



Humco Holding Group, Inc.  
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24-Hour Emergency Number (CHEMTREC)  
USA- 800-424-9300

All non-emergency calls should be directed to  
Customer Service at 800-662-3435

NAME: FLUCONAZOLE, USP

SDS NO. 8036

## 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

**Product Name:** Fluconazole, USP

**Synonyms:** 1H-1, 2, 4-Triazole-1-ethanol, 1-(2, 4-difluorophenyl)-1-(1H-1, 2, 4-triazol-1-ylmethyl)-

**Recommended Use:** Active Pharmaceutical Ingredient

**Manufacturer by:** Humco Holding Group, Inc.

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## 2. HAZARD IDENTIFICATION

<b>Pictogram:</b>	
<b>Classification:</b>	Acute Toxicity - Oral (Category 4) Toxic to Reproduction (Category 1B) Eye Irritation (Category 2A) Skin Irritation (Category 2) Acute Aquatic Toxicity (Category 3)
<b>Signal Word:</b>	Warning

<b>Hazard Statements:</b>	Harmful if swallowed. May damage fertility or the unborn child. Causes serious eye irritation. Causes skin irritation. May cause respiratory irritation. Harmful to aquatic life.
<b>Precautionary Statements</b>	<p>Prevention: Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves, protective clothing, eye protection, face protection. Avoid release to the environment.</p> <p>IF SWALLOWED: Immediately call a poison center or medical professional. Rinse mouth. If exposed or concerned: Get medical advice/attention.</p> <p>IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.</p> <p>IF ON SKIN (HAIR): Wash with plenty of water. If skin irritation occurs: Get medical advice/attention. Take off contaminated clothing and wash it before reuse.</p> <p>IF EXPOSED OR CONCERNED: Get medical advice/attention.</p> <p>Storage: Store locked up.</p> <p>Disposal: Dispose of contents and/or container in accordance with local regulations.</p>

### 3. COMPOSITION / INGREDIENTS

CHEMICAL NAME	CAS#
FLUCONZOLE, USP	86386-73-4

### 4. FIRST-AID MEASURES

IN CASE OF EYE CONTACT: Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.

IN CASE OF SKIN CONTACT: Wash with soap & water for 15minutes. If irritation persists seek medical aid.

IF SWALLOWED: Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.

IF INHALED: Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician

SYMPTOMS AND EFFECTS: Not expected to present a significant hazard under anticipated conditions of normal use.

## 5. FIRE-FIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL: Not applicable

FLAMMABLE PROPERTIES: May be combustible at high temperature

HAZARDOUS COMBUSTION PRODUCTS: Under fire conditions, hazardous fumes will be present.

EXTINGUISHING MEDIA: Small fire: dry chemical, CO<sub>2</sub> or water spray. Large fire: dry chemical, CO<sub>2</sub>, alcohol resistant foam or water spray. Do not get water inside containers.

PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS: Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

## 6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS: Wear respiratory protection. Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

METHODS & MATERIAL FOR CONTAINMENT: On land, sweep or shovel into suitable containers. Minimize generation of dust.

CLEANUP PROCEDURE: Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition.

Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

## 7. HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING: Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling.

STORAGE CONDITIONS: Store in original container, tightly sealed container, protected from direct sunlight, in a dry, cool and well ventilated area, away from incompatible materials. Store in accordance with local regulations. Eliminate all ignition sources. Separate from oxidizing materials. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. Preserve in tight, light-resistant containers.

## 8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

National occupational exposure limits  
United States

Components	OSHA	NIOSH	ACGIH	AIHA WHEEL
Fluconazole 86386-73-4	N/L	N/L	N/L	N/L

EXPOSURE GUIDELINES: Consult local authorities for provincial or state exposure limits

PERSONAL PROTECTIVE EQUIPMENT: Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. Skin: Wear appropriate gloves to prevent skin exposure. Clothing: Wear appropriate protective clothing to minimize contact with skin. Respirators: Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

SPECIFIC ENGINEERING CONTROLS: Adequate mechanical ventilation. Fume hood, eye wash station, and safety shower.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance:</b>	White or almost white, crystalline powder.	<b>Upper/Lower Flammability:</b>	Not determined
<b>Odor:</b>	Not determined	<b>Vapor Pressure</b>	Not determined
<b>Odor Threshold:</b>	Not determined	<b>Vapor Density:</b>	Not determined
<b>pH:</b>	5.5 - 7 (0.02%)	<b>Relative Density:</b>	Not determined
<b>Melting point /Freezing Point:</b>	(138 - 142)°C, (280.4-287.6)°F	<b>Solubilities:</b>	Not determined
<b>Boiling point/range:</b>	Not determined	<b>Partition coefficient: n-octanol/water:</b>	1.47 (20°C)
<b>Flash point</b>	Not determined	<b>Auto-ignition temperature</b>	450 °C, 842 °F
<b>Evaporation rate</b>	Not determined	<b>Decomposition Temperature:</b>	Not determined
<b>Flammability:</b>	Not determined	<b>Viscosity</b>	Not determined

## 10. STABILITY AND RACTIVITY

REACTIVITY: Not established

STABILITY: Stable under recommended storage conditions.

MATERIALS TO AVOID: Strong oxidants, strong acids.

HAZARDOUS DECOMPOSITION PRODUCTS: Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur.

HAZARDOUS POLYMERIZATION: Will not occur.

POSSIBILITY OF HAZARDOUS REACTION: Not established.

CONDITIONS TO AVOID: Moisture, sunlight and extreme temperatures

## 11. TOXICOLOGICAL INFORMATION

ACUTE TOXICITY:

Oral: Rat: LD50 (mg/Kg): 1,271 mg/kg

Dermal: Rabbit: LD50: Not available

Inhalation: Rat: LD50: Not available

SKIN CORROSION/IRRITATION: Causes skin irritation. 10 %

Draize test

Result: Irritant.

Species: Human

Organ: Skin.

Test Duration: 24 hours

Severity: Moderate.

SERIOUS EYE DAMAGE/EYE IRRITATION: Causes serious eye irritation.

RESPIRATORY OR SKIN SENSITIZATION: Not available

GERM CELL MUTAGENICITY:

In vitro human lymphocyte test

Result: Negative.

In vivo mouse bone marrow cells test

Result: Negative.

Mouse lymphoma L5178Y test (with and without activation)

Result: Negative.

S. typhimurium test (with and without activation)

Result: Negative.

Based on available data, the classification criteria are not met.

CARCINOGENICITY

OSHA: Not listed.

NTP: Not listed.

IARC: Not listed.

California Proposition 65: This product is not known to the State of California to cause cancer, birth defects, or any other reproductive harm

REPRODUCTIVE TOXICITY: May damage fertility or the unborn child. May cause harm to breast-fed children. Data from birth registries and/or retrospective studies show mixed results concerning the association between therapeutic use of this material during pregnancy and birth defects. Some case reports have found that chronic use during the first semester of pregnancy may be associated with certain birth defects in infants.

25 mg/kg/day Reproductivity study

Result: Maternal toxicity and embryotoxicity.

Species: Rat

5 mg/kg/day Reproductivity study

Result: Maternal toxicity.

Species: Rabbit

75 mg/kg/day Reproductivity study

Result: Evidence of miscarriage.

Species: Rabbit

80 mg/kg/day Reproductivity study

Result: Increased incidence of cleft palate and ossification abnormalities. These effects may be the result of lowered estrogen, an effect not seen in humans treated with this material.

Species: Rat

SPECIFIC TARGET ORGAN TOXICITY-SINGLE EXPOSURE: Not Available.

SPECIFIC TARGET ORGAN TOXICITY-REPEATED EXPOSURE: Not Available.

ASPIRATION HAZARDS: Not Available.

SIGNS AND SYMPTOMS OF EXPOSURE: Symptoms related to the physical, chemical, and toxicological characteristics: Triazole antifungals: Fever. Chills. Skin rash. Itching. Dizziness. Constipation. Loss of appetite. Taste perversion. Nausea. Headache. Vomiting. Upset stomach. Swelling of face. Bloating. Diarrhea. Gas. Abdominal pain. Difficulty breathing. Incoordination. Fatigue. Hallucinations. Paranoid behaviors. Cross sensitivity: Persons sensitive to imidazoles, azoles, or amphotericin B may be sensitive to this material also. Medical conditions aggravated by exposure: Triazole antifungals: Alcoholism. Ventricular dysfunction. Heart disease. Impaired liver function. Impaired kidney function. HIV or AIDS. Active malignancy.

POTENTIAL HEALTH EFFECTS

**Inhalation:** May be harmful if inhaled. May cause respiratory tract irritation.

**Ingestion:** May be harmful if swallowed.

**Skin:** May be harmful if absorbed through skin. Causes skin irritation.

**Eyes:** Causes serious eye irritation.

## 12. ECOLOGICAL INFORMATION

<b>Acute or chronic aquatic toxicity:</b>	No specific information available, but material is not intended to be released to the environment.
<b>Chemical degradation:</b>	Not determined.
<b>Biodegradation:</b>	Not determined.
<b>Bioaccumulation potential</b>	Not determined.
<b>Adsorption studies or leaching studies:</b>	Not determined.
<b>Other adverse effects</b>	Not determined.

## 13. DISPOSAL CONSIDERATIONS

Dispose in accordance with federal, state and local laws and regulations. Avoid release into environment.

## 14. TRANSPORT INFORMATION

<b>DOT Hazard Classification:</b>	NOT DANGEROUS GOOD
<b>UN number:</b>	Not applicable
<b>UN proper shipping name:</b>	Not applicable.
<b>Transport hazard class(es):</b>	Not applicable
<b>Packing group number:</b>	Not applicable
<b>Environmental hazards:</b>	Not applicable
<b>Special precautions:</b>	Do not freeze, avoid extreme heat

## 15. REGULATORY INFORMATION

Not determined

## 16. OTHER INFORMATION

The information in this SDS is considered current and reliable. However, the data is provided without any warranty, expressed or implied, regarding its correctness or accuracy. Since the conditions for use, handling, storage and disposal are beyond Humco's control, it is the responsibility of the user to determine safe conditions for use and to assume liability for loss, damage, or expenses arising from improper use. No warranty expressed or implied regarding the product described herein will be created by or inferred from any statement or omission. Various agencies may have specific regulations concerning the transportation, handling, storage, use or disposal of this product which may not be reflected in the SDS. The user should review these regulations to ensure full compliance.