



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

JAN 29 2007

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Joanne Cashin
Registration Compliance Advisor
ARC Specialty Products, Balchem Corporation
P.O. Box 600
North Hampton, NY 10958

Subject: Sterilizer Gas 4
EPA Registration No. 36736-4
EPA Received Date: October 31, 2006
Application Date: October 26, 2006

Dear Ms. Cashin,

The following amendment submitted in connection with registration under section 3(c) (7) (a) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, is acceptable with comment.

Proposed Amendment

- Addition of Directions for Use
- Deletion of claim

Comments

Make the following changes to your labeling:

1. According to the referenced Tolerance Reassessment and Risk Management Decision, the second paragraph must be revised, under the Sterilant and Funigant Gas section, to read:

"Place spices in the treatment chamber. Assure that the mixture of ethylene oxide and air is compatible with the chamber design, then; introduce into the chamber a concentration of Ethylene Oxide not to exceed 500mg/L, with a dwell time not to exceed 16 hours. Then evacuate the gas from the chamber using a sequence of not less than 16 steam washes (injections and evacuations) between 1.0 PSIA (28" Hg) and 2.0 PSIA (26 Hg) while maintaining a minimum chamber temperature of 120°F."

CONCURRENCES						
7510C						
Dale						
1/23/07						

Should you have any questions or comments concerning this letter, please contact Velma Noble at (703) 308-6233

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Management Branch 1
Antimicrobial Division (7510c)

CONCURRENCES

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. Sterilizing Gas 4 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 Sterilizing Gas 4, the label and valve tag attached to this

EPA Registration No. 36736-4

EPA Establishment No.

- 35084-PA-2
- 36736-NY-01
- 36736-SC-01
- 36736-MO-01

801465 (Rev. 10/06 - supercedes 12/03)

Keep Out of Reach of Children

DANGER PELIGRO

PRECAUTIONAL USARIO: Si usted no lee
Inglés, no use este producto hasta que
etiqueta le haya sido explicada en español.
EPA Label Dated:

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

FIRST AID, PPE, and Rodenticide Act as amended for the pesticide.

IN ALL CASES OF OVEREXPOSURE
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 Sterilizing Gas 4 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.

STERILIZING GAS 4

STERILANT/FUMIGANT

ACTIVE INGREDIENT ETHYLENE
OXIDE.....10%

(CAS NO: 75-21-8)

INERT INGREDIENT: CARBON
DIOXIDE..... 90%

(CAS NO: 124-38-9)

Refer to ARC Specialty Products' Sterilizing Gas 4 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.

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 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(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.

This product may not be used on or in any form of basil.

After August 1, 2008, this product may only be applied to or on spices, dried vegetables or seasonings utilizing an ETO sterilization method that uses a single sterilization chamber to pre-condition and aerate with an alternating vacuum and aeration purging procedure. If you wish to employ an alternative method to that described below, you must contact the Environmental Protection Agency Office of Pesticide Programs for instruction on how to receive authorization.

USE THIS PRODUCT WITHIN 120 DAYS
OF ITS PURCHASE.

DO NOT REMOVE THIS LABEL

801465 (Rev. 10/06 - supercedes 12/03)

Net Contents:

Place spices in the mixture of ethylene chamber design, concentration of with a dwell time the gas from the than 21 steam between 1.5 PSI maintaining a minimum

B. Sterilization/fumigation performed only in for use with Sterilizing Gas sterilizing/fumigation any); exposure concentration; type sterilized/fumigated chamber; microbial disinfection; and sterilized/fumigated D. The sterilization those prescribed cycle parameters alternate cycle parameters responsibility of the WHICH ALLOW STERILIZING GAS

2. INSTALLATION CONTAINER - F attached to this container

STORAGE AND DISPOSAL

Do not contaminate disposal. PESTICIDE STORAGE attached to valve. exposure to heat polymerization. PESTICIDE DISPOSAL hazardous. Improper mixture of rinsate wastes cannot be instructions, contact Control Agency, or the nearest EPA Field CONTAINER DISPOSAL only. Before return 1. Cylinder pre empty. Check 2. Replace valve 3. Check container shipment.

In case of a call CHEM

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