

PM

31

36736-3

6/12/97

Page 173

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUN 12 1997

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

Attention: Diane Powers
Vice President

Subject: Sterilizing Gas 3
EPA Registration Number 36736-3
Your Submission Dated May 16, 1997

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to update your label is acceptable.

A stamped copy of the labeling is enclosed for your records. Submit one copy of the final printed label before you release this product for shipment bearing the amended label.

If you have any questions concerning this letter, please contact Velma Noble at (703) 308-6233.

Sincerely yours,

Rebecca S. Cool
Product Manager 31
Regulatory Management Branch 1
Antimicrobial Division (7510W)

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JUN 12 1997

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as amended,
for the pesticide, registered under EPA Reg. No. #36736-3

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & 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 29CFR1910.1047).

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. Sterilizing Gas 3 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.

STERILIZING GAS 3

STERILANT/FUMIGANT ACTIVE INGREDIENTS:

ETHYLENE OXIDE 80% BY WEIGHT (CAS REGISTRY NUMBER 75-21-8)

CARBON DIOXIDE 20% BY WEIGHT (CAS REGISTRY NUMBER 124-38-9)

KEEP OUT OF REACH OF CHILDREN

DANGER PELIGRO

PRECAUTIONAL 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 (29CFR1910.1047).

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 breathing has stopped, administer artificial respiration or oxygen. Do not give anything by mouth to an unconscious person. Call a physician even if no symptoms are present. Keep under medical observation. Symptoms may be delayed.

IF ON SKIN - Immediately remove contaminated clothing and shoes. Wash contaminated area thoroughly with soap and water. 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.

IF IN EYES - Hold eyelid open and flush with a steady, gentle stream of water for at least 15 minutes. Call a physician.

NOTE TO PHYSICIAN - Skin exposure to Sterilizing Gas 3 will commonly result in skin

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 (29CFR1910.1047).

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 10% ethylene oxide, 90% 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 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(4d)) or to reduce microbial load on cosmetics, whole and ground spices or other seasoning materials (see 40CFR 180.151 and 40CFR 185.2850), 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: preconditioning (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

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 29CFR1910.1047).
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. Sterilizing Gas 3 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 Chemical's Material Safety Data Sheet for Sterilizing Gas 3, which accompanies this shipment, the label and valve tag attached to this drum.

EPA Registration No. 36736-3
EPA Establishment No. 35084-TX-1
 35084-PA-2
 36736-NY-01
 36736-SC-02

KEEP OUT OF REACH OF CHILDREN

DANGER PELIGRO

PRECAUTIONAL 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 (29CFR1910.1047).

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 breathing has stopped, administer artificial respiration or oxygen. Do not give anything by mouth to an unconscious person. Call a physician even if no symptoms are present. Keep under medical observation. Symptoms may be delayed.

IF ON SKIN - Immediately remove contaminated clothing and shoes. Wash contaminated area thoroughly with soap and water. 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.

IF IN EYES - Hold eyelid open and flush with a steady, gentle stream of water for at least 15 minutes. Call a physician.

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 Chemical Sterilizing Gas 3 MSDS, Section 6, Health Hazard Data. A Material Safety Data Sheet for Sterilizing Gas 3 is sent with each shipment. If unable to locate MSDS for this product, please call ARC Chemical at the telephone number below and request that one be sent immediately.

Distributed By:

**ARC Chemical Division
Balchem Corporation
P.O. Box 180
Slate Hill, NY 10973
Tel: 914-355-5311
Fax: 914-355-7619**

DO NOT REMOVE THIS LABEL.

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 10% ethylene oxide, 90% 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 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(4d)) or to reduce microbial load on cosmetics, whole and ground spices or other seasoning materials (see 40CFR 180.151 and 40CFR 185.2850), 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: preconditioning (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 & 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:

1. Pressurize container with nitrogen to 50 psig total pressure at 70 degrees F.
2. Replace valve plugs tightly in valve outlets.
3. Check container valve and plugs 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.

393

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUN 12 1997

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

Attention: Diane Powers
Vice President

Subject: Sterilizing Gas 3
EPA Registration Number 36736-3
Your Submission Dated May 16, 1997

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to update your label is acceptable.

A stamped copy of the labeling is enclosed for your records. Submit one copy of the final printed label before you release this product for shipment bearing the amended label.

If you have any questions concerning this letter, please contact Velma Noble at (703) 308-6233.

Sincerely yours,

Rebecca S. Cool
Product Manager 31
Regulatory Management Branch 1
Antimicrobial Division (7510W)

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

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 29CFR1910.1047).
- 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. Sterilizing Gas 3 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 Chemical's Material Safety Data Sheet for Sterilizing Gas 3, which accompanies this shipment, the label and valve tag attached to this drum.

- EPA Registration No. 36736-3
- EPA Establishment No. 35084-TX-1
- 35084-PA-2
- 36736-NY-01
- 36736-SC-02

KEEP OUT OF REACH OF CHILDREN

DANGER PELIGRO

PRECAUTIONAL 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 (29CFR1910.1047).

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 breathing has stopped, administer artificial respiration or oxygen. Do not give anything by mouth to an unconscious person. Call a physician even if no symptoms are present. Keep under medical observation. Symptoms may be delayed.

IF ON SKIN - Immediately remove contaminated clothing and shoes. Wash contaminated area thoroughly with soap and water. 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.

IF IN EYES - Hold eyelid open and flush with a steady, gentle stream of water for at least 15 minutes. Call a physician.

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 Chemical Sterilizing Gas 3 MSDS, Section 6, Health Hazard Data. A Material Safety Data Sheet for Sterilizing Gas 3 is sent with each shipment. If unable to locate MSDS for this product, please call ARC Chemical at the telephone number below and request that one be sent immediately.

Distributed By:

**ARC Chemical Division
Balchem Corporation
P.O. Box 180
State Hill, NY 10973
Tel: 914-355-5311
Fax: 914-355-7619**

DO NOT REMOVE THIS LABEL.

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 10% ethylene oxide, 90% 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 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(4d)) or to reduce microbial load on cosmetics, whole and ground spices or other seasoning materials (see 40CFR 180.151 and 40CFR 185.2850), 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: preconditioning (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 & 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:

- 1. Pressurize container with nitrogen to 50 psig total pressure at 70 degrees F.
- 2. Replace valve plugs tightly in valve outlets.
- 3. Check container valve and plugs 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.