

36736-7

09/15/2008

1/2



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

SEP 15 2008

Joanne K. Cashin
Registration Compliance Advisor
Arc Specialty Products
P.O. Box 600
New Hampton, New York 10958

Subject: Sterilizing Gas 8
EPA Registration 36736-7
Amendment Dated: June 16, 2008
EPA Received Date: June 17, 2008

Dear Joanne K. Cashin

The following amendment submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, is acceptable.

Proposed Amendment

Revised Label
Adding Language for Ethylene Oxide

General Comments

A stamped copy of the accepted label is enclosed for your records. Submit (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 Velma Noble at (703)308-6233.

Sincerely,

CONCURRENCES

YMBOL	7515				Velma Noble Product Manager (31) Regulatory Management Branch 1 Antimicrobial Division (7510c)		
URNAME							
DATE							

ACCEPTED

SEP 15 2008

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

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: 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 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).

PERSONAL PROTECTION EQUIPMENT (PPE):

A material that is chemical-resistant to this product is butyl rubber.

Handlers must wear at a minimum: long-sleeved shirt and long pants, shoes plus socks,

Chemical-resistant gloves, and

The employer shall provide a respirator that is adequate to protect the health of the employee and ensure compliance with all other OSHA statutory and regulatory requirements (see 29 CFR 1910.1047 and 29 CFR 1910.134).

When handlers could have eye or skin contact with ETO or ETO solutions, such as during maintenance and repair, vessel cleaning, or cleaning up spills, they must wear:

- Chemical-resistant attire, such as an apron, protective suit, or footwear that protects the area of the body that might contact ETO or ETO solutions, and
- face-sealing goggles, a full face shield, or a half-face respirator.

When wearing respirators:

- Follow the respirator manufacturer's user's instructions for changing cartridges.
- Respirators must be fit-tested and fit-checked using a program that conforms to OSHA's requirements (see 29CFR Part 1910.134).
- Respirator users must be trained using a program that conforms to OSHA's requirements (see 29CFR Part 1910.134).

In case of accident or emergency, call CHEMTREC at 1-800-424-9300.

DO NOT REMOVE THIS LABEL.
USE THIS PRODUCT WITHIN 120 DAYS
OF ITS PURCHASE

4. Respirator users must be examined by a qualified medical practitioner to ensure physical ability to safely wear the style of respirator to be worn. A qualified medical practitioner is a physician or other licensed health-care professional (PLHCP) who will evaluate the ability of a worker to wear a respirator. The initial evaluation consists of a questionnaire that asks about medical conditions (such as a heart condition) that would be problematic for respirator use. If concerns are identified, then additional evaluations, such as a physical exam, might be necessary. The initial evaluation must be done before respirator use begins. It does not need to be repeated unless the health status of respirator use conditions change (see 29CFR Part 1910.134).

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Users should remove clothing/PPE immediately if pesticide gets inside.

Users should remove clothing/PPE immediately if pesticide gets inside.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

PHYSICAL OR CHEMICAL HAZARDS:

DANGEROUS - NONFLAMMABLE LIQUID AND GAS UNDER PRESSURE. Contains 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 leave 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 Elimination 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 8, the label and valve tag attached to this cylinder.

EPA Registration No. 36736-7
EPA Establishment No.

- 36736-NY-01
- 36736-SC-01
- 36736-MO-01
- 35084-PA-2

STERILIZING

GAS 8

STERILIZANT/FUMIGANT
ACTIVE INGREDIENT: ETHYLENE OXIDE... 83%
(CAS NO. 75-21-8)
INERT INGREDIENT: CARBON DIOXIDE... 91.5%
(CAS NO. 124-38-9)

TOTAL... 100%

Keep Out of Reach of Children

DANGER PELIGRO

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

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 soiled items.

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 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 Specialty Products' Sterilizing Gas 8 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.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Employers in facilities that use ETO must comply with all of the requirements for ETO use specified in 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-ported (commercial) vacuum or gas-tight chambers designed for use with 20% ethylene oxide, 80% 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-ported (commercial) ethylene oxide gas sterilizers that have FDA clearance.

In contract sterilization facilities, including facilities treating medical equipment and supplies, medical instruments, library/museum artifacts, cosmetics, and spices the following requirements must be followed:

Sterilization/fumigation with ETO must be performed only in vacuum or gas tight chambers designed for use with ETO. Safety and awareness training is required for all employees including office staff. Information and training must be provided to all employees in the facility at the time of initial assignment and annually thereafter. The safety training must include, at a minimum, the following information:

- The most recent monitored ambient levels of ETO in the facility;
- The potential health effects from the levels of ETO in the facility;
- The emergency response plan and how to respond in an emergency;
- The availability of the Material Safety Data Sheet and other materials related to the health hazards of exposure to ETO.

In order to reduce ambient levels of ethylene oxide, lengthy facility aeration is encouraged. It can reduce potential long-term risks to employees not directly involved in the ethylene oxide applications.

Air monitoring should include the entire facility including office space, break areas, and loading/unloading areas.

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.

Distributed By:
ARC Specialty Products
Balchem Corporation
P.O. Box 600 - New Hampton, NY
10958
Tel: 845-326-5611
Fax: 845-326-5706
www.arcspecialtyproducts.com

Net Contents:

_____ lbs.

This product may not be used on or in any form of basil.

After August 1, 2008, this product may only be applied to or on spices, dried vegetables or seasonings utilizing an ETO sterilization method that uses a single sterilization chamber to pre-condition and aerate with an alternating vacuum and aeration purging procedure. If you wish to employ an alternative method to that described below, you must contact the Environmental Protection Agency Office of Pesticide Programs for instruction on how to receive authorization.

Place spices in the treatment chamber. Assure that the mixture of ethylene oxide and air is compatible with the chamber design, then, introduce into the chamber a concentration of Ethylene Oxide not to exceed 500 mg/L, with a dwell time not to exceed 6 hours. Then evacuate the gas from the chamber using a sequence of not less than 11 stem washers (injections and evacuations) between 1.6 PSIA (27" Hg) and 5.0 PSIA (20" Hg) while maintaining a minimum chamber temperature of 118° F.

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 sterilization/fumigation 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 8 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 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 residue 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. **CONTAINER DISPOSAL.**

When empty, return to supplier only. Before returning container to supplier: 1. Check that 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.

2/10