

36736-5

10/21/2011

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Joanne K. Cashin  
Registration Compliance Advisor  
ARC Specialty Products, Balchem Corporation  
52 Sunrise Park RD., New Hampton, NY 10958

OCT 21 2011

SUBJECT: Sterilizing Gas 5  
EPA Registration Number: 36736-5  
Application Date: September 19, 2011  
Receipt Date: September 23, 2011

Dear Ms. Cashin:

This letter acknowledges receipt of the notification identified above submitted under provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended and PR Notice 98-10.

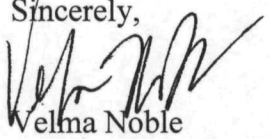
- To make add an explanatory statement to the label

Based on a review of the submitted information, this notification is acceptable. Your proposed change will be made part of the record for this file.

**General Comments**

Should you have any questions concerning this letter, please contact Emilia Oiguenblik at (703) 347-0199 or Velma Noble at (703) 308-6233.

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

Registration  
 Amendment  
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 36736-5	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Sterilizing Gas 5	PM# 31	
5. Name and Address of Applicant (Include ZIP Code)  ARC Specialty Products, Balchem Corporation 52 Sunrise Park Rd., 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.)

At the request of an official with a state pesticide regulatory agency, and as discussed with Agency staff, we are adding the following explanatory statement to our label for Sterilizing Gas 5 (highlighted for convenience on the enclosed label copies):  
"Note: Ethylene Oxide is also referred to herein as ETO"

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
* Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container	<input type="checkbox"/> Glass
					<input type="checkbox"/> Paper
					<input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> 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 O'Bannon	Title Regulatory Manager	Telephone No. (Include Area Code) 845-326-5648
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>Joanne K. Cashin</i>	3. Title Registration Compliance Advisor	
4. Typed Name Joanne K. Cashin	5. Date Sep 19, 2011	

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SPECIALTY PRODUCTS

September 19, 2011

Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
1200 Pennsylvania Ave. NW  
Washington, D.C. 20460

Re: Submission: Notification  
Company: ARC Specialty Products, Balchem Corporation  
Product: Sterilizing Gas 5  
EPA Registration No.: 36736-5

Dear Sir or Madam;

ARC Specialty Products, Balchem Corporation is herewith submitting a Notification to make a minor change to the approved label for our product, Sterilizing Gas 5 (EPA Reg. No.: 36736-5).

As discussed with EPA staff, this change involves adding an explanatory statement at the request of an official with a state pesticide regulatory agency.

If you have any questions, or require any further information, please don't hesitate to contact me at 845-326-5654 or 845-298-9057.

Sincerely,

*Joanne K. Cashin*

Joanne K. Cashin  
Registration Compliance Advisor

Enclosures:

Application for Pesticide Registration (Form 8570-1)  
Proposed Label (5 copies)

Handwritten marks consisting of several rows of small circles or dots, possibly a signature or initials.



**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:

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

EPA Registration No. 36736-5

EPA Establishment No.  35084-PA-2

36736-NY-01

36736-SC-01

36736-MO-01

- 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.  
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 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 Special  
Products' Material Safety Data Sheet for Sterilizing Gas 5, the label and  
valve tag attached to this cylinder.

USE THIS PRODUCT WITHIN 120 DAYS  
OF ITS PURCHASE.

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

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STERILAN  
ACTIVE INGREDIENT: ETO  
(CAS NO  
INERT INGREDIENT: CAI  
(CAS NO

TOTAL:.....

**Keep Out of R**

**DANGER**

PRECAUTIONAL USE  
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Users must follow requiremen  
Standard for ethylene oxide (2

(Note: Ethylene Oxide is also

**FIRST AID**

IN ALL CASES OF OVEREX  
MEDICAL ATTENTION IMME  
TAKE PERSON TO A DOCT  
EMERGENCY TREATMENT  
AT ONCE.

**IF INHALED** - Move person  
breathing, call 911 or an ar  
preferably by mouth-to-mouth  
oxygen. Call a poison contr  
advice, even if there are  
observation - symptoms may

**IF ON SKIN OR CLOTHIN**  
shoes. Rinse skin immediate  
Call a poison control center  
wash or clean contaminated

**IF SWALLOWED** - Call poi  
for treatment advice. Have  
swallow. Do not induce vom  
unconscious person.

**IF IN EYES** - Hold eye open  
15-20 minutes. Call a pois  
advice.

**HOTLINE NUMBER** - Have  
when calling a poison contr  
You may also contact 1  
treatment information.

**NOTE TO PHYSICIAN** - I  
commonly result in skin irri  
high concentrations, severe  
respiratory tract may occur,  
of systemic intoxication  
incoordination, and cardiac i

users must be examined by a qualified medical professional 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 evaluates the ability of a worker to wear a respirator. The evaluation consists of a questionnaire that asks about medical conditions (such as a heart condition) that would be a concern for respirator use. If concerns are identified, then further evaluations, such as a physical exam, might be required. The initial evaluation must be done before respirator use. It does not need to be repeated unless the health conditions for respirator use change (see 29CFR Part 1910.134).

Refer to the manufacturer's instructions for cleaning/maintaining PPE. If no other instructions exist, use detergent and hot water. Wash and dry PPE separately from other laundry.

**Recommendations**

Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Remove contaminated clothing/PPE immediately if pesticide gets inside. Immediately put on clean clothing.

Remove contaminated PPE immediately after handling this product. Wash hands and face with soap and water before removing. As soon as possible, change into clean clothing.

**HEALTH HAZARDS:**

**HEAVILY FLAMMABLE LIQUID AND GAS UNDER PRESSURE.**

Do not use near flame, sparks, hot surfaces, or sources of ignition near the sterilization/fumigation area. This product is extremely flammable and reactive. Ground all electrical equipment (this container) to prevent sparks. In case of leak evacuate area and keep personnel upwind. In case of ignition, use self-contained breathing apparatus, and shut off leak if without risk. Move container away from fire if without risk. Use water spray to keep container cool.

**HAZARDS:**

Do not discharge effluent containing this product into lakes, streams, rivers, oceans or other waters unless in accordance with the National Pollutant Discharge Elimination System and the permitting authority has been notified in writing. Do not discharge effluent containing this product to surface waters without previously notifying the local sewage treatment plant. For guidance contact your State Water Board or the EPA.

Users of this material be familiar with ARC Specialty Safety Data Sheet for Sterilizing Gas 5, the label and the contents of this cylinder.

USE PRODUCT WITHIN 120 DAYS OF PURCHASE.

In case of fire or emergency, call 1-800-424-9300

**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 las instrucciones, 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).

(Note: Ethylene Oxide is also referred to herein as ETO)

**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 if necessary. Do not reuse.

**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 Safety Data Sheet for this product. Locate MSDS for this product by calling the telephone number below and providing the product name.

**DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in violation of the requirements of the Ethylene Oxide Standard (29 CFR 1910.1047) unless the product may be used only in non-portable (or designed for use with 20% oxygen) sterilization chambers. The product may be used only in accordance with the Ethylene Oxide Standard (commercial) ethylene oxide clearance.

In contract sterilization facilities, sterilization equipment and supplies, must be used for cosmetics, and spices the following:

Sterilization/fumigation with ETO in gas tight chambers designed for use in safety and awareness training facilities. Information and training for the facility at the time of initial safety training must include, at least:

1. The most recent monitoring data.
2. The potential health effects of ETO.
3. The emergency response plan.
4. The availability of the Material Safety Data Sheet related to the health hazards.

In order to reduce ambient level of ETO, ventilation is encouraged. It is recommended that employees not directly involved in the process be removed from the area.

Air monitoring should include monitoring in break areas, and loading/unloading areas.

1. **AS A STERILANT AND FUMIGANT**. For complete use directions, refer to the product label. For complete use directions, refer to the product label. For complete use directions, refer to the product label. For complete use directions, refer to the product label.

**ARC SPECIALTY**  
**BALCO**  
 P.O. Box 600  
 Tel: 800-424-9300  
 Fax: 800-424-9300  
 www.arcs.com

# LING

GANT  
OXIDE.....20%  
OXIDE.....80%  
.....100%

## of Children

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OSHA Occupational Exposure  
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to herein as ETO)

# GET

air. Keep warm. If person is not  
then give artificial respiration,  
ble. If breathing is difficult, give  
or doctor for further treatment  
ptoms. Keep under medical  
ed.  
off contaminated clothing and  
enty of water for 15-20 minutes.  
r for treatment advice. Aerate,  
nd discard leather goods.  
ol center or doctor immediately  
two glasses of water if able to  
ot give anything by mouth to an  
slowly and gently with water for  
center or doctor for treatment

luct container or label with you  
r doctor, or going for treatment.  
9300 for emergency medical

sure to Sterilizing Gas 5 will  
extensive blister formation. At  
vitis can occur. Irritation of the  
it acute lung edema. Symptoms  
eadache, nausea, vomiting,  
s. 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. 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 40CFR 180.151), and artifacts, archival material or library objects.

**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**

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 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.