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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

NOV 14 2003

Ms. Joanne Cashin ARC Specialty Products Balchem Corp PO Box 600 New Hampton, NY 10958

Subject:

Sterilizing Gas 3

EPA Registration No. 36736-3 Amendment Date: August 12, 2003 EPA Receipt Date: August 18, 2003

Dear Ms. Cashin,

The following amendment submitted in connection with registration under FIFRA, as amended, is acceptable with the conditions listed below.

Update First Aid Statement per PR Notice 2001-1

Conditions

Revise the label as follows:

The Storage and Disposal Statements must be revised to comply with PR Notice 83-3 and the Label Manual 3rd Edition by stating:

Storage and Disposal

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

Pesticide Storage: Use in accordance with tag attached to valve. Store in cool, well-ventilated area. Avoid exposure to heat or direct sunlight as may cause polymerization.

Pesticide Disposal: Pesticide Wastes are acutely hazardous. Improper disposal of excess pesticide, spray, or mixture of rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal: When empty, return to supplier only. Before returning container to supplier:

CONCURRENCES										
SYMBOL										
SURNAME		•								
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

- 1. Cylinder pressure should be below 250 psig when empty. Check that container valve is closed.
- 2. Replace valve plug tightly in valve outlet.
- 3. Check container valve and plug for leaks prior to shipment.

General Comments

A stamped copy of the labeling accepted with conditions is enclosed. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,

Product Manager (31)

Regulatory Management Branch I Antimicrobials Division (7510C)

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EPA Form 1320-1A (1/90)			Printed on Recycled Paper				OFFICIAL FILE COPY				

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC **ANIMALS**

DANGER! CAUSES EYE AND SKIN BURNS, HARMFUL IF INHALED, MAY CAUSE NERVOUS SYSTEM DAMAGE

AND DANGER! CANCER HAZARD REPRODUCTIVE HAZARD.

EFFECTS OF OVEREXPOSURE: May be fatal if inhaled in high concentrations. May cause irritation of the 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 the lungs), immediate or delayed skin irritation or blisters, allergic skin reaction.

POSSIBLE DELAYED HEALTH OTHER FTFECTS:

cause nervous system injury, cataracts, adverse changes, and cancer.

1 PPM TWA (as per the Ethylene Oxide-Standard 29 CFR 1910.1047). PEL:

5 PPM - excursion limit 15 minutes ODOR: Ether-like at high concentrations. Exposure to toxic levels may occur without warning to 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 the Ethylene Oxide Standard (29 CFR 1910.1047).

PHYSICAL OR CHEMICAL HAZARDS: DANGER: - HIGHLY FLAMMABLE LIQUID AND GAS UNDER PRESSURE

Contents under pressure. Do not use near flame, sparks, hot surfaces, or allow sources of ignition near the sterilization/furnigation area. Sterilizing Gas 3 is extremely flammable and reactive. Ground all equipment (including this container) to prevent sparks.
* EAK - In case of leak evacuate area and reep

sonnel upwind. Shut off all sources of ignition. Use of-contained breathing apparatus and protective clothing, and shut off leak if without risk.

FIRE - In case of fire move container away from fire if without risk. Use water spray or fog nozzle to keep container cool.

ENVIRONMENTAL HAZARDS:

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other weters unless in accordance with the requirements of a National Pollutant Discharge Effluent System (NPL ES) permit and the permitting authority has been not fied in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment clant authority. For guidance contact your State Water Board or Regional Office of the EPA.

It is imperative that users of this many like the fulfilliar with ARC Specialty Products Chartest Market at the fulfilliar Sheet for Sterilizing Gas 3, the the fulfilliar tag attached to this cylinder.

EPA Registration No. 36736-3

EPA Establishment No. II 36736-31V.01

B01139 (Rev. 6/03 - supercedes 18.00) and 18.00 mm.

136736-NY-01

13673 Tedistered under Eby Red. No.

STERILIZING

GAS₃

STERILANT/FUMIGANT **ACTIVE INGREDIENT: ETHYLENE OXIDE....80%** (CAS NO: 75-21-8) INERT INGREDIENT: CARBON DIOXIDE.....20% (CAS NO: 124-38-9)

TOTAL:.....100%

KEEP OUT OF REACH OF CHILDREN

DANGER

PELIGRO

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

Users must follow requirements of the OSHA Occupational Exposure Standard for ethylene oxide (29 CFR 1910.1047).

FIRST AID

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

IF INHALED - Move person to fresh air. Keep warm. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. If breathing is difficult, give oxygen. Call a poison control center or doctor for further treatment advice, even if there are no symptoms. Keep under medical observation—

symptoms may be delayed.

IF ON SKIN OR CLOTHING— Take off contaminated clothing and shoes. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice. Aerate, wash or clean contaminated clothing and discard leather goods.

IF SWALLOWED - Call poison control center or

doctor immediately for treatment advice. Have person sip two glasses of water if able to swallow. Do not induce vomiting. Do not give anything by

mouth to an unconscious person.

IF IN EYES – Hold eye open and rinse stowly and gently with water for 15-20 minutes. Call a poison control center or doctor for treatment advice. HOTLINE NUMBER - Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-424-9300 for emergency medical treatment information.

NOTE TO PHYSICIAN - Skin exposure to Sterilizing Gas 3 will commonly result in skin irritation with extensive blister formation. At high concentrations, severe conjunctivitis can occur. Irritation of the respiratory tract may occur, but without acute lung edema. Symptoms of systemic intoxication are headache, nausea, vomiting, incoordination, and cardiac irregularities. Treatment is symptomatic

Refer to ARC Specialty Products' Sterilizing Gas 3 MSDS. If unable to locate MSDS for this product, please call ARC Specialty Products at the telephone number below and request that one be sent

immediately.

Distributed By: **ARC Specialty Products Balchem Corporation** P.O. Box 600 · New Hampton, NY 10958 Tel: 845-355-5311 Fax: 845-355-7619

Net Contents:

lbs.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. It is the employer's responsibility to follow the requirements of the Ethylene Oxide Standard (29 CFR 1910.1047). This product may be used only in facilities that meet the requirements of the be used only in facilities that these the tentrelients of the Ethylene Oxide Standard (29 CFR 1910.1047). This product may be used only in non-portable (commercial) vacuum or gas-tight chambers designed for use with 80% ethylene oxide, 20% carbon dioxide. This product may be used only by persons who have been trained in accordance with the Ethylene Oxide Standard (29 CFR 1910.1047). When used to sterilize health care items, this product must be used in non-portable (commercial) ethylene oxide gas sterilizers that have FDA clearance.

1. AS A STERILANT AND FUMIGANT GAS:

A. For complete use directions (including type of surfaces, objects, or items/products recommended for reatment, pre-cleaning instructions, concentration of gas per unit volume of closed space to be treated, exposure time/temperature, relative humidity, ventilation/aeration time, and method of monitoring to be used) refer to the ethylene oxide gas sterilizer manufacturers' Operators Manuals.

This product may be used only to sterilize medical or laboratory items, pharmaceuticals, and aseptic packaging, (see 21 CFR 201.1(d)(5)), or to reduce microbial load on cosmetics, whole and ground spices or other seasoning materials (see 40 CFR 180.151), and artifacts, archival

materials (see 40 CFR 180.151), and artifacts, archival material or library objects.

B. Sterilization/fumigation with Sterilizing Gas 3 must be performed only in vacuum or gas tight chambers designed for use with Sterilizing Gas 3.

C. Sterilizing Gas 3 cycle parameters depend on several sterilizing/fumigating variable factors: pre-conditioning (if any); exposure time; chamber air pressure; gas concentration; types and quantities of items to be sterilized/fumigated; packaging; load configuration in the sterilized/fumigated; packaging, load configuration in the chamber; microbial challenge method; desired degree of

chamber; microbial challenge method; desired degree of disinfection; and the desired performance of the sterilized/fumigated product and package. D. The sterilization/fumigation cycle parameters should be those prescribed by the equipment manufacturer. If other cycle parameters are used, the safety and efficacy of the alternate cycle parameters must be validated and are the responsibility of the user. NEVER USE PARAMETERS WHICH ALLOW FLAMMABLE MIXTURES OF STERILIZING GAS 3 AND AIR TO ENTER THE CHAMBER.

INSTALLATION AND OPERATION OF THE CONTAINER - Follow the directions on the valve tag attached to this container.

STORAGE& DISPOSAL

Use in accordance with tag attached to valve. Store in cool, well-ventilated area. Avoid exposure to heat or direct sunlight as may cause polymerization. When empty, return to supplier only. Before returning container to supplier:

Cylinder pressure should be below 250 psig when empty. Check that container valve is closed.
 Replace valve plug tightly in valve outlet.

Check container valve and plug for leaks prior to shipment.

> USE THIS PRODUCT WITHIN 120 DAYS OF ITS PURCHASE.

In case of accident or emergency call CHEMTREC at 800-424-9300.

DO NOT REMOVE THIS LABEL.