SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME  KETOCONAZOLE, USP (Micronized)
PRODUCT CODE  0279
SUPPLIER  
MEDISCA Inc.
Tel.: 1.800.932.1039 | Fax.: 1.855.850.5855
661 Route 3, Unit C, Plattsburgh, NY, 12901
3955 W. Mesa Vista Ave., Unit A-10, Las Vegas, NV, 89118
6641 N. Belt Line Road, Suite 130, Irving, TX, 75063
MEDISCA Pharmaceutique Inc.
Tel.: 1.800.665.6334 | Fax.: 514.338.1693
4509 Rue Dobrin, St. Laurent, QC, H4R 2L8
21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2
MEDISCA Australia PTY LTD
Tel.: 1.300.786.392 | Fax.: 61.2.9700.9047
Unit 7, Heritage Business Park
5-9 Ricketty Street, Mascot, NSW 2020
CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300
NSW Poisons Information Centre: 131 126
EMERGENCY PHONE

USES
Antifungal

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION
Acute Toxicity - Oral (Category 3)
Specific Target Organ Toxicity - Repeated Exposure (Category 2) - (adrenal gland, liver)
Toxic to Reproduction (Category 1B)
Chronic Aquatic Toxicity (Category 1)

PICTORGRAM

SIGNAL WORD
Danger

HAZARD STATEMENT(S)
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.

AUSTRALIA-ONLY HAZARDS
Not Applicable.

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

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

Storage
Store locked up.

Disposal
Dispose of container in accordance with local regulation.
SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

**CHEMICAL NAME**
1-[1-[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 available

**SYNONYM**

**CHEMICAL FORMULA**
C₂₆H₂₈Cl₂N₄O₄

**CAS NUMBER**
65277-42-1

**MOLECULAR WEIGHT**
531.4372

**COMPOSITION**

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS NUMBER</th>
<th>% BY WEIGHT</th>
</tr>
</thead>
<tbody>
<tr>
<td>KETOCONAZOLE</td>
<td>65277-42-1</td>
<td>100</td>
</tr>
</tbody>
</table>

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.

**NOTES**
Chemical family: Imidazole

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.

**SYMPTOMS AND EFFECTS**
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.

**EXTINGUISHING MEDIA**
Small fire: dry chemical, CO₂ or water spray. Large fire: dry chemical, CO₂, 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
SAFETY DATA SHEET

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.

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 unlabelled 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. Preserve in well-closed containers. Protect from light.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: KETOCONAZOLE    CAS #: 65277-42-1

<table>
<thead>
<tr>
<th></th>
<th>TWA</th>
<th>Ceiling</th>
<th>STEL</th>
<th>REL</th>
<th>IDLH</th>
<th>Remarks</th>
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<tbody>
<tr>
<td>OSHA PEL</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>ACGIH TLV</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>NIOSH</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
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<tr>
<td>AIHA WEEL</td>
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<td>N/L</td>
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<td>-</td>
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<tr>
<td>Safe Work Australia HSIS</td>
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<td>-</td>
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<tr>
<td>HSE</td>
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<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

N/L = Not Listed

EXPOSURE GUIDELINES
Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³

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. Fumehood, eye wash station, and safety shower.

NOTES
USP: ELV: Industrial TWA: 0.2 mg/m³

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE
Solid

DESCRIPTION
White or almost white powder.

Last Revision: 12/2017
# SAFETY DATA SHEET

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

**ODOR**
Not available.

**FLAMMABILITY**
May be combustible at high temperature

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
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<tbody>
<tr>
<td><strong>ODOR THRESHOLD</strong></td>
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<tr>
<td><strong>pH</strong></td>
<td>7.7 (≤ 0.01 g/L)</td>
</tr>
<tr>
<td><strong>MELTING POINT</strong></td>
<td>148 - 152 °C (298.4 - 305.6 °F)</td>
</tr>
<tr>
<td><strong>BOILING POINT</strong></td>
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</tr>
<tr>
<td><strong>FREEZING POINT</strong></td>
<td>148 - 152 °C (298.4 - 305.6 °F)</td>
</tr>
<tr>
<td><strong>FLASH POINT</strong></td>
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</tr>
<tr>
<td><strong>SPECIFIC GRAVITY</strong></td>
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</tr>
<tr>
<td><strong>EVAPORATION RATE</strong></td>
<td>Not available</td>
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<tr>
<td><strong>EXPLOSIVE LIMIT</strong></td>
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<tr>
<td><strong>UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>VAPOUR PRESSURE</strong></td>
<td>1.17E-15 mm Hg (25 °C)</td>
</tr>
<tr>
<td><strong>RELATIVE DENSITY (WATER = 1)</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>log P (OCTANOL-WATER)</strong></td>
<td>4.35 (20 °C)</td>
</tr>
<tr>
<td><strong>DECOMPOSITION TEMPERATURE</strong></td>
<td>520 °C, 968 °F</td>
</tr>
<tr>
<td><strong>VISCOSITY</strong></td>
<td>Not available</td>
</tr>
</tbody>
</table>

## SECTION 10: STABILITY AND REACTIVITY

**Reactivity**
Not established.

**Stability**
Stable under recommended storage conditions.

**Materials to Avoid**

**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.

## SECTION 11: TOXICOLOGICAL INFORMATION

**Acute Toxicity**
Oral: Rat: LD50: (mg/kg): 166
Dermal: Rabbit LD50: (mg/kg): Not available
Inhalation: Rat: LD50: (mg/L/4hr): Not available

**Skin Corrosion/Irritation**
Due to lack of data the classification is not possible.

**Serious Eye Damage/Eye Irritation**
Due to lack of data the classification is not possible.

**Respiratory or Skin Sensitization**
Due to lack of data the classification is not possible.

**Germ Cell Mutagenicity**
Based on available data, the classification criteria are not met.
Genotoxicity in vitro - Human – lymphocyte (DNA inhibition)
Dominant lethal test in mice. Result: Negative.
CARCINOGENICITY

OSHA
KETOCONAZOLE is not listed.

NTP
KETOCONAZOLE is not listed.

IARC
KETOCONAZOLE is not evaluated.

California Proposition 65
This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

ADDITIONAL CARCINOGENICITY INFORMATION

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

< 80 mg/kg/day Carcinogenicity study. Result: No evidence of carcinogenicity was seen in rats or mice in a long-term feeding study.

REPRODUCTIVE TOXICITY

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.

>= 80 mg/kg/day Reproductivity study. Result: Embryolethality was produced but no increase in incidence of malformations. Species: Rabbit

>= 80 mg/kg/day Reproductivity study. Result: Maternal toxicity, embryotoxicity, and congenital abnormalities were seen. Species: Rat

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.

SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE

Due to lack of data the classification is not possible.

SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE

May cause damage to organs (adrenal gland, liver) through prolonged or repeated exposure.

ASPIRATION HAZARDS

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

SIGNS AND SYMPTOMS OF EXPOSURE

Symptoms related to the physical, chemical, and toxicological characteristics


Delayed and immediate effects of exposure
Liver damage.

Cross sensitivity
Persons sensitive to one imidazole may be sensitive to this material also.

Medical conditions aggravated by exposure

POTENTIAL HEALTH EFFECTS

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

Ingestion
Toxic if swallowed.

Skin
May be harmful if absorbed through skin. May cause skin irritation.

Eyes
May cause eye irritation.

SECTION 12: ECOLOGICAL INFORMATION

TOXICITY

EC50: 48 Hr: Crustacea: (mg/L): Not available
LC50: 96 Hr: Fish: (mg/L): Not available
IC50: 72 Hr: Algae: (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.
SAFETY DATA SHEET

### BIOACCUMULATIVE POTENTIAL
High: logPow: 4.35

### MOBILITY IN SOIL
Practically insoluble in water: 0.087 mg/L (25°C)
Henry’s Law Constant: 5.59E-20 atm-m³/mole (25°C)

### OTHER ADVERSE EFFECTS
The substance is very toxic to aquatic organisms.
This product is not intended to be released into the environment.

### SECTION 13: DISPOSAL CONSIDERATIONS

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

### SECTION 14: TRANSPORT INFORMATION

**UNITED STATES & CANADA**
- **UN PROPER SHIPPING NAME**: TOXIC SOLID, ORGANIC, N.O.S.
- **UN NUMBER**: 2811
- **CLASS**: 6.1
- **PACKING GROUP**: III

**AUSTRALIA**
- **UN PROPER SHIPPING NAME**: TOXIC SOLID, ORGANIC, N.O.S.
- **UN NUMBER**: 2811
- **CLASS**: 6.1
- **PACKING GROUP**: III
- **HAZCHEM**: 2X

**ENVIRONMENTAL HAZARDS**
Very toxic to aquatic organisms. It is strongly advised not to let the chemical enter into the environment.

**SPECIAL SHIPPING INFORMATION**
Not applicable

### SECTION 15: REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Chemical Name &amp; CAS</th>
<th>CERCLA 40 CFR Part 302.4</th>
<th>SARA (Title III) 40 CFR Part 372.65</th>
<th>EPA 40 CFR Part 355 Appendix A</th>
<th>Pennsylvania</th>
<th>Right-to-know New Jersey</th>
<th>Massachusetts</th>
<th>California Prop 65</th>
</tr>
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<tbody>
<tr>
<td>KETOCONAZOLE 65277-42-1</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
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</tr>
</tbody>
</table>

N/L = Not Listed; X = Listed

**AUSTRALIAN REGULATIONS**

<table>
<thead>
<tr>
<th>Chemical Name &amp; CAS</th>
<th>Poisons and Therapeutic Goods Regulation</th>
<th>Therapeutic Goods Act</th>
<th>Code of Practices - Illicit Drug Precursors</th>
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</thead>
<tbody>
<tr>
<td>KETOCONAZOLE 65277-42-1</td>
<td>Not Listed</td>
<td>Listed as Schedule 4</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

SECTION 16: OTHER INFORMATION

REFERENCES
Available upon request

ABBREVIATIONS AND ACRONYMS
CAS – Chemical Abstract Service; GHS – Global Harmonized System; OSHA PEL – Occupational Safety & Health Administration Permissible Exposure Limits; TWA – Time Weighted Average; HSIS – Hazardous Substances Information System; STEL – Short Term Exposure Limit; AIHA WEEL – American Industrial Hygiene Association Workplace Environment Exposure Levels; LD50 – Lethal Dose, 50%; IARC – International Agency for Research on Cancer; NTP – National Toxicology Program; WHMIS – Workplace Hazardous Materials Information System; SARA – Superfund Amendments and Reauthorization Act; EPA – Environmental Protection Agency; CERCLA – Comprehensive Environmental Response, Compensation, and Liability Act; HMIS – Hazardous Materials Information System; NIOSH – National Institute for Occupational Safety and Health; MSHA – Mine Safety and Health Administration; ACGIH - American Conference of Governmental Industrial Hygienists; IDHL – Immediately Dangerous to Health or Life; TLV – Threshold Limit Value; HSE – Health and Safety Executive; REL – Recommended Exposure Limit

LAST REVISION
12/2017

SUPERSEDES
06/2015

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.