

36736-8

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JAN 29 2007

Ms. Joanne Cashin  
ARC Specialty Products  
Balchem Corporation  
P.O. Box 600  
New Hampton, NY 10958

Subject: Ethylene Oxide - MUP  
EPA Registration No.: 36736-8  
Submission Date: October 26, 2006  
EPA Receipt Date: October 31, 2006

Dear Ms. Cashin,

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

- Deletion of Basil
- Compliance with Tolerance Reassessment and Risk Management Decision for Ethylene Oxide

**Conditions**

Revise the label as follows:

The fifth paragraph under "For use in the formulation of Sterilizing Gas Mixtures" must be revised to reflect the labeling provided in the Tolerance Reassessment and Risk Management Decision under the Sterilant and Fumigant Section:

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 **16 hours**. Then evacuate the gas from the chamber using a sequence of not less than **16 steam washes** (injections and evacuations) between **1.0 PSIA (28" Hg)** and **2.0 PSIA (26" Hg)** while maintaining a minimum chamber temperature of **120°F**.

**General Comments**

A stamped copy of the accepted labeling is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

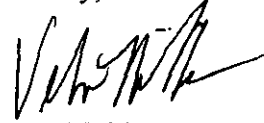
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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

Sincerely,



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

Enclosure: Stamped Label

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

ACCEPTED

**PRECAUTIONARY STATEMENTS**

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended for the pesticide registered under EPA Reg. No. 36736-8

JAN 29 2007

**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 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!** HIGHLY FLAMMABLE LIQUID UNDER PRESSURE

Contents under pressure. Do not use near flame, sparks, hot surfaces, or allow sources of ignition near the sterilization/fumigation area. Ethylene Oxide 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 self contained breathing apparatus and protective clothing, and shut off leak if with 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 100% Ethylene Oxide, the label and valve tag attached to this drum.

- EPA Registration No. 36736-8  
 EPA Establishment No.  36736-NY-01  
 36736-SC-01  
 36736-MO-01

**ETHYLENE OXIDE-MUP**  
 FOR MANUFACTURING USE  
 ACTIVE INGREDIENT: ETHYLENE OXIDE...100%  
 (CAS NO: 75-21-8)

**Keep Out of Reach of Children**

**DANGER PELIGRO**  
 PRECAUTIONAL 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 (29 CFR 1910.1047).

**FIRST AID**

**ALL CASES OF OVEREXPOSURE GET IMMEDIATE MEDICAL ATTENTION IMMEDIATELY. TAKE PERSON TO NEAREST HOSPITAL OR EMERGENCY TREATMENT FACILITY.**

**INHALED** - Move person to fresh air. Keep warm. If person is not breathing, call 911 or 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.

**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.

**SWALLOWED** - Call poison control center immediately for treatment advice. Have person sip at least two glasses of water if able to swallow. Do not induce vomiting. Do not give anything by mouth to an unconscious person.

**EYES** - Hold eye open and rinse slowly and gently with water for 15-20 minutes. Call poison control center or doctor for treatment advice.

**NOTICE 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.

**NOTED PHYSICIAN** - Skin exposure to Ethylene Oxide 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' Ethylene Oxide 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. 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 100% ethylene oxide. 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 ethylene oxide gas sterilizers that are approved by the registrant of the sterilant and listed in the current EPA registered, and/or FDA approved, instructions for use.

**FOR USE IN THE FORMULATION OF STERILIZING GAS MIXTURES:**

This product may be used for formulation into a sterilant/fumigant for the following pesticidal uses: to sterilize medical or laboratory items, pharmaceuticals and aseptic packaging, (see 21 CFR 201.1(d)(5)), or as a fumigant 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.

Any product formulated from this product that is registered for use on spices, dried vegetables, or seasonings must include the following label language:

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 21 steam washes (injections and evacuations) between 1.5 PSIA (27" Hg) and 5.0 PSIA (20" Hg) while maintaining a minimum chamber temperature of 115° F.

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A. This product contains hydrochlorofluorocarbon as an inerting gas. B. The amount of product shall be active ingredient. United States registered pesticide inerting gas ethylene oxide.

**2. INSTALL**

Follow the directions for installation.

**STORAGE**

Do not contact with water. Do not store in areas where PESTICIDE is used. Do not store in areas where PESTICIDE is used. Improper disposal is a violation of the Federal Insecticide, Fungicide, and Rodenticide Act. Waste representative.

**CONTAINER**

- 1. Pressurized container at 70° F.
- 2. Replace container.
- 3. Check container.

**USE THIS PRODUCT**

**In case of fire call CHEM**