

PA-31

Reg # 50756

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SEP 28 1995

ARC Chemical Corporation
PO BOX 180
Slate Hill, NY 10973

Attention: Mary F. Towle
Regulatory Specialist

Subject: Sterilizing Gas 5
EPA Registration No. 36736-5
Your Letter Dated July 14, 1995

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

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

a. The headings Active Ingredient and Inert Ingredient must be aligned to the same left margin.

b. The Misuse statement: "It is a violation of Federal Law to use this product in a manner inconsistent with its labeling" must be placed directly below the heading "Directions for Use".

c. Add the following precautionary heading:

KEEP OUT OF REACH OF CHILDREN

Place this heading directly above the signal word: Danger which appears in the center panel of the panel.

d. The statement "...wear impervious chemical resistant gloves, boots, head cover..." should be moved to the left panel precautionary labeling section.

e. Revise the statement: "... by medical professionals, or trained technical personnel..." to read: "...by medical professionals or trained technical personnel for sterilizing medical equipment such as instruments in hospitals.

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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f. The Note to Physician statement is required on pesticide labels, especially for this product. The EPA has only jurisdiction over pesticide labels and EPA has no authority over Material Safety Data Sheets(MSDS). The MSDS are under the purview of OSHA.

2. According to our records the company name on file is ARC Chemical Corporation. A formal request must be submitted to change the company name to ARC Chemical Divison Balchem Corporation.

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

4. A stamped copy of the 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, contact V. Goncarovs at 703-305-6663.

Sincerely yours,

Marion Johnson
Product Manager (31)
Antimicrobial Program Branch
Registration Division (7505C)

Enclosures

CONCURRENCES							
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STERILIZING GAS 5

Active Ingredient

Ethylene Oxide 20%
 Inert Ingredients 80%
 Total 100%

EPA EST. NO.

- 35084-TX-1
- 35084-PA-2
- 36736-NY-01
- 36736-SC-02

DOT SHIPPING NAME:

FLAMMABLE GAS

UN 1041

RQ

ARC Chemical Division Balchem Corporation

P.O. Box 180

Slate Hill, NY 10973

(914) 355 - 2891

EPA REG. NO. 36736-5

DO NOT REMOVE THIS LABEL

NET CONTENTS ___ LBS. NET

Ethylene Oxide CAS #75-21-8

Carbon Dioxide CAS #124-38-9

DANGER

PELIGRO

PRECAUTION AL USARIO: Si usted no lee Ingles, no use este producto hasta que la etiqueta le haya sido explicada ampliament.

KEEP OUT OF REACH OF CHILDREN

DANGER! FLAMMABLE LIQUID AND GAS UNDER PRESSURE. CAUSES EYE AND SKIN BURNS. HARMFUL IF INHALED. HARMFUL IF SWALLOWED. MAY CAUSE RESPIRATORY AND NERVOUS SYSTEM DAMAGE.

DANGER! CONTAINS ETHYLENE OXIDE. CANCER HAZARD AND REPRODUCTIVE HAZARD.

PRECAUTIONARY STATEMENTS:

Hazards to Humans and Domestic Animals
 Do not breathe vapor. Do not get in eyes, on skin, or on clothing. Store and use with adequate ventilation.
 Wash thoroughly with soap and water after handling.

EFFECTS OF OVEREXPOSURE: 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 lungs), immediate or delayed skin irritation and 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: 1PPM-TWA (OSHA-29 CFR1910.1047).

EL: 5PPM-excursion limit, 15 minutes.

ODOR: Ether-like at high concentrations. Exposure to toxic levels may occur without warning or detection by the user.

PHYSICAL AND CHEMICAL HAZARDS

Contents under pressure. Use only in a closed system. No part of the container may be exposed above 125°F (52°C). Close valve when not in use and when empty. Use in accordance with tag attached to valve.

ENVIRONMENTAL HAZARDS

Ethylene oxide, the active ingredient in Sterilizing Gas 5 is not intended for outdoor use. Ethylene oxide is a nonpersistent chemical structure which would not be expected to accumulate in the environment. Its moderate level of aquatic toxicity coupled with this nonpersistence should prevent any long-term toxic effects on aquatic systems

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: Move container away from fire if without risk. Use water spray or fog nozzle to keep container cool.

DIRECTIONS FOR USE: This product is limited to use ONLY in commercial gas sterilizers by medical professionals or trained technical personnel. There are a number of critical variables which must be in proper relationship with each other in order for Ethylene Oxide to be an effective sterilizing/fumigating agent. Refer to instructions specific to the sterilizing unit as issued by the sterilizer manufacturer. In situations where a risk of dermal exposure and/or contact with ethylene oxide exists users must wear impervious, chemical resistant gloves, boots, head cover, and clean impervious body covering clothing to prevent any possibility of skin contact.

STORAGE AND DISPOSAL: Store in a cool, well ventilated area. Avoid exposure to heat or direct sunlight. Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE DISPOSAL - Do not dispose of this product. Any surplus product should remain in this cylinder and be returned to the manufacturer for reclaiming through an appropriate scrubbing system.

CONTAINER DISPOSAL - Return this container to manufacturer only.

STATEMENT OF PRACTICAL TREATMENT: IN ALL CASES OF OVEREXPOSURE, 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.

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 or unconscious person. Call a physician.

NOTE TO PHYSICIAN: REFER TO ARC CHEMICAL'S MATERIAL SAFETY DATA SHEET for Sterilizing Gas 5.

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

IN CASE OF EMERGENCY IN USA:
 Call CHEMTREC 1-800-424-9300

SEP 28 1995

BEST COPY AVAILABLE

36736-5