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MAR 03 1995

ARC Chemical Corporation
 PO BOX 180
 Slate Hill, NY 10973

Attention: Joanne K. Cashin
 Manager - Regulatory Affairs

Subject: Sterilizing Gas 4
 EPA Registration No. 36736-4
 Your Amendment Dated November 14, 1994

The amendment (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. Add the following additional statement to the storage disposal section:

Do not contaminate water, food, or feed by storage or disposal.

b. In the storage and disposal section, include the following subheadings:

Pesticide Disposal
 Container Disposal

c. Add the following headings: DIRECTIONS FOR USE

d. Revise Total contents to read: Net Contents

e. Add the following precautionary heading:

KEEP OUT OF REACH OF CHILDREN

Place this heading directly above the signal word: Danger

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- f. Add the following additional precautionary statements to the side panel:

PRECAUTIONARY STATEMENTS
Hazards to Humans and Domestic Animals

- g. Clearly identify the types of objects or items intended for treatment eg. medical instruments and description of surfaces compositions. eg. stainless steel, glass.
- h. Our records indicate now that company number 36736 is assigned to ARC Chemical Corporation. This company must appear on the label.
- i. Revise "First Aid" to read: Statement of Practical Treatment
- j. Refer to PR Notice 83-3 for the appropriate Storage and Disposal statements for the Pesticide Disposal and Container Disposal section of your label.
- k. Refer to PR Notice 93-10 for the appropriate Environmental Hazards statements.
- l. EPA has no jurisdiction over Material Safety Data Sheets. The responsibility of these documents are under the purview of OSHA. Therefore a reference to that MSDS sheet for the Note to Physician statements is not applicable. The reference must be made to another document such as a technical bulletin or tag.
- m. Clearly indicate that this product is to be used only in commercial gas sterilizers.
- n. Add a referral statement to clearly indicate that full use directions for the use of this product are contained in some document or bulletin.
- o. The statement "Industrial Use areas" requires clarification. Clearly indicate the industrial use areas and applications or delete the claim.
- p. Refer to the DIS/TSS-15 for guidance in complete use directions.
- q. Add the following additional precautionary statement:

Wash thoroughly with soap and water after handling.

- r. Include some type of statement regarding protective clothing when using the product.

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

3. 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.

4. Submit five draft copies of the technical bulletin and/or tag for our files and for our review. Just a reminder that bulletins, tags, and master labels should always travel together, especially when submitting amendments to the Agency.

If you have any questions concerning this letter, contact V. Goncarovs at 703-305-6663.

Sincerely yours,

Walter C. Francis
Acting Product Manager (31)
Antimicrobial Program Branch
Registration Division (H7505C)

Enclosures

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STERILIZING GAS 4

Active Ingredient

Ethylene Oxide 10%
 Inert Ingredients 90%
 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

EPA REG. NO. 36736-4

TOTAL CONTENTS LBS. NET

Ethylene Oxide CAS #75-21-8
 Carbon Dioxide CAS #124-38-9

DANGER PELIGRO

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

HAZARDS TO HUMANS

DANGER! NON-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

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.

PRECAUTIONS: Do not breathe vapor. Do not swallow. Do not get in eyes, on skin, or on clothing. Store and use with adequate ventilation.

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.

STORAGE AND DISPOSAL - Store in a cool, well ventilated area. Avoid exposure to heat or direct sunlight. When empty, return to manufacturer only.

ENVIRONMENTAL HAZARDS

Ethylene oxide, the active ingredient in

Sterilizing Gas 4 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.

STATEMENT OF PRACTICAL TREATMENT: IN ALL CASES OF OVEREXPOSURE, GET MEDICAL ATTENTION IMMEDIATELY. TAKE PERSON TO A DOCTOR OR EMERGENCY TREATMENT FACILITY AT ONCE.

FIRST AID:

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 an unconscious person. Call a physician.

NOTE TO PHYSICIAN: REFER TO ARC CHEMICAL'S MATERIAL SAFETY DATA SHEET for Sterilizing Gas 4.

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 of without risk.

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

It is in violation of federal law to use this product in a manner inconsistent with its labeling. The product is limited to use by medical professionals or trained technical personnel in medical and industrial use areas.

IN CASE OF EMERGENCY IN USA:

Call Chemtrec 1-800-424-9300

ARC Chemical Division Balchem Corporation
 P.O. Box 180
 Slate Hill, NY 10973

ACCEPTED
 MAR 03 1995

DO NOT REMOVE THIS LABEL

BEST AVAILABLE COPY

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