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UNI STATES ENVIRONMENTAL PROTECT AGENCY

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Sheril L. Dolan
Agent for Honeywell
THE Acta Group, LLC
1203 Nineteenth Street, NW., Suite 300
Washington D.C. 20036

APR 19 2011

Subject: Steriflo
EPA Registration Number 67470-10
Amendment Date: January 19, 2011
EPA Receipt Date: January 19, 2011

Dear Ms. Dolan:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable subject to the conditions listed below:

- Resubmission of Fast-Track Amendment for Minor Label Changes in response to EPA letter dated October 4, 2010

**Conditions:**

Revise the Ingredient statement of label to read:

| | |
|---|---|
| **ACTIVE INGREDIENT:** ETHYLENE OXIDE (CAS 75-21-8) | 10.4% |
| **OTHER INGREDIENTS:** | |
| HEPTAFLUOROPROPANE (354-33-6) | 7.7% |
| PENTAFLUOROETHANE (CAS 431-89-0) | 81.9% |
| **TOTAL** | 100.0% |

**General Comments**

A stamped copy of the accepted labeling is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling.
Should you have any questions concerning this letter, please contact Emilia Oiguenblik at (703) 347-0199 or Velma Noble at (703) 308-6233.

Sincerely,

Tracy Fasty

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

| CONCURRENCES | | | | | | | |
|---|---|---|---|---|---|---|---|
| SYMBOL | | | | | | | |
| SURNAME | | | | | | | |
| DATE | | | | | | | |

STT-SF TAG FRONT
01/19/2011 Revision



DO NOT REMOVE TAG
**Steriflo®**
STERILANT-FUMIGANT GAS
DANGER! LIQUID AND GAS UNDER PRESSURE.
HARMFUL IF INHALED.

**DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**NOTE TO USER:** When used in the workplace, it is the employer's responsibility to ensure that all personnel are familiar with and adhere to 29 CFR 1910.1047. Steriflo is a highly hazardous material and must be used only by personnel trained in its proper use. All persons working with Steriflo must have knowledge of the hazards of this chemical mixture and must be trained in the proper use of required respirator equipment, monitoring and detection devices, and in the implementation of emergency procedures.

To be used only by persons experienced in Steriflo sterilization and fumigation, or by persons under direct supervision of persons who are experienced in Steriflo sterilization and fumigation. Use only in accordance with the directions and the safety precautions listed on the label and this tag. See current Honeywell Material Safety Data Sheet for Steriflo.

1. Always check cylinder valves and relief valves for leaks before moving cylinder into your facility.
2. This cylinder is equipped with an eductor tube for liquid delivery. Use vaporizing equipment to convert the liquid into a gas.
3. The approximate vapor pressure exerted by this gas mixture will be 50 psig (5.50 kg/cm2) at 70°F (21.1°C) while liquid is present. Vapor pressure will be higher if temperature is above 70°F (21.1°C); lower if temperature is below 70°F (21.1°C).
4. Cylinder must be in an upright position when discharging. Cylinder must be secured to prevent falling over.
5. Discharge valve outlet is provided with a CGA 510 connection which has left-hand threads.
6. Remove protective valve plug and make sure valve threads are undamaged. The connection to the cylinder valve should be brass CGA 510 connector. Use of other metals could cause damage to the brass cylinder valve. Do not attach an ordinary pipe fitting to this valve.
7. All other piping and fittings should be steel or stainless steel, capable of withstanding the pressure to be encountered. Do not use rubber or plastic materials. Install relief devices where liquid can be trapped between valves.
8. Install check valves in the discharge line from this cylinder to processing equipment to prevent back-flow into cylinder.
9. To open cylinder valve, turn handwheel counterclockwise. Do not use a wrench or other leverage device to open or close cylinder valve.
10. Use with adequate general and local ventilation.
11. Determine the quantity of product withdrawn from this cylinder by using an appropriate scale.

STERILIZATION AND FUMIGATION

Steriflo must be used only to sterilize medical and laboratory items, pharmaceuticals, aseptic packaging, and reduce microbial load on cosmetics. Items to be sterilized must be thoroughly cleaned of soil before being placed in any type of sterilizer.

A. Steriflo must be used only in facilities that meet the requirements of 29 CFR 1910.1047 in non-portable (commercial) vacuum or gas-tight chambers designed for use with 10.4% ethylene oxide, 7.7% heptafluoropropane and 81.9% pentafluoroethane. Steriflo may be used only by persons who have been trained in accordance with 29 CFR 1910.1047. In hospitals and healthcare facilities, sterilization/fumigation with Steriflo must be performed only in vacuum or gas-tight chambers designed for use with Steriflo that have FDA clearance and in accordance with directions supplied by the sterilizer manufacturer.

After February 28, 2010, a single chamber process is required for ethylene oxide treatment (sterilization and aeration are to occur in the same chamber) in hospitals and healthcare facilities.

NOTE: It is a violation of Federal Law to use Steriflo Sterilant/Fumigant Gas for the fumigation of beehives, airplanes, trains, buses, ships, trucks, trailers, warehouses, or other similar spaces.

In contract sterilization facilities, including facilities, treating medical equipment and supplies, library/museum artifacts and cosmetics the following requirements must be followed:
Sterilization/fumigation with Steriflo must be performed only in vacuum or gas-tight chambers designed for use with Steriflo.
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 ethylene oxide in the facility;
2. the potential health effects from the levels of ethylene oxide 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 ethylene oxide.

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

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

B. Steriflo cycle parameters depend on several sterilizing/fumigating variable factors: preconditioning (if any); exposure time; chamber air concentration; ethylene oxide concentration; chamber temperature; humidity level; types and quantities of items to be sterilized/fumigated; packaging; load configuration in the chamber; microbial challenge method; desired level of sterility assurance; and the desired performance of the sterilized; fumigated product and package.
C. The following is a list of ranges for the critical variables which must be in proper relationship for Steriflo to be an effective sterilizing/fumigating agent. This information must be considered general, and not as a replacement for detailed information issued by manufacturers.
TEMPERATURES - 70°F TO 150°F.
PRE-VACUUM - typically 10 to 25 inches of mercury. Use vacuums compatible with the products and packages to be sterilized/fumigated.
MOISTURE - relative humidity of 33% to 80%
GAS CONCENTRATION - 250 mg/L to 1500 mg/L milligrams of ethylene oxide per liter of chamber volume.
EXPOSURE TIME - 45 minutes to 20 hours.
POST-VACUUMS - Steriflo is removed from the chamber and vented to an appropriate ethylene oxide capture or destruction device.
AERATION - aerate sterilized/fumigated materials before use. Do not allow any person to enter the chamber or aeration area if such entry will result in exposures to ethylene oxide above the levels established in 29 CFR 1910.1047.
Cycle parameters and post-cycle aeration parameters (temperature, time, air flow-rate) can affect residue levels. The user must determine that the parameters chosen result in goods which comply with applicable Federal and State residue requirements.
For residual limits of ethylene oxide on drug products and medical products see 21 CFR 201.1 sub-section (d).
D. The sterilization/fumigation cycle parameters must be those prescribed by the sterilizer 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.
E. Employers in facilities that use ethylene oxide must comply with all of the requirements for ethylene oxide use specified in 29 CFR 1910.1047.

101 Columbia Road
Morristown, NJ 07962-1053
EPA Registration No. 67470-10

STORAGE AND DISPOSAL
Do not contaminate food, feed, or water by storage and disposal.
PESTICIDE STORAGE: Store according to instructions provided on label and this tag. Store away from heat in an area with adequate ventilation. Do not store in direct sunlight. To minimize polymer growth, Steriflo must not be stored in any place where the temperature consistently exceeds 100°F. To control ethylene oxide polymer growth, use all sterilant gas on a first-in, first-out basis.
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:
Refillable container. Refill this container only with a non-flammable ethylene oxide mix. Do not reuse this container for any other purpose unless reconditioned as described below. When empty, return container to supplier/reconditioner only. Before returning container to supplier/reconditioner:
A. Replace valve plug tightly in valve outlet. If valve plug is not available, contact supplier.
B. Check container valve for leaks prior to shipment. If leaks are detected contact supplier.
The container may be refilled with other than a non-flammable ethylene oxide mix only when the container has been reconditioned as follows: To recondition the container and to remove residue, first perform vacuum and nitrogen purges, remove all valves and labels, and then clean by steam and hot water. Reconditioning may only be performed at a facility that can manage ethylene oxide at concentrations exceeding 0.5 ppm in air (8-hour time-weighted average) and comply with 29 C.F.R. §1910.1047.

PATENT INFORMATION
This product and its use for sterilization are protected by US Patent #s 5039485, 5342579, 6432357, 5976554. The purchase of this product gives you a license under the patent for single use only, and subsequent use constitutes patent infringement. Any re-use of this product, or unauthorized reconditioning (which may not meet stringent requirements), is potentially unsafe and a violation of the license terms granted to you upon sale of this product.

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# Steriflo®

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|---|---|
| **ACTIVE INGREDIENT:** ETHYLENE OXIDE (CAS 75-21-8) | 10.4% |
| **OTHER INGREDIENTS:*** | 89.6% |
| *HEPTAFLUOROPROPANE (CAS 354-33-6) 7.7% | |
| *PENTAFLUOROETHANE (CAS 431-89-0) 81.9% | |
| Total | 100.0% |

**KEEP OUT OF REACH OF CHILDREN**

**DANGER PELIGRO**
**PRECAUCION AL USUARIO:** Si usted no lee Ingles, no use este producto hasta que la etiqueta la haya sido explicada ampliamente.
Users must follow the requirements of the OSHA occupational exposure standard for ethylene oxide (29 CFR 1910.1047).

**PRECAUTIONARY STATEMENTS**
**HAZARDS TO HUMANS AND DOMESTIC ANIMALS.**
**DANGER!** CAUSES EYE AND SKIN BURNS.
HARMFUL IF INHALED. HARMFUL IF SWALLOWED.
MAY CAUSE RESPIRATORY AND NERVOUS SYSTEM DAMAGE. **DANGER!** CANCER HAZARD AND REPRODUCTIVE HAZARD.
**EFFECTS OF OVEREXPOSURE:** May be fatal if inhaled in high concentrations. May cause irritation of 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 lungs), immediate or delayed skin irritation and 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:** 1PPM-TWA Ethylene Oxide (OSHA 29CFR1910.1047)
**EL:** 5PPM-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, on clothing. Store and use with adequate ventilation in accordance with 29 CFR 1910.1047**
**PHYSICAL AND CHEMICAL HAZARDS**
Contents under pressure. Use only in closed system. No part of the container may be exposed above 125°F (52°C). Close valve when not in use and when empty.
**LEAK:** Evacuate area and keep personnel upwind. Use self-contained breathing apparatus and protective clothing, and shut off leak if without risk.
**FIRE:** Move container away from fire if without risk. Use water spray or fog nozzle to keep container cool.

Personal Protective Equipment
Some materials that are chemical resistant to this product are 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 (including 29CFR 1910.1047 and 29CFR 1910.134), under routine and reasonably foreseeable emergency situations.

When handlers could have eye or skin contact with ethylene oxide or ethylene oxide 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 ethylene oxide or ethylene oxide solutions, and
> Face-sealing goggles, a full-face shield, or a full-face respirator.

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 confirms 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 or 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 Requirements
Users must wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

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

Users must 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.

**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 Pollution 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.

**FIRST AID**
IN ALL CASES OF OVEREXPOSURE, GET MEDICAL ATTENTION IMMEDIATELY. CALL THE POISON CONTROL CENTER OR DOCTOR FOR TREATMENT ADVICE.
**IF INHALED:** Remove exposed person to fresh air, keep warm. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call the Poison Control Center or doctor for advice even if no symptoms are present. Keep under medical observation. Symptoms may be delayed.
**IF IN EYES:** Hold eyelids open and rinse slowly and gently with water for 15-20 minutes. Call the Poison Control Center or doctor for advice.
**IF ON SKIN OR CLOTHING:** Immediately rinse with plenty of water for 15-20 minutes while removing contaminated clothing and shoes. Call the Poison Control Center or doctor for advice. Aerate, wash or clean contaminated clothing and discard leather goods.
**IF SWALLOWED:** Call the Poison Control Center or doctor for advice. Give at least two glasses of water. Do not induce vomiting. Do not give anything by mouth to an unconscious person.
**NOTE TO PHYSICIAN:** REFER TO SECTION IV, FIRST AID MEASURES OF THE MSDSs FOR EACH INGREDIENT. To obtain MSDSs, call 1-800-522-8001. Skin exposure to Steriflo 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 lung edema. Symptoms of systemic intoxication are headache, nausea, vomiting, incoordination, and cardiac irregularities. Treatment is symptomatic.
**IN CASE OF EMERGENCY CALL:**
1-800-498-5701. Have a copy of the label or the MSDS when calling a poison control center or doctor or going for treatment.

BEFORE USING OR HANDLING THIS PRODUCT YOU MUST ALSO READ AND UNDERSTAND THE HONEYWELL MATERIAL SAFETY DATA SHEET FOR THIS PRODUCT.
FOR HEALTH CARE FACILITY AND INDUSTRIAL USE AS INDICATED IN THE DIRECTIONS FOR USE.
**DOT/IMO Shipping Name: Liquefied Gas, N.O.S., (Ethylene Oxide, Pentafluoroethane, Heptafluoropropane)**
**US DOT Hazard Class: 2.2** Honeywell

STB-Steriflo
01/19/2011 Revision

**US DOT ID Number: UN 3163 DOT-SP 10184** 101 Columbia Rd., Morristown, NJ 07962-1053
EPA Registration No. 67470-10 EPA Establishment No. **67470-AZ-001**
BATCH - DO NOT REMOVE THIS LABEL MADE IN USA STB-SF-US (01/11)