SAFETY DATA SHEET

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME
CLOTRIMAZOLE, USP

PRODUCT CODE
0019

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

MEDISCA UK Limited
Tel.: 0800.029.4641
33 St. James's Square, London, United Kingdom SW1Y 4JS

EMERGENCY PHONE
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

USES
Antifungal; Anti-infective.

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION
Acute Toxicity - Oral (Category 4)
Eye Irritation (Category 2B)
Chronic Aquatic Toxicity (Category 1)

PICTOGRAM

SIGNAL WORD
Warning

HAZARD STATEMENT(S)
Harmful if swallowed.
Causes eye irritation.
Very toxic to aquatic life with long lasting effects.
Repeated exposure may cause skin dryness or cracking.

ADVERSE PHYSICOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS

PRECAUTIONARY STATEMENT(S)
Prevention
Wash thoroughly after handling.
Do not eat, drink or smoke when using this product.
Avoid release to the environment.
SAFETY DATA SHEET

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME: 1-[(2-chlorophenyl) diphenylmethyl]-1H-imidazole

NOTES

Chemical family: Imidazole derivative.

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.

SUITABLE & UNSUITABLE 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.

Response

IF SWALLOWED: Immediately call a poison center or medical professional. Rinse mouth. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

COLLECT SPILLAGE

Storage

Store locked up.

Disposal

Dispose of contents and/or container in accordance with local regulations.

HMIS CLASSIFICATION

Health Hazard: 2

Flammability: 0

Reactivity: 0

Personal Protection: E

COMPOSITION

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.

EC NUMBER

245-764-8
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. Preserve in tight containers, protected from light.

SPECIFIC END USE(S)
See Section 1

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: CLOTRIMAZOLE  CAS #: 23593-75-1

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<th></th>
<th>TWA</th>
<th>Ceiling</th>
<th>STEL</th>
<th>REL</th>
<th>IDLH</th>
<th>Remarks</th>
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<td>N/L</td>
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<td>-</td>
<td>-</td>
<td>-</td>
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<td>ACGIH TLV</td>
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<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
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<tr>
<td>NIOSH</td>
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<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
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<tr>
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<td>Safe Work Australia HSIS</td>
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<td>N/L</td>
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<td>N/L</td>
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<td>-</td>
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</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.
- **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.

NOTES
- Pharmacologically active material. Occupational exposure may cause physiological effects.
- USP: ELV: Industria: TWA: 100 micrograms/m³

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>PHYSICAL STATE</th>
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<tbody>
<tr>
<td>DESCRIPTION</td>
<td>White to pale yellow, crystalline powder.</td>
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<tr>
<td>SOLUBILITY</td>
<td>Practically insoluble in water; freely soluble in methanol, in acetone, in chloroform, and in alcohol.</td>
</tr>
<tr>
<td>ODOR</td>
<td>Odorless</td>
</tr>
<tr>
<td>FLAMMABILITY</td>
<td>May be combustible at high temperature</td>
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</table>

<table>
<thead>
<tr>
<th>AUTO-IGNITION TEMPERATURE</th>
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<tbody>
<tr>
<td>BOILING POINT</td>
<td>Not available</td>
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<tr>
<td>DECOMPOSITION TEMPERATURE</td>
<td>(141 - 149)°C, (285.8 - 300.2)°F</td>
</tr>
<tr>
<td>EVAPORATION RATE</td>
<td>Not available</td>
</tr>
<tr>
<td>EXPLOSIVE LIMIT</td>
<td>Not available</td>
</tr>
<tr>
<td>FLASH POINT</td>
<td>Not available</td>
</tr>
<tr>
<td>log P (OCTANOL-WATER)</td>
<td>4.1 (20°C)</td>
</tr>
<tr>
<td>LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)</td>
<td>Not available</td>
</tr>
<tr>
<td>MELTING/FREEZING POINT</td>
<td>(141 - 149)°C, (285.8 - 300.2)°F (decomposes)</td>
</tr>
<tr>
<td>ODOR THRESHOLD</td>
<td>Not available</td>
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<tr>
<td>OXIDIZING PROPERTY</td>
<td>Not available</td>
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<tr>
<td>pH</td>
<td>6 - 8 (10%)</td>
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<tr>
<td>RELATIVE DENSITY (WATER = 1)</td>
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</tr>
<tr>
<td>SPECIFIC GRAVITY</td>
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</tr>
<tr>
<td>UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)</td>
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<tr>
<td>VAPOR DENSITY (AIR = 1)</td>
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<tr>
<td>VAPOR PRESSURE</td>
<td>&lt; 0.0000001 kPa (25°C)</td>
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<tr>
<td>VISCOSITY</td>
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The physical data presented above are typical values and should not be construed as a specification.

SECTION 10: STABILITY AND REACTIVITY

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<th>REACTIVITY</th>
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<tr>
<td>CHEMICAL STABILITY</td>
<td>Stable under recommended storage conditions</td>
</tr>
<tr>
<td>INCOMPATIBLE MATERIALS</td>
<td>Strong oxidants agents</td>
</tr>
<tr>
<td>HAZARDOUS DECOMPOSITION PRODUCTS</td>
<td>Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride and other gases may occur</td>
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</tbody>
</table>
### HAZARDOUS POLYMERIZATION
Will not occur

### POSSIBILITY OF HAZARDOUS REACTION
Not established

### CONDITIONS TO AVOID
Moisture, sunlight, extreme temperatures and dust generation.

## SECTION 11: TOXICOLOGICAL INFORMATION

### ACUTE TOXICITY
- **Oral:** Rat: LD_{50} (mg/kg): 708
- **Dermal:** Rabbit: LD_{50} (mg/kg): Not available
- **Inhalation:** Rat: LC_{50} (mg/L/4hr): Not available

### SKIN CORROSION/IRRITATION
Based on available data, the classification criteria are not met.

### SERIOUS EYE DAMAGE/EYE IRRITATION
Causes eye irritation.

### RESPIRATORY SENSITIZATION
Respiratory sensitization: Due to lack of data the classification is not possible.

### SKIN SENSITIZATION
Due to lack of data the classification is not possible. Suspected skin sensitiser: CAESAR skin sensitisation model in VEGA (Q)SAR platform predicts that the chemical is Sensitizer (experimental value).

### GERM CELL MUTAGENICITY
- **OSHA**
  - CLOTRIMAZOLE is not listed.
- **NTP**
  - CLOTRIMAZOLE is not listed.
- **IARC**
  - CLOTRIMAZOLE 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.

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

### SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE
Based on available data, the classification criteria are not met.

### SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE
Based on available data, the classification criteria are not met.

### ASPIRATION HAZARDS
Pharmacologically active material. Occupational exposure may cause physiological effects.

### SIGNS AND SYMPTOMS OF EXPOSURE
Symptoms related to the physical, chemical, and toxicological characteristics:

### POTENTIAL HEALTH EFFECTS
**Inhalation**
- May be harmful if inhaled. May cause respiratory tract irritation.

**Cross sensitivity:** Persons sensitive to one azole may be sensitive to this material also.
SAFETY DATA SHEET

Ingestion  Toxic if swallowed.
Skin  May be harmful if absorbed through skin. May cause skin irritation.
Eyes  Causes serious eye irritation.

SECTION 12: ECOLOGICAL INFORMATION

TOXICITY
EC50: 48 Hr: Crustacea: Daphnia magna: (mg/L): 0.1
LC50: 96 Hr: Fish: (mg/L): > 0.29
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.
Biodegradation: 0 % (28D). Not easily biodegradable

BIOACCUMULATIVE POTENTIAL
High: Log Pow: 4.1 (20°C)
Suspected bioaccumulative: The Danish QSAR database contains information indicating that the substance is predicted as bioaccumulative (BCF > 2000 L/kg)

MOBILITY IN SOIL
Practically insoluble in water.

OTHER ADVERSE EFFECTS
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

UN PROPER SHIPPING NAME
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
UN NUMBER
3077
CLASS
9
PACKING GROUP
III
AUSTRALIA
HAZCHEM
2Z
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

Last Revision: 06/2019
SAFETY DATA SHEET

--- | --- | --- | --- | --- | --- | --- | --- | ---
CLOTRIMAZOLE 23593-75-1 | N/L | N/L | N/L | N/L | N/L | N/L | N/L | N/L

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

<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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<td>CLOTRIMAZOLE 23593-75-1</td>
<td>N/L</td>
<td>Listed as Schedule 4</td>
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N/L = Not Listed

EU REGULATIONS

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<td>N/L</td>
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</tbody>
</table>

N/L = Not Listed; X = Listed

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

SECTION 16: OTHER INFORMATION

REFERENCES

Available upon request

ABBREVIATIONS AND ACRONYMS


LAST REVISION

06/2019

SUPERSEDES

06/2019

For a list of changes to the SDS since the last version, please communicate with MEDISCA at www.medisca.com
SAFETY DATA SHEET

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.