1. IDENTIFICATION

Product Identifier: Ketoconazole
Product Number: K006
Distributor Name: TOKU-E Company
Distributor Address: 715 W Orchard Dr. Suite 3
Bellingham, WA 98225

Phone Number: (360)734-1789
Emergency Phone Number (International): +1 (352) 353-3500
Emergency Phone Number (US Only): 1 (800) 535-5053
Safety Data Sheet Issued by: TOKU-E USA
CAS-Number: [65277-42-1]
EC/REACH Number: [265-667-4]

Recommended Use: Ketoconazole is a broad spectrum antifungal agent.
Restrictions of Use: Not for human or animal use

2. HAZARD(S) IDENTIFICATION

GHS Classification:
- Acute toxicity, oral (Category 3)
- Reproductive toxicity (Category 1B)
- Specific organ toxicity, repeated exposure (Category 2)
- Hazardous to the aquatic environment, acute hazard (Category 1)

GHS Label Elements, Including

Signal Word: Danger

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
- H400: Very toxic to aquatic life

Precautionary Statements:
- P264: Wash hands/skin thoroughly after handling.
- P270: Do not eat, drink, or smoke when using this product.
- P301+P310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician
- P321: Specific treatment, see applicable response statements on this label
- P330: Rinse mouth
- P405: Store locked up.
- P501: Dispose of contents/container in accordance with governmental regulation
- P201: Obtain special instructions before use
- P202: Do not handle until all safety precautions have been read and understood
- P280: Wear protective gloves/protective clothing/eye protection/face protection.
3. COMPOSITION/INFORMATION ON INGREDIENTS

Synonym(s)  
Ketoconazol, Ketoderm, Ketoisdin, KW-1414, Nizoral, Orifungal M, Panfungol, R 41400

Formula  
C_{26}H_{28}Cl_{2}N_{4}O_{4}

Molecular Weight  
531.43

CAS-Number  
[65277-42-1]

EC/ REACH Number  
[265-667-4]

Hazardous Components  
Ketoconazole  
Acute toxicity, oral (Category 3)  
Reproductive toxicity (Category 1B)  
Specific organ toxicity, repeated exposure (Category 2)  
Hazardous to the aquatic environment, acute hazard (Category 1)

4. FIRST-AID MEASURES

General Advice  
Consult a doctor/physician if exposed - additional medical care may be required. Show this Safety Data Sheet to the medical provider.

If Inhaled  
If inhaled, move to fresh air. If not breathing, give artificial respiration and immediately call local emergency telephone number.

In Case of Skin Contact  
Wash skin thoroughly with soap and water.

In Case of Eye Contact  
Flush eye with water. After initial flush, remove any contact lenses and continue flushing for at least 15 minutes.

If Swallowed  
Rinse mouth with water. Immediately call a doctor, physician, or poison control center. Never give anything by mouth to an unconscious person.

Specific Treatment  
Please see Section 2 precautionary statements and/or Section 11.

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media  
Water spray, alcohol-resistant foam, dry chemical, carbon dioxide

Special Protective Equipment for Firefighters  
Wear self-contained breathing apparatus

Hazardous Combustion Products  
Formed under fire conditions: carbon and nitrogen oxides, carbon monoxide, hydrogen peroxide

6. ACCIDENTAL RELEASE MEASURES

TOKU-E Company  
Safety Data Sheet  
Page 2 of 7
General
Evacuate personnel to a safe location. Use appropriate personal protective equipment while in contact with product. Avoid dust formation. Ensure adequate ventilation.

Personal Precautions
Prevent contamination of skin, eyes and clothing with appropriate protective equipment (Section 8). Wear respiratory protection.

Environmental Precautions
Recover waste, if possible, and place in suitable closed container for licensed disposal. Prevent spillage - do not let product enter drains.

7. Handling and Storage
Precautions for Safe Handling
Wear appropriate protective clothing/gear to prevent contact with skin and eyes. Provide exhaust ventilation or respiratory protection in areas where dust is formed.

Precautions for Safe Storage
Store in a tightly closed container. Protect from humidity.
Recommended storage temperature: 2-8°C

Incompatibilities
No Data Available

8. Exposure Controls/ Personal Protection
Contains no substance/substances with occupational exposure limit values

OSHA Permissible Exposure Limits
No Data Available

NIOSH Recommended Exposure Limits
No Data Available

ACGIH Threshold Limit Values
No Data Available

PPE: 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)

PPE: Hand Protection
Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal techniques to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices, and wash and dry hands

PPE: Eye Protection
Use a 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)

PPE: Skin and Body Protection
Handle with gloves. Wear protective clothing. Choose body protection according to the amount and
concentration of the dangerous substance at the work place. When deemed needed according to the concentration and amount of this product, use a complete body suit.

9. **PHYSICAL/CHEMICAL PROPERTIES**
   - **Appearance**: A white or almost white powder
   - **Lower Flammability/Explosion Limit**: No Data Available
   - **Upper Flammability/Explosion Limit**: No Data Available
   - **Odor**: No Data Available
   - **Vapor Pressure**: No Data Available
   - **Odor Threshold**: No Data Available
   - **Vapor Density**: No Data Available
   - **pH**: No Data Available
   - **Relative Density**: No Data Available
   - **Melting Point**: 147° – 151°C
   - **Water Solubility**: No Data Available
   - **Solubility in Other Solvents**: No Data Available
   - **Boiling Point and Range**: No Data Available
   - **Flash Point**: No Data Available
   - **Evaporation rate**: No Data Available
   - **Flammability (solid, gas)**: No Data Available
   - **Partition Coefficient: n-octanol/water**: No Data Available
   - **Ignition Temperature**: No Data Available
   - **Auto-Ignition Temperature**: No Data Available
   - **Decomposition Temperature**: No Data Available
   - **Viscosity**: No Data Available
   - **Density**: No Data Available
   - **Specific Rotation**: -1° - +1°
   - **Absorbance (290nm, 5% in H₂O)**: No Data Available
   - **Water Content (Loss on Drying)**: ≤0.5%

10. **STABILITY AND REACTIVITY**
   - **Chemical Stability**: Stable under recommended storage conditions
   - **Possibility of Hazardous Reactions**: No Data Available
   - **Conditions to Avoid**: No Data Available
   - **Materials to Avoid**: Strong oxidizing agents
   - **Hazardous Decomposition Products**: Formed under fire conditions: carbon and nitrogen oxides, carbon monoxide, hydrogen peroxide

11. **TOXICOLOGICAL INFORMATION**
   - **Oral LD₅₀**: Rat: 166 mg/kg
   - **Inhalation LC₅₀**: No Data Available
   - **Dermal LD₅₀**: No Data Available
   - **Intraperitoneal LD₅₀**: Rat: 1474 mg/kg
   - **Intravenous LD₅₀**: Rat: 86 mg/kg
Subcutaneous $\text{LD}_{50}$  
Rat: >2400 mg/kg

Skin Corrosion/Irritation  
No Data Available

Serious Eye Damage/ Eye Irritation  
No Data Available

Respiratory or Skin Sensitization  
No Data Available

Germ Cell Mutagenicity  
**Human lymphocyte, 10 mg/L**

DNA inhibition

Carcinogenicity  
This substance has not been identified as a potential carcinogen within the National Toxicology Program Report on Carcinogens or within the International Agency for Research on Cancer Monograph.

Reproductive Toxicity  
**Rat: Male TDLp 6480 mg/kg, oral**

9 weeks pre-mating

Reproductive - Fertility - mating performance

**Rat: Female TDLp 600 mg/kg, oral**

2 weeks pre-mating - 7 days after conception

Reproductive - Fertility - female fertility index.

**Rat: Female TdLo 880 mg/kg, oral**

7-17 days after conception

Reproductive - Fertility - litter size

Reproductive - Effects on Embryo or Fetus - fetal death

Reproductive - Specific Developmental

Abnormalities - musculoskeletal system.

**Mouse: Male TDLp 300 mg/kg, oral**

1 day pre-mating

Reproductive - Paternal effects - spermatogenesis

Specific Target Organ Toxicity: Single Exposure (GHS)  
No Data Available

Specific Target Organ Toxicity: Repeated Exposure (GHS)  
May cause damage to organs through prolonged or repeated exposure

Aspiration Hazard  
No Data Available

Potential Heath Effects  
See Section 2, Hazard(s) Identification

Signs and Symptoms of Exposure  
To the best of our knowledge, the chemical, physical, and toxicological properties of this material have not been thoroughly investigated

Synergistic Effects  
No Data Available

Additional Information  
No Data Available

12. ECOLOGICAL INFORMATION

Toxicity  
No Data Available

Persistence and Degradability  
No Data Available

Bio accumulative Potential  
No Data Available

Mobility in Soil  
No Data Available

PBT and vPvB Assessment  
No Data Available

In the absence of complete ecological information, treat product as environmentally hazardous. Use proper storage, handling, and disposal to prevent unintentional release into the environment.

13. DISPOSAL CONCENTRATIONS

Product  
Dispose of product through a licensed disposal
Contaminated Packaging
company.
Dispose of as unused product.

14. TRANSPORTATION INFORMATION

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

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

IATA  
UN Number: 2811 Class 6.1, Packing group III
Proper shipping name: Toxic solid, organic, n.o.s.  
(Ketoconazole)

15. REGULATORY INFORMATION

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

SARA 313 Components  
No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 313.

SARA 311/312 Hazards  
No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 311/312

Massachusetts Right to Know  
No components are subject to the Massachusetts Right to Know Act

Pennsylvania Right to Know  
No components are subject to the Pennsylvania Right to Know Act

New Jersey Right to Know  
No components are subject to the New Jersey Right to Know Act

California Prop. 65 Components  
No
This product does not contain any chemicals known to the State of California to cause birth defects, cancer, or any other reproductive harm

EU Information  
SDS in accordance with REACH 1907/2006
EC/ REACH Number [265-667-4]
CAS-Number [65277-42-1]
Name: Ketoconazole
Envisaged Registration Deadline: 30/11/2010
See GHS Information under Section 2, Hazard
16. OTHER INFORMATION

Revision Date: 2016-09-29

HMIS Rating
- Health Hazard 2
- Chronic Health Hazard Y
- Flammability 0
- Physical Hazard 0

NFPA Rating
- Health Hazard 2
- Fire Hazard 0
- Reactivity Hazard 0

This safety data sheet represents TOKU-E Company’s current understanding of the hazards associated with this product. The stated hazard information is based on existing experimental data and is not guaranteed to be all-inclusive. TOKU-E Company strives to maintain current and comprehensive safety information but recognizes that this safety data sheet may require revision as new information becomes available. TOKU-E Company shall not be held liable for damage or injury resulting from contact, handling, or storage of this product.