

PM 31 10330-16

10/5

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAR 12 1997

Praxair, Inc.
39 Old Ridgebury Road
Danbury, CT 06810-5113

Attention: Mr. Algirdas Vilkas

Subject: Ethylene Oxide 10% Carbon Dioxide
Sterilizing Gas
EPA Registration Number 10330-16
EPA Received Date January 31, 1997

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to update your label, using the Ethylene Oxide Model will be acceptable provided that you make the labeling changed listed below before you release the product for shipment bearing the amended label.

Delete the word "Carboxide" from the product name on the label.

A stamped copy of your labeling is enclosed for your records. Submit one (1) copy of the final printed label prior to release of the product for shipment.

If you have any questions concerning this letter, please contact Velma Noble at (703) 308-6233.

Sincerely,

for

Marion J. Johnson, Jr.
Product Manager (31)
Antimicrobial Program Branch
Registration Division (7505W)

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

CENTER PANEL OF LABEL OR ON RIGHT SIDE PANEL FOR TWO PANEL LABEL AND A DIRECTIONS FOR USE TAG.

Carboxide 10% Ethylene Oxide and Carbon Dioxide Sterilizing Gas

Active Ingredient: Ethylene Oxide CAS No. 75-21-8 ----- 10%

Inert Ingredient: Carbon Dioxide CAS No. 124-38-9 ----- 90%

USERS MUST FOLLOW THE REQUIREMENTS OF THE OSHA OCCUPATIONAL EXPOSURE STANDARD FOR ETHYLENE OXIDE 29 CFR 1910.1047.

Keep Out of Reach of Children

DANGER PELIGRO

PRECAUCION AL USUARIO: SI USTED NO LEE INGLES, NO USE ESTE PRODUCTO HASTA QUE LA ETIQUETA LEE HAYA SIDO EXPLICADO AMPLIAMENTE.

STATEMENT OF PRACTICAL TREATMENT

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

IF INHALED, remove exposed person to fresh air, keep warm. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician even if no symptoms are present. Keep under medical observation. Symptoms may be delayed.

IN CASE OF CONTACT, immediately flush eyes or skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Call a physician. Aerate wash or clean contaminated clothing and discard leather goods.

IF SWALLOWED, give at least two glasses of water. Do not induce vomiting. Do not give anything by mouth to an unconscious person. Call a physician.

NOTE TO PHYSICIAN

For contact, the affected areas should be thoroughly cleaned and treated symptomatically. Management of inhalation exposures should include extended observation and respiratory support as indicated by the patient's progress and presentation. Due to the underlying respiratory irritation in cases of pulmonary edema the use of hyperbaric oxygen must be carefully considered. Symptoms may be delayed.

ACCEPTED
WITH COMMENTS
IN EPA Letter dated

MAR 12 1997

10330-16

Use in accordance with the labeling and material safety data sheet for this product. Obtain a material safety data sheet from your supplier of sterilant gas.

SIDE PANEL OF LABEL

ACCEPTED
WITH COMMENTS
in EPA Letter dated

MAR 12 1997

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 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 lungs), immediate or delayed skin irritation and 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 Ethylene Oxide (OSHA 29 CFR 1910.1047).

EL : 5 PPM- excursion limit, 15 minutes.

ODOR: Ether-like in high concentrations. Exposure to toxic levels may occur without warning or detection by the user.

PRECAUTIONS : Do not breathe the vapor. Do not swallow. Do not get in eyes, on skin or clothing. Store and use with adequate ventilation in accordance with 29 CFR 1910.1047.

PHYSICAL OR CHEMICAL HAZARDS:

DANGER. FLAMMABLE LIQUID AND GAS UNDER PRESSURE. CAN FORM EXPLOSIVE MIXTURES WITH AIR.

Extremely flammable and reactive. Back flow into cylinder could cause rupture. Always use a back flow preventive device in the cylinder discharge piping. Container temperature should not exceed 125 F (52C). Secure the cylinder in an upright position during storage and use. Keep protective valve cap in place when not in use. Use only in closed systems which are rated for cylinder pressure (750psig). Close valve when not in use and when empty. Do not use near flame, sparks, hot surfaces, or allow sources of ignition near the sterilization area. Ground all equipment (including this container) to prevent sparks.

U.S. Environmental Protection Agency
Washington, D.C. 20460
EPA Regional Office
for the Pacific
Region
Registered under EPA Reg. No.
10330-16

LEAK Leak evacuate area and keep personnel upwind. Shut off all sources of ignition. Use a self-contained breathing apparatus and protective clothing, and shut off leak if without risk.

FIRE Do not extinguish burning gas if flow cannot be shut off immediately. 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.

ACCEPTED
with COMMENTS
in EPA Letter dated

MAR 12 1997

EPA REG. No. 10330-16

EPA Establishment No. XXXXXXXXXX (To be added by fill plant)

Net Contents _____ lbs. (To be added by fill plant)

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
10330-16

**FOR INDUSTRIAL AND MEDICAL USE IN COMMERCIAL GAS STERILIZERS
DESIGNED FOR USE WITH ETHYLENE OXIDE.**

IN CASE OF EMERGENCY CALL 1 800 645 4633

DOT SHIPPING NAME: Ethylene Oxide and Carbon Dioxide Mixtures UN 1041

Praxair, Inc. Danbury, CT 06810-5110 Do Not Remove This Label Label #, 1/97
Logo

**THIS INFORMATION IS PRINTED ON A TAG ATTACHED TO CYLINDER OR ON
SIDE PANEL OF LABEL**

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. It is the responsibility of the employer of any person engaged in the handling or application of this product to follow the requirements of 29 CFR 1910.1047.

This product may be used only in facilities that meet the requirements of 29 CFR 1910.1047 in non-portable (commercial) vacuum or gas tight chambers designed for use with 10% ethylene oxide and 90% carbon dioxide. This product may be used only by persons who have been trained in accordance with 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.

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 manufacturer's Operator's Manuals.

This product may be used only to sterilize medical or laboratory items, pharmaceuticals, and aseptic packaging or to reduce microbial load on cosmetics, whole and ground spices, and other processed natural seasoning materials except mixtures to which salt has been added (see 40 CFR 180.151 and CFR 185.2850).

This product should be used only by persons experienced in the use of ethylene oxide/carbon dioxide sterilizing gas mixtures or under the supervision of such an experienced person.

Use this product in accordance with the sterilizer manufacturer's equipment and only after reading and understanding the Praxair Material Safety Data Sheet Form No. P-xxxx. Obtain the MSDS from your local supplier. Always check for leaks of the cylinder valve before moving the cylinder into the sterilizing facility. Do not use any oil or grease on valves, regulator, or fittings for delivery of this gas into the sterilizer. Back flow into the container could cause rupture. Always use a back flow preventive device in the cylinder discharge piping. Check for leaks after connecting cylinder to chamber inlet piping.

ACCEPTED
WITH COMMENTS
in EPA Letter dated

STORAGE AND DISPOSAL

MAR 12 1997

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

Storage: Do not store near sources of heat, open flames, or in direct sunlight. Cylinder temperature must not exceed 125 F (52C). To minimize polymerization of ethylene oxide, storage at less than ambient temperature is recommended. Do not puncture or drop cylinders. Secure in upright position. Keep protective cap in place when not in use. Close valve after each use and when empty.

Disposal: The contents of this cylinder must either be used for the label purpose or must be returned to the supplier. Return cylinder to supplier. Do not attempt to dispose of the product.

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, the pesticide registration number is 10330-16