

Safety Data Sheet

Revision Date: 5/2/2024

Section 1: Chemical Identification

1.1 Chemical Identification

Product Name: Ketoconazole
Alternative Name:
Catalog Number: K-500

1.2 Relevant Uses and Uses Advised Against

Recommended use: This product is not for use in humans. It is for research purposes only.

1.3 Supplier Contact Information

Distributed by: Gold Biotechnology, Inc.
1328 Ashby Rd.
St. Louis, MO 63132
Phone: (314) 890-8778
Fax: (314) 890-0503
Email: contactgoldbio86@goldbio.com

1.4 Emergency Contact Information

Emergency Phone: (800)248-7609 (Monday-Friday, 9:00 a.m. – 5:00 p.m. CST)

Section 2: Hazardous Information

2.1 GHS Classification

Acute Toxicity, Oral (Category 3)
Reproductive Toxicity (Category 1B)
Specific Target Organ Toxicity, Repeated exposure (Category 2)
Acute Aquatic Toxicity (Category 1)
Chronic Aquatic Toxicity (Category 1)

2.2 GHS Label Elements, Including Precautionary statements



DANGER!

2.3 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

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2.4 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/fume/gas/mist/vapours/spray
P264: Wash skin thoroughly after handling
P270: Do not eat, drink or smoke when using this product
P273: Avoid release to the environment
P280: Wear protective gloves/protective clothing/eye protection/face protection
P301+310+330: IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician;
Rinse mouth
P308+313: IF exposed or concerned: Get medical advice/attention
P391: Collect spillage
P405: Store locked up
P501: Dispose of contents/container to an approved waste disposal plant

Section 3: Composition/Information on Ingredients

3.1 Composition

Identity:	Ketoconazole
IUPAC:	1-[4-[4-[[[(2R,4S)-2-(2,4-dichlorophenyl)-2-(imidazol-1-ylmethyl)-1,3-dioxolan-4-yl]methoxy]phenyl]piperazin-1-yl]ethanone
Synonyms:	
CAS Number:	65277-42-1
Molecular Formula:	C ₂₆ H ₂₈ Cl ₂ N ₄ O ₄
Molecular Weight:	531.43 g/mol

Section 4: First Aid Measures

4.1 Detailed First Aid Measures

Inhalation:	If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.
Skin:	Immediately wash skin copiously with soap and water. Take victim immediately to hospital. Consult a physician.
Eye:	Immediately rinse out with water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Consult a physician.
Ingestion:	Wash out mouth with water. Drink plenty of water. Consult a physician. Never give anything by mouth to an unconscious person.
Notes to Physician:	Treat symptomatically and supportively.

4.2 Most Important Symptoms And Effects, Either Acute Or Delayed

The most important known symptoms and effects are described in the labeling (see section2). And /or in section 11.

4.3 Indication of immediate medical attention and special treatment needed

Not available

Section 5: Fire Fighting Measures

5.1 Conditions of flammability:

Not flammable or combustible.

5.2 Suitable extinguishing media:

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

5.3 Specific hazards arising from the chemical

During a fire, highly toxic gases may be generated by thermal decomposition or combustion
– Carbon Oxides, Nitrogen Oxides (NOx), Hydrogen Chloride Gas.

5.4 Specific protective actions for fire-fighters:

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

Section 6: Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures:

Use personal protective equipment. Avoid breathing vapors, mist or gas. Ensure adequate ventilation.

6.2 Environmental precautions:

Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up:

Soak up with absorbent material, discard.

Section 7: Handling and Storage

7.1 Precautions for safe handling:

Always wear personal protective equipment (PPE, see section 8).

7.2 Conditions for safe storage, including and incompatibilities:

Keep container tightly closed.

Store at 4°C.

Section 8: Exposure Controls / Personal Protection

8.1 Control Parameters:

Contains no substances with occupational exposure limit values.

8.2: Appropriate engineering controls:

Contains no substances with occupational exposure limit values.

8.3 Personal Protective Equipment (PPE):

Eye/Face Protection: Safety glasses with side-shields conforming to EN166. 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 outer surface of glove - 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. 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).

Other Protective Clothing or Equipment: Wear appropriate protective clothing to prevent exposure.

Section 9: Physical and Chemical Properties

9.1 General chemical and physical properties

Appearance:	White to Light Brown Powder
Odor:	Not Available
Odor Threshold:	Not Available
pH:	Not Available
Melting Point:	146°C
Freezing Point:	Not Available
Boiling Point/Range:	Not Available
Flash Point:	Not Available
Evaporation Rate:	Not Available
Lower Explosion Limit:	Not Available
Upper Explosion Limit:	Not Available
Vapor Pressure:	Not Available
Vapor Density:	Not Available
Relative Density:	Not Available
Solubility:	Not Available
Partition Coefficient n-octanol/water:	ca.log Pow: 4.043 at 25°C - Potential Bioaccumulation
Auto-Ignition Temperature:	Not Available

Decomposition

Temperature: Not Available

Viscosity: Not Available

Section 10: Stability and Reactivity Data

10.1 Reactivity:

Not available

10.2 Chemical Stability:

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions:

Not available.

10.4 Conditions to avoid:

Incompatible materials.

10.5 Incompatible materials:

Strong oxidizing agents.

10.6 Hazardous decomposition products:

Hazardous decomposition products formed under fire conditions. – Carbon Oxides, Nitrogen Oxides (NOx), Hydrogen Chloride Gas.

Section 11: Toxicological Information

11.1 Toxicological effects

Acute toxicity:

Ketoconazole Oral: LD₅₀ (Rat) - 166 mg/kg

Skin corrosion/irritation:

Not available.

Respiratory or skin sensitization:

Not available.

Germ cell mutagenicity:

Human - Lymphocyte - DNA inhibition

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 probable, possible or confirmed human carcinogen by ACGIH.

NTP: 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 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.

Reproductive toxicity:

May damage fertility. Presumed human reproductive toxicant

STOT-single exposure:

Not available.

STOT-repeated exposure:

May cause damage to organs through prolonged or repeated exposure.

Aspiration hazard:

Not available.

Likely routes of exposure:

Respiratory organs, mouth, skin, and eyes.

Symptoms of exposure:

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Additional Information:

RTECS: TK7912300

Liver - Irregularities - Based on Human Evidence

Section 12: Ecological Information

12.1 Toxicity:

Not available.

12.2 Persistence and degradability:

Inherent biodegradability.

12.3 Bioaccumulative potential:

Does not bioaccumulate.

12.4 Mobility in soil:

Not available.

12.5 Other adverse effects:

None.

Section 13 Disposal Considerations

Dispose of product in accordance with local rules and regulations.

Section 14: Transport Information

14.1 US Department of Transportation (DOT)

UN Number: 2811
Proper shipping name: Toxic solids, organic, n.o.s. (Ketoconazole)
Class: 6.1
Packing Group: III
Marine Pollutant: Yes

14.2 International Maritime Dangerous Goods (IMDG):

UN Number: 2811
Proper shipping name: Toxic solids, organic, n.o.s. (Ketoconazole)
Class: 6.1
Packing Group: III
Marine Pollutant: Yes

14.2 International Air Transportation Association (IATA)

UN Number: 2811
Proper shipping name: Toxic solids, organic, n.o.s. (Ketoconazole)
Class: 6.1
Packing Group: III
Marine Pollutant: Yes

Section 15: Regulatory Information

SARA 302 Components:

SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, 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 Hazards:

Acute Health Hazard, Chronic Health Hazard

Massachusetts Right To Know Components:

Ketoconazole

CAS - No.

65277-42-1

Pennsylvania Right To Know Components:

Ketoconazole

CAS - No.

65277-42-1

New Jersey Right To Know Components:

Ketoconazole

CAS - No.

65277-42-1

California Prop. 65 Components:

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

Section 16: Other Information

While Gold Biotechnology, Inc. believes the information contained herein to be true and

accurate, it has relied on information provided by others. Gold Biotechnology, INC. makes no warranties, express or implied, as to the accuracy or adequacy of the information contained herein or with respect to the results to be obtained from the use of the product. Gold Biotechnology, Inc. disclaims all liability with respect to the use of this product, including without limitation, liability for injury to the user or third-party persons.

Preparation Information

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