36736-2 4/8/2013 1/7

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: **Ethylene Oxide**
EPA Registration Number 36736-2
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 100% EO 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								

2/7

Please read instructions on reverse before compl[illegible] form. Form Approved. O[illegible] No. 2070-0060 Print Form

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
36736-2	Velma Noble	☒ None ☐ Restricted
4. Company/Product (Name) Ethylene Oxide 100%	PM# 31	

5. Name and Address of Applicant *(Include ZIP Code)*
ARC Specialty Products, Balchem Corporation
52 Sunrise Park Road, New Hampton, NY 10958
☐ *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

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☒ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☐ 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 Ethylene Oxide label that was approved in September 2008. The phrase is highlighted on the enclosed labels: 5 copies of the corrected label & 1 copy of the 2008 label with the incorrect language (the corresponding phrase from ARC's Sterilizing Gas 5 label - also enclosed - was inadvertently copied onto the EO label)

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☒ No	☐ Yes ☒ No	☐ Yes ☒ No	☒ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ 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	4. Size(s) Retail Container	5. Location of Label Directions
☒ Label ☒ Container		☒ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product: ☒ Lithograph / Paper glued / Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Gary M. O'Bannon	Regulatory Manager	845-326-5698

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.

2. Signature	3. Title	6. Date Application Received (Stamped)
Gary M. O'Bannon	Regulatory Manager	
4. Typed Name: Gary M. O'Bannon	5. Date: 3/4/2013	

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

BALCHEM CORPORATION

ARC
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: 100% Ethylene Oxide
EPA Registration No.: 36736-2

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, 100% Ethylene Oxide (EO).

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 100% EO label that was approved on September 15, 2008. The correct language was included in the final printed labels, which were submitted to the Agency in March 2009.

For your convenience, along with the required 5 copies of the corrected label for 100% EO, we have included a copy of the EO 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.

Corporate Office: P.O. Box 600 • New Hampton, New York 10958 • 845.326.5611 • Fax 845.326.5742 • arc@balchem.com

South Carolina Location: P.O. Box 337 • Green Pond, South Carolina 29446 • 843.844.8511 • Fax 843.844.2845 • arc@balchem.com

4/7

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that, if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA, and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

If you have any questions, or require any further information, please don't hesitate to contact me, or to call Joanne Cashin at 845-326-5654.

Sincerely,

Gary M. O'Bannon /jc.

Gary M. O'Bannon

Enclosures:

Notification application
Current approved EO label
Corrected EO label (5copies)
Copy Sterilizing Gas 5 label

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 plants,
Shoes plus socks,
Chemical-resistant gloves, and

- The employer should 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 29CFR Part 1910.134).
3. Respirator users must be trained using a program that conforms to OSHA's requirements (see 29CFR Part 1910.134).
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.

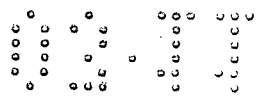
PHYSICAL OR CHEMICAL HAZARDS:
DANGER! - HIGHLY FLAMMABLE LIQUID AND GAS UNDER PRESSURE.

Contents under pressure. Do not use near flame, sparks, hot surfaces, or allow sources of ignition near the sterilization/fumigation area. Ethylene Oxide 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 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 100% Ethylene Oxide, the label and valve tag attached to this cylinder.

EPA Registration No. 36736-2
EPA Establishment No. ☐ 36736-NY-01
☐ 36736-SC-01
☐ 36736-MO-01



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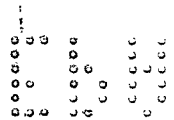

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PHYSICAL OR CHEMICAL HAZARDS:
DANGER! - HIGHLY FLAMMABLE LIQUID AND GAS UNDER PRESSURE.

Contents under pressure. Do not use near flame, sparks, hot surfaces, or allow sources of ignition near the sterilization/fumigation area. Ethylene Oxide 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 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 100% Ethylene Oxide, the label and valve tag attached to this cylinder.

EPA Registration No. 36736-2
EPA Establishment No. ☐ 36736-NY-01
☐ 36736-SC-01
☐ 36736-MO-01

ETHYLENE OXIDE

STERILANT/FUMIGANT
ACTIVE INGREDIENT: ETHYLENE OXIDE...100%
(CAS NO: 75-21-8)

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 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 Ethylene Oxide 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' Ethylene Oxide 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 m with its labeling. Employers in facilities that use ETO mus the requirements for ETO use specified in 29 CFR 1910. may be used only in facilities that meet the requiremen *Oxide Standard (29 CFR 1910.1047). This product ma* non-portable (commercial) vacuum or gas-tight chamber with 20% ethylene oxide, 80% carbon dioxide. This pro only by persons who have been trained in accordance Oxide Standard (29 CFR 1910.1047). When used to st items, this product must be used in non-portable (con *oxide gas sterilizers that have FDA clearance.*

In contract sterilization facilities, including facilities treatin equipment and supplies, musical instruments, library/mus cosmetics, and spices the following requirements must be

Sterilization/fumigation with ETO must be performed only tight chambers designed for use with ETO.
Safety and awareness training is required for all employee staff. Information and training must be provided to all emp at the time of initial assignment and annually thereafter. T must include, at a minimum, the following information:

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

In order to reduce ambient levels of ethylene oxide, length encouraged. It can reduce potential long-term risks to emp involved in the ethylene oxide applications.

Air monitoring should include the entire facility including o areas, and loading/unloading areas.

1. **AS A STERILANT AND FUMIGANT GAS:**
A. For complete use directions (including type of sur items/products recommended for treatment, pre-clea concentration of gas per unit volume of closed spa exposure time/temperature, relative humidity, ventilation/ method of monitoring to be used) refer to the ethylene manufacturers' Operators Manuals.

This product may be used only to sterilize medical or pharmaceuticals, and aseptic packaging, (see 21 CFR reduce microbial load on cosmetics, whole and groun seasoning materials (see 40 CFR 180.151) and artifacts or library objects.

USE THIS PRODUCT WITHIN 120 DAYS OF ITS PURCHASE.

DO NOT REMOVE THIS LABEL.

In case of accident or emergency, call CHEMTREC at 1-800-424-9300.

801137 (Rev. 06/08 - supersedes *05/07)*

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Keep under medical observation -

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nt advice. Aerate, wash or clean
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glasses of water if able to swallow.
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C Specialty Products at the telephone
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 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.

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:**
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.

USE THIS PRODUCT WITHIN 120 DAYS OF ITS PURCHASE.

DO NOT REMOVE THIS LABEL.

Date Reviewed: NOTIFICATION
Reviewed By:

In case of accident or emergency, call CHEMTREC at 1-800-424-9300.

801137 (Rev. 06/08 - supersedes *05/07)*

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 Ethylene Oxide must be performed only in vacuum or gas tight chambers designed for use with Ethylene Oxide.
C. Ethylene Oxide 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 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 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. *Pressurize 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:
ARC Specialty Products
Balchem Corporation
P.O. Box 600 · New Hampton, NY 10958
Tel: 845-326-5611
Fax: 845-326-5706
www.arcspecialtyproducts.com