

OCT 18 1988

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

Attention: Diane Powers  
Vice President

Subject: Sterilizing Gas 4  
EPA Registration No. 36736-4  
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 .....	10%
Inert Ingredients.....	90%
Total	100%

- c. The entire precautionary labeling section is blurry and illegible. Readable copies must always be submitted for review.
- d. Add the following headings:

Precautionary Statements  
Hazards to Human and Domestic Animals

In addition refer to Attachment E and include all the appropriate statements to be used with the above headings.

- 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

Note: Refer to the above attachment E for the correct statements to use with the above heading.

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g. Delete reference statement:

Refer the MG Industries Material Safety Data Sheet No. 1002.

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".

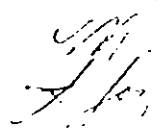
2. The entire label must be redone to meet all the items outlined in the enclosure "The Label". Just a reminder - Legible readable labels must be submitted for review. In addition always submit five (5) drafts for review.

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

4. If you have any questions concerning this letter, contact Valdis Goncarovs at 703-557-3663.

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 1956



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

EPA REG. NO. 36736-4

(ACTIVE INGREDIENT)  
**ETHYLENE OXIDE 10 WEIGHT %**  
(INERT INGREDIENT)  
**CARBON DIOXIDE 90 WEIGHT %**

TOTAL CONTENTS \_\_\_\_\_ LBS. NET

**DANGER:** Liquid and gas under pressure. 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 sterilizer manufacturers operating instructions. Refer to MG Industries Material Safety Data Sheet No. 1002. **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 lukewarm water. **DO NOT USE HOT WATER.**

ACCEPTED  
with COMMENTS  
by EPA

OCT 13 1988

36736-4

**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 limited to  
use by medical profes-  
sionals or appropriately  
trained technical person-  
nel in medical and  
industrial use areas.

Distributed by:

**ARC CHEMICAL Div. of Balchem Corp.**

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