

36736-5

1/29/2007

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

JAN 29 2007

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

Subject: Sanitizing Gas 5
EPA Registration 36736-5
Amendment Dated: Oct 26, 2006
EPA Received Date: Oct 31, 2006

Dear Joanne K. Cashin

The following amendment submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, is acceptable with comments.

Proposed Amendment

- Revised Label

Label Comments

The second paragraph must be revised to reflect the labeling as provided by the Tolerance Reassessment and Risk Management Decision under the Sterilant and Fumigant Section and should read as follows:

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 and concentration of Ethylene Oxide not to exceed 500 mg/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						
SI	75116					
SURNAME	Balmer					
DATE	11-26-07					

General Comments

A stamped copy of the accepted label with conditions is enclosed for your records. Submit (3) copies of your final printed label before distributing or selling the product bearing the revised labeling. Submit and /or cite all data required for the registration/re-registration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

A stamped copy of the accepted label is enclosed for your records. Submit (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 Velma Noble at (703) 308-6233.

Sincerely,



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

**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
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 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 5 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 sewerage 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 5, the label and valve tag attached to this cylinder.

801466 (Rev. 10/06 - supercedes 12/03)

ACCEPTED
with COMMENTS
in EPA Letter dated
JAN 29 2007
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended for the pesticide,
registered under EPA Reg. No. 36736-5

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 amoliamente.

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 Sterilizing Gas 5 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 5**

STERILANT/FUMIGANT

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

TOTAL: 100%

Refer to ARC Specialty Products' Sterilizing Gas 5 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 manne
inconsistent with its labeling. It is the employer's responsibility to
follow the requirements of the Ethylene Oxide Standard (29 CFF
1910.1047). This product may be used only in facilities that mee
the requirements of the Ethylene Oxide Standard (29 CFF
1910.1047). This product may be used only in non-portable
(commercial) vacuum or gas-tight chambers designed for use with
20% ethylene oxide, 80% 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-por
table (commercial) ethylene oxide gas sterilizers that have FD
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' Operator
Manuals.

This product may be used only to sterilize medical or laborator
items, pharmaceuticals, and aseptic packaging, (see 21 CFF
201.1(d)(5)), or to reduce microbial load on cosmetics, whole and
ground spices or other seasoning materials (see 40CFR 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 o
on spices, dried vegetables or seasonings utilizing an ETC
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 contac
the Environmental Protection Agency Office of Pesticid
Programs for instruction on how to receive authorization.

USE THIS PRODUCT WITHIN 120 DAYS
OF ITS PURCHASE.

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

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 EPC Registration No. 36736-5
 EPA Establishment No. 35084-PA-2
 36736-NY-01
 36736-SC-01
 36736-MO-01
 Insecticide,
 Fungicide, Act as
 Disinfectant,
 and
 Sterilizing Gas
 Reg. No. 36736-5

STERILIZING GAS 5

STERILANT/FUMIGANT
 ACTIVE INGREDIENT: ETHYLENE OXIDE...20%
 (CAS NO: 75-21-8)
 INERT INGREDIENT: CARBON DIOXIDE.....80%
 (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 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 for 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 5 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 5 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 20% ethylene oxide, 80% 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 40CFR 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.

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

Net Contents: _____ lbs.

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 500 mg/L, with a dwell time not to exceed 6 hours. Then evacuate the gas from the chamber using a sequence of not less than 21 steam washes (injections and evacuations) between 1.5 PSIA (27" Hg) and 5.0 PSIA (20" Hg) while maintaining a minimum chamber temperature of 115° F.

B. Sterilization/fumigation with Sterilizing Gas 5 must be performed only in vacuum or gas tight chambers designed for use with Sterilizing Gas 5.

C. Sterilizing Gas 5 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 STERILIZING GAS 5 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 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:

1. Cylinder pressure should be below 600 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.

Distributed By:
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