibility to follow the requirements of the Ethylene Oxide Standard (29CFR1910.1047).

This product may be used only in facilities that meet the requirements of the Ethylene Oxide Standard (29 CFR 1910.1047). This product may be used only in non-portable (commercial) vacuum or gas-tight chambers designed for use with 8.5% ethylene oxide, 91.5% carbon dioxide. This product may be used only by persons who have been trained in accordance with the Ethylene Oxide Standard (29 CFR 1910.1047). When used to sterilize health care items, this product must be used in non-portable (commercial) ethylene oxide gas sterilizers that have FDA clearance.

1. AS A STERILANT AND FUMIGANT GAS:

A. For complete use directions (including type of surfaces, objects, or items/products recommended for treatment, pre-cleaning instructions, concentration of gas per unit volume of closed space to be treated, exposure time/temperature, relative humidity, ventilation/aeration time, and method of monitoring to be used) refer to the ethylene oxide gas sterilizer manufacturers' Operators Manuals.

This product may be used only to sterilize medical or laboratory items, pharmaceuticals, and aseptic packaging. (see 21 CFR 201.1(4d)) or to reduce microbial load on cosmetics, whole and ground spices or other seasoning materials (see 40CFR 180.151 and 40CFR 185.2850), and museum artifacts, archival material or library objects.

B. Sterilization/fumigation with Sterilizing Gas 8 must be performed only in vacuum or gas tight chambers designed for use with Sterilizing Gas 8.

C. Sterilizing Gas 8 cycle parameters depend on several sterilizing/fumigating variable factors: preconditioning (if any); exposure time; chamber air pressure; gas concentration; types and quantities of items to be sterilized/fumigated; packaging; load configuration in the chamber; microbial challenge method; desired degree of disinfection; and the desired performance of the sterilized/fumigated product and package.

D. The sterilization/fumigation cycle parameters should be those prescribed by the equipment manufacturer. If other cycle parameters are used, the safety and efficacy of the alternate cycle parameters must be validated and are the responsibility of the user. NEVER USE PARAMETERS WHICH ALLOW FLAMMABLE MIXTURES OF ETHYLENE OXIDE AND AIR TO ENTER THE CHAMBER.

2. INSTALLATION AND OPERATION OF THE CONTAINER - Follow the directions on the valve tag attached to this container.

STORAGE & DISPOSAL

Use in accordance with tag attached to valve. Store in cool, well ventilated area. Avoid exposure to heat or direct sunlight. When empty, return to supplier only. Before returning container to supplier:

1. Pressurize container with nitrogen to 50 psig total pressure at 70 degrees F.
2. Replace valve plugs tightly in valve outlets.
3. Check container valve and plugs for leaks prior to shipment.
4. Store this product out of sun and away from heat to avoid polymerization.
5. Use this product within 120 days of its purchase.

In case of accident or emergency, call CHEMTREC at 800-424-9300.

DEC 9 1996
Industrial Act
for the pesticide
EPA Reg. No.
36736-7

ACCEPTED
with COMMENTS
in EPA Letter Dated:

DEC 19 1996

Under the Fungicide, Insecticide, and Plant Growth Regulator Act as amended, for the pesticides registered under EPA Reg. No.

36736-7

EPA REGISTRATION NO. 36736-7
EPA ESTABLISHMENT NO. 36736-NY-01

DO NOT REMOVE THIS TAG

STERILIZING GAS 8

**DANGER! EXTREMELY FLAMMABLE AND EXPLOSIVE.
HARMFUL IF INHALED.**

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. It is the employer's responsibility to follow the requirements of the Ethylene Oxide Standard (29 CFR 1910.1047). Use only in accordance with the directions and safety precautions listed on the label and on this tag. See current ARC Chemical Material Safety Data Sheet for this product.

General Directions

1. Always check container valves and plugs for leaks before moving container into your facility.
2. This container is designed to discharge only liquid ethylene oxide. If ethylene oxide gas is required, use vaporizing equipment.
3. This container has been pressurized with nitrogen to a pressure of 50 psig (3.52 kg/cm²) at 70°F (21.1°C). Pressure will be higher if temperature is above 70°F; lower if temperature is below 70°F. Contact supplier if, upon receipt, container pressure is below 50 PSIG at 70°F.
4. Container must be in an upright position at all times. Cylinders must be secured to prevent falling over.
5. Liquid withdrawal valve outlet is provided with a CGA 510 connection which has left hand threads.
6. Cylinders and DOT 5P drums are also provided with a CGA inert pressurizing valve which has right hand threads. Do not discharge product from the inert pressurizing valve.
7. Remove protective valve plugs carefully and make sure valve threads are undamaged.
8. All other piping and fittings should be steel or stainless steel fittings and piping capable of withstanding the pressure to be encountered. Do not use rubber, plastic, or copper materials. Install relief valves where liquid can be trapped between valves.
9. Ground all equipment, including this container, to prevent static sparks.
10. Use only spark - proof tools.
11. Use only explosion - proof electrical equipment which conforms to the current requirements of the National Electric Code (see NFPA #70) where ethylene oxide may be present.
12. Install check valves in the discharge line from this container to processing equipment to prevent back flow into the container.

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13. Connect the inert pressurizing valve to a source of nitrogen using a line equipped with a pressure regulator, safety relief valve, and check valve. The source of nitrogen should be used for ethylene oxide and for no other purpose. Nitrogen pressure must not exceed the service pressure of the container. Never use compressed air or other gases to pressurize the cylinder or drum. **DO NOT APPLY HEAT TO THIS CONTAINER BY ANY MEANS.**
14. To open container valves, turn counterclockwise. For those containers which are equipped with a handwheel do not use a wrench or other leverage device. Use a "T" wrench to open the inert pressurizing valve on EOX and SS.55 cylinders and 5P drums.
15. Use with adequate general and local ventilation. Vapors form from this product travel and may be moved by air currents and ignited by pilot lights, other flames, smoking, sparks, heaters, electrical equipment, static discharges, or other at locations distant from product handling point.
16. Determine the quantity of product withdrawn from this container by using an appropriate scale.

STORAGE AND DISPOSAL

Store according to the directions provided on this tag and on the product label. To control ethylene oxide polymer growth, use all sterilant gas on a first in/first out basis. Our recommendation is to use all of this product within 120 days of its receipt. To minimize polymer growth, this product should not be stored in any place where the temperature exceeds 100°F. Do not store this product in direct sunlight.

STORE IN AN AREA WITH ADEQUATE VENTILATION

RETURN CONTAINER TO SUPPLIER FOR REUSE. BEFORE RETURNING CONTAINER TO SUPPLIER:

- A. PRESSURIZE CONTAINER WITH NITROGEN TO 50 PSIG TOTAL PRESSURE AT 70° AND BE SURE CONTAINER VALVES ARE CLOSED.
- B. REPLACE VALVE PLUGS SECURELY IN VALVE OUTLET. IF VALVE PLUGS ARE NOT AVAILABLE, CONTACT SUPPLIER.
- C. CHECK CONTAINER VALVES AND PLUGS FOR LEAKS PRIOR TO SHIPMENT. IF LEAKS ARE DETECTED, CONTACT SUPPLIER.
- D. **THIS TAG MUST REMAIN AFFIXED TO DRUM OR CYLINDER AT ALL TIMES. WHEN EMPTY THIS CONTAINER MUST BE RETURNED TO THE ORIGINAL SHIPPING POINT IN ACCORDANCE WITH THE DIRECTIONS ABOVE. IT IS THE PROPERTY OF:**

**ARC CHEMICAL DIVISION
BALCHEM CORPORATION
ROUTES 6 & 284, P.O. BOX 180
SLATE HILL, NY 10973
(914) 355-5311**

with COMMENTS
in ERA Label List

DEC 19 1996

Under the Fungicide, Herbicide,
Fungicide, and Botanicals Act
as amended, for the pesticide
registered under EPA Reg. No.

36736-7