

89514-1

5/20/2013

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U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

EPA Reg. Number: 89514-1

Date of Issuance: MAY 20 2013

Term of Issuance: Conditional

Name of Pesticide Product: Ethylene Oxide

NOTICE OF PESTICIDE:

[x] Registration
Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Sterigenics U.S., LLC
2015 Spring Road
Oak Brook, IL 60523

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 (OPP Decision No. D-472787) 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 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 re-registration of your product under FIFRA section 4.
2. Make the labeling changes listed below before you release the product for shipment:
a. Revise the "EPA Registration Symbol to read, "EPA Reg. No." 89514-1

Signature of Approving Official:

Verma Noble
Product Manager Team-31
Regulatory Management Branch
Antimicrobials Division (7510P)

Date:

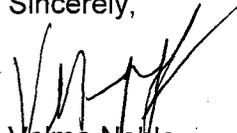
MAY 20 2013

3. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised 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. Should you have any questions regarding this letter, please contact Drusilla Copeland at (703) 308-6224 or Velma Nobel at (703) 308-6233.

Sincerely,



Velma Nobel
Product Manager (31)
Regulatory Management Branch
Antimicrobials Division (7510P)

Enclosure: stamped label, product chemistry review dated 3/13/2013 and tox review dated 4/24/2013

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ETHYLENE OXIDE

STERILANT/FUMIGANT

ACTIVE INGREDIENT: ETHYLENE OXIDE... 100%
(CAS NO: 75-21-8)

DANGER PELIGRO

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

Keep Out of Reach of Children

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 SWALLOWED - Call poison control center or doctor immediately for treatment advice. Have person sip two glasses of water if able to swallow. Do not induce vomiting. Do not give anything by mouth to an unconscious person.

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

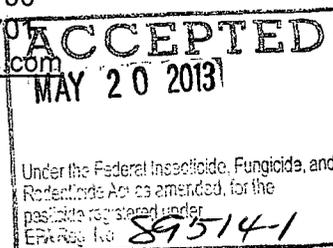
HOTLINE NUMBER- Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-424-9300 for emergency medical treatment information.

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.

EPA Registration No.: 89514-R
EPA Establishment No.: XXXXX-XX-XX

Sterigenics U.S., LLC
2015 Spring Road, Suite 650
Oakbrook, IL 60523
Tel.: 630-928-1700
Fax: 630-928-1700
www.sterigenics.com

Net Contents: _____ lbs



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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.

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, lightheaded 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).

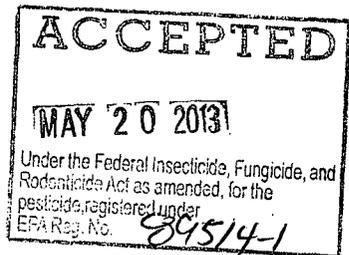
PERSONAL PROTECTIVE EQUIPMENT (PPE):

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 should 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 contract ETO or ETO solutions, and
- Face-sealing goggles, a full face shield, or a full-face respirator.

When wearing respirators:

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 29 CFR Part 1910.134).
3. Respirator users must be trained using a program that conforms to OSHA's requirements (see 29 CFR 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 of respirator use conditions change (see 29 CFR Part 1910.134).

Follow manufacturer's instructions for cleaning/maintenance 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.

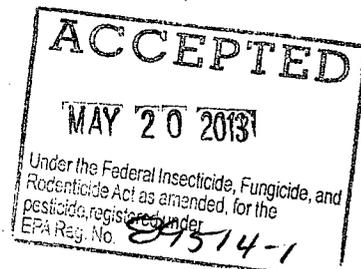
LEAK - In case of leak evacuate area and keep personnel upwind. Shut off all sources of ignition. Use self-contained breathing apparatus and protective clothing, and shut off leak if without risk.

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 Effluent 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 Sterigenics' Material Safety Data Sheet for 100% Ethylene Oxide, the label and valve tag attached to this pressurized drum.



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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 of 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 20% ethylene oxide, 80% carbon dioxide. 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 non-portable (commercial) ethylene oxide gas sterilizers that have FDA clearance.

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. AS A STERILANT AND FUMIGANT GAS:

A. 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, (see 21 CFR 201.1(d)(5)), or 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.

USE THIS PRODUCT WITHIN 120 DAYS OF ITS PURCHASE.

DO NOT REMOVE THIS LABEL.

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

ACCEPTED
MAY 20 2013
 Under the Federal Insecticide, Fungicide, and
 Rodenticide Act as amended, for the
 pesticide registered under
 EP: Reg. No. 89514-1

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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.

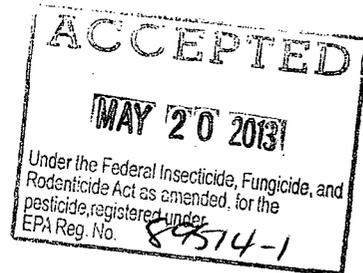
B. Sterilization/fumigation with Ethylene Oxide must be performed only in vacuum or gas tight chambers designed for use with Ethylene Oxide.

C. Ethylene Oxide cycle parameters depend on several sterilizing/fumigating variable factors: pre-conditioning (if any); exposure time; chamber air pressure; gas concentration; types and quantities of items to be sterilized/fumigated; packaging; load configuration in the chamber; microbial challenge method; desired degree of disinfection; and the desired performance of the sterilized/fumigated product and package.

D. The sterilization/fumigation cycle parameters should be those prescribed by the 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.

2. INSTALLATION AND OPERATION OF THE CONTAINER - Follow the directions on the valve tag attached to this container.



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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 under lock and key. Avoid exposure to heat or direct sunlight as may cause polymerization. Post as a pesticide storage area.

Pressurized drums should not be subjected to rough handling or mechanical shock such as dropping, bumping, dragging, or sliding. Do not use rope slings, hooks, tongs, or similar devices to unload drums. Transport drums using hand truck, fork truck or other device to which the drum can be firmly secured.

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 HANDLING: Nonrefillable container. Do not reuse or refill this container.
When drum is empty, close valve and screw safety cap onto valve outlet before returning to shipper. Only the registrant is authorized to refill drums. Do not use drums for any other purpose. Follow registrant's instructions for return of empty or partially empty drums.

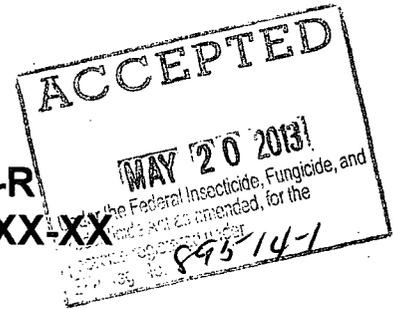
ACCEPTED
MAY 20 2013
Under the Federal Insecticide, Fungicide, and
Rodenticide Act as amended, for the
pesticide, registered under
EPA Reg. No. 89514-1

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DO NOT REMOVE THIS TAG

ETHYLENE OXIDE

**EPA REGISTRATION NO. 89514-R
EPA ESTABLISHMENT NO. XXXXX-XX-XX**



**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. It is the employer's responsibility to follow the requirements of the Ethylene Oxide Standard (29 CFR 1910.1047). Use only in accordance with the directions and safety precautions listed on the label and on this tag. See current Sterigenics' Material Safety Data Sheet for this product.

General Directions

1. Always check container valves and plugs for leaks before moving container into your facility.
2. This container is designed to discharge only liquid ethylene oxide. If ethylene oxide gas is required, use vaporizing equipment.
3. This container has been pressurized with nitrogen to a pressure of 50 psig (3.52 kg/cm²) at 70°F (21.1°C); lower if temperature is below 70°F. Contact supplier if, upon receipt, container pressure is below 50 psig at 70°F.
4. Container must be in an upright position when discharging.
5. Liquid withdrawal valve is provided with a CGA 510 connection, which has left-hand threads.
6. Cylinders and DOT 1A1 drums are also provided with a CGA inert pressurizing valve, which has right-hand threads. Do not discharge product from the inert pressurizing valve.
7. Remove protective valve plugs carefully and make sure valve threads are undamaged.
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, plastic, or copper materials. Install relief valves where liquid can be trapped between valves.
9. Ground all equipment, including this container, to prevent static sparks.
10. Use only spark-proof tools.
11. Use only explosion-proof electrical equipment which conforms to the current requirements of the National Electric Code (see NFPA #70) where ethylene oxide may be present.
12. Install check valves in the discharge line from this container to processing equipment to prevent back flow into the container.
13. Connect the inert pressurizing valve 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 exclusively used 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 gasses to pressurize the cylinder or drum. **DO NOT APPLY HEAT TO THIS CONTAINER BY ANY MEANS.**

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14. To open container valves, turn counterclockwise. For those containers with are equipped with a handwheel, do not use a wrench or other leverage device.
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 locations distant from product handling point.
16. Determine the quantity of product withdrawn from this container by using an appropriate scale.

STORAGE AND DISPOSAL

Store according to the directions provided on this tag and on the product label. To control ethylene oxide polymer growth, use all sterillant gas on a first in/ first out basis. Our recommendation is to use all of this product within 120 days of its receipt. To minimize polymer growth, this product should not be stored in any place where the temperature exceeds 100°F. Do not store this product in direct sunlight.

STORE IN AN AREA WITH ADEQUATE VENTILATION

CONTAINER SHOULD BE RETURNED TO SUPPLIER FOR REUSE. BEFORE RETURNING CONTAINER TO SUPPLIER:

- A. PRESSURIZE CONTAINER WITH NITROGEN TO 50 PSIG TOTAL PRESSURE AT 70°F AND BE SURE CONTAINER VALVES ARE CLOSED.
- B. REPLACE VALVE PLUGS SECURELY IN VALVE OUTLET. 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.
- D. THIS TAG MUST REMAIN AFFIXED TO DRUM OR CYLINDER AT ALL TIMES. WHEN EMPTY THIS CONTAINER MUST BE RETURNED TO THE ORIGINAL SHIPPING POINT IN ACCORDANCE WITH THE DIRECTIONS ABOVE. IT IS THE PROPERTY OF:

STERIGENICS U.S., LLC
2015 SPRING ROAD
OAK BROOK, IL 60523

