

36736-8

09/15/2008

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

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

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

SEP 15 2008

Subject: Ethylene Oxide -MUP  
EPA Registration 36736-8  
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  | 7510c |  |  |  | Velma Noble<br>Product Manager (31)<br>Regulatory Management Branch1<br>Antimicrobial Division (7510c) |  |  |
| URNAME |       |  |  |  |  |  |  |
| DATE   |       |  |  |  |  |  |  |

**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**DANGER! CAUSES EYE AND SKIN BURNING. 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).

**PERSONAL PROTECTION EQUIPMENT (PPE):**

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

All 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 full-face respirator.

When wearing respirators:

- Follow the respirator manufacturer's user's instructions for changing canisters.
- 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).

- 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. Then wash thoroughly and put on clean clothing.

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:**

**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. 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 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.

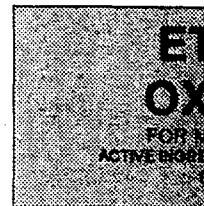
**ENVIRONMENTAL HAZARDS:**

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.

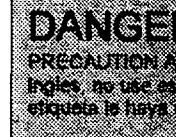
It is imperative that users of this material be familiar with ARC Specialty Products' Material Safety Data Sheet for 100% Ethylene Oxide, the label and valve tag attached to this drum.

EPA Registration No. 36736-8

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



Keep Out



Users must follow required Standard for ethylene o

**FIRST AID**

**IN ALL CASES OF O IMMEDIATELY TAKE TREATMENT FACILITY**

**IF INHALED** - Move per breathing, call 911 or an preferably by mouth-to-n oxygen. Call a poison co advice, even if there are symptoms may be delay

**IF ON SKIN OR CLOTH** Rinse skin immediately poison control center or clean contaminated cloth

**IF SWALLOWED** - Call advice. Have person sip Do not induce vomiting, unconscious person.

**IF IN EYES** - Hold eye o 15-20 minutes. Call pois **HOTLINE NUMBER** - Ha calling a poison control c also contact 1-800-424-4 information.

**NOTE TO PHYSICIAN** - result in skin irritation wif concentrations, severe c respiratory tract may occ systemic intoxication are and cardiac irregularities Refer to ARC Specialty i locate MSDS for this pro telephone number below

**ACCEPTED**

**SEP 15 2008**

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

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container away from fire if without risk. Use p container cool.

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this material be familiar with ARC Specialty a Sheet for 100% Ethylene Oxide, the label frum.

**ETHYLENE OXIDE MUP**  
FOR INDUSTRIAL USE  
Active Ingredient: Ethylene Oxide, 100%  
EPA Reg. No. 36736-8

**Keep Out of Reach of Children**

**DANGER PELIGRO**  
PRECAUTIONAL LABEL: Should not be used by children. Keep out of reach of children. To have safe use, read and understand the label.

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 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.

**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 IN EYES** - 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.

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

**IF ON SKIN OR CLOTHING** - 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 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 incons with its labeling. Employers in facilities that use ETO must comply with the requirements for ETO use specified in 29 CFR 1910.1047. This pr may be used only in facilities that meet the requirements of the Eth Oxide Standard (29 CFR 1910.1047). This product may be used only in portable (commercial) vacuum or gas-tight chambers designed for us 100% ethylene oxide. This product may be used only by persons who been trained in accordance with the Ethylene Oxide Standard (29 1910.1047). When used to sterilize health care items, this product m used in ethylene oxide gas sterilizers that are approved by the regist the sterilant and listed in the current EPA registered, and/or FDA app instructions for use.

In contract sterilization facilities, including facilities treating m equipment and supplies, musical instruments, library/museum ar cosmetics, and spices the following requirements must be followed: Sterilization/fumigation with ETO must be performed only in vacuum t tight chambers designed for use with ETO. Safety and awareness training is required for all employees including staff. Information and training must be provided to all employees facility at the time of initial assignment and annually thereafter. The training must include, at a minimum, the following information:

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

In order to reduce ambient levels of ethylene oxide, lengthy facility at is encouraged. It can reduce potential long-term risks to employe directly involved in the ethylene oxide applications.

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

**FOR USE IN THE PREPARATION OF COSMETICS**  
This product may be used for formulation into a sterilant/fumigant following pesticidal uses: to sterilize medical or laboratory pharmaceuticals and aseptic packaging. (see 21 CFR 201.1(d)(5)). fumigant to reduce microbial load on cosmetics, whole and ground sp other seasoning materials, (see 40 CFR 180.151), and artifacts. a material or library objects.

**Any product formulated from this product that is registered for u: spices, dried vegetables, or seasonings must include the followi 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 s) dried vegetables or seasonings utilizing an ETO sterilization met that uses a single sterilization chamber to pre-condition and aera with an alternating vacuum and aeration purging procedure. If y wish to employ an alternative method to that described below, yc must contact the Environmental Protection Agency Office of Pes Programs for instruction on how to receive authorization.**

**Place spices in the treatment chamber. Assure that the mixture i ethylene oxide and air is compatible with the chamber design, th introduce into the chamber a concentration of Ethylene Oxide no 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 21 steam washes (injections and evacuations) between 1.5 PSIA Hg) and 5.0 PSIA (20"Hg) while maintaining a minimum chamber temperature of 115° F.**

36736-NY-01  
36736-SC-01  
36736-MO-01

**ACCEPTED**

**SEP 15 2008**

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

**EYLENE E-MUP**  
FACTURING USE  
ETHYLENE OXIDE, 100%  
7-7521-6

each of Children

**PELIGRO**  
RIS: No debe haber niños hasta que se coloque el producto

s of the OSHA Occupational Exposure 19 CFR 1910.1047).

**EXPOSURE GET MEDICAL ATTENTION GO TO A DOCTOR OR EMERGENCY ROOM**

fresh air. Keep warm. If person is not lante, then give artificial respiration. If possible, if breathing is difficult, give center or doctor for further treatment mptoms. Keep under medical observation-

Take off contaminated clothing and shoes. nty of water for 15-20 minutes. Call a for treatment advice. Aerate, wash or id discard leather goods. 1 control center immediately for treatment st two glasses of water if able to swallow. : give anything by mouth to an

id rinse slowly and gently with water for trol center or doctor for treatment advice. : product container or label with you when or doctor, or going for treatment. You may r emergency medical treatment

xposure to Ethylene Oxide will commonly nsive blister formation. At high stivitis can occur. Irritation of the t without acute lung edema. Symptoms of ache, nausea, vomiting, incoordination. ment is symptomatic. ts' Ethylene Oxide MSDS. If unable to lease call ARC Specialty Products at the equest 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-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.

In contract sterilization facilities, including facilities treating medical equipment and supplies, musical 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:

1. The most recent monitored ambient levels of ETO in the facility;
2. The potential health effects from the levels of ETO in the facility;
3. The emergency response plan and how to respond in an emergency;
4. 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.

**1. 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.

Net Contents: \_\_\_\_\_ lbs.

- A. This product may be mixed with carbon dioxide, hydrochlorofluorocarbon material, or chlorofluorocarbon material, as an inerting substance to reduce flammability.
- B. The amount of Ethylene Oxide used to formulate the blended product shall be an amount sufficient to equal the percent of the active ingredient in the formulators' product as registered with the United States Environmental Protection Agency (i.e. - in a registered product containing 10% ethylene oxide and 90% inerting gas in a 100 lb. container, fill container with 10 lb. ethylene oxide and 90 lbs. inerting substance).

**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 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.

**CONTAINER REUSE** When empty, return to supplier only. Before returning container to supplier:  
1. Pressurize container with nitrogen to 50 psig total pressure at 70° F.  
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 1-800-424-9300**

**DO NOT REMOVE THIS LABEL**

Distributed by:  
ARC Specialty Products  
Babson Corporation  
P.O. Box 437, New Hampton, NY 10958  
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www.arcspecialtyproducts.com