

7182-1

04/09/2010

111

Susan M. Price
Senior Regulatory Specialist
3M Company.
3M Center Bldg 220-6E-03
St. Paul MN 55144-1000

APR - 9 2010

SUBJECT: 3M Steri-Gas Cartridges
EPA Registration Number: 7182-1
Application Date: March 4, 2010
Receipt Date: March 11, 2010

Dear Ms Price:

This letter acknowledges receipt of the notification identified above submitted under the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

Proposed Notification

- Add Language for Ethylene Oxide
- Revise canister label by adding the phrase, "Use only after reading directions for use."

Based on a review of the submitted information, this notification is acceptable and will be made part of the record for this file. Your proposed label language is in agreement with the 2008 Reregistration Eligibility Document (RED) for Ethylene Oxide.

General Comments

Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,

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

CONCURRENCES							
SYMBOL	7510P:T.Lantz:4/9/10:7182-1a ETO RED notification						
SURNAME	S. Lantz						
DATE	4/9/10						



March 4, 2010

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
US EPA
1200 Pennsylvania Ave, NW
Washington DC 20460-0001

TO: Velma Noble
PM Team 31
Antimicrobials Division

RE: Notification to Amend Package Insert and canister label
3M Steri-Gas (EPA Reg # 7182-1)

Dear Ms. Noble,

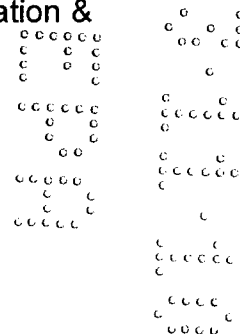
3M is re-submitting changes to the label and package insert for the above referenced product. Instead of using the more succinct language EPA approved on our supplier's labels (Balchem 36736-2), this submittal has inserted exact language outlined in the Ethylene Oxide RED (Mar. 2008) with one exception. In the rejection letter, we were instructed to use the term "must" in place of "should" in the User Safety Recommendation boxed statements regarding removal of PPE/clothing. "Should" is the mandatory wording in the RED document which we have been directed to follow exactly.

This submittal consists of 2 parts:

Canister label – with one added statement alerting user to read new use directions on package insert

Package Insert (deletions/changes are highlighted on the enclosed (5) copies):

- Delete use on ground spices and other seasoning materials
- Adds "offer for recycling" to Container Disposal
- Adds PPE sections and amends Directions for Use as per RED requirements for occupational use in contract sterilization & hospitals/health care facilities



Page 2 USEPA Notification 7182-1

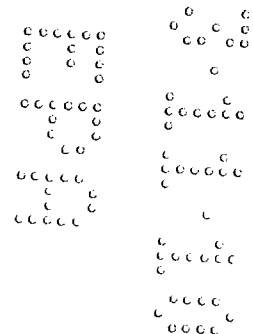
These changes should not be subject to a processing fee since all are at the request of US EPA and are not substantive changes requiring data review. If you have any questions or need anything else, please let me know.

Sincerely,



Susan M Price
Sr. Regulatory Specialist
3M Materials Environmental Health and Safety
3M Center Bldg 220-6E-03
St. Paul MN 55144-1000
Tel: 651 733 3461
Email: smprice1@mmm.com

Barbara C. Swenson
3M Infection Prevention Division, Regulatory Affairs
3M Center, Bldg 275-5W-06
St. Paul, MN 55144
Tel: (651) 733-3010
Fax: (651) 737-5320



Column one

Steri-Gas™

EO Gas Cartridge **8-170**

Active Ingredient: Ethylene Oxide 100%
• Net wt. 170 g (5.99 oz.)

Keep Out of Reach of Children
DANGER
 Extremely Flammable—Do Not Use Near Flame
 Causes Eye and Skin Burns. May Cause Nervous System
 Damage
CANCER HAZARD AND REPRODUCTIVE HAZARD
~~USE ONLY AFTER READING DIRECTIONS FOR USE~~
 Use Only in Accordance With Manufacturer's instructions in
 Steri-Vac™ Gas Sterilizer Model 8XL

Users must follow requirements of the OSHA Occupational Exposure Standard for Ethylene Oxide (29 CFR 1910.1047).
SEE PACKAGE INSERT FOR DIRECTIONS FOR USE, STORAGE AND DISPOSAL AND ENVIRONMENTAL HAZARDS.

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

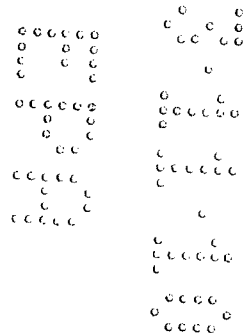
IF INHALED: Move exposed person to fresh air. Keep warm. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. If breathing is difficult, give oxygen. Call a poison control center or doctor immediately for further treatment advice. Call a physician even if no symptoms are present. Keep under medical observation. Symptoms may be delayed.

IF ON SKIN OR CLOTHING: Immediately flush skin with plenty of water for 15-20 minutes while removing contaminated clothing and shoes. Call a poison control center or doctor immediately for treatment advice. Aerate, wash or clean contaminated clothing and discard leather goods.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN: Persons exposed to ethylene oxide may develop severe and intractable vomiting, requiring the use of antiemetics given intravenously. Prolonged or high vapor concentration exposure may result in respiratory tract irritation and the development of pulmonary edema after a latent phase of several hours.



Column two

Skin exposure to Ethylene Oxide will commonly result in skin irritation with extensive blister formation, which may be delayed. At high concentrations, severe conjunctivitis can occur. Symptoms of systemic intoxication are headache, nausea, vomiting, incoordination, and cardiac irregularities. Treatment is symptomatic.

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 OVER EXPOSURE: 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 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 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 AND CHEMICAL HAZARDS: DANGER! FLAMMABLE LIQUID

AND GAS UNDER PRESSURE. Contents under pressure. Do not use near flame, electrical sparks or hot surfaces, or allow sources of ignition near the sterilization/ fumigation area. Ethylene Oxide is extremely flammable and reactive.

Ground all equipment to prevent static sparks. Do not puncture or incinerate container.

Exposure to temperatures above 150°F may cause bursting.

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.

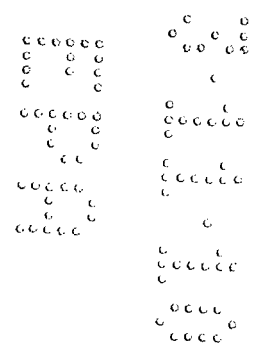
FIRE: In case of fire move container away from fire if without risk. Use water spray or fog nozzle to keep container cool.

SHELF LIFE: Shelf life is five years from date of manufacture as printed on the cartridge.

Made in U.S.A. for 3M Health Care, St. Paul, MN 55144-1000 ©3M 2004

EPA Reg. No. 7182-1

EPA Est 36736-SC-01



Blue text is changes made on the previous submission for the spice/labeling changes.
Red text are RED required changes

PACKAGE INSERT

3M™ Steri-Gas™ Cartridges
(English USA)

KEEP OUT OF REACH OF CHILDREN

DANGER

**EXTREMELY FLAMMABLE – DO NOT USE NEAR FLAME
CAUSES EYE AND SKIN BURNS. MAY CAUSE NERVOUS SYSTEM DAMAGE.
CANCER HAZARD AND REPRODUCTIVE HAZARD**

**Use Only in Accordance With Manufacturer’s instructions in
3M™ Steri-Vac™ Gas Sterilizers**

Users must follow the requirements of the OSHA Occupational Exposure Standard for Ethylene Oxide (29 CFR 1910.1047).

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

IF INHALED: Move exposed person to fresh air. Keep warm. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. If breathing is difficult, give oxygen. Call a poison control center for doctor immediately for further treatment advice. Call a physician even if no symptoms are present. Keep under medical observation. Symptoms may be delayed.

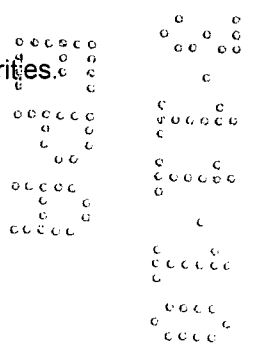
IF ON SKIN OR CLOTHING: Immediately flush skin with plenty of water for 15-20 minutes while removing contaminated clothing and shoes. Call a poison control center for doctor immediately for treatment advice. Aerate, wash or clean contaminated clothing and discard leather goods.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a poison control center for doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN: Persons exposed to ethylene oxide may develop severe and intractable vomiting, requiring the use of antiemetics given intravenously. Prolonged or high vapor concentration exposure may result in respiratory tract irritation and the development of pulmonary edema after a latent phase of several hours. Skin exposure to Ethylene Oxide will commonly result in skin irritation with extensive blister formation, which may be delayed. At high concentrations, severe conjunctivitis can occur. Symptoms of systemic intoxication are headache, nausea, vomiting, incoordination, and cardiac irregularities. Treatment is symptomatic.

**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 OVER EXPOSURE: 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 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 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.

Personal Protection Equipment (PPE):

A material that is chemical-resistant to this product is butyl rubber.

All handlers must wear at a minimum:

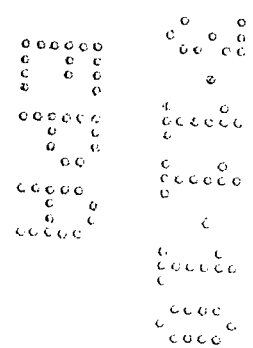
- Long sleeved shirt and long pants,
- Shoes plus socks,
- Chemical-resistant gloves and
- when the ambient ETO concentration is 1 to 50 ppm, full-facepiece respirator with ETO approved canister, front or back mounted,
- when the ambient ETO concentration is 50 to 2,000 ppm, (1) positive-pressure supplied-air respirator equipped with full-facepiece, hood, or helmet: or (2) continuous-flow supplied-air respirator (positive pressure) equipped with hood, helmet, or suit,
- when the ambient ETO concentration is > 2,000 ppm or unknown (e.g. emergency situations), (1) positive-pressure self-contained breathing apparatus equipped with full-facepieces; or (2) positive-pressure full-facepiece supplied-air respirator equipped with an auxiliary positive-pressure self-contained breathing apparatus.

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 contact 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 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 of 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

PHYSICAL AND CHEMICAL HAZARDS: DANGER! FLAMMABLE LIQUID AND GAS UNDER PRESSURE.

Contents under pressure. Do not use near flame, electrical sparks or hot surfaces, or allow sources of ignition near the sterilization/fumigation area. Ethylene Oxide is extremely flammable and reactive. Ground all equipment to prevent static sparks. Do not puncture or incinerate container. Exposure to temperatures above 150°F may cause bursting.

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.

SHELF LIFE: Shelf life is five years from date of manufacture as printed on the cartridge.

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.

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 for ETO use specified in 29 CFR 1910.1047. This product may be used only in facilities that meet requirements of 29 CFR 1910.1047 in 3M™ Steri-Vac™ Gas Sterilizers designed for use with 3M™ Steri-Gas™ EO Gas Cartridges containing 100% ethylene oxide. This product may be used only by persons who have been trained in accordance with 29 CFR 1910.1047.

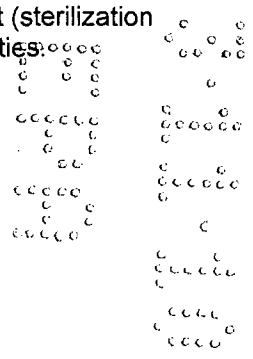
In hospital and healthcare facilities, sterilization/fumigation with ETO must be performed only in vacuum or gas tight chambers designed for use with ETO.

After February 28, 2010, a single chamber process is required for ETO treatment (sterilization and aeration are to occur in the same chamber) in hospitals and healthcare facilities.

In contract sterilization facilities, including facilities treating medical equipment and supplies, musical instruments, library/museum artifacts, and cosmetics, 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. Achieving an ambient level of 0.25 ppm (measured as a daily time-weighted average) greatly reduces 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.

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

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.

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.

STORAGE AND DISPOSAL: Do not contaminate food, feed or water by storage and disposal.

Pesticide Storage: Store at room temperature. Store in accordance with 29 CFR 1910.1047.

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: Do not puncture or incinerate unused cartridges. Aerate empty cartridges according to instructions in equipment manual. After aeration offer for recycling or dispose of immediately with nonincinerated waste

3M
 Made in U.S.A. for
 3M Health Care
 St. Paul, MN 55144-1000
 EPA Reg. No. 7182-1
 EPA Est. 36736-SC-01
 © 3M 2004, All rights reserved.
 34-7057-4930-6

