



U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs  
Registration Division (E7505C)  
401 "M" St., S.W.  
Washington, D.C. 20460

EPA Reg. Number:  
36736-8

Date of Issuance:  
JUL 28 1997

NOTICE OF PESTICIDE:  
  x   Registration  
       Reregistration

Term of Issuance: Until  
Reregistration

Name of Pesticide Product:  
Ethylene Oxide-MUP

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

ARC Chemical Division  
Balchem Corporation  
Box 180  
Slate Hill, NY 10973

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.
2. Add the phrase "EPA Registration No. 36736-8" to your label before you release the product for shipment.

Signature of Approving Official:

*DNZ*

Velma Noble  
Acting Product Manager 31  
Regulatory Management Branch 1  
Antimicrobials Division

Date:

JUL 28 1997

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3. Submit two copies of final printed labeling before you release this product for shipment.

On March 26, 1996, EPA and Eto registrants agreed to label changes that would reduce risks to workers who handle Eto and enable EPA to conclude the Special Review for Eto. As part of that agreement, all Eto products must bear revised labeling after July 31, 1997. Any products bearing labels with uses that are no longer approved will violate FIFRA section 12(a)(2)(G). This section of FIFRA provides that it is unlawful for a person to use any pesticide in a manner inconsistent with its labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

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

Sincerely,



Velma Noble  
Acting Product Manager 31  
Regulatory Manager Branch 1  
Antimicrobials Division (E7510W)

Enclosure

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

PRECAUTIONARY  
STATEMENTS JUL 28 1997

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, and the Pesticide  
Registration Act, this product is  
registered under EPA Reg. No. 36736-218

**HAZARDOUS TO HUMANS &  
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 irri-  
tation of the respiratory tract, chest tightness,  
headache, nausea, vomiting, diarrhea, light-  
headed feeling, dizziness, weakness, drowsi-  
ness, cyanosis, loss of coordination, convulsions,  
coma, delayed lung injury (fluid in the lungs), im-  
mediate or delayed skin irritation or blisters, al-  
lergic skin reaction.

**OTHER POSSIBLE DELAYED HEALTH EF-  
FECTS:** May cause nervous system injury, cata-  
racts, adverse reproductive effects, chromosomal  
and mutagenic changes, and cancer.

**PEL:** 1 PPM TWA (as per the Ethylene  
Oxide Standard 29CFR1910.1047).  
**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 cloth-  
ing. Store and use with adequate ventilation in  
accordance with the Ethylene Oxide Standard (29  
CFR1910.1047).

**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. 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 igni-  
tion. 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 prod-  
uct 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 permit-  
ting 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 author-  
ity. For guidance contact your State Water Board  
or Regional Office of the EPA.

It is imperative that users of this material be fa-  
miliar with ARC Chemical's Material Safety Data  
Sheet for 100% Ethylene Oxide, which accom-  
panies this shipment, the label and valve tag  
attached to this drum.

# ETHYLENE OXIDE - MUP

FOR MANUFACTURING USE

ACTIVE INGREDIENT  
ETHYLENE OXIDE 100% BY WEIGHT  
CAS REGISTRY NUMBER 75-21-8

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  
ampliamente.

Users must follow requirements of the  
OSHA Occupational Exposure Standard  
for ethylene oxide (29CFR1910.1047).

### STATEMENT OF PRACTICAL TREATMENT

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

**IF INHALED -** Remove exposed person to fresh air.  
Keep warm. If breathing has stopped, administer  
artificial respiration or oxygen. Do not give any-  
thing by mouth to an unconscious person. Call a  
physician even if no symptoms are present. Keep  
under medical observation. Symptoms may be  
delayed.

**IF ON SKIN -** Immediately remove contaminated  
clothing and shoes. Wash contaminated area thor-  
oughly with soap and water. Call a physician. Aer-  
ate, wash or clean contaminated clothing and dis-  
card leather goods.

**IF SWALLOWED -** Give at least two glasses of  
water. Do not induce vomiting. Do not give any-  
thing by mouth to an unconscious person. Call a  
physician.

**IF IN EYES -** Hold eyelid open and flush with a  
steady, gentle stream of water for at least 15 min-  
utes. Call a physician.

**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 res-  
piratory 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 Chemical Ethylene Oxide MSDS,  
Section 6, Health Hazard Data. A Material Safety  
Data Sheet for Ethylene Oxide is sent with each  
shipment. If unable to locate MSDS for this prod-  
uct, please call ARC Chemical at the telephone  
number below and request that one be sent im-  
mediately.

Distributed By:  
ARC Chemical Division  
Balchem Corporation  
P.O. Box 180 • Slate Hill, NY 10973  
Tel: 914-355-5300  
Fax: 914-355-6314

Net Contents: 400 lb.   
175 lb.   
20 lb.

**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  
(29CFR1910.1047).  
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 according to its EPA-registered instructions for  
use. This product may be used only by persons  
who have been trained in accordance with the Eth-  
ylene 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.

**1. FOR USE IN THE FORMULATION OF STER-  
ILIZING GAS MIXTURES:**

This product may be used for formulation into a  
sterilant/fumigant for the following pesticidal uses:  
to sterilize medical or laboratory items, pharma-  
ceuticals and aseptic packaging, (see 21 CFR  
201.1(4d)) or as fumigant to reduce microbial load  
on cosmetics, whole and ground spices or other  
seasoning materials, (see 40 CFR 180.151 and 40  
CFR 185.2850), and artifacts, archival material  
or library objects.

**A** This product may be mixed with carbon dioxide,  
hydrochlorofluorocarbon material, or chlorofluoro-  
carbon material, as an inerting substance to re-  
duce flammability

**B** The amount of Ethylene Oxide used to formu-  
late the blended product shall be an amount suffi-  
cient 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 lbs. ethylene oxide and 90 lbs.  
inerting substance).

**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 re-  
turning container to supplier:

1. Pressurize container with nitrogen to 50 psig  
total pressure at 70 degrees F.
2. Replace valve plugs tightly in valve outlets.
3. Check container valve and plug for leaks prior  
to shipment.

USE THIS PRODUCT WITHIN 120 DAYS OF  
ITS PURCHASE.  
EPA Registration No. 36736-  
EPA Establishment No  36736-NY-01  
 36736-SC-01

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

**DO NOT REMOVE THIS LABEL.**