

67470-10

04/05/2007

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U.S. ENVIRONMENTAL PROTECTION AGENCY
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510C)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

EPA Reg. Number:

67470-10

Date of Issuance:

APR - 5 2007

Term of Issuance:

Unconditional

Name of Pesticide Product:

Steriflo

NOTICE OF PESTICIDE:

- Registration
- Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (Include ZIP Code):

Honeywell International, Inc.
101 Columbia Road
Morristown, NJ 07962-1053

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

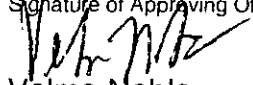
On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA sec 3(c)(5) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.
2. Make the labeling changes listed below before you release the product for shipment:
 - a. Revise the "EPA Registration Number to read, "EPA Reg. No. 67470-10".

Signature of Approving Official:



Velma Noble
Product Manager Team-31
Regulatory Management Branch 1
Antimicrobials Division (7510C)

Date:

APR - 5 2007

EPA Form 8570-6

CONCURRENCES

SYMBOL	7510C					
SURNAME	S. Noble					
DATE	4.2.07					

CHEMISTRY

1. The requirements of PR Notice 91-2 were satisfied. The nominal concentration of the active ingredient given in the proposed new Basic CSF dated 11/28.2006, agreed with the percentage declared on the product label.,
2. The upper and lower certified limits for both the active and ingredients were acceptable.
3. The active ingredient, ethylene oxide, is from a registered EPA Reg. no. 67470-6.
4. The proposed new ingredient, pentafluoroethane (HFC-125) and heptafluoropropane (HFC-227ea) utilized in the formulation are approved for use in this and other pesticide formulations.
5. The proposed registration based on its purpose and similarity to the existing EPA registered product, OXyfume 2002, meets the requirements of a "me-too" registration.
6. The product chemistry requirements were addressed via the selective method of support utilizing the product chemistry data generated under MRID #433109-01. As a "me-too" registration this method of data support is accepted.
7. All other elements of this new product registration submission and the proposed new Basic CSF, dated 11/28/06, were accepted.

FIRST AID STATEMENTS

- 1) Move the "Leak" and "Fire" statements such that it appears under the "Physical and Chemical Hazards" section.
- 2) Delete the first statement under "Environmental Hazards" section.
- 3) Several statements, specifically, the 3rd, 8th, 9th, and 10th statements under "Directions for Use" and 4th statement under "Storage," must be revised by deleting the term, "should", and stating "**must**" such that the label is in compliance with PR Notice 2000-5, Mandatory Language.
- 4) Revise the "First Aid" statements:
 - a) Delete the phrase, call a physician. State "Call the Poison Control Center or doctor for treatment advice."
 - b) Revise the first statement under "If in Eyes" to read "Hold eyelids open and rinse slowly and gently with water for 15-20 minutes."
- 5) The "Note to Physician" guidance must be added to the label. It must state:

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 acute lung edema. Symptoms of systemic intoxication are headache, nausea, vomiting, incoordination, and cardiac irregularities. Treatment is symptomatic.

A stamped copy of the accepted labeling is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Zenobia Jones at 703-308-6198.

Sincerely,



Velma Noble
Product manager 31
Regulatory Management Branch 1
Antimicrobial Division (7510C)

Steriflo®

ETHYLENE OXIDE	CAS: 75-21-8	10.4%
HEPTAFLUOROPROPANE	CAS: 354-33-6	7.7%
PENTAFLUOROETHANE	CAS: 431-89-0	81.9%
		100.0%

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DANGER PELIGRO

PRECAUCION AL USUARIO: Si usted no lee Ingles, no use este producto hasta que la etiqueta la haya sido explicada ampliamente.
 Note to Users: 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 OR 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-29 CFR 1910.1047)
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.

ACCEPTED
 with COMMENTS
 in EPA Letter Dated:
 APR - 5 2007
 Under the Federal Insecticide,
 Fungicide, and Rodenticide Act as
 amended, this pesticide,
 registered under EPA Reg. No. 67470-10

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.
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.
PHYSICAL AND CHEMICAL HAZARDS
 LIQUID AND GAS 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.
ENVIRONMENTAL HAZARDS
 Ethylene oxide is not intended for outdoor use. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public waters unless this is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

FIRST AID: IN ALL CASES OF EXPOSURE, GET MEDICAL ATTENTION IMMEDIATELY. TAKE PERSON TO DOCTOR OR EMERGENCY TREATMENT FACILITY AT ONCE.
IF INHALED: Move exposed person to fresh air and keep warm. If not breathing, call 911 or an ambulance, then give artificial respiration. If breathing is difficult, give oxygen. Call a physician even if no symptoms are present. Keep under medical observation. Symptoms may be delayed.
IF IN EYES: Wash eyes immediately with large amounts of water for at least 15 minutes, lifting the lower and upper eyelids. Call a physician.
IF ON SKIN OR CLOTHING: Immediately rinse skin with plenty of water for 15 - 20 minutes while removing contaminated clothing and shoes. Call a physician. Aerate, wash or clean contaminated clothing and discard leather goods.
IF SWALLOWED: Call a poison control center or doctor for treatment advice. Give at least two glasses of water. Do not induce vomiting unless told to do so by a physician. Do not give anything by mouth to an unconscious person.
IN CASE OF MEDICAL 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.
NOTE TO PHYSICIAN: REFER TO SECTION IV, FIRST AID MEASURES OF THE MSDSs FOR EACH INGREDIENT. To obtain MSDSs, call 1-800-522-8001.

BEFORE USING OR HANDLING THIS PRODUCT YOU MUST ALSO READ AND UNDERSTAND THE MATERIAL SAFETY DATA SHEETS FOR THIS PRODUCT.

DOT/IMO Shipping Name: Liquefied Gas, N.O.S. (Ethylene Oxide, Pentafluoroethane, Heptafluoropropane)

Hazard Class: 2.2

ID Number: UN 3163 DOT-SP 10184

EPA Registration No. 67470-_____

EPA Establishment No. 67470-AZ-001

Honeywell
 101 Columbia Rd.
 Morristown, NJ 07962-1053

BATCH-

DO NOT REMOVE THIS LABEL

MADE IN USA

STB-STF(9/06)

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 should 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.

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

A. Steriflo may 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. When used to sterilize health care items, Steriflo must be used in non-portable (commercial) ethylene oxide gas sterilizers that have FDA clearance, and in accordance with directions supplied by the sterilizer manufacturer.

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.

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 should 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 should 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.

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GENERAL INSTRUCTIONS

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.

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 in a cool, well ventilated area. Do not store in direct sunlight. To minimize polymer growth, Steriflo should 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: When empty, return to supplier only. Before returning to supplier:
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.

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.

Honeywell

101 Columbia Road
Morristown, NJ 07962-1053

EPA Registration No: 67470-__

STT-Steriflo (9/06)