

US ENVIRONMENTAL PROTECTION AGENCY  
OFFICE OF PESTICIDES PROGRAMS  
REGISTRATION DIVISION (TS-767)  
WASHINGTON, DC 20460

EPA REGISTRATION NO.  
36736-7

DATE OF ISSUANCE  
MAY 11 1995

NOTICE OF PESTICIDE:  REGISTRATION  
 REREISTRATION  
(Under the Federal Insecticide, Fungicide,  
and Rodenticide Act, as amended)

TERM OF ISSUANCE

NAME OF PESTICIDE PRODUCT  
Sterilizing Gas 8

NAME AND ADDRESS OF REGISTRANT (Include ZIP code)

PM-31 Reg # 36736-7 196  
ARC Chemical Division Balchem Corporation  
P.O. Box 180  
Slate Hill, NY 10973

NOTE: Changes in labeling formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above U.S. EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby Registered/Reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act.

A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith.

Registration is in no way to be construed as an indorsement or approval of this product by this Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit/cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

2. Make the labeling changes listed below before you release the product for shipment:

- a. Add the phrase "EPA Registration No. 36736-7"
- b. Include the statement "For industrial use, and for use in health care facilities which have equipment designed for Sterilizing Gas 8 use." on the cylinder label.
- c. Delete the statement "First Aid:".

ATTACHMENT IS APPLICABLE

SIGNATURE OF APPROVING OFFICIAL

DATE

196

3. Submit five (5) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for a further description of final printed labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely,



Marion Johnson  
Product Manager (31)  
Antimicrobial Program Branch  
Registration Division (7505C)

Enclosures

# STERILIZING GAS 8

**Active Ingredient**  
 Ethylene Oxide . . . . . 8.5%  
**Inert Ingredients** . . . . . 91.5%  
**Total** . . . . . 100%

## EPA EST. NO.

- 35084-TX-1
- 35084-PA-2
- 36736-NY-01

ACCEPTED  
 with COMMENTS  
 in EPA Letter Dated:

MAY 11 1995

**DOT SHIPPING NAME:**  
**NON FLAMMABLE GAS**  
**UN 1952**

Under the Federal Insecticide,  
 Fungicide, and Rodenticide Act  
 as amended, for the pesticide  
 registered under EPA Reg. No.  
36736-7

EPA REG. NO. 36736-7

**TOTAL CONTENTS** \_\_\_ LBS. NET  
 Ethylene Oxide CAS #75-21-8  
 Carbon Dioxide CAS #124-38-9

FOR INDUSTRIAL USE, AND FOR USE IN HEALTH CARE  
 FACILITIES WHICH HAVE EQUIPMENT DESIGNED FOR  
 STERILIZING GAS 8 USE.

**DANGER PELIGRO**

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

**HAZARDS TO HUMANS**  
**DANGER! NON-FLAMMABLE LIQUID AND GAS UNDER PRESSURE. CAUSES EYE AND SKIN BURNS. HARMFUL IF INHALED. HARMFUL IF SWALLOWED. MAY CAUSE RESPIRATORY AND NERVOUS SYSTEM DAMAGE.**

Sterilizing Gas 8 is not intended for outdoor use. Ethylene oxide is a nonpersistent chemical structure which would not be expected to accumulate in the environment. Its moderate level of aquatic toxicity coupled with this nonpersistence should prevent any long-term toxic effects on aquatic systems.

**DANGER! CONTAINS ETHYLENE OXIDE. CANCER HAZARD AND REPRODUCTIVE HAZARD.**

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

**EFFECTS OF OVEREXPOSURE:** 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 reaction.

**FIRST AID:**  
 IF INHALED, remove exposed person to fresh air, keep warm. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.

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

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.

PEL: 1PPM-TWA (OSHA-29 CFR1910.1047).  
 EL: 5PPM-excursion limit, 15 minutes.

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.

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

NOTE TO PHYSICIAN: REFER TO ARC CHEMICALS MATERIAL SAFETY DATA SHEET for Sterilizing Gas 8.

PRECAUTIONS: Do not breathe vapor. Do not swallow. Do not get in eyes, on skin, or on clothing. Store and use with adequate ventilation.

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.

**PHYSICAL AND CHEMICAL HAZARDS**  
 Contents under pressure. Use only in a closed system. No part of the container may be exposed above 125°F (52°C). Close valve when not in use and when empty. Use in accordance with tag attached to valve.

FIRE: Move container away from fire without risk. Use water spray or fog nozzle to keep container cool.

**STORAGE AND DISPOSAL** - Store in a cool, well ventilated area. Avoid exposure to heat or direct sunlight. When empty, return to manufacturer only.

It is in violation of federal law to use this product in a manner inconsistent with its labeling. The product is limited to use by medical professionals or trained technical personnel in medical and industrial use areas.

**ENVIRONMENTAL HAZARDS**  
 Ethylene oxide, the active ingredient in

IN CASE OF EMERGENCY IN USA:  
 Call CHEMTREC - 1-800-262-8200

**ARC CHEMICAL Division of Balchem Corporation**  
 P.O. Box 180  
 Slate Hill, NY 10973

DO NOT REMOVE THIS LABEL

496

ACCEPTED  
with COMMENTS  
to EPA Letter Dated:

MAY 1 1 1995

DO NOT REMOVE THIS TAG

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

36736-7

# STERILIZING GAS 8

STERILANT-FUMIGANT GAS

**DANGER: NON-FLAMMABLE LIQUID AND GAS UNDER PRESSURE  
HARMFUL IF INHALED**

## DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. When used in the workplace, it is the employer's responsibility to ensure that all personnel are familiar with and adhere to 29 CFR 1910.1047. Sterilizing Gas 8 is a highly hazardous material and should be used only by personnel trained in its proper use. All persons working with Sterilizing Gas 8 must have knowledge of the hazards of this chemical mixture and must be trained in the proper use of required respirator equipment, monitoring and detection devices, and in the implementation of emergency procedures.

To be used only by persons experienced in 10% EC 90% CO<sub>2</sub> sterilization and fumigation, or by persons under direct supervision of persons who are experienced in 10% EO 90% CO<sub>2</sub> sterilization and fumigation. Use only in accordance with the directions and the safety precautions listed on the label and this tag. See current ARC Chemical Material Safety Data Sheet for Sterilizing Gas 8.

## GENERAL INSTRUCTIONS

1. Always check cylinder valve for leaks before moving cylinder into your facility.
2. This cylinder is equipped with an eductor tube for liquid delivery. Use vaporizing equipment to convert the liquid into a gas.
3. The approximate vapor pressure exerted by this gas mixture will be 750 psig (53.76 kg/cm<sup>2</sup>) at 70°F (21.1°C) while liquid is present. Vapor pressure will be higher if temperature is above 70°F (21.1°C); lower if temperature is below 70°F (21.1°C).
4. Cylinder must be in an upright position when discharging. Cylinder must be secured to prevent falling over.
5. Discharge valve outlet is provided with a GCA 350 connection which has left hand threads.
6. Remove protective valve plug and make sure valve threads are undamaged. The connection to the cylinder valve should be a brass CGA 350 connector. Use of other metals could cause damage to the brass cylinder valve. Do not attach an ordinary pipe fitting to this valve.
7. All other piping and fittings should be steel or stainless steel, capable of withstanding the pressure to be encountered. Do not use rubber, plastics, or copper materials. Install relief

4

devices where liquid can be trapped between valves.

- 8. Install check valves in the discharge line from this cylinder to processing equipment to prevent back-flow into cylinder.
- 9. To open cylinder valve, turn handwheel counter clockwise. Do not use a wrench or other leverage device to open or close cylinder valve.
- 10. Use with adequate general and local ventilation.
- 11. Always open the cylinder valve wide open when discharging contents. Do not restrict flow of gas from cylinder valve or use pressure regulators because the ratio of carbon dioxide to ethylene oxide in the gas mixture will be changed.
- 12. If dosage required is less than the entire contents of this cylinder, determine the quantity withdrawn by using an appropriate scale. The proper gas mixture can only be maintained by discharging a minimum of 12 pounds (5.4 kg.) from each cylinder.

RECEIVED  
 MAY 11 1995  
 Under the Federal Hazardous Materials Act  
 as amended by the Emergency Response Act  
 36736-7

1. STERILIZATION AND FUMIGATION

- ✓ Sterilizing Gas 8 may be safely used to reduce microbial load and/or sterilize medical and laboratory items, pharmaceuticals, aseptic packaging, whole and ground spices and other processed natural seasoning materials except mixtures to which salt has been added (see 21 CFR 193.200), cosmetics, and other inanimate objects.
- ✓ Items to be sterilized should be thoroughly cleaned of soil before being placed in any type of sterilizer.
- ✓ A. Sterilization/fumigation with Sterilizing Gas 8 must be performed only in vacuum or gas tight chambers designed for use with 10% ethylene oxide by weight and 90% carbon dioxide by weight and in accordance with directions supplied by the chamber manufacturer.

NOTE: It is a violation of Federal Law to use Sterilizing Gas 8 for the fumigation of airplanes, trains, buses, ships, trucks, trailers, warehouses or other similar spaces.

- ✓ B. Sterilizing Gas 8 cycle parameters depend on several sterilizing/fumigating variable factors: preconditioning (if any); exposure time; chamber air concentration; ethylene oxide concentration; chamber temperature; humidity level; types and quantities of items to be sterilized/fumigated; packaging; load configuration in the chamber; microbial challenge method; desired level of sterility assurance; and the desired performance of the sterilized/fumigated product and package.
- ✓ C. The following is a list of ranges for the critical variables which must be in proper relationship for Sterilizing Gas 8 to be an effective sterilizing/fumigating agent. This information should be considered general, and not as a replacement for detailed information issued by manufacturers.

Temperatures - 70° to 150° F

Pre-Vacuum - typically 20 to 28 inches of mercury. Use vacuums and/or inert gas purges compatible with the products and packages to be sterilized/fumigated.

6 9 6

Moisture - Relative humidity of 33% to 80%

Gas Concentration - 150 mg/L to 800 mg/L (milligrams of ethylene oxide per liter of chamber volume).

Exposure Time - 45 minutes to 20 hours

Post-Vacuums - Sterilizing Gas 8 is removed from the chamber and vented to an appropriate ethylene oxide capture or destruction device.

Aeration - aerate sterilized/fumigated materials before use. Do not allow any person to enter the chamber or aeration area if such entry will result in exposures to ethylene oxide above the levels established in 29 CFR 1910.1047.

Cycle parameters and post cycle aeration parameters (temperature, time, air flow-rate) can affect residue levels. The user must determine that the parameters chosen result in goods which comply with applicable Federal and State residue requirements.

For residual limits of ethylene oxide on drug products and medical products see 21 CFR 211.70 and 21 CFR 821.100 or subsequent revisions. For residual limits on agricultural commodities, see 40 CFR 180.151 and 21 CFR 193.200 or subsequent revisions.

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.

#### STORAGE AND DISPOSAL

Store according to instructions provided on label and this tag. To control ethylene oxide polymer growth, use all sterilant gas on a first-in, first-out basis. A good rule of thumb is to use Sterilizing Gas 8 within 12 months of the fill date marked on the container (batch number). Do not store outside in direct sunlight. To minimize polymer growth, Sterilizing Gas 8 should not be stored in any place where the temperature consistently exceeds 100° F.

STORE IN AN AREA WITH ADEQUATE VENTILATION.

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

- A. REPLACE VALVE PLUG TIGHTLY IN VALVE OUTLET. IF VALVE PLUG IS NOT AVAILABLE, CONTACT SUPPLIER.
- B. CHECK CONTAINER VALVE AND PLUG FOR LEAKS PRIOR TO SHIPMENT. IF LEAKS ARE DETECTED, CONTACT SUPPLIER.

ACCEPTED  
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in EPA Letter Dated:

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