# Safety Data Sheet

For Compliance with OSHA 29 CFR 1910.1200 and ANSI Z400.1-1998

## Section 1: Identification

**Product Name** Miconazole USP
**Commercial Name** Not available.
**Product Use** Being a pharmacological active ingredient.
**Restrictions On Use** Not available.

**Product Code** 30-2094

**Company**
PCCA
9901 South Wilcrest
Houston, TX 77099
Phone: 1-800-331-2498
Fax: 1-800-874-5760

In case of emergency contact:
**CHEMTREC (24hr) 1-800-424-9300**

## Section 2: Hazard(s) Identification

**OSHA Haz Com: CFR 1910.1200** Acute toxicity, oral Category 4 Sensitization, skin Category 1

**Signal Word** WARNING

**Hazard Statement(s)** Harmful if swallowed. Very toxic to aquatic life with long lasting effects.

**Pictogram(s) or Symbol(s)**

**Precautionary Statement(s):**

**Prevention** Avoid release to the environment.
**Response** If swallowed: Call a poison center/doctor if you feel unwell. Collect spillage.
**Storage** Store in a closed container.
**Disposal** Dispose of contents/container in accordance with local/regional/national/international regulations.

## Section 3: Composition/Information on Ingredients

**Substance/Mixture** Substance
**Components** Miconazole
**% By Weight** 100
**CAS#** 22916-47-8
**Molecular Weight** 416.14 g/mole
**Chemical Formula** C18H14Cl4N2O
**Synonym(s)** 1H-Imidazole,1-(2-(2,4-dichlorophenyl)-2-((2,4-dichlorophenyl)methoxy)ethyl)-; Imidazole, 1-(20(2,4-dichlorophenyl)-2-((2,4-dichlorophenyl)methoxy)ethyl)- Miconazole Nitrate

**Mixtures**

| Name | CAS# | % by Weight | TLV/PEL | LC50/LD50 |
|---|---|---|---|---|
| Miconazole | 22916-47-8 | 100 | Not available. | ORAL (LD50): Acute: 500 mg/kg [Rat]. 519 mg/kg [Mouse]. |

## Section 4: First-Aid Measures

**Inhalation** Move to fresh air. Call a physician if symptoms develop or persist.

**Skin Contact** Rinse skin with water/shower. Get medical attention if irritation develops and persists. For minor skin contact, avoid spreading material on unaffected skin.

**Eye Contact** Rinse with water. Get medical attention if irritation develops and persists.

**Ingestion** Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.

**Symptoms/Effects**

**Acute** May cause allergic skin reaction. Pharmacologically active material. Occupational exposure may cause physiological effects.

**Delayed** May cause allergic skin reaction. Pharmacologically active material. Occupational exposure may cause physiological effects.

**Immediate Medical Attention**

Provide general supportive measures and treat symptomatically. Treatment of imidazole antifungal overdose may include the following: Toxicity after ingestion is unlikely. Gastrointestinal decontamination is generally unnecessary. For severe diarrhea or vomiting, monitor and correct fluid status. For mild/moderate allergic reactions, administer antihistamines with or without inhaled beta agonists, corticosteroids, or epinephrine. For severe allergic reaction, administer oxygen, antihistamines, epinephrine, or corticosteroids. (Poisindex)

## Section 5: Fire-Fighting Measures

**Suitable Extinguishing Media**

Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.

**Unsuitable Extinguishing Media**

Not available.

**Products of Combustion**

Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard

**Firefighters Special Equipment and Precautions**

Wear suitable protective equipment. Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing. Use standard firefighting procedures and consider the hazards of other involved materials.

## Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures: Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid inhalation of dust from the spilled material. Ensure adequate ventilation. Wear appropriate personal protective equipment. For personal protection, see section 8 of the SDS. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Methods and materials for containment and cleaning up: For waste disposal, see section 13 of the SDS. Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. Environmental precautions: Avoid discharge into drains, water courses or onto the ground.

## Section 7: Handling and Storage

Handling: As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Combustible dust clouds may be created where operations produce fine material (dust). Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential. Storage: Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

## Section 8: Exposure Controls/Personal Protection

| | |
|---|---|
| **Exposure Limits** | The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits. TWA 0.75 mg/m3 |
| **Engineering Controls** | For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred. |
| **Personal Protection** | Eye/face protection: Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available. Skin protection Hand protection: Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent. Other: Train employees in proper gowning and degowning practices. Wear lab coat. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors. Respiratory protection: Respirators are generally not required for laboratory operations. Use a tight-fitting full-face respirator with HEPA filters for spill cleanup. Chose respiratory protection appropriate to the task and the level of existing engineering controls. Thermal hazards: Wear appropriate thermal protective clothing, when necessary. General hygiene considerations: Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment. |

## Section 9: Physical and Chemical Properties

| | |
|---|---|
| **Appearance** | White. Off-white. Powder. Solid. |
| **Odor** | Slight |
| **Odor Threshold** | Not available. |

| | | | |
|---|---|---|---|
| **Melting Point** | 352.4 - 361.4 °F (178 - 183 ° | **pH** | in aqueous solution 4 (at 0.16 gram |
| **Freezing Point** | Not available. | **Vapor Pressure** | < 0.0000001 kPa at 25 °C |
| **Boiling Point/Range** | Not available. | **Vapor Density** | Not available. |
| **Decomposition temperature** | Not available. | **Viscosity** | Not available. |
| **Partition Coefficient: n-octanol/water** | 4.5, 5.79 | **Evaporation Rate** | Not available. |
| **Flash Point** | Not available. | **Autoignition temperature** | 662 °F (350 °C) |
| **Flammability** | Not available. | **Flammability or Explosive Limits:** | |
| | | **Lower** | Not available. |
| | | **Upper** | Not available. |

| | |
|---|---|
| **Solubility(ies)** | Very slightly soluble in water. |
| **Other** | Chloroform: Slightly soluble. Dimethyl sulfoxide: Freely soluble. Dimethylformamide: Freely soluble. Ethanol: Slightly soluble. Ether: Insoluble. Isopropyl alcohol: Very slightly soluble. Methanol: Sparingly soluble. Propylene glycol: Slightlly soluble Chemical family Imidazole. Dust explosion properties: Kst 166 bar.m/s Minimum ignition energy (MIE) - dust cloud 80 mJ Molecular formula C18H14Cl4N2O . HNO3 Molecular weight 479.14 |

## Section 10: Stability and Reactivity

| | |
|---|---|
| **Reactivity** | The product is stable and non-reactive under normal conditions of use, storage and transport. |
| **Chemical Stability** | Material is stable under normal conditions |
| **Hazardous Polymerization** | No dangerous reaction known under conditions of normal use. |
| **Conditions to Avoid** | Contact with incompatible materials |
| **Incompatible Materials** | Oxidizing agents. Strong bases. |
| **Hazardous Decomposition Products** | Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx. Cl- |

## Section 11: Toxicological Information

**RTECS** NI4770000

**Acute Toxicity**
Harmful if swallowed. Oral LD50 Dog > 160 mg/kg Guinea pig 275.9 mg/kg Mouse 578 mg/kg Rat 920 mg/kg

**Skin Corrosion/Irritation**
May cause an allergic skin reaction. Allergic skin reactions have been reported in literature

**Serious Eye Damage/Irritation**
Not available.

**Respiratory or Skin Sensitization**
Rare occurrences of anaphylactic reactions following therapeutic use of this material have been reported

**Germ Cell Mutagenicity**
Not available.

**Carcinogenicity**
Not available.

**Reproductive Toxicity**
Not available.

**Routes of Entry**
Skin. Ingestion.

**Symptoms Related to Exposure**
Imidazole antifungals: Gastrointestinal disturbances. Central nervous system effects. Back pain. Fever. Chills. Skin rash. Itching. Blistering. Burning. Skin redness. Flushing. Visual disturbances. Yellowed eyes or skin. Swelling in arms or legs. Difficulty breathing.

**Potential Health Effects**
Not available.

**Target Organ(s)** Not available.

## Section 12: Ecological Information

**Ecotoxicity**
Very toxic to aquatic life with long lasting effects Aquatic Fish LC50 Fish 0.11 mg/l, 96 hours

**Persistance and Degradability**
Not available.

**Bioaccumulative Potential**
Octanol/water partition coefficient log Kow 4.5 5.79

**Mobility in Soil**
Not available.

**Other Adverse Effects**
Not available.

## Section 13: Disposal Considerations

**Waste Disposal**
Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste. The waste code should be assigned in discussion between the user, the producer and the waste disposal company. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

**Disposal of Container**
Since emptied containers may retain product residue, follow label warnings even after container is emptied.

**Other Considerations**
Not available.

## Section 14: Transport Information

**DOT Classification**
DOT UN number: UN3077 UN proper shipping name: Environmentally hazardous substance, solid, n.o.s. (Miconazole nitrate) Transport hazard class(es) Class 9 Subsidiary risk - Packing group III

## Section 15: Regulatory Information

**Regulations**
US federal regulations: This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200 TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D) Not regulated. CERCLA Hazardous Substance List (40 CFR 302.4) Not listed. SARA 304 Emergency release notification Not regulated. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050) Not regulated. Superfund Amendments and Reauthorization Act of 1986 (SARA) Immediate Hazard - Yes Delayed Hazard - No Fire Hazard - Yes Pressure Hazard - No Reactivity Hazard - No Hazard categories SARA 302 Extremely hazardous substance Not listed. YesSARA 311/312 Hazardous chemical SARA 313 (TRI reporting) Not regulated. Other federal regulations Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List Not regulated. Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130) Not regulated. Not regulated.Safe Drinking Water Act (SDWA) California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

**Other**

WHMIS Not controlled under WHMIS (Canada). (Canada);DSCL (EEC) R36/37/38- Irritating to eyes, respiratory system and skin.;Gloves.;Lab coat.;Dust respirator. Be sure to use an approved/certified respirator or equivalent.;Splash goggles.

## Section 16: Other Information

Information given herein is offered in good faith as accurate, but without guarantee. Conditions of use and suitability of the product for particular uses are beyond our control; all risks of use of the product are therefore assumed by the user. Nothing is intended as a recommendation for uses which infringe valid patents or as extending licences under valid patents. Appropriate warnings and safe handling procedures should be provided to handlers and users.