

67470-3

11-14-2007

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

John W. Jones
Global Leader Product Stewardship
Honeywell
101 Columbia Road
Morristown, NJ 07962

NOV 14 2007

Subject: Oxyfume® 12
EPA Reg. No.67470-3
EPA Application Dated: August 15, 2007
EPA Receipt Date: August 20, 2007

Dear Mr. Jones,

The following amendment submitted in connection with registration under the section 3(c)(7)(a) of Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended is acceptable.

Proposed Amendment

- Revise label

General Comments

A stamped copy of the acceptable label is enclosed for your records. 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 Velma Noble at (703) 308- 6233.

Sincerely,

Velma Noble
Product Manager (31)
Regulatory Management Branch1
Antimicrobial Division
(7510p)

CONCURRENCES						
SYMBOL	7510C				Enclosure: Stamped label	
SURNAME						
DATE	11/9/07					

OXYFUME® 12

STERILANT-FUMIGANT GAS.

ACTIVE INGREDIENT: ETHYLENE OXIDE (CAS 75-21-8)

OTHER INGREDIENT: DICHLORODIFLUOROMETHANE (CAS 75-71-8)

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).

Honeywell

12.0%

88.0%

100.0%

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS.

DANGER! LIQUID AND GAS UNDER PRESSURE.
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. Use in accordance with tag attached to valve.

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.

WARNING: Contains CFC-12, a substance which harms human health and the environment by destroying ozone in the upper atmosphere.

ENVIRONMENTAL HAZARDS

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 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 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.

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 HEALTHCARE FACILITIES AND INDUSTRIAL USE ONLY.

DOT/IMO Shipping Name: Ethylene Oxide and Dichlorodifluoromethane Mixture

Hazard Class: 2.2

ID Number: UN 3070 **DOT-SP:** 10184

EPA Registration No.: 67470-3 **EPA Establishment No.:** 67470-AZ-001

BATCH-

DO NOT REMOVE THIS LABEL

MADE IN USA

STB-0200 (2/07)

Honeywell

101 Columbia Rd., Morristown, NJ 07962-1053

ACCEPTED

NOV 14 2007

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 67470-3

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DO NOT REMOVE TAG

OXYFUME 12
STERILANT-FUMIGANT GAS

DANGEROUS 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. Oxyfume 12 is a highly hazardous material and must be used only by personnel trained in its proper use. All persons working with Oxyfume 12 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 Oxyfume 12 sterilization and fumigation, or by persons under direct supervision of persons who are experienced in Oxyfume 12 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 Oxyfume 12.

STERILIZATION AND FUMIGATION

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 splices, 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 splices 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 16 hours. Then evacuate the gas from the chamber using a sequence of not less than 16 steam washed (injections and evacuations) between 1.0 PSIA (28" Hg) and 2.0 PSIA (25" Hg) while maintaining a minimum chamber temperature of 120°F. US Patent No. 6,132,879.

Oxyfume 12 must be used only to sterilize medical and laboratory items, pharmaceuticals, aseptic packaging, and to reduce the microbial load on cosmetics and whole and ground spices, and artifacts, archival material or literary objects.

Items to be sterilized must be thoroughly cleaned of soil before being placed in any type of sterilizer.

- A. Oxyfume 12 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 10.0% ethylene oxide, and 88.0% dichlorodifluoromethane. Oxyfume 12 must be used only by persons who have been trained in accordance with 29 CFR 1910.1047. When used to sterilize health care items, Oxyfume 12 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 Oxyfume 12 Sterilant/Fumigant Gas for the fumigation of beehives, airplanes, trains, buses, ships, trucks, trailers, warehouses, or other similar spaces.

- B. Oxyfume 12 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 Oxyfume 12 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 - Oxyfume 12 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.

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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). For residual limits on agricultural commodities see 40 CFR 180.151.

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.

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 60 psig (5.25 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 away from heat in an area with adequate ventilation. Do not store in direct sunlight. To minimize polymer growth, ethylene oxide 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. To minimize sterilizer downtime, it is recommended to use product within 12 months of the fill date marked on the container (batch number).

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

Return container to supplier for reuse. Before returning container to supplier:

- A. Replace valve plugs tightly in valve outlets. If valve plugs are not available, contact supplier.
- B. Check container valves and plugs for leaks prior to shipment. If leaks are detected, contact supplier.

Honeywell

101 Columbia Road
Morristown, NJ 07962-1053

EPA Registration No. 67470-3

STT-0200 (2-07)