

7182-1

12/21/2003

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DEC 21 2003

Ms. Joann Huehn
3M Health Care
3M Center- Building 275-5W-06
St. Paul, MN 55144-1000

Subject: Steri-Gas Brand Cartridge
EPA Registration No. 7182-1
Amendment Date: November 19, 2003
EPA Receipt Date: November 19, 2003

Dear Ms. Huehn,

The following amendment submitted in connection with registration under FIFRA, as amended, is acceptable with the following conditions for the reasons listed below.

- Response to Agency letter dated October 21, 2003

Conditions

Revise the label as follows:

Revise the "Storage and Disposal" Statements so that they comply with PR Notice 83-3 by stating:

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, dispose of immediately with nonincinerated waste.

CONCURRENCES

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

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General Comments

A stamped copy of the labeling accepted with conditions is enclosed. Submit three (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 Jacqueline McFarlane at (703) 308-6416.

Sincerely,



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

Enclosure: Stamped Label

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SYMBOL								
SURNAME								
DATE								

**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, 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 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, or on 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.**

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.

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 sewerage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

NOT RECOMMENDED
with COMMENTS
in EPA Letter Dated:

DEC 2 1 2003

3M

Made in U.S.A. for
3M Health Care

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as

E.P.A. Reg. No. 7182-1

recommended, for the pesticide,

EPA Est. 36736-SC-01

registered under EPA Reg. No. 7182-1

STERI-GAS™

EO GAS CARTRIDGE

C

Active Ingredient: Ethylene Oxide 100% •

A

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
Steri-Vac™ Gas Sterilizer Model**

B

Users must follow 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 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 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. 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. Treat is symptomatic.

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 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.

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 PARAMETER WHICH ALLOW FLAMMABLE MIXTURES OF ETHYLENE OXIDE AND AIR TO ENTER THE CHAMBER.

STORAGE AND DISPOSAL: Do not contaminate water, food or feed by storage or disposal. Store at room temperature. Store in use in accordance with 29 CFR 1910.1047.

Pesticide Disposal: Do not puncture or incinerate unused cartridges. Pesticide wastes are acutely hazardous. Improper disposal of excess pesticides is a violation of Federal Law. Contact your State Pesticide or Environmental Control Agency or the Hazardous Waste Representative at the nearest EPA Regional Office for Guidance.

Container Disposal: Aerate empty cartridges according to instructions in equipment manual. After aeration, dispose of immediately with nonincinerated waste.

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