

**Section 1: Identification**

**Product Name** Miconazole Nitrate USP  
**Commercial Name** Not available.  
**Product Use** Antifungal  
**Restrictions On Use** Not available  
**Product Code** 30-1154  
**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:** Acute toxicity: Oral, Category 4 Skin Sensitization, Category 1  
**CFR 1910.1200**

**Signal Word** WARNING

**Hazard Statement(s)** Harmful if swallowed. May cause an allergic skin reaction.

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



**Precautionary Statement(s):**

**Prevention** Avoid breathing dust/fume/gas/mist/vapors/spray. Wash thoroughly after handling. Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves.  
**Response** If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse  
**Storage** Not available.  
**Disposal** Dispose of contents/container in accordance with local/regional/national/international regulations

**Section 3: Composition/Information on Ingredients**

**Substance/Mixture** Substance  
**Components** Miconazole nitrate  
**% By Weight** 100  
**CAS#** 22832-87-7  
**Molecular Weight** 479.14 g/mole  
**Chemical Formula** C<sub>18</sub>H<sub>14</sub>Cl<sub>4</sub>N<sub>2</sub>O.HNO<sub>3</sub>  
**Synonym(s)** 1-(2,4-Dichloro-beta-((2,4-dichlor benzyl)oxy)phenethyl)-imidazole nitrate Afloxin, Micotin, Brentan, Micatin

**Mixtures**

Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
Miconazole nitrate	22832-87-7	100	Not available.	ORAL (LD50):Acute: 920mg/kg [Rat]. 578 mg/kg [Mouse]. 276mg/kg [Guineapig].

**Section 4: First-Aid Measures**

<b>Inhalation</b>	Move to fresh air. Call a physician if symptoms develop or persist.
<b>Skin Contact</b>	Rinse skin with water/shower. Get medical attention if irritation develops and persists. For minor skin contact, avoid spreading material on unaffected skin.
<b>Eye Contact</b>	Rinse with water. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
<b>Symptoms/Effects</b>	
<b>Acute</b>	May cause allergic skin reaction. Pharmacologically active material. Occupational exposure may cause physiological effects.
<b>Delayed</b>	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 CO<sub>2</sub>. Use fire-extinguishing media appropriate for surrounding materials.

**Unsuitable Extinguishing Media**

None known

**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**

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**

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. 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. 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**

<b>Exposure Limits</b>	TWA 0.75 mg/m <sup>3</sup>
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**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 consideration:** 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**

<b>Appearance</b>	Solid. White Off-white Powder		
<b>Odor</b>	Slight		
<b>Odor Threshold</b>	Not available.		
<b>Melting Point</b>	352.4 - 361.4 °F (178 - 183 °	<b>pH</b>	Not available.
<b>Freezing Point</b>	Not available.	<b>Vapor Pressure</b>	< 0.0000001 kPa at 25 °C
<b>Boiling Point/Range</b>	Decomposes.	<b>Vapor Density</b>	Not available.
<b>Decomposition temperature</b>	Not available	<b>Viscosity</b>	Not available.
<b>Partition Coefficient: n-octanol/water</b>	4.5	<b>Evaporation Rate</b>	Not available.
<b>Flash Point</b>	289.5C	<b>Autoignition temperature</b>	662 °F (350 °C)
<b>Flammability</b>	Non-flammable	<b>Flammability or Explosive Limits:</b>	
		<b>Lower</b>	Not available.
		<b>Upper</b>	Not available.
<b>Solubility(ies)</b>	Very slightly soluble		
<b>Other</b>	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: Slightly soluble. Chemical family Imidazole. Dust explosion properties Kst 166 bar.m/s Minimum ignition energy (MIE) - dust cloud 80 mJ Molecular formula C <sub>18</sub> H <sub>14</sub> Cl <sub>4</sub> N <sub>2</sub> O . HNO <sub>3</sub> Molecular weight 479.14 pH in aqueous solution 4 (at 0.16 grams/liter)		

**Section 10: Stability and Reactivity**

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

**Section 11: Toxicological Information**

<b>RTECS</b>	NI4771000
<b>Acute Toxicity</b>	Harmful if swallowed Oral LD50 Dog > 160 mg/kg Guinea pig 275.9 mg/kg Mouse 578 mg/kg Rat 920 mg/kg
<b>Skin Corrosion/Irritation</b>	Not available
<b>Serious Eye Damage/Irritation</b>	Not available
<b>Respiratory or Skin Sensitization</b>	May cause an allergic skin reaction
<b>Germ Cell Mutagenicity</b>	Not available
<b>Carcinogenicity</b>	Not available.
<b>Reproductive Toxicity</b>	

Based on available data, the classification criteria are not met. Epidemiological studies have not shown an association between therapeutic use of a related material during pregnancy and an increased incidence of birth defects. Adverse reproductive effects were seen in animal studies with a related material.

**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**

Aquatic Fish LC50 Fish 0.11 mg/l, 96 hours

**Persistence and Degradability**

Not available.

**Bioaccumulative Potential**

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

**Disposal of Container**

Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner

**Other Considerations**

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

**Section 14: Transport Information****DOT Classification**

Not a DOT controlled material (United States). This material is not classified dangerous good according to international transportation regulations (ADR/RID-IMDG-ICAO/IATA). UN number Environmentally hazardous substance, solid, n.o.s. (Miconazole nitrate) UN proper shipping name 9Class Transport hazard class(es) -Subsidiary risk III Packing group

**Section 15: Regulatory Information****Regulations**

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. Yes SARA 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 CLASS D-1B: Material causing immediate and (Canada) serious toxic effects (TOXIC). CLASS D-2A: Material causing other toxic effects (VERY TOXIC).;DSCG (EEC) R22- Harmful if swallowed. R38- Irritating to skin. R41- Risk of serious damage to eyes.;Gloves.;Lab coat.;Dust respirator. Be sure to use an approved/certified respirator or equivalent. Wear appropriate respirator when ventilation is inadequate.;Splash goggles.

**Section 16: Other Information**

This information is given without any warranty or representation. It is believed to be correct but does not claim to be all inclusive and shall be used only as a guide. Gufic Biosciences Ltd., shall not be held liable for any damage resulting from handling or contact with the above product. It is offered solely for your consideration, investigation and verification.