Section 1. Product and Company Identification

Product Name: Ketoconazole
Product ID: K1676
Chemical Name (Synonyms): Fungarest; Fungoral; Ketoderm.
Supplier: LKT Laboratories, Inc
545 Phalen Blvd.
St. Paul, MN 55130 USA
Ph: 651-644-8424 Fax: 651-644-8357
www.lktlabs.com - getinfo@lktlabs.com

Emergency Phone #: 1-800-424-9300

Section 2. Hazards Identification

GHS Classification
Acute toxicity, Oral (Category 3), H301
Reproductive toxicity (Category 1B), H360
Specific target organ toxicity - repeated exposure (Category 2), H373
Acute aquatic toxicity (Category 1), H400
Chronic aquatic toxicity (Category 1), H410

GHS Label elements including precautionary statements

Pictogram
Signal word: Danger

Hazard and precautionary statements
Hazard statements
H301 - Toxic if swallowed.
H360 - May damage fertility or the unborn child.
H373 - May cause damage to organs through prolonged or repeated exposure.
H410 - Very toxic to aquatic life with long lasting effects.
Precautionary statements
P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P260 - Do not breathe dust.
P264 - Wash skin thoroughly after handling.
P270 - Do not eat, drink or smoke when using this product.
P273 - Avoid release to the environment.
P281 - Use personal protective equipment as required.
P301 + P310: IF SWALLOWED: Immediately call a POISON CENTER or doctor.
P308 + P313: IF exposed or concerned: Get medical advice.
P314 - Get medical advice if you feel unwell.
P330 - Rinse mouth.
P391 - Collect spillage.
P405 - Store locked up.
P501 - Dispose of contents/ container to an approved waste disposal plant.

HMIS Classification
Health hazard: 2
Chronic health hazard: *
Flammability: 0
Physical hazard 0

NFPA Rating
Health hazard: 2
Flammability: 0
Reactivity hazard 0

Potential Health Effects
Inhalation: May be harmful if inhaled. Causes respiratory tract irritation.
Skin: May be harmful in contact with skin.
Eyes: May cause eye irritation. Organs: May cause damage to organs through prolonged or repeated exposure.
Ingestion: Acute toxicity. Toxic if swallowed. Reproduction: May damage fertility or the unborn child. Reproductive toxicity.

Section 3. Composition/Information on Ingredients

<table>
<thead>
<tr>
<th>Substances</th>
<th>Formula</th>
<th>CAS No.</th>
<th>Formula Wt.</th>
<th>EC No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>C26H28Cl2N4O4</td>
<td>65277-42-1</td>
<td>531.44</td>
<td>265-667-4</td>
<td></td>
</tr>
</tbody>
</table>

Section 4. First Aid Measures

General advice
Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

Eye Contact
Flush eyes with water as a precaution.

Skin Contact
Wash with soap and plenty of water for 15 minutes and seek medical attention immediately. Wash contaminated clothing before use. Consult a physician.

Inhalation
If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

Ingestion
Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

Section 5. Firefighting Measures

Flash Point
Not available.

Extinguishing Media
Use water spray, alcohol-resistant foam, dry chemical, or carbon dioxide.

Firefighting Procedures
Wear self-contained breathing apparatus for firefighting if necessary.

Unusual Fire Hazards
Carbon oxides, nitrogen oxides (NOx), hydrogen chloride gas.

Section 6. Accidental Release Measures

Personal Precautions
Wear respiratory protection. Avoid dust formation. Avoid breathing dust, vapors, mist, or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.

Environmental Precautions
Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

Methods and materials for containment and cleanup
Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

Section 7. Handling and Storage

Handling
Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed.

Storage Conditions
Keep container tightly closed in a dry and well-ventilated place. Recommended storage temperature: Ambient

Hazardous Decomposition Products
Carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride gas.

Other Remarks
None
Section 8. Exposure Controls/Personal Protection

**Personal protective equipment**

**EXPOSURE CONTROLS**
Contains no substances with occupational exposure limit values. Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

**PERSONAL PROTECTION**
- **Eye/Face Protection** - Face shield and safety glasses. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU).
- **Skin Protection** - Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove’s outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. Full and splash contact - Material: Nitrile rubber. Minimum layer thickness: 0.11 mm, Break through time: 480 min., Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M).

**Body Protection** - Complete suit protecting against chemicals. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

**Respiratory Protection** - Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Section 9. Physical and Chemical Properties

**Physical State**
Solid.

**Color**
White powder.

**Boiling Point**
Not available.

**Melting Point**
148°C-149°C

**Density**
Not available.

**Solubility**
Not available.

**Flash Point**
Not available.

**Ignition temperature**
Not available.

**Autoignition temperature**
Not available.

**Lower explosion limit**
Not available.

**Upper explosion limit**
Not available.

**Vapor pressure**
Not available.

**Water solubility**
Not available.

**Odor**
Not available.

**Partition coefficient: n-octanol/water**
Log Pow: 3.507

**Odor Threshold**
Not available.

**Relative vapor density**
Not available.

**Evaporation rate**
Not available.

Section 10. Stability and Reactivity

**Stability**
Stable under recommended storage conditions.

**Materials To Avoid**
Strong oxidizing agents.

**Hazardous Decomposition Products**
Carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride gas.
Section 11. Toxicological Information

**Oral LD50**
Rat - 166 mg/kg

**Inhalation LC50**
Not available.

**Dermal LD50**
Not available.

**Other information on acute toxicity**
Not available.

**Skin corrosion/irritation**
Not available.

**Serious eye damage/irritation**
Not available.

**Respiratory or skin sensitization**
Not available.

**Germ cell mutagenicity**
Human lymphocyte DNA inhibition

**Reproductive Toxicity**
Not available. Presumed human reproductive toxicant.

**Aspiration Hazard**
Not available.

**Specific organ toxicity single exposure (GHS)**
Not available.

**Specific organ toxicity repeated exposure (GHS)**
May cause damage to organs through prolonged or repeated exposure.

**Additional Information**
RTECS: TK7912300

**Teratogenicity**
Not available.

**Synergistic effects**
Not available.

**Signs and symptoms of exposure**
Liver, irregularities, based on human evidence

**Potential Health Effects**
Inhalation: May be harmful if inhaled. Causes respiratory tract irritation. 
Skin: May be harmful in contact with skin. 
Eyes: May cause eye irritation. Organs: May cause damage to organs through prolonged or repeated exposure. 
Reproduction: May damage fertility or the unborn child. Reproductive toxicity.

**Carcinogenicity**
IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible, or confirmed human carcinogen by IARC. 
ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH. 
NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP. 
OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

Section 12. Ecological Information

**Toxicity**
Not available.

**Mobility in soil**
Not available.

**PBT and vPvB assessment**
PBT/vPvB assessment not available as chemical safety assessment not required/ not
Persistence and degradability: Not available.

Bioaccumulative potential: Not available.

Other adverse effects: An environmental hazard cannot be excluded in the event of unprofessional handling/disposal. Very toxic to aquatic life with long lasting effects.

Section 13. Disposal Considerations

Waste Disposal
Dispose of material according to all federal, state, and local regulations. Offer material to a licensed professional disposal company to dispose of as unused product. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Section 14. Transport Information

DOT (US)
UN number: 2811
Class: 6.1
Packing group: III
Proper shipping name: Toxic solid, organic, n.o.s. (Ketoconazole)
Marine pollutant: No
Poison inhalation hazard: No

IATA
UN number: 2811
Class: 6.1
Packing group: III
Proper shipping name: Toxic solid, organic, n.o.s. (Ketoconazole)
Marine pollutant: No

IMDG
UN number: 2811
Class: 6.1
Packing group: III
EMS-No: F-A, S-A
Proper shipping name: TOXIC SOLID, ORGANIC, N.O.S. (Ketoconazole)
Marine pollutant: No

Section 15. Regulatory Information

Reach No.

SARA 302 Components: SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title II, Section 302.

SARA 313 Components: SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312 Components: Acute Health Hazard, Chronic Health Hazard

Massachusetts Right To Know Components: No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know Components: Ketoconazole  CAS #: 65277-42-1  Revision Date:  2009-07-17

New Jersey Right To Know Components: Ketoconazole  CAS #: 65277-42-1  Revision Date:  2009-07-17

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

Section 16. Other Information

Other information: The information in this document is believed to be correct but is not necessarily complete. LKT does not guarantee the accuracy of the information. The burden of verifying the information in this document rests solely upon the user.