

36736-4

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

APR - 8 2013

Gray M. O'Bannon
Regulatory Manager
ARC Specialty Products, Balchem Corporation
52 Sunrise Park road
New Hampton, NY 10958

Subject: **Sterilizing Gas 4**
EPA Registration Number 36736-4
Notification Application Dated March 4, 2013
EPA Received Date March 11, 2013

Dear Mr. O'Bannon:

This will knowledge receipt of your notification, submitted under the provisions of FIFRA section 3c 9. Based on a review of the submitted material the following comment apply.

Proposed Amendment:

- To reinsert previously approved language that was inadvertently omitted (and replaced with language from ARC's Sterilizing Gas 5 label) on the SG4 label that was approve on 9/15/2008
- Replace P.O. Box with street address

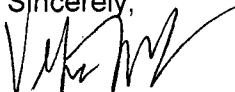
General Comments:

Based on a review of the material submitted, the following comment apply:

The notification is acceptable. A copy has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, please contact Drusilla Copeland at (703) 308-6224.

Sincerely,



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

CONCURRENCES

SYMBOL							
SURNAME							
DATE							



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 36736-4	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Sterilizing Gas 4	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) ARC Specialty Products, Balchem Corporation 52 Sunrise Park Road, New Hampton, NY 10958 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
 The purpose of this notification is to reinsert previously approved language that was inadvertently omitted from the Sterilizing Gas 4 label that was approved in September 2008. The relevant phrase is highlighted on the enclosed labels: 5 copies of the corrected label & 1 copy of the 2008 SG4 label with the incorrect language (the corresponding phrase from ARC's Sterilizing Gas 5 label - also enclosed - was inadvertently copied onto the SG4 label).

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Gary M. O'Bannon		Title Regulatory Manager		Telephone No. (Include Area Code) 845-326-5098	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature <i>Gary M. O'Bannon</i>		3. Title Regulatory Manager			
4. Typed Name Gary M. O'Bannon		5. Date 3/4/2013			



SPECIALTY PRODUCTS

March 4, 2013

Document Processing Desk (NOTIF)

Attn: Ms. Velma Noble, PM-31
Antimicrobials Division
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, D.C. 20460

Re: Submission: **Notification** of Typographical Error per PR Notice 98-10
Company: ARC Specialty Products, Balchem Corporation
Product: Sterilizing Gas 4
EPA Registration No.: 36736-4

Dear Ms. Noble:

Per PR Notice 98-10 and correspondence with AD staff, ARC Specialty Products, Balchem Corporation (ARC) is herewith submitting a notification to correct our registered label for the above-referenced product, Sterilizing Gas 4 (SG4).

As previously discussed with Agency personnel, the purpose of this notification is to reinsert previously approved language that was inadvertently omitted (and replaced with language from ARC's Sterilizing Gas 5 label) on the SG4 label that was approved on September 15, 2008.

For your convenience, along with the required 5 copies of the corrected label for SG4, we have included a copy of the SG4 label as it currently appears in the PPLS, and a copy of the Sterilizing Gas 5 label from which the incorrect language was taken. We have highlighted the phrase at issue on each label copy.

This notification does not involve a change to our current Confidential Statement of Formula, nor will it alter the production, processing, or formulation of this product, nor its physical/chemical characteristics.

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).

PERSONAL PROTECTION EQUIPMENT (PPE):

A material that is chemical-resistant to this product is butyl rubber.

All handlers must wear at a minimum:

Long-sleeved shirt and long pants,
Shoes plus socks.

Chemical-resistant gloves, and

The employer shall provide a respirator that is adequate to protect the health of the employee and ensure compliance with all other OSHA statutory and regulatory requirements (see 29 CFR 1910.1047 and 29 CFR 1910.134).

When handlers could have eye or skin contact with ETO or ETO solutions, such as during maintenance and repair, vessel cleaning, or cleaning up spills, they must wear:

- Chemical-resistant attire, such as an apron, protective suit, or footwear that protects the area of the body that might contact ETO or ETO solutions, and
- face-sealing goggles, a full face shield, or a full-face respirator.

When wearing respirators:

1. Follow the respirator manufacturer's user's instructions for changing canisters.
2. Respirators must be fit-tested and fit-checked using a program that conforms to OSHA's requirements (see 29 CFR Part 1910.134).
3. Respirator users must be trained using a program that conforms to OSHA's requirements (see 29 CFR Part 1910.134).

801465 (Rev. 06/08 - supersedes 10/06)

4. Respirator users must be examined by a qualified medical practitioner to ensure physical ability to safely wear the style of respirator to be worn. A qualified medical practitioner is a physician or other licensed health care professional (PLHCP) who will evaluate the ability of a worker to wear a respirator. The initial evaluation consists of a questionnaire that asks about medical conditions (such as a heart condition) that would be problematic for respirator use. If concerns are identified, then additional evaluations, such as a physical exam, might be necessary. The initial evaluation must be done before respirator use begins. It does not need to be repeated unless the health status of respirator use conditions change (see 29CFR Part 1910.134).

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Users should remove clothing/PPE immediately if pesticide gets inside.
Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

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/irrigation 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 Elimination 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 4, the label and valve tag attached to this cylinder.

STERILIZING

GAS 4

STERILIZANT/FUMIGANT

ACTIVE INGREDIENT: ETHYLENE OXIDE.....10%

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

(CAS NO. 75-21-8)

(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. Lea la etiqueta para obtener ayuda o explicación adicional.

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 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.

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.

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STERILIZING

GAS 4

STERILANT/FUMIGANT

ACTIVE INGREDIENT: ETHYLENE OXIDE, 100%

(CAS NO: 75-21-8)

INERT INGREDIENT: CARBON DIOXIDE, 90%

(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. Lea que la etiqueta ha sido explicada anteriormente.

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 medical 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 - If ill person, 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 medical 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.

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. Employers in facilities that use ETO must comply with all of the requirements for ETO use specified in 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.

In contract sterilization facilities, including facilities treating medical equipment and supplies, musical instruments, library/museum artifacts, cosmetics, and spices the following requirements must be followed:

Sterilization/fumigation with ETO must be performed only in vacuum or gas-tight chambers designed for use with ETO.

Safety and awareness training is required for all employees including office staff. Information and training must be provided to all employees in the facility at the time of initial assignment and annually thereafter. The safety training must include, at a minimum, the following information:

1. The most recent monitored ambient levels of ETO in the facility;
2. The potential health effects from the levels of ETO in the facility;
3. The emergency response plan and how to respond in an emergency;
4. The availability of the Material Safety Data Sheet and other materials related to the health hazards of exposure to ETO.

In order to reduce ambient levels of ethylene oxide, lengthy facility aeration is encouraged. It can reduce potential long-term risks to employees not directly involved in the ethylene oxide applications.

Air monitoring should include the entire facility including office space, break areas, and loading/unloading areas.

1. AS A STERILANT AND FUMIGANT GAS:
For complete use directions (including type of surfaces, objects, or items/products recommended for treatment, pre-cleaning instructions, concentration, or 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 other seasoning materials (see 40 CFR 180.151), and artifacts, archival material or library objects.

USE THIS PRODUCT WITHIN 120 DAYS OF ITS PURCHASE.

DO NOT REMOVE THIS LABEL

In case of accident or emergency, Date Reviewed: 4/5/13
call CHEMTREC at 1-800-424-9300 Reviewed By: ML

NOTIFICATION

Distributed By:

ARC Specialty Products

Balchem Corporation

52-Sunrise Park Rd, New Hampton, NY 10958

Tel: 845-326-5611

Fax: 845-326-5706

www.arcspecialtyproducts.com

Net Contents: _____ lbs.

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.

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 4 must be performed only in vacuum or gas tight chambers designed for use with Sterilizing Gas 4.

C. Sterilizing Gas 4 cycle parameters depend on several exposure time, chamber air pressure, pre-conditioning (if any), quantities of items to be sterilized/fumigated; packaging, types and configuration in the chamber; microbial challenge method; load 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 4 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.

EPA Registration No. 36736-4

EPA Establishment No. 35084-PA-2

36736-NY-01

36736-SC-01

36736-MO-01