

36736-6

1/29/2007

Page 184



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 6
EPA Registration 36736-6
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							
SURNAME	M. S. L.						
DATE	11-26-07						

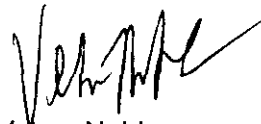
General Comments

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,

A handwritten signature in black ink, appearing to read 'Velma Noble', with a stylized flourish at the end.

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 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! - NONFLAMMABLE 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. 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 6, the label and valve tag attached to this cylinder.

EPA Registration No. 36736-6
EPA Establishment No. □ 36736-NY-01
□ 36736-SC-01
□ 36736-MO-01

ACCEPTED
with **COMMENTS**
in EPA Letter Dated:
JAN 29 2007

Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
amended, for the purposes,
registered under EPA Reg. No. **36736-6**

**STERILIZING
GAS 6**

STERILANT/FUMIGANT
ACTIVE INGREDIENT: ETHYLENE
(CAS NO: 75-21-8)
INERT INGREDIENTS
DICHLORODIFLUOROMETHANE
(CAS NO: 124-38-9)
TOTAL:

Keep Out of Reach of Children

DANGER PELIGRO

PRECAUTION AL USARIO: Si usted no lee
Inglés, 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 6
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.

DO NOT REMOVE THIS LABEL

324

STERILIZING GAS 6

STERILANT/FUMIGANT
ACTIVE INGREDIENT: ETHYLENE OXIDE... 12%
(CAS NO: 75-21-8)
INERT INGREDIENT:
DICHLORODIFLUOROMETHANE.....88%
(CAS NO: 124-38-9)
TOTAL:.....100%

ACCEPTED
with COMMENTS
in EPA Letter Dated:
JAN 29 2007

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
amended, for the pesticide
registered under EPA Reg. No. 36736-6

Keep Out of Reach of Children

DANGER PELIGRO

PRECAUTION AL USARIO: Si usted no lee
Ingles, no use este producto hasta que la
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Users must follow requirements of the
OSHA Occupational Exposure Standard
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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.

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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.

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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.

DO NOT REMOVE THIS LABEL

Refer to ARC Specialty Products' Sterilizing Gas 6 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 12% ethylene oxide, 88% dichlorodifluoromethane. 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.

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 6 must be
performed only in vacuum or gas tight chambers designed for
use with Sterilizing Gas 6.

C. Sterilizing Gas 6 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 6 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 Wasted
representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL

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

1. Pressurized 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.

Distributed By:
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Balchem Corporation
P.O. Box 600 · New Hampton, NY 10958
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Fax: 845-326-5706
www.arcspecialtyproducts.com

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