

10/2

AUG 18 1997

Medical Products Group
3M Center 275-3E-08
St Paul, MN 55144-1000

Attention: Marvin L. Hart
Senior Regulatory Affairs Specialist

Subject: Steri-Gas Brand EO Cartridge
EPA Registration Number 7182-1
Your Submission Dated July 30, 1997

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to update your label is acceptable provided that you do the following:

- Under the heading Storage and Disposal, augment the standard storage and disposal statements with specific information regarding shelf-life and conditions which cause EtO to polymerize and possibly become less efficacious. As discussed with Lisa Nisenson on August 1, 1997, a reference to the users manual is acceptable.

The Agency will allow an extra two weeks from the date of receipt to allow for printing and providing inserts to existing stocks.

A stamped copy of your labeling is enclosed for your records. Submit one (1) copy of the final printed label prior to release of the product for shipment.

If you have any questions concerning this letter, please contact Velma Noble at (703) 305- 6233.

Sincerely yours,
Velma Noble
Velma Noble
Acting Product Manager 31
Regulatory Branch 1
Antimicrobial Division (7510W)

CONCURRENCES

SYMBOL								
SURNAME								
DATE							AUG 18 1997	

ATTACHMENT A

ACCEPTED
with COMMENTS
in EPA Letter Dated:

AUG 18 1997

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 7182-1

3M

D

Steri-Gas™

EO Gas Cartridge

C

Active Ingredient: Ethylene Oxide 100% • **A**

top of tube

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 _____

SEE PACKAGE INSERT FOR DIRECTIONS FOR USE, STORAGE AND DISPOSAL.

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.

PRECAUTIONARY STATEMENTS:
HAZARDS TO HUMANS CAUSES EYE AND SKIN BURNS. HARMFUL IF INHALED.
MAY CAUSE NERVOUS SYSTEM DAMAGE.

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 feelings, dizziness, weakness, drowsiness, cyanosis, 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. DDOR: 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. Do not use near flame, electrical sparks or hot surfaces. Ground all equipment to prevent static sparks. Contents under pressure. Do not puncture or incinerate container. Exposure to temperatures above 150deg F may cause bursting.

EPA Reg. No. 7182-1
EPA Est 3657-WI-2

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

INSERT THIS END → **D**

Legend

(A) Net. Wt.	(B) Sterilizer Model No.	(C) Part No.	(D) Accent Color
100 g (3.52 oz)	4XL, 5XL, 400C	4-100	Green
127 g (4.47 oz)	400B	4-134	Red
170 g (5.99 oz)	8XL	8-170	Green