

PM 101 36736-3
1994 11-7
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

FEB 03 1995

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

Subject: Sterilizing Gas 3
EPA Registration No. 36736-3
Amendment Dated October 3, 1994

Dear Ms Powers:

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to revise your product labeling and product valve tag (supplemental labeling), is acceptable, provided that you:

1. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:

For product labels only and not for the product valve tag (supplemental labeling).

a. Include a precautionary heading to read:

Precautionary Statements

b. Revise the "Hazards to Humans" to "Hazards to Humans and Domestic Animals".

c. Delete the "First Aid" heading.

d. In the precautionary statement, include the word "corrosive".

e. In the precautionary statements, include the phrase "Wear goggles or face shield and rubber gloves".

f. The child warning hazard statement "Keep Out of Reach of Children" must appear in the English version.

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

g. Include the heading "Directions For Use" immediately above the misuse statement "It is a violation of Federal Law..."

2. Submit five (5) copies of your final printed labeling before you release the product for shipment.

Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

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

If you have any questions concerning this letter, please contact Martha Terry at (703) 305-6982.

Sincerely yours,



Walter C. Francis
Acting Product Manager (31)
Antimicrobial Program Branch
Registration Division (7505C)

Enclosure

STERILIZING GAS 3

Active Ingredient
Ethylene Oxide 80%
Inert Ingredients 20%
Total 100%

EPA EST. NO.

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

DOT SHIPPING NAME:
FLAMMABLE GAS
UN 1041
RQ

ACCEPTED
with COMMENTS
in EPA Letter Dated:

FEB 03 1995

EPA REG. NO. 36736-3

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

36736-3

TOTAL CONTENTS 160 LBS. NET
Ethylene Oxide CAS #75-21-8
Carbon Dioxide CAS #124-38-9

DANGER PELIGRO

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

HAZARDS TO HUMANS

DANGER! FLAMMABLE LIQUID AND GAS UNDER PRESSURE. CAUSES EYE AND SKIN BURNS. HARMFUL IF INHALED. HARMFUL IF SWALLOWED. MAY CAUSE RESPIRATORY AND NERVOUS SYSTEM DAMAGE.

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

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.

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

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

EL: 5PPM-excursion limit, 15 minutes.

ODOR: Ether-like at high concentrations. Exposure to toxic levels may occur without warning 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.

PHYSICAL AND CHEMICAL HAZARDS

May form explosive mixtures air. Keep away from heat, flame and sparks.

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 and sterilizer manufacturer instructions.

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

ENVIRONMENTAL HAZARDS

Ethylene oxide, the active ingredient in Sterilizing Gas 3 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.

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

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.

IN CASE OF CONTACT, immediately flush eyes or skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. In case of frostbite or cryogenic burns flush affected area with lukewarm water. DO NOT USE HOT 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.

NOTE TO PHYSICIAN: REFER TO ARC CHEMICALS MATERIAL SAFETY DATA SHEET for Sterilizing Gas 3.

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

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

IN CASE OF EMERGENCY IN USA:
Call CHEMTREC - 1-800-424-9300

ARC CHEMICAL DIVISION OF BALCHEM CORPORATION
P.O. BOX 180
SLATE HILL, NY 10973

DO NOT REMOVE THIS LABEL

BEST AVAILABLE COPY

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with COMMENTS
in EPA Letter Dated:

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

36736-3

DO NOT REMOVE THIS TAG

STERILIZING GAS 3
80% Ethylene Oxide/ 20% Carbon Dioxide
Sterilant Gas

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. 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 3 is a highly hazardous material and should be used only by personnel trained in its proper use. All persons working with Sterilizing Gas 3 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 80% EO/ 20% CO₂ sterilization or by persons under direct supervision of persons who are experienced in 80% EO/ 20% CO₂ sterilization. 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 this product.

GENERAL INSTRUCTIONS

1. Always check cylinder valve and plugs 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 175 psig (13.33 kg/cm²) 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 secure to prevent falling over.

5. Discharge valve outlet is provided with a CGA 510 connection which has lefthand threads.
6. Remove the protective valve plug and make sure the valve threads are not damaged. The connection to the cylinder valve should be a brass CGA 510 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 devices where liquid can be trapped between
8. Ground all equipment including containers, to avoid sparks.
9. Use only spark-proof tools.
10. Use only explosion proof electrical Sterilizing Gas 3 may be present.
11. Install check valves in the discharge line from this cylinder to processing equipment to prevent back-flow into the cylinder.
12. To open the cylinder valve, turn handwheel counter clockwise. Do not use a wrench or any other leverage device to open or close cylinder valve.
13. Use with adequate general and local ventilation. Vapors from this product may travel or be moved by air currents and ignited by pilot lights, other flames, smoking, sparks, heaters, electrical equipment, static discharges or other ignition sources at locations distant from product handling point.
14. Determine the quantity of product withdrawn from this cylinder by using an appropriate scale.

ACCEPTED
with COMMENTS
in EPA Lab. 2112
FEB 03 1995

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
equipment, where
registered under EPA Reg. No.
36736-3

1.) STERILIZATION

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Sterilizing Gas 3 may be safely used to reduce microbial load and/or sterilize medical and laboratory items, pharmaceuticals, aseptic packaging, 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 with Sterilizing Gas 3 must be performed only in vacuum or gas tight chambers designed for use with 80%

ethylene oxide by weight and 20% carbon dioxide by weight, and in accordance with directions supplied by the chamber manufacturer.

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

~~36736-3~~

B. Sterilizing Gas 3 cycle parameters depend on several sterilizing variable factors: preconditioning (if any); exposure time; chamber air or inert gas concentration; ethylene oxide concentration; chamber temperature; humidity level; types and quantities of items to be sterilized; packaging; load configuration in the chamber; microbial challenge method; desired level of sterility assurance; and the desired performance of the sterilized product and package.

C. The following is a list of ranges for the critical variables which must be in proper relationship for Sterilizing Gas 3 to be an effective sterilizing agent. This information should be considered general, and not as a replacement for detailed information issued by manufacturers.

Temperature - 70°C to 180°F

Pre-Vacuum - typically 25 to 29 inches of mercury. Use and/or inert gas purges compatible with the products and packages to be sterilized, and such that explosive atmospheres are never present in the chamber.

Moisture - Relative humidity of 33% to 80%

Gas Concentration - 350 mg/L to 1500 mg/L (milligrams of ethylene oxide per liter of chamber volume)

Exposure Time - 45 minutes to 20 hours

Post-Vacuums - Sterilizing Gas 3 is removed from the chamber and vented to an appropriate ethylene oxide capture or destruction device.

Aeration - aerate sterilized materials before use. Do not allow any person to enter the chamber or aeration area if such entry will result in exposure 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 29 CFR 211.70 and 21 CFR 821.100 or subsequent revisions.

D. The sterilization 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 STERILIZING GAS 3 AND AIR TO ENTER THE CHAMBER.

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 3 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 3 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.

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