

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

NOV 14 2003

Ms. Joanne Cashin
ARC Specialty Products
Balchem Corp
PO Box 600
New Hampton, NY 10958

Subject: Sterilizing Gas 4
EPA Registration No. 36736-4
Amendment Date: August 12, 2003
EPA Receipt Date: August 18, 2003

Dear Ms. Cashin,

The following amendment submitted in connection with registration under FIFRA, as amended, is acceptable with the conditions listed below.

- Update First Aid Statement per PR Notice 2001-1

Conditions

Revise the label as follows:

The Storage and Disposal Statements must be revised to comply with PR Notice 83-3 and the Label Manual 3rd Edition by stating:

Storage and Disposal

Do not contaminate food, feed, or water by storage and disposal.

Pesticide Storage: Use in accordance with tag attached to valve. Store in cool, well-ventilated area. Avoid exposure to heat or direct sunlight as may cause polymerization.

Pesticide Disposal: Pesticide Wastes are acutely hazardous. Improper disposal of excess pesticide, spray, or mixture of rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use 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.

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Container Disposal: When empty, return to supplier only. Before returning container to supplier:

- 1. Cylinder pressure should be below 600 psig when empty. Check that container valve is closed.
- 2. Replace valve plug tightly in valve outlet.
- 3. Check container valve and plug for leaks prior to shipment.

General Comments

A stamped copy of the labeling accepted with conditions is enclosed. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,



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

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND 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:

cause nervous system injury, cataracts, adverse reproductive effects, chromosomal and mutagenic changes, and cancer.

PEL: 1 PPM TWA (as per the Ethylene Oxide Standard 29 CFR 1910.1047).
EL: 5 PPM - excursion limit 15 minutes.
ODOR: Ether-like at high concentrations. Exposure to toxic levels may occur without warning or to 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! - HIGHLY FLAMMABLE 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. Sterilizing Gas 4 is extremely flammable and reactive. 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 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 Specialty Products' Material Safety Data Sheet for Sterilizing Gas 4. See label and valve tag attached to this cylinder.

EPA Registration No. 36736-4
EPA Establishment No. 35084-PA-2

with COMMERCIAL Valve Tag
EPA Letter Dated: NOV 14 2003
Insecticide, Fungicide Act as Pesticide.
36736-4
supercedes 3/00
registered under EPA Reg. No.

801465 (Rev. 6/03 - supercedes 3/00)

STERILIZING GAS 4

STERILANT/FUMIGANT
ACTIVE INGREDIENT: ETHYLENE OXIDE.....10%
(CAS NO: 75-21-8)
INERT INGREDIENT: CARBON DIOXIDE.....90%
(CAS NO: 124-38-9)
TOTAL:.....100%

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

Users must follow requirements of the OSHA Occupational Exposure Standard for ethylene oxide (29 CFR 1910.1047).

FIRST AID

IN ALL CASES OF OVEREXPOSURE GET MEDICAL ATTENTION IMMEDIATELY. TAKE PERSON TO A DOCTOR OR EMERGENCY TREATMENT FACILITY AT ONCE.
IF INHALED - Move person to fresh air. Keep warm. If person is not breathing, call 911 for an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. If breathing is difficult, give oxygen. Call a poison control center or doctor for further treatment advice, even if there are no symptoms. Keep under medical observation - symptoms may be delayed.
IF ON SKIN OR CLOTHING - Take off contaminated clothing and shoes. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice. Aerate, wash or clean contaminated clothing and discard leather goods.
IF SWALLOWED - Call poison control center or doctor immediately for treatment advice. Have person sip two glasses of water if able to swallow. Do not induce vomiting. Do not give anything by mouth to an unconscious person.
IF IN EYES - Hold eye open and rinse slowly and gently with water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
HOTLINE NUMBER - Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-424-9300 for emergency medical treatment information.

NOTE TO PHYSICIAN - Skin exposure to Sterilizing Gas 4 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 Specialty Products' Sterilizing Gas 4 MSDS. If unable to locate MSDS for this product, please call ARC Specialty Products at the telephone number below and request that one be sent immediately.

Distributed By:
ARC Specialty Products
Balchem Corporation
P.O. Box 600 · New Hampton, NY 10958
Tel: 845-355-5311
Fax: 845-355-7619

Net Contents: _____ lbs.

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). 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 10% ethylene oxide, 90% 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(d)(5)), or to reduce microbial load on cosmetics, whole and ground spices or other seasoning materials (see 40 CFR 180.151), and artifacts, archival material or library objects.
B. Sterilization/fumigation with Sterilizing Gas 4 must be performed only in vacuum or gas tight chambers designed for use with Sterilizing Gas 4.
C. Sterilizing Gas 4 cycle parameters depend on several sterilizing/fumigating variable factors: pre-conditioning (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 STERILIZING GAS 4 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 as may cause polymerization. When empty, return to supplier only. Before returning container to supplier:
1. Cylinder pressure should be below 600 psig when empty. Check that container valve is closed.
2. Replace valve plug tightly in valve outlet.
3. Check container valve and plug for leaks prior to shipment.

USE THIS PRODUCT WITHIN 120 DAYS OF ITS PURCHASE.

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

DO NOT REMOVE THIS LABEL.