

MAY 24 2005

Ms. JoAnn Cashin
Arc Specialty Products
Balchem Corporation
P.O. Box 600
New Hampton, NY 10958

Subject: Ethylene Oxide 100%
EPA Registration No. 36736-2
Amendment Date: July 22, 2004
EPA Receipt Date: July 26, 2004

Dear Ms. Cashin,

The amendment referenced above, submitted in connection with registration under FIFRA section 3(c)(7)(B), will be acceptable provided that you agree in writing that:

- 1. You will submit the data listed below, conducted in accordance with Agency test guidelines no later than August 1, 2005.

The Agency has determined your submission to be incomplete because your study did not identify the analytical method for ethylene oxide, ethylene chlorohydrin, and ethylene glycol nor did it provide documentation on the method validation. We would also like control and spike samples to be included.

We could not conclude that the residue data are valid. The submitted data supported only two samples (one for rubber mouthpieces and the other for plastic mouthpieces) that showed detectable residues of ethylene oxide, ethylene chlorohydrin, and ethylene glycol. The Agency requires at least 5 replicated for statistical analysis.

Therefore, we need additional residue data submitted to confirm the findings of this analysis. Your residue data must be conducted with at least 5 replicates tested in two different chambers, each containing one rubber and one plastic mouthpiece.

We would also like additional information pertaining to the type of chamber used for the sterilization of musical instruments, the duration of treatment, the aeration period of ethylene oxide, and the concentration of ethylene oxide in the chamber to be efficacious against micro-organisms.

CONCURRENCES								
MSOL								
SURNAME								
DATE								

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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2. You will submit and/or cite all data for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

3. You must make the following label change before you release the product for shipment bearing the amending labeling:

For the Valve Tags: Under "Directions for Use" revise the statement, "Use only in accordance with the directions and safety precautions listed on the label and this tag" to read "Use only in accordance with the directions and safety precautions listed on the label, this tag, and the ethylene oxide gas sterilizer manufacturers' Operators Manuals."

4. You must submit five copies of your final printed labeling before you release this product for shipment.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

If you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510C)

Enclosure: Risk Assessment on Ethylene Oxide for Use on Musical Wind Instruments
Stamped Label

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

PRECAUTIONARY STATEMENTS**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

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

DANGER! CANCER HAZARD AND 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.

OTHER POSSIBLE DELAYED HEALTH EFFECTS:

May cause nervous system injury, cataracts, adverse reproductive effects, chromosomal and mutagenic changes, and cancer.

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

EL: 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/fumigation area. Ethylene Oxide is extremely flammable and reactive. Ground all equipment (including this container) to prevent sparks.

LEAK - In case of 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 - 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 waters unless in accordance with the requirements of a National Pollutant Discharge Effluent System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

It is imperative that users of this material be familiar with ARC Specialty Products' Material Safety Data Sheet for 100% Ethylene Oxide, the label and valve tag attached to this cylinder.

EPA Registration No. 36736-2

EPA Establishment No. 36736-NY-01

36736-SC-01

36736-MD-01

801137 (Rev. 12/03, with amendments) in EPA Letter Dated:

In case of accident or emergency, call CHEMTREC at 1-800-424-9300

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the purpose of...

* Higher label under EPA Reg. No. 36736-2

ETHYLENE OXIDE

STERILANT/FUMIGANT
ACTIVE INGREDIENT: ETHYLENE OXIDE...100%

(CAS NO: 75-21-8)

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 ampliamente.

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 slowly 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 Ethylene Oxide 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' Ethylene Oxide 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: 845-328-5611

Fax: 845-326-5706

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 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 100% ethylene oxide. 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 treatment, 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 material or library objects.

B. Sterilization/fumigation with Ethylene Oxide must be performed only in vacuum or gas tight chambers designed for use with Ethylene Oxide.

C. Ethylene Oxide 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 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 ETHYLENE OXIDE AND AIR TO ENTER THE CHAMBER.

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

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 rinseate 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:

1. Pressurize container with nitrogen to 50 psig total pressure at 70° F.
2. Replace valve plug tightly in valve outlet.
3. Check container valve and plug for leaks prior to shipment.

USE THIS PRODUCT WITHIN 120 DAYS OF ITS PURCHASE

DO NOT REMOVE THIS LABEL.

DO NOT REMOVE THIS TAG
ETHYLENE OXIDE 100%
 EPA REGISTRATION NO. 36736-2
 EPA ESTABLISHMENT NO. 36736-NY-01

DANGER!
EXTREMELY FLAMMABLE AND EXPLOSIVE.
HARMFUL IF INHALED.

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 (29CFR 1910.1047). Use only in accordance with the directions and safety precautions listed on the label and on this tag. See current ARC Specialty Products' Material Safety Data Sheet for this product.

General Directions

1. Always check container valves and plugs for leaks before moving container into your facility.
2. This container is designed to discharge only liquid ethylene oxide. If ethylene oxide gas is required, use vaporizing equipment.
3. This container has been pressurized with nitrogen to a pressure of 50 PSIG (3.52 kg/cm²) at 70°F (21.1°C). Pressure will be higher if temperature is above 70°F, lower if temperature is below 70°F. Contact supplier if, upon receipt, container pressure is below 50 PSIG at 70°F.
4. Container must be in an upright position at all times. Cylinders must be secured to prevent falling over.
5. Liquid withdrawal valve outlet is provided with a CGA 510 connection which has left hand threads.
6. Cylinders and DOT 1A1 drums are also provided with a CGA inert pressurizing valve which has right hand threads. Do not discharge product from the inert pressurizing valve.
7. Remove protective valve plugs carefully and make sure valve threads are undamaged.
8. All other piping and fittings should be steel or stainless steel fittings and piping capable of withstanding the pressure to be encountered. Do not use rubber, plastic, or copper materials. Install relief valves where liquid can be trapped between valves.
9. Ground all equipment, including this container, to prevent static sparks.
10. Use only spark-proof tools.
11. Use only explosion-proof electrical equipment which conforms to the current requirements of the National Electric Code (see NFPA #70) where ethylene oxide may be present.

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12. Install check valves in the discharge line from this container to processing equipment to prevent back flow into the container.
13. Connect the inert pressurizing valve to a source of nitrogen using a line equipped with a pressure regulator, safety relief valve, and check valve. The source of nitrogen should be used for ethylene oxide and for no other purpose. Nitrogen pressure must not exceed the service pressure of the container. Never use compressed air or other gases to pressurize the cylinder or drum. **DO NOT APPLY HEAT TO THIS CONTAINER BY ANY MEANS.**
14. To open container valves, turn counterclockwise. For those containers which are equipped with a handwheel do not use a wrench or other leverage device.
15. Use with adequate general and local ventilation. Vapors from this product travel and may be moved by air currents and ignited by pilot lights, other flames, smoking, sparks, hot surfaces, electrical equipment, static discharges, or other forms of ignition at locations distant from product handling point.
16. Determine the quantity of product withdrawn from this container by using an appropriate scale.

STORAGE AND DISPOSAL

Store according to the directions provided on this tag and on the product label. To control ethylene oxide polymer growth, use an inert gas on a first in/first out basis. Our recommendation is to use all of this product within 120 days of its receipt. To minimize polymer growth, this product should not be stored in any place where the temperature exceeds 100°F. Do not store this product in direct sunlight.

STORE IN AN AREA WITH ADEQUATE VENTILATION.

CONTAINER SHOULD BE RETURNED TO SUPPLIER FOR REUSE BEFORE RETURNING CONTAINER TO SUPPLIER:

- A. PRESSURIZE CONTAINER WITH NITROGEN TO 50 PSIG TOTAL PRESSURE AT 70°F AND BE SURE CONTAINER VALVES ARE CLOSED.
- B. REPLACE VALVE PLUGS SECURELY IN VALVE OUTLET. IF VALVE PLUGS ARE NOT AVAILABLE, CONTACT SUPPLIER.
- C. CHECK CONTAINER VALVES AND PLUGS FOR LEAKS PRIOR TO SHIPMENT. IF LEAKS ARE DETECTED, CONTACT SUPPLIER.
- D. THIS TAG MUST REMAIN AFFIXED TO DRUM OR CYLINDER AT ALL TIMES. WHEN EMPTY THIS CONTAINER MUST BE RETURNED TO THE ORIGINAL SHIPPING POINT IN ACCORDANCE WITH THE DIRECTIONS ABOVE. IT IS THE PROPERTY OF:

ARC SPECIALTY PRODUCTS
BALCHAM CORPORATION
 2007 ROUTE 284
 PO BOX 180
 SLATE HILL, NY 10873
 (848) 386-6311

8/00 (supersedes 6/89)

800789

* We will continue to attach this valve tag to all product packages sent to other customers.

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PROPOSED ALTERNATE VALVE TAG *
(Additional Language Highlighted)

DO NOT REMOVE THIS TAG

ETHYLENE OXIDE 100%
EPA REGISTRATION NO. 36738-2
EPA ESTABLISHMENT NO. 36738-SC-01

DANGER!
EXTREMELY FLAMMABLE AND EXPLOSIVE.
HARMFUL IF INHALED.

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 (29CFR 1910.1047). Use only in accordance with the directions and safety precautions listed on the label and on this tag. See current ARC Specialty Products' Material Safety Data Sheet for this product.

**THIS PRODUCT MAY BE USED FOR THE STERILIZATION OF
MUSICAL WIND INSTRUMENTS**

GENERAL DISPOSAL Directions

1. Always check container valves and plugs for leaks before moving container into your facility.
2. This container is designed to discharge only liquid ethylene oxide. If ethylene oxide gas is required, use vaporizing equipment.
3. This container has been pressurized with nitrogen to a pressure of 50 PSIG (3.52 kg/cm²) at 70°F (21.1° C). Pressure will be higher if temperature is above 70° F; lower if temperature is below 70° F. Contact supplier if, upon receipt, container pressure is below 50 PSIG at 70° F.
4. Container must be in an upright position at all times. Cylinders must be secured to prevent falling over.
5. Liquid withdrawal valve outlet is provided with a CGA 510 connection which has left hand threads.
6. Cylinders and DOT 1A1 drums are also provided with a CGA inert pressurizing valve which has right hand threads. Do not discharge product from the inert pressurizing valve.
7. Remove protective valve plugs carefully and make sure valve threads are undamaged.
8. All other piping and fittings should be steel or stainless steel fittings and piping capable of withstanding the pressure to be encountered. Do not use rubber, plastic, or copper materials. Install relief valves where liquid can be trapped between valves.
9. Ground all equipment, including this container, to prevent static sparks.
10. Use only spark-proof tools.

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Gas Spill
Operations Manual

11. Use only explosion-proof electrical equipment which conforms to the current requirements of the National Electric Code (see NFPA #70) where ethylene oxide may be present.
12. Install check valves in the discharge line from this container to processing equipment to prevent back flow into the container.
13. Connect the inert pressurizing valve to a source of nitrogen using a line equipped with a pressure regulator, safety relief valve, and check valve. The source of nitrogen should be used for ethylene oxide and for no other purpose. Nitrogen pressure must not exceed the service pressure of the container. Never use compressed air or other gases to pressurize the cylinder or drum. DO NOT APPLY HEAT TO THIS CONTAINER BY ANY MEANS.
14. To open container valves, turn counterclockwise. For those containers which are equipped with a handwheel do not use a wrench or other leverage device.
15. Use with adequate general and local ventilation. Vapors from this product travel and may be moved by air currents and ignited by pilot lights, other flames, smoking, sparks, heaters, electrical equipment, static discharges, or other forms of ignition at locations distant from product handling point.
16. Determine the quantity of product withdrawn from this container by using an appropriate scale.

STORAGE AND DISPOSAL
Store according to the directions provided on this tag and on the product label. To control ethylene oxide polymer growth, use all sterilant gas on a first in/first out basis. Our recommendation is to use all of this product within 120 days of its receipt. To minimize polymer growth, this product should not be stored in any place where the temperature exceeds 100° F. Do not store this product in direct sunlight or consistent of label guidance heat.

STORE IN AN AREA WITH ADEQUATE VENTILATION.

CONTAINER SHOULD BE RETURNED TO SUPPLIER FOR REUSE. BEFORE RETURNING CONTAINER TO SUPPLIER:

- A. PRESSURIZE CONTAINER WITH NITROGEN TO 50 PSIG TOTAL PRESSURE AT 70° F AND BE SURE CONTAINER VALVES ARE CLOSED.
- B. REPLACE VALVE PLUGS SECURELY IN VALVE OUTLET. IF VALVE PLUGS ARE NOT AVAILABLE, CONTACT SUPPLIER.
- C. CHECK CONTAINER VALVES AND PLUGS FOR LEAKS PRIOR TO SHIPMENT. IF LEAKS ARE DETECTED, CONTACT SUPPLIER.
- D. THIS TAG MUST REMAIN AFFIXED TO DRUM OR CYLINDER AT ALL TIMES. WHEN EMPTY THIS CONTAINER MUST BE RETURNED TO THE ORIGINAL SHIPPING POINT IN ACCORDANCE WITH THE DIRECTIONS ABOVE. IT IS THE PROPERTY OF:

**ARC SPECIALTY PRODUCTS
BALCHEM CORPORATION
HIGHWAY 17
PO BOX 337
GREEN POND, SC 29448
(843) 844-8511**

7/04 800769-M

* This valve tag will only be attached to product packages sent to those contract sterilizers authorized to sterilize musical wind instruments.