

PM 31 70009-1

1046



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (H7505C)
401 "M" St., S.W.
Washington, D.C. 20460

EPA Reg. Number:

Date of Issuance:

70009-1

APR 30 1997

Term of Issuance: Conditional

Name of Pesticide Product:

Ethylene Oxide 100

NOTICE OF PESTICIDE:

Registration
 Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Cosmed Group, Inc.
Eight Industrial Drive
Coventry, RI 02816

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. Make the following label changes:

a. Revise the EPA Registration Number to read, "EPA Reg. No. ". 70009-1.

b. Delete the words museum, archival or library objects from the label.

c. Specify product name as being Ethylene Oxide 100 or delete the word "Cosmed" from the label.

3. Submit two copies of the revised final printed label for the record.

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.

Signature of Approving Official:

Date:

M. Windell PM 31/AD/OPP

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ACCEPTED
NO COMMENTS
EPA Letter Dated:

Cosmed ETHYLENE OXIDE 100

APR 30 1987

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

70009-1

Active Ingredient:

Ethylene Oxide.....100.0%

This product contains 7.25 pounds of Ethylene Oxide per gallon at 20°C.

User must follow the requirements of OSHA occupational exposure standard
for ethylene oxide (29 CFR 1910.1047)

Keep Out of Reach of Children DANGER - PELIGRO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

STATEMENT OF PRACTICAL TREATMENT

IN ALL CASES 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 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

ANTIDOTE: No specific antidote. Treat symptomatically and supportively.

Manufactured for:
Cosmed Group, Inc.
Eight Industrial Drive
Coventry, Rhode Island 02816
Phone: (401) 828-0080

NET CONTENTS: 400 Pounds

EPA Reg. No: 70009-R

EPA Est. No:

97 FEB 11 12:49

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER!

CAUSES EYE AND SKIN BURNS. HARMFUL IF INHALED. MAY CAUSE NERVOUS SYSTEM DAMAGE.

CANCER HAZARD AND REPRODUCTIVE HAZARD.

EFFECTS FROM 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, cyanoses, loss of coordination, convulsions, coma, delayed lung injury (fluid in lungs), immediate or delayed skin irritation and blisters, allergic skin.

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

PHYSICAL OR CHEMICAL HAZARDS

DANGER. Nonflammable Liquid and Gas Under Pressure. Do not use or store near heat or flame.

FIRE AND EXPLOSION HAZARD: Dangerous fire hazard when exposed to heat or flame. Vapors are heavier than air and may travel a considerable distance to a source of ignition and flash back. Vapor-air mixtures are explosive.

EXTINGUISHING MEDIA: Dry chemical, carbon dioxide, water spray or alcohol-resistant foam (1993 Emergency Response Guidebook, RSPA P 5800.6). For larger fires, use water spray, fog or alcohol-resistant foam (1993 Emergency Response Guidebook, RSPA P 5800.6).

FIREFIGHTING: Let burn unless leak can be stopped immediately. Move container from fire area if you can do it without risk. Fight fire from maximum distance. Stay away from ends of tanks. For massive fire in cargo area, use unmanned hose holder or monitor nozzles; if this is impossible, withdraw from area and let fire burn. Withdraw immediately in case of rising sound from venting safety device or any discoloration of tank due to fire. Isolate for 1 mile in all directions if tank, rail car or tank truck is involved in fire (1993 Emergency Response Guidebook, RSPA P 5800.6, Guide Page 69). Extinguish only if flow can be stopped; use water in flooding amounts as a fog, solid streams may not be effective. Apply water from as far a distance as possible. Cool containers with flooding quantities of water. Avoid breathing corrosive vapors, keep upwind. Evacuate to a radius of 5000 feet if fire is prolonged and material is confined in the containers. Evacuate to a radius of 5000 feet for uncontrollable fire. Water may be ineffective. (NFPA 325, Fire Hazard Properties of Flammable Liquids, Gases, and Volatile Solids, 1994).

FLASH POINT: -20 °F (-29 °C) (CC); **LOWER EXPLOSIVE LIMIT:** 3% ; **UPPER EXPLOSIVE LIMIT:** 100%; **AUTOIGNITION:** 804 °F (429 °C); **FLAMMABILITY CLASS (OSHA):** 1A

HAZARDOUS COMBUSTION PRODUCTS: Thermal decomposition products may include toxic oxides of carbon.

ACCEPTED
with COMMENTS
by EPA Letter Dated

APR 30 1997

Under the Federal Insecticide, Fungicide, and Rodenticide Act
is granted, for the pesticide
under EPA Reg
7007-1

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Precautionary Statements Continued

OCCUPATIONAL SPILL OR LEAK: Shut off ignition sources. Stop leak if you can do it without risk. Use water spray to reduce vapors. Do not get water inside container. For small spills, flush area with flooding amounts of water. For larger spills, dike spill for disposal. No smoking, flames or flares in hazard area! Keep unnecessary people away; isolate hazard area and deny entry. Evacuate area endangered by gas.

Environmental Hazards:

Do not discharge effluent containing this active ingredient into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

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 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 100% ethylene oxide. 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 manufacturers' Operators 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 185.2850), and museum, archival or library objects.

1. **KEEP THIS CONTAINER AND ITS CONTENTS AWAY FROM HEAT, LIGHTS, FLAMES, FIRES AND SPARK PRODUCING DEVICES.** Ethylene Oxide is extremely flammable and its vapors will explode if ignited. Ethylene Oxide vapor decomposes explosively when heated above 550° C. Store and use in adequately ventilated area.
2. This container is designed to discharge only liquid Ethylene Oxide. If ethylene oxide gas is required, use vaporizing equipment.
3. Use only spark proof tools. Use only steel piping and connections when using Ethylene Oxide with an inert gas as it may contain acetylene. Do not use copper, magnesium or silver materials since they may react with acetylene and an explosion may result. Never use rubber. Ground all equipment including this container to avoid static sparks. Only explosion-proof electrical equipment should be used where Ethylene Oxide may be present.
4. Keep drum upright for discharge (see 2 above). Connect "Y" valve marked "VENT" (number 7200) through pressure regulator and check-valve to source of inert gas, such as nitrogen. The working pressure of this drum is 50 psi gauge. **DO NOT USE COMPRESSED AIR. DO NOT APPLY HEAT TO THIS CONTAINER BY ANY MEANS.**
5. Always install check-valve in line from this drum to processing equipment to prevent backflow into drum. Then open valve marked "LIQUID" (number 7201) which is connected to an eductor tube for liquid discharge. **THIS VALVE HAS LEFT-HAND THREADS.** Keep valve nos. 7200 and 7201 closed when not in use.

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EPA LETTER DATED

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- 6. Observe all local laws, regulations, ordinances, and insurance regulations covering the storage and use of flammable material.

Storage and Disposal

Storage: Do not store near heat or open flame in a well ventilated area. Do not contaminate water, food or feed by storage, disposal or cleaning of equipment. To delay deterioration store out of sun and away from heat. **USE WITHIN 120 DAYS OF RECEIPT.**

Disposal:

Pesticide: Do not discharge effluent containing this active ingredient into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Container: Do not reuse empty container. When empty, this drum should be returned to the original shipping point with a nitrogen pressure of 50 psig at 70° F or equivalent at ambient temperature.

Stability and Reactivity

Reactivity: Decomposes violently above 800 F, and may be readily initiated into explosive decomposition in absence of air.

Conditions to Avoid: Extremely flammable; may be ignited by heat, sparks or flames. Vapors may travel to a source of ignition and flash back. Container may explode in heat of fire.

INCOMPATIBILITIES:

- ACIDS: Exothermic polymerization.
- ALCOHOLS: Possible explosion.
- ALKALI METAL HYDROXIDES: Violent polymerization reaction.
- ALKANETHIOLS: May react violently under pressure.
- ALUMINUM CHLORIDE: Exothermic polymerization.
- ALUMINUM OXIDE: Violent polymerization.
- AMINES: Possible explosive polymerization.
- AMMONIA: Violent polymerization.
- BROMOETHANE: Incompatible.
- COPPER AND ALLOYS: Possible explosion if traces of acetylene are present.
- GLYCEROL: Violent condensation.
- IRON CHLORIDES: Violent polymerization.
- IRON(III) HEXACYANOFERRATE(4-)(“IRON BLUE PIGMENT”): Exothermic reaction yielding spontaneously combustible product.
- IRON OXIDES: Violent polymerization.
- MAGNESIUM: Possible explosion if traces of acetylene are present.
- MAGNESIUM PERCHLORATE: Possible explosion.
- MERCAPTANS: Possible explosion.
- MERCURY AND ALLOYS: Possible explosion if traces of acetylene are present.
- M-NITROANILINE: Possible explosion on heating.

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 WITH COMMENTS
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Storage And Disposal Continued

- OXIDIZERS (STRONG): Fire and explosion hazard.
- OXYGEN: Possible ignition if rapidly compressed.
- PLASTICS, RUBBER, COATINGS: May be attacked.
- POTASSIUM: Explosive reaction.
- RUST: Explosive polymerization.
- SILVER AND ALLOYS: Possible explosion if traces of acetylene are present.
- SODIUM HYDROXIDE: Exothermic polymerization.
- SUCROGLYCERIDE: Exothermic reaction when heated.
- TIN CHLORIDES: Violent polymerization.
- TRIMETHYLAMINE: Exothermic polymerization.

HAZARDOUS DECOMPOSITION:

Thermal decomposition products may include toxic oxides of carbon.

POLYMERIZATION:

May polymerize violently when exposed to heat or flame, or when catalyzed by acids, alkalis, metal oxides, metal chlorides or some active metals.

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