

## Material Safety Data Sheet

### Oxyfume<sup>®</sup> 2002 Sterilant Mixture

#### 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

**PRODUCT NAME:** OXYFUME<sup>®</sup> 2002 Sterilant Mixture

**OTHER/GENERIC NAMES:** Sterilant gas

**PRODUCT USE:** Sterilant gas used to sterilize medical products. Users must follow the requirements of the OSHA occupational exposure standard for ethylene oxide (29 CFR 1910.1047).

**MANUFACTURER:** Honeywell  
101 Columbia Road  
Box 1053  
Morristown, New Jersey 07962-1053

**FOR MORE INFORMATION CALL:**  
(Monday-Friday, 8:00am-5:00pm EST)  
1-800-522-8001

**IN CASE OF EMERGENCY CALL:**  
(24 Hours/Day, 7 Days/Week)  
**Transportation:** 1-800-424-9300  
**Medical:** 1-800-498-5701

#### 2. COMPOSITION/INFORMATION ON INGREDIENTS

<u>INGREDIENT NAME</u>	<u>CAS NUMBER</u>	<u>WEIGHT %</u>
Ethylene Oxide	75-21-8	10.0
Chlorodifluoromethane (HCFC-22)	75-45-6	27.0
Chlorotetrafluoroethane (HCFC-124)	2837-89-0	63.0

Trace impurities and additional material names not listed above may also appear in Section 15 toward the end of the MSDS. These materials may be listed for local "Right-To-Know" compliance and for other reasons.

#### 3. HAZARDS IDENTIFICATION

**EMERGENCY OVERVIEW: 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 and reproductive hazard. Do not breathe vapor. Do not swallow. Do not get in eyes, on skin, on clothing. Exposure to toxic levels may occur without warning or detection by user. KEEP OUT OF REACH OF CHILDREN.**

**This mixture is a gas at normal temperature and pressure.**

#### POTENTIAL HEALTH HAZARDS

**SKIN:** Causes skin burns and irritation with extensive blister formation. Liquid may cause frostbite. Liquid or solutions in water may cause localized redness, inflammation, swelling and blisters. There may be a latent period of several hours prior to onset of these symptoms. Sustained contact with the skin is unlikely, but can cause headache, dizziness, nausea and vomiting. A dilute solution may penetrate skin, producing a chemical burn. Effects from overexposure include immediate or delayed skin irritation and blisters, allergic skin reaction (sensitization).

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**EYES:** Causes eye burns. Liquid causes severe irritation, redness and swelling and chemical burns of the cornea. Vapor causes moderate irritation resulting in redness and swelling. At high concentrations severe conjunctivitis can occur.

**INHALATION:** May be fatal if inhaled in high concentrations. Harmful if inhaled. May cause irritation of the respiratory tract. Depending on the degree of exposure, there may be stinging of the nose and throat, coughing, chest tightness, nausea, vomiting, diarrhea, light headedness, weakness, drowsiness, cyanosis, incoordination, convulsions and coma. May cause lung injury and the delayed onset of pulmonary edema. Treatment is symptomatic.

**INGESTION:** Not a probable route of exposure. Harmful if swallowed. Frostbite of the lips and mouth may result from contact with the liquid. Will cause severe irritation and ulceration of the mouth and throat, abdominal pain, nausea, vomiting, collapse and coma.

**DELAYED EFFECTS:** Ethylene oxide may present cancer, reproductive, mutagenic, genotoxic, neurologic, cataracts and sensitization hazards.

Ingredients found on one of the OSHA designated carcinogen lists are listed below.

<u>INGREDIENT NAME</u>	<u>NTP STATUS</u>	<u>IARC STATUS</u>	<u>OSHA LIST</u>
Ethylene oxide	Known carcinogen	1 - Known carcinogen	Regulated carcinogen

#### 4. FIRST AID MEASURES

IN ALL CASES OF OVEREXPOSURE, GET MEDICAL ATTENTION IMMEDIATELY. CALL THE POISON CONTROL CENTER OR DOCTOR FOR TREATMENT ADVICE.

**SKIN:** Immediately rinse with plenty of water for 15-20 minutes while removing contaminated clothing and shoes. For exposure to liquid, immediately warm frostbite area with warm water (not to exceed 105°F). Call the Poison Control Center or doctor for advice. Aerate and wash or clean contaminated clothing before reuse. Discard leather goods and shoes.

**EYES:** Hold eyelids open and rinse slowly and gently with water for 15-20 minutes. Call the Poison Control Center or doctor, preferably an ophthalmologist, for advice.

**INHALATION:** Remove to fresh air, keep warm. Give artificial respiration if not breathing. Give oxygen if breathing is difficult. Call the Poison Control Center or doctor for advice even if no symptoms are present. Keep under medical observation. Symptoms may be delayed.

**INGESTION:** 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.

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**ADVICE TO PHYSICIAN:** Because of possible disturbances of cardiac rhythm from overexposure to HCFCs, catecholamine drugs such as epinephrine, should be used with special caution and only in situations of emergency life support. Treatment of overexposure should be directed at the control of symptoms and the clinical conditions.

1) Symptoms of systemic intoxication are headache, nausea, vomiting, incoordination, and cardiac irregularities. Treatment is symptomatic.

2) Persons exposed to Ethylene Oxide may develop severe and intractable vomiting, requiring the use of antiemetics given intravenously.

3) Irritation of the respiratory tract may occur. Prolonged or high vapor concentration exposure may result in the development of pulmonary edema after a latent phase of several hours. Also, respiratory tract injury caused by Ethylene Oxide may predispose to the development of a secondary respiratory infection. Individuals exposed to moderately high vapor concentrations of Ethylene Oxide should be retained for observation.

4) Skin exposure to Ethylene Oxide will commonly result in skin irritation with extensive blister formation.

5) Eye exposure to high concentrations of Ethylene Oxide can cause severe conjunctivitis.

6) When introduced directly into the bloodstream, Ethylene Oxide may act as a hapten and lead to the development of anaphylactoid reaction of varying severity. This has been noted in a few hemodialysis and plasmapheresis patients due to desorption of Ethylene Oxide from the sterilized equipment. There appears to be close associations with the presence of IgE antibodies to Albumin/Ethylene Oxide conjugates.

## 5. FIRE FIGHTING MEASURES

### FLAMMABLE PROPERTIES

**FLASH POINT:** Not applicable.

**FLASH POINT METHOD:** Not applicable.

**AUTOIGNITION TEMPERATURE:** Not determined.

**UPPER FLAME LIMIT (volume % in air):** 23.5% (E-681 Spark Ignition)  
22.0% (E-681 Fused Wire Ignition)

**LOWER FLAME LIMIT (volume % in air):** 22.7% (E-681 Spark Ignition)  
20.5 % (E-681 Fused Wire Ignition)

**FLAME PROPAGATION RATE (solids):** Not applicable.

**OSHA FLAMMABILITY CLASS:** Not flammable

### **EXTINGUISHING MEDIA:**

Use media appropriate for surrounding fire.

### **UNUSUAL FIRE AND EXPLOSION HAZARDS:**

Contents under pressure. Container may rupture due to heat of fire. No part of a container should be subjected to a temperature higher than 52°C (approximately 125°F). Containers are designed to vent contents when they are exposed to

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elevated temperatures. Under ordinary conditions, Oxyfume 2002 Sterilant Mixture cannot catch fire. In the event of a liquid spill and a subsequent formation of a pool of liquid, it is possible for some of the HCFC ingredients to boil off first, leaving a mixture enriched in ethylene oxide. This enriched mixture may be flammable. Avoid exposing stored Oxyfume 2002 Sterilant Mixture to heat or sources of ignition.

#### **SPECIAL FIRE FIGHTING PRECAUTIONS/INSTRUCTIONS:**

Evacuate all personnel from danger area and keep upwind. Immediately cool containers with water spray from maximum distance until cool. Use self-contained breathing apparatus operated in the pressure demand mode and appropriate protective clothing. Stop flow of gas if without risk, while continuing cooling water spray. Remove all containers from area of fire if without risk.

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#### **6. ACCIDENTAL RELEASE MEASURES**

##### **IN CASE OF SPILL OR OTHER RELEASE:**

(Always wear recommended personal protective equipment.)

Immediately evacuate all personnel from danger area and keep upwind. Wear self-contained breathing apparatus operated in the pressure demand mode and appropriate protective clothing. Ethylene oxide vapors can be reduced with fog or fine water spray. Shut off leak if without risk. Flood spills with water spray. Prevent runoff, collect for disposal. Neither Oxyfume 2002 or its aqueous solutions should be discharged to streams or sewers. Ventilate area of leak or move leaking assembly to well ventilated area. Test area, especially confined areas, for sufficient oxygen and ethylene oxide concentration prior to permitting re-entry of personnel. Emergency planning as described in 29 CFR 1910.1047, is required for handling releases, spills or emergencies associated with ethylene oxide.

**Spills and releases may have to be reported to Federal and/or local authorities. See Section 15 regarding reporting requirements.**

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#### **7. HANDLING AND STORAGE**

##### **NORMAL HANDLING:**

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

Use only in a closed system.

Always wear recommended personal protective equipment.

Use with adequate ventilation in accordance with 29 CFR 1910.1047.

Use piping and equipment adequately designed to withstand pressures to be encountered. Use with adequate ventilation at all times. Use only in a closed system. Cylinder valves should be closed and valve plugs inserted on full or empty cylinders when not in use. Never work on a pressurized system. If there is a leak, close the cylinder valve if without risk, blow down the system by venting to a safe place, then repair the leak. Do not breathe vapor. Do not swallow. Do not get in eyes, on skin, on clothing. Wash thoroughly after handling.

##### **STORAGE RECOMMENDATIONS:**

Store away from heat in an area with adequate ventilation. Do not store in direct sunlight. Keep away from sparks and open flame. Store and use with adequate ventilation in accordance with 29 CFR 1910.1047.

Do not contaminate food, feed or water by storage or disposal.

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#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

##### **ENGINEERING CONTROLS:**

Use local exhaust system with sufficient air flow velocity to maintain the concentration of ethylene oxide below its Action Level (0.5 ppm) in the worker's breathing zone. General mechanical ventilation is acceptable although local exhaust is preferred. Ventilation should be designed in such a manner that no person is exposed to concentrations of ethylene oxide exceeding the OSHA PEL of 1 ppm or the OSHA EL (Excursion Limit) of 5 ppm.

##### **PERSONAL PROTECTIVE EQUIPMENT**

##### **SKIN PROTECTION:**

Butyl rubber gloves. Gloves have a lifetime of approximately 1/2 to 1 hour after contact with liquid ethylene oxide. If risk of a liquid spill exists, also use butyl rubber shoes and apron.

##### **EYE PROTECTION:**

Full faceshield and safety glasses or goggles. Contact lenses should not be worn.

##### **RESPIRATORY PROTECTION:**

Ethylene oxide is considered to have poor warning properties. Therefore, when exposures requiring the use of a respirator are indicated, the respirator must have either an end-of service-life indicator or be a positive pressure, full facepiece supplied air respirator for use up to 2000 ppm. See 29 CFR 1910.1047(g) for details on specific respirator selection criteria.

##### **ADDITIONAL RECOMMENDATIONS:**

Steel-toe shoes for cylinder handling, safety shower and eyewash fountain. Contaminated rubber gloves and rubber clothing should be allowed to air out for several days before cleaning and reuse.

#### **EXPOSURE GUIDELINES**

<u>INGREDIENT NAME</u>	<u>ACGIH TLV</u>	<u>OSHA PEL</u>	<u>OTHER LIMIT</u>
Ethylene oxide	1 ppm TWA - 8	1 ppm TWA - 8; 5 ppm EL - 15 min.	None
Chlorodifluoromethane (HCFC-22)	1000 ppm TWA - 8	1000 ppm TWA - 8	None
Chlorotetrafluoroethane (HCFC-124)	None established	None established	*1000 ppm TWA - 8 **1000 ppm TWA - 8

\* = Limit established by Honeywell.

\*\* = Workplace Environmental Exposure Level (AIHA).

\*\*\* = Biological Exposure Index (ACGIH).

##### **OTHER EXPOSURE LIMITS FOR POTENTIAL DECOMPOSITION PRODUCTS:**

Hydrogen Fluoride: 2 ppm ceiling (ACGIH). 0.5ppm TLV-TWA

#### **9. PHYSICAL AND CHEMICAL PROPERTIES**

**APPEARANCE:** Clear, colorless liquid and vapor  
**PHYSICAL STATE:** Gas at normal temperature and pressure  
**MOLECULAR WEIGHT:** 99.9 (average)  
**CHEMICAL FORMULA:** CH<sub>2</sub>CH<sub>2</sub>O/CHClF<sub>2</sub>/CHClFCF<sub>3</sub>

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**ODOR:** Ether-like odor at high concentrations (above approximately 500 ppm)  
**SPECIFIC GRAVITY (water = 1.0):** 1.255 @ 70°F  
**SOLUBILITY IN WATER (weight %):** Ethylene oxide is completely miscible in water.  
HCFC-22 has a water solubility of 0.3 Wt % @ 77°F (25°C)  
HCFC-124 has a water solubility of 1.71 Wt % @ 75.2°F (24°C)

**pH:** Not applicable  
**BOILING POINT:** -6.8°F (-21.6°C)  
**MELTING POINT:** Not applicable  
**VAPOR PRESSURE:** 50 psig @ 70°F (21°C)  
**VAPOR DENSITY (air = 1.0):** 3.46  
**EVAPORATION RATE:** High **COMPARED TO:** Butyl Acetate  
**% VOLATILES:** 100  
**FLASH POINT:** Not applicable  
(Flash point method and additional flammability data are found in Section 5.)

#### 10. STABILITY AND REACTIVITY

**NORMALLY STABLE? (CONDITIONS TO AVOID):**

Mixture is stable at normal conditions or temperature and pressure and in ordinary use, handling and storage. Avoid mixing with air or oxygen above atmospheric pressure. Avoid open flames and high temperatures

**INCOMPATIBILITIES:**

Incompatible with alkali or alkaline earth metals, powdered Al, Zn, Be, etc., amines, acids, water metal chlorides, metal oxides and a wide variety of other organic and inorganic materials.

**HAZARDOUS DECOMPOSITION PRODUCTS:**

Thermal decomposition may form hydrochloric and hydrofluoric acids and possibly carbonyl halides, carbon monoxide and/or carbon dioxide.

**HAZARDOUS POLYMERIZATION:**

May occur. Trace polymers may be present under ordinary conditions of temperature, pressure, etc. However, ethylene oxide will polymerize violently if contaminated with aqueous alkalies, amines, mineral acids, metal chlorides or metal oxides.

#### 11. TOXICOLOGICAL INFORMATION

**IMMEDIATE (ACUTE) EFFECTS:**

Ethylene oxide component

LC<sub>50</sub> (Mouse-Inhalation): 836 ppm/4 hr  
LC<sub>50</sub> (Rat-Inhalation): 1741 ppm/4hr, 5029 ppm / 1 hr  
Rabbit, eye: 18 mg/6 hr, moderate irritant

Chlorodifluoromethane component

Animal studies report this material reduces heart efficiency at concentrations of 25,000 ppm or more. Cardiac Sensitization to epinephrine has been observed at concentrations of 50,000 ppm. A 2-year inhalation study indicated a slight increase in salivary gland tumors (rat) at the highest level of exposure tested (50,000 ppm). There were no observable effects in rats at exposure levels of 1000 and 10,000 ppm, and none in mice at any dose level.

Chlorotetrafluoroethane component

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Acute Inhalation: 4 hr LC<sub>50</sub> (rat) = 360,000 ppm  
Cardiac Sensitization Threshold: 25,000 ppm (dog)  
Central Nervous System Depression: 10 min EC<sub>50</sub> = 140,000 ppm

#### **DELAYED (SUBCHRONIC AND CHRONIC) EFFECTS:**

##### Ethylene oxide component

Peripheral neuropathies have been reported from chronic inhalation. Occupational exposure to ethylene oxide has been linked with spontaneous abortions and various cancers including leukemia, stomach and pancreatic, breast and non-Hodgkins lymphoma.

Laboratory studies with mice have shown that acute exposure to ethylene oxide vapor at concentrations of 300 ppm and above cause testicular injury as evidenced by concentration-related increased embryonic deaths following the mating of exposed males to nonexposed females (Dominant Lethal Test). In a developmental toxicity study with rats exposed to ethylene oxide vapor, there was maternal toxicity at 225 ppm and 125 ppm. Fetotoxicity was present as reduced fetal body weight at all concentrations and increased incidence of skeletal variants at 225 ppm, and to a lesser extent, at 125 ppm. There were no indications of embryotoxicity or malformation. In a two-generation reproduction study involving exposure of rats to ethylene oxide vapor for 6 hrs/day, 5 days/week, there was parental toxicity at 33 and 100 ppm. The no observable effects concentration for adult toxicity, offspring effects and reproductive effects was 10 ppm.

##### Chlorotetrafluoroethane component

Subchronic inhalation: NOEL (rat and mouse)...15,000 ppm  
2-year inhalation study (rat): no compound related visible or microscopic changes observed. NOAEL = 50,000 ppm  
Not teratogenic, mutagenic or embryotoxic

##### Chlorodifluoromethane component

Subchronic Inhalation: NOEL = 10,000 ppm  
Not teratogenic, not mutagenic in *in-vitro* and *in-vivo* studies

#### **OTHER DATA:**

None

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## **12. ECOLOGICAL INFORMATION**

##### Ethylene oxide component

LC<sub>50</sub> (96 hr): 84 mg/L for fathead minnow.

##### Chlorotetrafluoroethane component

Octanol Water Partition Coefficient: Log P<sub>ow</sub> = 1.94  
Low potential for bioaccumulation

##### Chlorodifluoromethane component

Octanol Water partition Coefficient: Unknown  
Low potential for bioaccumulation

##### Additional Information

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.

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Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority.

**In case of accidental release, notify local health and wildlife officials and operators of nearby water intakes.**

#### 13. DISPOSAL CONSIDERATIONS

##### RCRA

**Is the unused product a RCRA hazardous waste if discarded?** Yes

**If yes, the RCRA ID number is:** U115

##### **OTHER DISPOSAL CONSIDERATIONS:**

**PESTICIDE DISPOSAL:** Pesticides 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.

The information offered here is for the product as shipped. Use and/or alterations to the product such as mixing with other materials may significantly change the characteristics of the material and alter the RCRA classification and the proper disposal method.

#### 14. TRANSPORT INFORMATION

**US DOT HAZARD CLASS:** Proper Shipping Name: Liquefied gas, n.o.s. (Chlorotetrafluoroethane, Chlorodifluoromethane and Ethylene Oxide)  
Hazard Class: 2.2

**US DOT ID NUMBER:** UN 3163

For additional information on shipping regulations affecting this material, contact the information number found in Section 1.

#### 15. REGULATORY INFORMATION

##### TOXIC SUBSTANCES CONTROL ACT (TSCA)

**TSCA INVENTORY STATUS:** All components are listed on the TSCA Inventory

**OTHER TSCA ISSUES:** Ethylene oxide & Chlorodifluoromethane & Chlorotetrafluoroethane  
TSCA section 8(d) Health & Safety Data Reporting (40 CFR 716, Subpt. B)  
TSCA High Production Volume (HPV) Chemicals: 1990, 1994 & Post-1994 Additions (01/20/06)

##### SARA TITLE III/CERCLA

"Reportable Quantities" (RQs) and/or "Threshold Planning Quantities" (TPQs) exist for the following ingredients.

<u>INGREDIENT NAME</u>	<u>SARA/CERCLA RQ (lb)</u>	<u>SARA EHS TPQ (lb)</u>
Ethylene oxide	10	1000

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Spills or releases resulting in the loss of any ingredient at or above its RQ requires immediate notification to the National Response Center [(800) 424-8802] and to your Local Emergency Planning Committee.

**SECTION 311 HAZARD CLASS:** Immediate  
Delayed  
Pressure

#### **SARA 313 TOXIC CHEMICALS:**

The following ingredients are SARA 313 "Toxic Chemicals". CAS numbers and weight percents are found in Section 2.

#### INGREDIENT NAME

Ethylene oxide  
Chlorodifluoromethane (HCFC-22)  
Chlorotetrafluoroethane (HCFC-124)

#### COMMENT

de minimis concentration is 0.1%  
de minimis concentration is 1.0%  
de minimis concentration is 1.0%

#### CALIFORNIA PROP 65

ATTENTION: This product contains a chemical know to the State of California to cause cancer or birth defects or other reproductive harm.

Ethylene Oxide

#### **ADDITIONAL REGULATORY INFORMATION:**

Federal Emissions Regulations for Ethylene oxide - NESHAP, 40 CFR Part 63

HCFC-124 and HCFC-22 are substances which harm public health and the environment by destroying ozone in the upper atmosphere.

HCFC-22 and HCFC-124 are subject to U.S. Environmental Protection Agency Clean Air Act regulations at 40 CFR Part 82

Oxyfume 2002 is a registered pesticide under FIFRA: EPA reg. No. 67470-9

#### **WHMIS CLASSIFICATION (CANADA):**

This product has been evaluated in accordance with the hazard criteria of the CPR and the MSDS contains all the information required by the CPR.

#### **FOREIGN INVENTORY STATUS:**

The components are listed on the following foreign inventories:

Australia (AICS)  
China (IECSC)  
European Union (EINECS)  
Japan (ENCS)  
Korea (KECI)  
New Zealand (NZIoC)  
Philippines (PICCS)  
Switzerland

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### **16. OTHER INFORMATION**

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**CURRENT ISSUE DATE:** August, 2008

**PREVIOUS ISSUE DATE:** December, 2005

**CHANGES TO MSDS FROM PREVIOUS ISSUE DATE ARE DUE TO THE FOLLOWING:**

Updates to Sections 3, 4, 5, 6, 7, 12, 13, 15 and 16 to conform MSDS to EPA labeling guideline and to reflect label changes.

**OTHER INFORMATION:** HMIS Code: Health - 2, Fire - 0, Reactivity - 1