


**SECTION 1: PRODUCT IDENTIFICATION**

<b>PRODUCT NAME</b>	<b>MICONAZOLE NITRATE, USP</b>
<b>PRODUCT CODE</b>	<b>0038</b>
<b>SUPPLIER</b>	<b>MEDISCA Inc.</b> Tel.: 1.800.932.1039   Fax.: 1.855.850.5855 626 Tom Miller Road, Plattsburgh, NY, 12901 <b>MEDISCA Pharmaceutique Inc.</b> Tel.: 1.800.665.6334   Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 <b>MEDISCA Australia PTY LTD</b> Tel.: 1.300.786.392   Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020
<b>EMERGENCY PHONE</b>	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126 National Chemical Emergency Centre 44(0)1235239670
<b>RECOMMENDED USES</b>	Pharmaceutical Manufacturing
<b>RESTRICTIONS ON USE</b>	Not applicable

**SECTION 2: HAZARDS IDENTIFICATION**

<b>GHS CLASSIFICATION</b>	Acute Toxicity - Oral (Category 4) Sensitization - Skin (Category 1B) Chronic Aquatic Toxicity (Category 1)
<b>PICTOGRAM</b>	
<b>SIGNAL WORD</b>	Warning
<b>HAZARD STATEMENT(S)</b>	Harmful if swallowed. May cause an allergic skin reaction. Very toxic to aquatic life with long lasting effects.
<b>ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS PRECAUTIONARY STATEMENT(S)</b>	<b>Not Applicable.</b>  <b>Prevention</b> Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Avoid breathing dust, fume, gas, mist, vapors, and spray. Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves. Avoid release to the environment.

HMIS CLASSIFICATION	<b>Response</b>	IF SWALLOWED: Immediately call a poison center. Get medical help. Rinse mouth. IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical help advice/attention. Take off contaminated clothing and wash it before reuse. COLLECT SPILLAGE.		
	<b>Storage</b>	Not Applicable.		
	<b>Disposal</b>	Dispose of contents and/or container in accordance with local regulations.		
	<b>Health Hazard</b>	2	<b>Flammability</b>	0
	<b>Reactivity</b>	0	<b>Personal Protection</b>	E

### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

<b>CHEMICAL NAME</b>	1H-Imidazole, 1-(2-(2,4-dichlorophenyl)-2-((2,4-dichlorophenyl)methoxy)ethyl)-, mononitrate
<b>BOTANICAL NAME</b>	Not applicable
<b>SYNONYM</b>	1-[2,4-Dichloro-β-[(2,4-dichlorobenzyl)oxy]phenethyl]imidazole mononitrate
<b>CHEMICAL FORMULA</b>	C <sub>18</sub> H <sub>14</sub> Cl <sub>4</sub> N <sub>2</sub> O • HNO <sub>3</sub>
<b>CHEMICAL FAMILY</b>	Imidazole
<b>CAS NUMBER</b>	22832-87-7
<b>ALTERNATE CAS NUMBER</b>	Not applicable
<b>MOLECULAR WEIGHT</b>	479.14

CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
MICONAZOLE NITRATE	22832-87-7	245-256-6	100

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

### SECTION 4: FIRST-AID MEASURES

<b>IN CASE OF EYE CONTACT</b>	Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.
<b>IN CASE OF SKIN CONTACT</b>	Wash with soap & water for 15 minutes. If irritation persists seek medical aid.
<b>IF SWALLOWED</b>	Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.
<b>IF INHALED</b>	Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician
<b>MEDICAL ATTENTION AND SPECIAL TREATMENT</b>	Get emergency medical help.
<b>SYMPTOMS CAUSED BY EXPOSURE</b>	Not expected to present a significant hazard under anticipated conditions of normal use.

### SECTION 5: FIREFIGHTING MEASURES

<b>SPECIFIC HAZARDS ARISING FROM THE CHEMICAL</b>	Not applicable
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**FLAMMABLE PROPERTIES**

May be combustible at high temperature

**HAZARDOUS COMBUSTION PRODUCTS**

Under fire conditions, hazardous fumes will be present.

**SUITABLE & UNSUITABLE 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.

**NOTES**

Dust explosion properties:

Kst: 166 bar.m/s

St class: 1 estimated

Minimum ignition energy (MIE) – dust cloud : 80 mJ

Potential for dust explosion: Weak explosion hazard.

**SECTION 6: ACCIDENTAL RELEASE MEASURES****PERSONAL PRECAUTIONS**

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, 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.

**REFERENCE TO OTHER SECTIONS**

See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

**SECTION 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. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

**CONDITIONS FOR SAFE STORAGE**

Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

**STORAGE CONDITIONS**

Store in original container, tightly sealed, protected from direct sunlight and moisture.

Store at controlled room temperature. Controlled room temperature indicates a temperature 20° to 25°C (68° to 77°F); that results in a mean kinetic temperature calculated to be not more than 25°C; and that allows for excursions between 15° and 30°C (59° and 86°F) that are experienced in pharmacies, hospitals, and warehouses. Provided the mean kinetic temperature remains in the allowed range, transient spikes up to 40°C (104°F) are permitted as long as they do not exceed 24 hours.

**SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION**
**Chemical Name: MICONAZOLE NITRATE CAS #: 22832-87-7**

	Country	Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes
		ppm	mg/m <sup>3</sup>	ppm	mg/m <sup>3</sup>				
OSHA	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
ACGIH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
NIOSH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
WEEL	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSIS	Australia	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSE	UK	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Add Country	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A

N/L = Not listed ; N/A = Not Available

PELs are 8-hour TWAs = Limit value - Eight hours

Ceiling or Short-Term TWA = STEL = Limit value - Short term

**EXPOSURE GUIDELINES**

 Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m<sup>3</sup>
**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. **Thermal Hazards:** For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

**SPECIFIC ENGINEERING CONTROLS**

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

**BIOLOGICAL MONITORING**

Not available

**CONTROL BANDING**

Not available

**NOTES**

 USP: ELV: Industrial: TWA: 0.75 mg/m<sup>3</sup>
**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**
**PHYSICAL STATE**

Solid

**DESCRIPTION**

White or practically white, crystalline powder, having not more than a slight odor.

**SOLUBILITY**

Very slightly soluble in water and in isopropyl alcohol; insoluble in ether; slightly soluble in alcohol, in chloroform, and in propylene glycol; sparingly soluble in methanol; soluble in dimethylformamide; freely soluble in dimethyl sulfoxide.

**ODOR**

Not more than a slight odor

**FLAMMABILITY**

May be combustible at high temperature

**AUTO-IGNITION TEMPERATURE**

350°C, 662°F

**BOILING POINT**

Not available

**DECOMPOSITION TEMPERATURE**

 (178-183)°C,  
(352.4-361.4)°F

<b>EVAPORATION RATE</b>	Not available	<b>EXPLOSIVE LIMIT</b>	Not available	<b>FLASH POINT</b>	Not available
<b>log P (OCTANOL-WATER)</b>	5.79 (20°C)	<b>LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)</b>	Not available	<b>MELTING/FREEZING POINT</b>	(178-183)°C, (352.4-361.4)°F (decomposes)
<b>PARTICLE CHARACTERISTICS</b>	Not available	<b>OXIDIZING PROPERTY</b>	Not available	<b>pH</b>	4 (0.16 g/L)
<b>RELATIVE DENSITY (WATER = 1)</b>	Not available	<b>SPECIFIC GRAVITY</b>	Not available	<b>UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)</b>	Not available
<b>VAPOR DENSITY (AIR = 1)</b>	Not available	<b>VAPOR PRESSURE</b>	< 0.0000001 kPa (25°C)	<b>VISCOSITY</b>	Not available

The physical data presented above are typical values and should not be construed as a specification.

## SECTION 10: STABILITY AND REACTIVITY

<b>REACTIVITY</b>	Not established
<b>CHEMICAL STABILITY</b>	Stable under recommended storage conditions
<b>INCOMPATIBLE MATERIALS</b>	Oxidizing agents. Strong bases.
<b>HAZARDOUS DECOMPOSITION PRODUCTS</b>	Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride and other gases may occur
<b>HAZARDOUS POLYMERIZATION</b>	Will not occur
<b>POSSIBILITY OF HAZARDOUS REACTION</b>	Not established
<b>CONDITIONS TO AVOID</b>	Moisture, sunlight and extreme temperatures

## SECTION 11: TOXICOLOGICAL INFORMATION

<b>ACUTE TOXICITY</b>	Oral: Rat: LD50: (mg/kg): 920 Dermal: Rabbit LD50: (mg/kg): Not available Inhalation: Rat: LC50: (mg/L/4hr): Not available
<b>SKIN CORROSION/IRRITATION</b>	Due to lack of data the classification is not possible.
<b>SERIOUS EYE DAMAGE/EYE IRRITATION</b>	Due to lack of data the classification is not possible.
<b>RESPIRATORY SENSITIZATION</b>	Based on available data, the classification criteria are not met. Rare occurrences of anaphylactic reactions following therapeutic use of this material have been reported.
<b>SKIN SENSITIZATION</b>	May cause allergic skin reaction. Allergic skin reactions have been reported in literature.
<b>GERM CELL MUTAGENICITY</b>	Based on available data, the classification criteria are not met.
<b>CARCINOGENICITY</b>	<b>OSHA</b> MICONAZOLE NITRATE is not listed. <b>NTP</b> MICONAZOLE NITRATE is not listed.

**ADDITIONAL CARCINOGENICITY INFORMATION**

**IARC** MICONAZOLE NITRATE is not evaluated.

**California Proposition** This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

Due to lack of data, the classification is not possible.

**REPRODUCTIVE TOXICITY**

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

Suspected toxic for reproduction. Epidemiological studies have not shown an association between therapeutic use of a related material during pregnancy and an increased incidence of birth defects. A related material did not cause birth defects in animal studies. Adverse reproductive effects were seen in animal studies with a related material.

**SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE**

Due to lack of data, the classification is not possible.

**SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE**

Due to lack of data, the classification is not possible.

**ASPIRATION HAZARDS**

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

**SIGNS AND SYMPTOMS OF EXPOSURE**
**ROUTES OF EXPOSURE:**

Oral, Dermal, Inhalation, Eye contact

**EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:**

Not available

**DELAYED HEALTH EFFECT FROM EXPOSURE:**

For imidazole antifungals: Heart rhythm disorder.

**Symptoms related to the physical, chemical, and toxicological characteristics:**

Imidazole antifungals: Nausea. Vomiting. Diarrhea. Abdominal pain. Headache. Back pain. Fever. Chills. Drowsiness. Fatigue. Dizziness. Skin rash. Itching. Blistering. Burning. Skin redness. Flushing. Constipation. Loss of appetite. Visual disturbances. Yellowed eyes or skin. Swelling in arms or legs. Difficulty breathing. Confusion. Depression. Sedation. Trembling. Convulsions.

**Cross sensitivity:**

Persons sensitive to one azole may be sensitive to this material also.

**Medical conditions aggravated by exposure:**

Porphyria. Liver impairment.

**POTENTIAL HEALTH EFFECTS**

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

**Ingestion** Harmful if swallowed. May cause nausea and vomiting. May also cause diarrhoea (usually on long-term treatment).

**Skin** May be harmful if absorbed through skin. May cause skin irritation. May cause allergic skin reaction.

**Eyes** May cause eye irritation.

**SECTION 12: ECOLOGICAL INFORMATION**
**ECOTOXICITY**

EC50: 48 Hr: Crustacea (Daphnia Magna): (mg/L): 0.1819\*

LC50: 96 Hr: Fish: (mg/L): 0.11

EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available

**PERSISTENCE AND DEGRADABILITY**

Suspected persistent in the environment: The Danish QSAR database contains information indicating that the substance is predicted as non readily biodegradable.

**BIOACCUMULATIVE POTENTIAL**

High: LogPow: 5.79 (20°C)  
BCF: > 2000 L/kg  
Bioaccumulative potential: strong, not readily biodegradable  
Suspected bioaccumulative: The Danish QSAR database contains information indicating that the substance is predicted as bioaccumulative.

**MOBILITY IN SOIL**

Very slightly soluble in water

**OTHER ADVERSE EFFECTS**

Very toxic to aquatic life with long lasting effects.

**NOTES**

This product is not intended to be released into the environment

\*DEMETRA Daphnia Magna toxicity model in VEGA (Q)SAR platform predicts

**SECTION 13: DISPOSAL CONSIDERATIONS**
**DISPOSAL METHODS**

Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.

**SECTION 14: TRANSPORT INFORMATION**
**UN PROPER SHIPPING NAME**

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

**UN NUMBER**

3077

**CLASS**

9

**PACKING GROUP**

III

**AUSTRALIA**
**HAZCHEM**

2X

**EU**
**TRANSPORT IN BULK ACCORDING  
TO ANNEX II OF MARPOL 73/78  
AND THE IBC CODE**

Not Listed

**ENVIRONMENTAL HAZARDS**

Not available

**SPECIAL SHIPPING  
INFORMATION**

Not applicable

**SECTION 15: REGULATORY INFORMATION**
**UNITED STATES REGULATIONS**

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR	EPA 40 CFR Part 355 Appendix A	Appendix B	Pennsylvania	Right-to-know New Jersey	Massachusetts	California Prop 65
MICONAZOLE NITRATE, 22832-87-7	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

**AUSTRALIAN REGULATIONS**



**DISCLAIMER**

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.

**SUPPLEMENTARY INFORMATION**

For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.