

67470-7

09/15/2008

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

John Jones
Global Leader Product Stewardship
Honeywell Specialty Materials
101 Columbia Road
Morristown, NJ 07962

SEP 15 2008

Subject: Ethylene Oxide 100R
EPA Registration 67470-7
Amendment Dated: June 16, 2008
EPA Received Date: June 17, 2008

Dear John Jones

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					Velma Noble Product Manager (31)		
URNAME					Regulatory Management Branch 1		
ATE					Antimicrobial Division (7510c)		

PRECAUTIONARY STATEMENTS

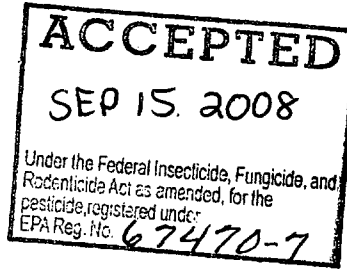
HAZARDS TO HUMANS AND DOMESTIC ANIMALS.

DANGER! EXTREMELY FLAMMABLE LIQUID AND GAS UNDER PRESSURE. MAY CAUSE EXPLOSIVE MIXTURES WITH AIR. CAUSES EYE AND SKIN BURNS. HARMFUL IF INHALED. HARMFUL IF SWALLOWED. MAY CAUSE RESPIRATORY AND 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, lightheaded 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: 1PPM-TWA Ethylene Oxide (OSHA-29CFR1910.1047)
EL: 5PPM-excursion limit, 15 minutes.



ETHYLENE OXIDE 100R

STERILANT-FUMIGANT GAS.

ACTIVE INGREDIENT: ETHYLENE OXIDE (CAS 75-21-8) 100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER PELIGRO

PRECAUCION AL USUARIO: Si usted no lee Ingles, no use este producto hasta que la etiqueta la haya sido explicada ampliamente.

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

ODOR: Ether-like at 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, on clothing. Store and use with adequate ventilation in accordance with 29 CFR 1910.1047

PHYSICAL AND CHEMICAL HAZARDS

Ethylene oxide is extremely flammable and reactive. Contents under pressure. Keep away from heat, flame, sparks or hot surfaces. Do not allow sources of ignition near the sterilization/fumigation area. Use only in closed system. No part of the container may be exposed above 125°F (52°C). Close valve when not in use and when empty. Use in accordance with tag attached to valve. Ground all equipment, including containers, to avoid static sparks.

LEAK: Evacuate area and keep personnel upwind. Use 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.

Personal Protective Equipment

Some materials that are chemical-resistant to this product are 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 (including 29CFR 1910.1047 and 29CFR 1910.134), under routine and reasonably foreseeable emergency situations.

When handlers could have eye or skin contact with ethylene oxide or ethylene oxide 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 ethylene oxide or ethylene oxide solutions, and
- > Face-sealing goggles, a full face shield, or a full-face respirator.

1. Follow the respirator manufacturer's user's instructions for changing canisters.
2. Respirators must be fit-tested and fit-checked using a program that conforms to OSHA's requirements (see 29CFR, Part 1910.134).

3. Respirator users must be trained using a program that confirms to OSHA's requirements (see 29CFR Part 1910.134).

4. 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 or 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."

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public waters unless this 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.

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 Pollution 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.

FIRST AID

IN ALL CASES OF OVEREXPOSURE, GET MEDICAL ATTENTION IMMEDIATELY. CALL THE POISON CONTROL CENTER OR DOCTOR FOR TREATMENT ADVICE.

IF INHALED: Remove exposed person to fresh air, keep warm. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call the Poison Control Center or doctor for advice even if no symptoms are present. Keep under medical observation. Symptoms may be delayed.

IF IN EYES: Hold eyelids open and rinse slowly and gently with water for 15-20 minutes. Call the Poison Control Center or doctor for advice.

IF ON SKIN OR CLOTHING: Immediately rinse with plenty of water for 15-20 minutes while removing contaminated clothing and shoes. Call the Poison Control Center or doctor for advice. Aerate, wash or clean contaminated clothing and discard leather goods.

IF SWALLOWED: Call the Poison Control Center or doctor for advice. Give at least two glasses of water. Do not induce vomiting. Do not give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN: REFER TO SECTION IV, FIRST AID MEASURES OF THE MSDSs FOR EACH INGREDIENT. To obtain MSDSs, call 1-800-522-8001.

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.

IN CASE OF EMERGENCY CALL:

1-800-498-5701. Have a copy of the label or the MSDS when calling a poison control center or doctor or going for treatment.

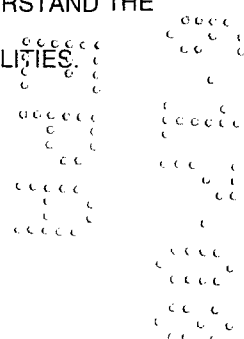
BEFORE USING OR HANDLING THIS PRODUCT YOU MUST ALSO READ AND UNDERSTAND THE HONEYWELL MATERIAL SAFETY DATA SHEET FOR THIS PRODUCT.

FOR INDUSTRIAL USE ONLY. NOT FOR USE IN HOSPITALS OR HEALTHCARE FACILITIES.

DOT/IMO Shipping Name: Ethylene Oxide

Hazard Class: 2.3, (2.1) Honeywell

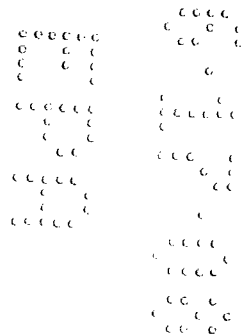
ID Number: UN1040 INHALATION HAZARD



STB 0800 EO 6/13/2008

101 Columbia Rd., Morristown, NJ 07962-1053
EPA Registration No. **67470-7** EPA Establishment No. **67470-AZ-001**
NET CONTENTS- BATCH- DO NOT REMOVE THIS LABEL MADE IN USA STB-0800 (11/07)

STB 0800 EO 6/13/2008



DO NOT REMOVE TAG
ETHYLENE OXIDE 100R
STERILANT-FUMIGANT GAS
DANGER! EXTREMELY FLAMMABLE AND EXPLOSIVE
HARMFUL IF INHALED.
DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.
NOTE TO USER:When used in the workplace, it is the employer's responsibility to ensure that all personnel are familiar with and adhere to 29 CFR 1910.1047. Ethylene Oxide is a highly hazardous material and must be used only by personnel trained in its proper use. All persons working with Ethylene Oxide must have knowledge of the hazards of this chemical and must be trained in the proper use of required respirator equipment, monitoring and detection devices, and in the implementation of emergency procedures.

To be used only by persons experienced in Ethylene Oxide sterilization and fumigation, or by persons under direct supervision of persons who are experienced in ethylene oxide sterilization and fumigation. Use only in accordance with the directions and the safety precautions listed on the label and this tag. See current Honeywell Material Safety Data Sheet for Ethylene Oxide.

STERILIZATION AND FUMIGATION

Any product formulated from this product that is registered as a technical or manufacturing use product must include the following label language.

Only for formulation into a biocide, fungicide, fumigant, herbicide, insecticide, or rodenticide for the following use(s) medical equipment and supplies, musical instruments, library/museum artifacts, cosmetics

This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator or user group has complied with U.S. EPA submission requirements regarding support of such use(s).

This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator or user group has complied with U.S. EPA submission requirements regarding support of such use(s).

Ethylene oxide must be used only to sterilize medical and laboratory items, pharmaceuticals, aseptic packaging, and to reduce the microbial load on cosmetics and artifacts, archival material or library objects. Items to be sterilized must be thoroughly cleaned of soil before being placed in any type of sterilizer.

A. Ethylene oxide must be used only in facilities that meet the requirements of 29 CFR 1910.1047 in nonportable (commercial) vacuum or gas-tight chambers designed for use with 100.0% ethylene oxide.

Ethylene oxide must be used only by persons who have been trained in accordance with 29 CFR 1910.1047. When used to sterilize health care items, ethylene oxide must be used in non-portable (commercial) ethylene oxide gas sterilizers that have FDA clearance, and in accordance with directions supplied by the sterilizer manufacturer. In hospitals and healthcare facilities, sterilization/fumigation with ethylene oxide must be performed only in vacuum or gas tight chambers designed for use with ethylene oxide. After February 28, 2010, a single chamber process is required for ethylene oxide treatment (sterilization and aeration are to occur in the same chamber) in hospitals and healthcare facilities.

NOTE: It is a violation of Federal Law to use ethylene oxide sterilant/fumigant gas for the fumigation of beehives, airplanes, trains, buses, ships, trucks, trailers, warehouses, or other similar spaces.

In contract sterilization facilities, including facilities treating medical equipment and supplies, library/museum artifacts and cosmetics the following requirements must be followed:

Sterilization/fumigation with 100R must be performed only in vacuum or gas tight chambers designed for use with 100R. Safety and awareness training is required for all employees including office staff. Information must be provided to all employees in the facility at the time of initial assignment and annually thereafter.

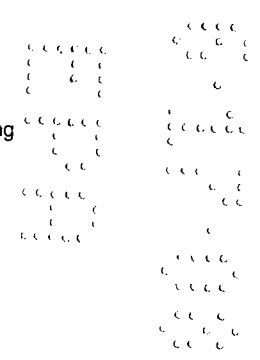
The safety training must include, at a minimum, the following information:

- 1. the most recent monitored ambient levels of ethylene oxide in the facility;
- 2. the potential health effects from the levels of ethylene oxide 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 ethylene oxide.

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.

B. Ethylene oxide cycle parameters depend on several sterilizing/fumigating variable factors: preconditioning (if any); exposure time; chamber air concentration; ethylene oxide concentration; chamber temperature; humidity level; types and quantities of items to be sterilized/fumigated; packaging; load configuration in the chamber; microbial challenge method; desired level of sterility assurance; and the desired performance of the sterilized; fumigated product and package.



C. The following is a list of ranges for the critical variables which must be in proper relationship for ethylene oxide to be an effective sterilizing/fumigating agent. This information should be considered general, and not as a replacement for detailed information issued by manufacturers.

TEMPERATURES - 70°F TO 150°F

PRE-VACUUM - typically 25 to 28 inches of mercury. Use vacuums compatible with the products and packages to be sterilized/fumigated, and such that explosive atmospheres are never present in the chamber.

MOISTURE - relative humidity of 33% to 80%

GAS CONCENTRATION - 250 mg/L to 1500 mg/L milligrams of ethylene oxide per liter of chamber volume.

EXPOSURE TIME - 45 minutes to 20 hours

POST-VACUUMS - Ethylene oxide is removed from the chamber and vented to an appropriate ethylene oxide capture or destruction device.

AERATION - aerate sterilized/fumigated materials before use. Do not allow any person to enter the chamber or aeration area if such entry will result in exposures to ethylene oxide above the levels established in 29 CFR 1910.1047.

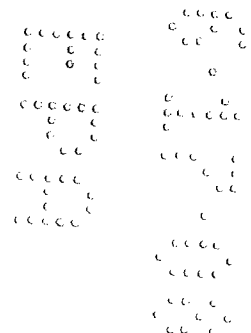
Cycle parameters and post cycle aeration parameters (temperature, time, air flow-rate) can affect residue levels. The user must determine that the parameters chosen result in goods which comply with applicable Federal and State residue requirements. For residual limits of ethylene oxide on drug products and medical products see 21 CFR 201.1 sub-section (d). For residual limits on agricultural commodities see 40 CFR 180.151.

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D. The sterilization/fumigation cycle parameters should be those prescribed by the sterilizer equipment manufacturer. If other cycle parameters are used, the safety and efficacy of the alternate cycle parameters must be validated and are the responsibility of the user.

NEVER USE PARAMETERS WHICH ALLOW FLAMMABLE MIXTURES OF ETHYLENE OXIDE AND AIR TO ENTER THE CHAMBER.

E. Employers in facilities that use ethylene oxide must comply with all of the requirements for ethylene oxide use specified in 29 CFR 1910.1047.



GENERAL INSTRUCTIONS

1. Always check container valves and relief valves for leaks before moving cylinder into your facility.
2. This container is equipped with an eductor tube for liquid delivery. If ethylene oxide gas is required, use vaporizing equipment.
3. This container has been pressurized with nitrogen to a pressure of 50 psig (3.52kg/cm²) at 70°F (21.1°C). Vapor pressure will be higher if temperature is above 70°F (21.1°C); lower if temperature is below 70°F (21.1°C). Contact supplier if, upon receipt, container pressure is below 50 psig (3.52kg/cm²) at 70°F (21.1°C).
4. Container must be in an upright position when discharging. Cylinders must be secured to prevent falling over.
5. Liquid withdrawal valve (marked "Liquid") is provided with a CGA 510 connection which has left-hand threads.
6. EOX and SS.55 style cylinders and DOT 5P drums are also provided with a CGA 580 inert pressurizing valve (marked "Vent") which has right-hand threads. Do not discharge product from the CGA 580 inert pressurizing valve.
7. Remove protective valve plugs and make sure valve threads are undamaged. Do not attach an ordinary pipe fitting to these valves. The connections to the container valves should be brass CGA 510 and CGA 580 connectors. Use of other metals could cause damage to the brass container valves.
8. All other piping and fittings should be steel or stainless steel fittings and piping capable of withstanding the pressure to be encountered. Do not use rubber, plastics, or copper materials. Install relief devices where liquid can be trapped between valves.
9. Ground all equipment, including containers, to avoid static sparks.
10. Use only spark-proof tools.
11. Use only explosion-proof electrical equipment where ethylene oxide may be present.
12. Install check valves in the discharge line from this container to processing equipment to prevent backflow into the container.
13. Connect the CGA 580 inert pressurizing valve (marked "Vent") to a source of nitrogen using a line equipped with a pressure regulator, safety relief valve and check valve. The source of nitrogen should be used exclusively for ethylene oxide and for no other purpose. Nitrogen pressure must not exceed the service pressure of the container. Never use compressed air or other gases to pressurize the cylinder or drum.
14. To open container valves, turn counterclockwise. The liquid discharge valve is equipped with a handwheel. Do not use a wrench or other leverage device on handwheel. Use a "T" wrench to open the inert pressurizing valve on the EOX and SS.55 cylinders and 5P drums.
15. Use with adequate general and local ventilation. Vapors form from this product and may travel or be moved by air currents and ignited by pilot lights, other flames, smoking, sparks, heaters electrical equipment, static discharges or other ignition sources at location distant from product handling point.
16. Determine the quantity of product withdrawn from this container by using an appropriate scale.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE

Store according to instructions provided on label and this tag. Store away from heat in an area with adequate ventilation. Do not store in direct sunlight. To minimize polymer growth, ethylene oxide must not be stored in any place where the temperature consistently exceeds 100°F. To control ethylene oxide polymer growth, use all sterilant gas on a first-in, first-out-basis. To minimize sterilizer downtime, it is recommended to use product within 12 months of the fill date marked on the container (batch number).

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 DISPOSAL

Return container to supplier for reuse. Before returning container to supplier:

- A. Pressure container with nitrogen to 50 psig total pressure at 70°F (21.1°C) and be sure container valves are closed.
- B. Replace valve plugs tightly in valve outlets. If valve plugs are not available, contact supplier.
- C. Check container valves and plugs for leaks prior to shipment. If leaks are detected, contact supplier.

101 Columbia Road
Morristown, NJ 07962-1053
EPA Registration No. 67470-7 STT-0800 (11-07)

