


**SECTION 1: PRODUCT IDENTIFICATION**

<b>PRODUCT NAME</b>	<b>KETOCONAZOLE, USP (Micronized)</b>
<b>PRODUCT CODE</b>	<b>0279</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 3) Toxic to Reproduction (Category 1B) Specific Target Organ Toxicity - Repeated Exposure (Category 2) - (adrenal gland, liver) Chronic Aquatic Toxicity (Category 1)
<b>PICTOGRAM</b>	
<b>SIGNAL WORD</b>	Danger
<b>HAZARD STATEMENT(S)</b>	Toxic if swallowed. May damage fertility or the unborn child. May cause damage to organs (adrenal gland, liver) through prolonged or repeated. exposure. Very toxic to aquatic life with long lasting effects.
<b>ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS</b>	Not Applicable.

**PRECAUTIONARY STATEMENT(S)**
**Prevention**

Wash thoroughly after handling.  
Do not eat, drink or smoke when using this product.  
Obtain, read and follow all special instructions before use.  
Do not handle until all safety precautions have been read and understood.  
Do not breathe dust/fume/gas/mist/ vapors/spray.  
Wear protective gloves, protective clothing, eye and face protection and hearing protection.  
Avoid release to the environment.

**Response**

IF SWALLOWED: Immediately call a poison center. Get emergency medical help immediately. Rinse mouth.  
IF EXPOSED OR CONCERNED: Get medical advice.  
Get medical advice/attention if you feel unwell.  
COLLECT SPILLAGE.

**Storage**

Store locked up.

**Disposal**

Dispose of container in accordance with local regulation.

**HMIS CLASSIFICATION**
**Health Hazard**

4

**Flammability**

0

**Reactivity**

0

**Personal Protection**

G

**SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**
**CHEMICAL NAME**

1-[4-[4-[[[(2R,4S)-2-(2,4-dichlorophenyl)-2-(imidazol-1-ylmethyl)-1,3-dioxolan-4-yl]methoxy]phenyl]piperazin-1-yl]ethanone

**BOTANICAL NAME**

Not applicable

**SYNONYM**

Not available

**CHEMICAL FORMULA**

C<sub>26</sub>H<sub>28</sub>Cl<sub>2</sub>N<sub>4</sub>O<sub>4</sub>

**CHEMICAL FAMILY**

Imidazole

**CAS NUMBER**

65277-42-1

**ALTERNATE CAS NUMBER**

Not applicable

**MOLECULAR WEIGHT**

531.4372

**COMPOSITION**

CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
KETOCONAZOLE	65277-42-1	265-667-4	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**
**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 15 minutes. 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

**MEDICAL ATTENTION AND  
SPECIAL TREATMENT**

Get emergency medical help.

SYMPTOMS CAUSED BY  
EXPOSURE

Not expected to present a significant hazard under anticipated conditions of normal use.

## SECTION 5: FIREFIGHTING 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.

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.

## 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.

Short term excursions, temperature excursions as experienced during shipping and warehousing, up to 40°C are acceptable.

**SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION**
**Chemical Name: KETOCONAZOLE CAS #: 65277-42-1**

	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: 0.2 mg/m<sup>3</sup>
**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**
**PHYSICAL STATE**

Solid

**DESCRIPTION**

White or almost white powder.

**SOLUBILITY**

Practically insoluble in water, freely soluble in methylene chloride, soluble in methanol, sparingly soluble in alcohol.

**ODOR**

Odorless

**FLAMMABILITY**

May be combustible at high temperature

**AUTO-IGNITION TEMPERATURE**

520 °C (968 °F)

**BOILING POINT**

Not available

**DECOMPOSITION TEMPERATURE**

Not available

<b>EVAPORATION RATE</b>	Not available	<b>EXPLOSIVE LIMIT</b>	Not available	<b>FLASH POINT</b>	Not available
<b>log P (OCTANOL-WATER)</b>	4.35 (20 °C)	<b>LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)</b>	Not available	<b>MELTING/FREEZING POINT</b>	148 - 152 °C (298.4 - 305.6 °F)
<b>PARTICLE CHARACTERISTICS</b>	Not available	<b>OXIDIZING PROPERTY</b>	Not available	<b>pH</b>	7.7 (< 0.01 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>	Strong oxidants. Acids. Strong Bases.
<b>HAZARDOUS DECOMPOSITION PRODUCTS</b>	Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides 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): 166 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>	Due to lack of data the classification is not possible.
<b>SKIN SENSITIZATION</b>	Due to lack of data the classification is not possible.
<b>GERM CELL MUTAGENICITY</b>	Based on available data, the classification criteria are not met. Genotoxicity in vitro - Human – lymphocyte (DNA inhibition) Dominant lethal test in mice; Result: Negative.
<b>CARCINOGENICITY</b>	<b>OSHA</b> KETOCONAZOLE is not listed.

<b>ADDITIONAL CARCINOGENICITY INFORMATION</b>	<p><b>NTP</b> KETOCONAZOLE is not listed.</p> <p><b>IARC</b> KETOCONAZOLE is not evaluated.</p> <p><b>California Proposition</b> This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.</p>
<b>REPRODUCTIVE TOXICITY</b>	<p>Based on available data, the classification criteria are not met. &lt; 80 mg/kg/day Carcinogenicity study. Result: No evidence of carcinogenicity was seen in rats or mice in a long-term feeding study.</p> <p>May damage fertility or the unborn child. 800 - 1200 mg/kg/day Reproductivity study. Result: Therapeutic doses in men were reported to decrease testosterone levels. Rabbit: &gt;= 80 mg/kg/day Reproductivity study. Result: Embryoletality was produced but no increase in incidence of malformations. Rat: &gt;= 80 mg/kg/day Reproductivity study. Result: Maternal toxicity, embryotoxicity, and congenital abnormalities were seen. Suspected toxic for reproduction: The Toolbox profiler DART scheme v.1.0 gives an alert for toxicity to reproduction; Developmental/Reproductive Toxicity library (PG) in VEGA (Q)SAR platform predicts that the chemical is Toxicant (EXPERIMENTAL value); DART database in the Toolbox reports that this substance as Known developmental potential.</p> <p>Due to lack of data the classification is not possible.</p> <p>May cause damage to organs (adrenal gland, liver) through prolonged or repeated exposure.</p>
<b>SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE</b>	Based on available data, the classification criteria are not met.
<b>SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE</b>	Based on available data, the classification criteria are not met.
<b>ASPIRATION HAZARDS</b>	<p><b>ROUTES OF EXPOSURE:</b> Oral, Dermal, Inhalation, Eye contact</p> <p><b>EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:</b> Not available</p> <p><b>DELAYED HEALTH EFFECT FROM EXPOSURE:</b> Liver damage</p>
<b>SIGNS AND SYMPTOMS OF EXPOSURE</b>	<p>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.</p> <p><b>Cross sensitivity:</b> Persons sensitive to one imidazole may be sensitive to this material also.</p> <p><b>Medical conditions aggravated by exposure:</b> Alcoholism. Impaired liver function. Achlorhydria. Porphyria.</p>
<b>POTENTIAL HEALTH EFFECTS</b>	<p><b>Inhalation</b> May be harmful if inhaled. May cause respiratory tract irritation.</p> <p><b>Ingestion</b> Toxic if swallowed.</p> <p><b>Skin</b> May be harmful if absorbed through skin. May cause skin irritation.</p> <p><b>Eyes</b> May cause eye irritation.</p>

**SECTION 12: ECOLOGICAL INFORMATION**

<b>ECOTOXICITY</b>	EC50: 48 Hr: Crustacea: (mg/L): Not available LC50: 96 Hr: Fish: (mg/L): Not available EC50: 96 Hr: Algae: Green Algae: (mg/L): <1*
<b>PERSISTENCE AND DEGRADABILITY</b>	Suspected persistent in the environment: The Danish QSAR database contains information indicating that the substance is predicted as non readily biodegradable.
<b>BIOACCUMULATIVE POTENTIAL</b>	High: logPow: 4.35
<b>MOBILITY IN SOIL</b>	Practically insoluble in water: 0.087 mg/L (25°C) Henry's Law Constant: 5.59E-20 atm-m <sup>3</sup> /mole (25°C)
<b>OTHER ADVERSE EFFECTS</b>	The substance is very toxic to aquatic organisms.
<b>NOTES</b>	This product is not intended to be released into the environment *Danish QSAR database

### SECTION 13: DISPOSAL CONSIDERATIONS

<b>DISPOSAL METHODS</b>	Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.
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### SECTION 14: TRANSPORT INFORMATION

<b>UN PROPER SHIPPING NAME</b>	TOXIC SOLID, ORGANIC, N.O.S.
<b>UN NUMBER</b>	2811
<b>CLASS</b>	6.1
<b>PACKING GROUP</b>	III
<b>AUSTRALIA HAZCHEM</b>	2X
<b>EU TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE</b>	Not Listed
<b>ENVIRONMENTAL HAZARDS</b>	Very toxic to aquatic organisms. It is strongly advised not to let the chemical enter into the environment.
<b>SPECIAL SHIPPING INFORMATION</b>	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	EPA 40 CFR Part 355 Appendix B	Pennsylvania	Right-to-know New Jersey	Massachusetts	California Prop 65
KETOCONAZOLE 65277-42-1	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

**AUSTRALIAN REGULATIONS**

Chemical Name & CAS	Poisons and Therapeutic Goods	Therapeutic Goods Act	Code of Practices - Illicit Drug	Poisons Standard	Work Health and Safety Regulations	Inventory of Industrial Chemicals
KETOCONAZOLE 65277-42-1	N/L	Listed as Schedule 4	N/L	Listed	N/L	N/L

N/L = Not Listed

**EU REGULATIONS**

Chemical Name & CAS	REACH ANNEX XVII	REACH ANNEX XIV	EC 1005/2009	EC 850/2004	EC 1107/2009	PIC - Prior Informed Consent Regulation	EC 2012/18
KETOCONAZOLE 65277-42-1	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

Any EU regulation not listed above is not applicable to this product.

SUBJECT TO INTERNATIONAL AGREEMENT Not applicable

**SECTION 16: OTHER INFORMATION**
**REFERENCES**
**ABBREVIATIONS AND ACRONYMS**

Available upon request

**ACGIH** - American Conference of Governmental Industrial Hygienists; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **CAESAR** – Computer Assisted Evaluation of industrial chemical Substances According to Regulations; **CAS** – Chemical Abstract Service; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **EC50** – Effective Concentration, 50%; **EPA** – Environmental Protection Agency; **GHS** – Global Harmonized System; **HMIS** – Hazardous Materials Information System; **HSE** – Health and Safety Executive; **HSIS** – Hazardous Substances Information System; **IARC** – International Agency for Research on Cancer; **IDLH** - Immediately Dangerous to Life or Health; **IRFMN** – Ready Biodegradability Model; **ISS** – Istituto Superiore Sanità; **LC50** – Lethal Concentration, 50%; **LD50** – Lethal Dose, 50%; **MSHA** - Mine Safety and Health Administration; **NIOSH** – National Institute for Occupational Safety and Health; **NTP** – National Toxicology Program; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **QSAR** – Quantitative Structure-activity relationship; **REL** - Recommended Exposure Limit; **SARA** – Superfund Amendments and Reauthorization Act; **STEL** – Short Term Exposure Limit; **TLV** – Threshold Limit Value; **TWA** – Time Weighted Average; **WHMIS** – Workplace Hazardous Materials Information System

**LAST REVISION**

03/2023

**SUPERSEDES**

05/2021

For a list of changes to the SDS since the last version, please communicate with MEDISCA at [www.medisca.com](http://www.medisca.com)

**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.