



SHARON BIO MEDICINE LTD. API UNIT II

Material Safety Data Sheet

1. Substance Identification :

Product Name : **KETOCONAZOLE**
Company Name : SHARON BIO MEDICINE LTD. API Unit II
L-6, MIDC TALOJA,
DIST: RAIGAD, MAHARASHTRA, (INDIA)
Contact No.: (91-22) 27410490 / 65132070 – 71, Fax: 2741 1394
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2. Composition :

Synonym : 1-Acetyl-4-[4-[[[(2RS,4SR)-2-(2,4-dichlorophenyl)-2-(1H-imidazol-1-yl methyl)1, 3- dioxolan-4-yl] methoxy] phenyl] piperazine.
Formula : $C_{26}H_{28}Cl_2N_4O_4$
Molecular Wt. : 531.44
CAS number : 65277-42-1

3. Hazard Identification :

Hazard description : Toxic
R 23/24/25 - Toxic by inhalation, in contact with skin and if swallowed.
R 37/38 - Irritating to respiratory system and skin.
R 39 - Danger of very serious irreversible effects.
NFPA ratings (scale 0-4),
Health = 2
Fire = 0
Reactivity = 0

4. First Aid Measures :

Skin : Immediately wash with water and soap and rinse thoroughly.
Eye contact : Rinse opened eye for 15 minutes under running water. Then consult a doctor.
Ingestion : If swallowed, rinse mouth with water, get medical help immediately.

5. Fire Fighting Measures :

Suitable extinguishing agents
CO₂, ABC multipurpose dry chemical or water spray. Fight larger fires with water spray or alcohol resistant foam.
Special hazards caused by the material, its products of combustion or resulting gases:
During heating or in case of fire toxic gases may be produced.
Protective equipment:
Wear fully protective suit.
Wear self-contained respiratory protective device.



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6. Accidental Release Measures :

Person-related safety precautions:

Avoid formation of dust.

Use respiratory protective device against the effects of fumes/dust/aerosol.

Measures for environmental protection: Wipe up with damp sponge or mop.

Measures for cleaning/collecting:

Dispose contaminated material as waste according to item 13.

Ensure adequate ventilation.

Additional information:

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7. Handling and Storage :

Handling

Information for safe handling:

Thorough dedusting.

Ensure good ventilation/exhaustion at the workplace.

Open and handle receptacle with care.

Prevent formation of dust.

Information about protection against explosions and fires: Keep respiratory protective device available.

Storage

Information about storage in one common storage facility: Store away from oxidizing agents.

Further information about storage conditions: Preserve in well closed containers.

8. Exposure Control :

General protective and hygienic measures:

The usual precautionary measures for handling chemicals should be followed.

Avoid contact with the eyes and skin.

Personal Protection Equipment:

Eyes : Safety glasses.

Skin : Use protective clothing and chemical resistant gloves.

Inhalation : Do not inhale dust.

Wear a protective mask. Recommendation ensure normal ventilation of work area.



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9. Physical and Chemical Properties :

Form:	Solid.
Color:	White
Odor:	Unknown
Flash point	Not applicable
Flammability (solid, gaseous)	Product is not flammable.
Danger of explosion:	Product does not present an explosion hazard.
Vapor pressure:	Not applicable
Density:	Not determined
Solubility in Water:	Insoluble
Solubility in other solvents:	Freely soluble in methylene chloride, soluble in methanol, sparingly soluble in alcohol.
pH-value:	Not applicable
Formula Weight	531.4

10. Stability and Reactivity :

Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

Materials to be avoided: Incompatible material: strong oxidizers.

Dangerous reactions No dangerous reactions known

Dangerous products of decomposition:

Carbon monoxide (CO) and carbon dioxide (CO₂)

Hydrogen chloride (HCl)

Nitrogen oxides (NO_x)

11. Toxicological Information :

Acute toxicity:

LD/LC50 values that are relevant for classification:

Oral LD50 178 mg/kg (Dog)

618 mg/kg (Mouse)

166 mg/kg (Rat)

45 mg/kg (human)

412 mg/kg (human)

Primary irritant effect:

on the skin: Irritant to skin and mucous membranes.

on the eye: Irritating effect.

Sensitization: No sensitizing effects known.

Subacute to chronic toxicity: Target organs: liver



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12. Ecological Information :

Not Reported.

13. Disposal Considerations :

Recommendation:

Dissolve or mix material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Must not be disposed of with solid waste.

Dispose of material in accordance with federal (40 CFR 261), state and local requirements.

This product is not considered a RCRA hazardous waste.

Uncleaned packagings:

Recommendation: Disposal must be made according to state and federal regulations.

Recommended cleansing agent: Water, if necessary with cleansing agents.

14. Transport Information :

DOT regulations:

Hazard class: 6.1

Identification number: UN2811

Packing group: III

Poison inhalation hazard: Possible

Proper shipping name: TOXIC SOLID, ORGANIC, N.O.S. (Ketoconazole)

Label Toxic substance

Land transport ADR/RID (cross-border)

ADR/RID class: -

Air transport ICAO-TI and IATA-DGR:

ICAO/IATA Class: 6.1

Packaging group: III

15. Regulatory Information :

Not listed.

16. Other Information :

THIS DATA SHEET IS COMPILED TO BE OF ASSISTANCE BUT WITHOUT GUARANTEE USERS ARE RESPONSIBLE FOR SAFE WORKING.