

1/3 36736-3 PM:31

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 14 1988

Arc Chemical Division
Balchem Corp.
Box 180
Slate Hill, NY 10973

Attention: Diane Powers
Vice President

Gentlemen:

Subject: Sterilizing Gas 3
EPA Registration No. 36736-3
Your Submission Dated September 30, 1988

The amendment referred to above, submitted in connection with registration under FIFRA, is acceptable provided that you:

1. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:

- a. Revise the statement: Distributed by to read: Manufactured by.
- b. Revise the ingredient statement to read:

Active Ingredient
 Ethylene Oxide 80%
 Inert Ingredients..... 20%
 Total 100%

- c. The entire precautionary labeling section is blurry and illegible. Refer to Attachment E and include all the appropriate statements.
- d. Add the following headings:
 Precautionary Statements
 Hazards to Human and Domestic Animals
- e. Include the heading Direction For Use.

Note: This statement must be placed above the misuse statement.

f. Include the heading:

Physical or Chemical Hazards

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

g. Delete reference statement:

Refer the MG Industries Material Safety Data Sheet No. 1001.

This registration doesn't belong to MG Industries.

h. This label must include the Storage and Disposal instructions especially instructions for disposal of empty cylinder.

i. Delete the statement:


"Cancer Hazard and Reproductive Hazard".

2. The entire label must be redone to meet all the items outlined in the enclosure "The Label". Just a reminder - Legible readable labels must be submitted for review. In addition always submit five (5) drafts for review.

3. Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the labeling is enclosed for your records.

Sincerely yours,


John H. Lee
Product Manager 31
Antimicrobial Programs Branch
Registration Division (TS-767C)

COMPRESSED GAS
N.O.S.
UN 1954



EPA REG. NO. 36736-3

EPA EST. NO.

- 35084-NJ-1
- 35084-MD-1
- 35084-TN-1
- 35084-TX-1
- 35084-CA-1
- 35084-PA-2
- 35084-GA-1
- 36736-NY-01

(ACTIVE INGREDIENT)

ETHYLENE OXIDE 80 WEIGHT %

(INERT INGREDIENT)

CARBON DIOXIDE 20 WEIGHT %

TOTAL CONTENTS _____ LBS. NET

DANGER: Flammable liquid and gas under pressure. May form explosive mixtures with air. Keep away from heat, flame and sparks. Use equipment rated for cylinder pressure. Store and use with adequate ventilation. Close valve after each use and when empty. Always replace cylinder cap when not in use. Cylinder temperature should not exceed 130°F (54°C). Use in accordance with the sterilizer manufacturer's operating instructions. Refer to MG Industries Material Safety Data Sheet No. 1001. **HEALTH HAZARDS:** Inhalation may result in delayed nausea, narcotic and possible neurotoxic effects which could lead to emphysema, bronchitis and pulmonary edema. Exposure to large concentrations causes rapid circulatory insufficiency leading to coma and death. Contact with rapidly evaporating liquids may cause frostbite or cryogenic burns. **FIRST AID:** If inhaled, remove to fresh air. If not breathing, give artificial respiration, preferably mouth to mouth. If breathing is difficult, give Oxygen. CALL A PHYSICIAN IMMEDIATELY and advise him of the exposure to this gas mixture. In case of eye or skin contact, or frostbite, remove contaminated clothing and flush affected area with luke warm water. **DO NOT USE HOT WATER.**

ACCEPTED
with COMMENTS
in EPA J...

OCT 14 1988

36736-3

**KEEP OUT OF REACH
OF CHILDREN**

DANGER

STATEMENT OF PRACTICAL TREATMENT

- IF INHALED** - Remove to fresh air. If breathing has stopped administer oxygen.
- IF ON SKIN** - Remove contaminated clothing, shower affected areas with water for 15 minutes.
- IF IN EYES** - Irrigate with copious amounts of water for 15 minutes.

DANGER

Contains Ethylene Oxide
Cancer Hazard and
Reproductive Hazard
Avoid Breathing this Gas

It is a violation of Federal
Law to use this product
in a manner inconsistent
with its labeling.

The product is intended to
use by medical profes-
sionals or appropriately
trained technical person-
nel in medical and
industrial use areas.

Distributed by:

ARG CHEMICAL DIV. of Balchem Corp.

P.O. Box 180
Slate Hill, N.Y. 10973