Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: Ketoconazole

Synonyms: "cis-1-acetyl-4-[(2-(2, 4-dichlorophenyl)-2-(1H-imidazol-1-ylmethyl)-", "1, 3-", dioxolan-4-yl]-methoxy]phenyl]piperazine,

CAS – No: 65277-42-1
Emperical Formula: $C_{26}H_{28}Cl_2N_4O_4$
Molecular Weight: 531.48

PRODUCT USE: Broad spectrum anti-fungal agent

Company Address:
Head Office (Hyderabad)
Piramal Enterprises Limited
5-9-30, Road No.4,
Basheerbagh Palace Colony,
Basheerbagh, Hyderabad-500 063.
Telangana , India.

Site address:
Piramal Enterprises Limited
Sy .nos 7-70,70/1 and 70/2
Digwal Village
Kohir Mandal
Sangareddy dist 502321
Telangana. India
Emergency telephone: Direct - +91-8451-287 531, 287 508.
Mobile - +9739073485.
E Mail: D.DamodaramReddy@piramal.com

Section 2 - HAZARDS IDENTIFICATION

Classification according to Regulation (EC) No. 1272/2008

Hazard Pictogram:

Acute Toxicity (Oral): Category 3

Label elements
Labeling according to Regulation (EC) No 1272/2008
The substance is classified and labeled according to the CLP regulation.

Signal Word: Danger

Hazard Statement:

H301: Toxic if swallowed
H361: Suspected of damaging the unborn child
H401: Toxic to aquatic life
H411: Toxic to aquatic life with long lasting effects.

PRECAUTIONARY STATEMENTS

Prevention

Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Wash thoroughly after handling.
Do not eat, drink or smoke when using this product.
Avoid release to the environment.
Use personal protective equipment as required.

Response

IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
IF exposed or concerned: Get medical advice/ attention. Rinse mouth. Collect spillage.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME	CAS RN	%
ketoconazole	65277-42-1	100

Section 4 - FIRST AID MEASURES

SWALLOWED

- IF SWALLOWED, REFER FOR MEDICAL ATTENTION, WHERE POSSIBLE, WITHOUT DELAY.
- Urgent hospital treatment is likely to be needed.
- In the mean time, qualified first-aid personnel should treat the patient following observation and employing supportive measures as indicated by the patient's condition.
- If the services of a medical officer or medical doctor are readily available, the patient should be placed in his/her care and a copy of the MSDS should be provided. Further action will be the responsibility of the medical specialist.
- If medical attention is not available on the worksite or surroundings send the patient to a hospital together with a copy of the MSDS.
- Where medical attention is not immediately available or where the patient is more than 15 minutes from a hospital or unless instructed otherwise:
- INDUCE vomiting with fingers down the back of the throat, ONLY IF CONSCIOUS. Lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.

NOTE: Wear a protective glove when inducing vomiting by mechanical means.

EYE

If this product comes in contact with the eyes:

- Immediately hold eyelids apart and flush the eye continuously with running water.
- Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.
- Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes.
- Transport to hospital or doctor without delay.
- Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

SKIN

If skin or hair contact occurs:
- Flush skin and hair with running water (and soap if available).
- Seek medical attention in event of irritation.

INHALED

- If fumes or combustion products are inhaled remove from contaminated area.
- Lay patient down. Keep warm and rested.
- Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures.
- Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary.
- Transport to hospital, or doctor.

Section 5 - FIRE FIGHTING MEASURES

EXTINGUISHING MEDIA
- Water spray or fog.
- Foam.
- Dry chemical powder.
- BCF (where regulations permit).
- Carbon dioxide.

FIRE FIGHTING
- Alert Fire Brigade and tell them location and nature of hazard.
- Wear full body protective clothing with breathing apparatus.
- Prevent, by any means available, spillage from entering drains or water course.
- Use fire fighting procedures suitable for surrounding area.
- Do not approach containers suspected to be hot.
- Cool fire exposed containers with water spray from a protected location.
- If safe to do so, remove containers from path of fire.
- Equipment should be thoroughly decontaminated after use.

FIRE/EXPLOSION HAZARD
- Combustible solid which burns but propagates flame with difficulty; it is estimated that most organic dusts are combustible (circa 70%) - according to the circumstances under which the combustion process occurs, such materials may cause fires and / or dust explosions.
- Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion.

FIRE INCOMPATIBILITY
- Avoid contamination with oxidizing agents i.e. nitrates, oxidizing acids, chlorine bleaches, pool chlorine etc. as ignition may result.

Personal Protective Equipment
Gas tight chemical resistant suit.

Section 6 - ACCIDENTAL RELEASE MEASURES

MINOR SPILLS

- Clean up waste regularly and abnormal spills immediately.
- Avoid breathing dust and contact with skin and eyes.
- Wear protective clothing, gloves, safety glasses and dust respirator.
- Use dry clean up procedures and avoid generating dust.
- Vacuum up or sweep up. NOTE: Vacuum cleaner must be fitted with an exhaust micro filter (HEPA type) (consider explosion proof machines designed to be grounded during storage and use).
- Dampen with water to prevent dusting before sweeping.
- Place in suitable containers for disposal.

MAJOR SPILLS

- Clear area of personnel and move upwind.
- Alert Fire Brigade and tell them location and nature of hazard.
- Wear full body protective clothing with breathing apparatus.
- Prevent, by any means available, spillage from entering drains or water course.
- Stop leak if safe to do so.
- Contain spill with sand, earth or vermiculite.
- Collect recoverable product into labelled containers for recycling.
- Neutralise/decontaminate residue.
- Collect solid residues and seal in labelled drums for disposal.
- Wash area and prevent runoff into drains.
- After clean up operations, decontaminate and launder all protective clothing and equipment before storing and re-using.
- If contamination of drains or waterways occurs, advise emergency services.

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING

- Avoid all personal contact, including inhalation.
- Wear protective clothing when risk of exposure occurs.
- Use in a well-ventilated area.
- Prevent concentration in hollows and sumps.
- DO NOT enter confined spaces until atmosphere has been checked.
- DO NOT allow material to contact humans, exposed food or food utensils.
- Avoid contact with incompatible materials.
- When handlings, DO NOT eat, drink or smoke.
- Keep containers securely sealed when not in use.
- Avoid physical damage to containers.
- Always wash hands with soap and water after handling.
- Work clothes should be laundered separately. Launder contaminated clothing before re-use.
- Use good occupational work practice.
- Observe manufacturer's storing and handling recommendations.
- Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.

Empty containers may contain residual dust which has the potential to accumulate following settling. Such dusts may explode in the presence of an appropriate ignition source.

- Do NOT cut, drill, grind or weld such containers
- In addition ensure such activity is not performed near full, partially empty or empty containers without appropriate workplace safety authorization or permit.

SUITABLE CONTAINER

- Glass container is suitable for laboratory quantities
- Lined metal can, lined metal pail/ can.
- Plastic pail.
- Polyliner drum.
- Packing as recommended by manufacturer.
- Check all containers are clearly labeled and free from leaks.

STORAGE INCOMPATIBILITY

- Avoid reaction with oxidizing agents

STORAGE REQUIREMENTS

- Store in original containers.
- Keep containers securely sealed.
- Store in a cool, dry, well-ventilated area.
- Store away from incompatible materials and foodstuff containers.
- Protect containers against physical damage and check regularly for leaks.
- Observe manufacturer's storing and handling recommendations.

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

Component	OSHA - PEL	ACGIH - TLV
Ketoconazole	Not Established	Not Established

PERSONAL PROTECTION




EYE

For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs:

- Chemical goggles
- Face shield. Full face shield may be required for supplementary but never for primary protection of eyes

HANDS/FEET

Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include: such as:

- Frequency and duration of contact,
- Chemical resistance of glove material,
- Glove thickness and
- Dexterity

Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739).

- When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374) is recommended.
- When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374) is recommended.
- Contaminated gloves should be replaced.

ENGINEERING CONTROLS

Powders Handling:

- To prevent contamination and overexposure, no open handling of powder should be allowed.
- Powder handling operations are to be done in powders weighing hood, a glove box, or other equivalent ventilated containment system.
- In situations where these ventilated containment hoods have not been installed, a non-ventilated enclosed containment hood should be used.
- Pending changes resulting from additional air monitoring data, up to 300 mg can be handled outside of an enclosure provided that no grinding, crushing or other dust-generating process occurs.
- An air-purifying respirator should be worn by all personnel in the immediate area in cases where non-ventilated containment is used, where significant amounts of material (e.g., more than 2 grams) are used, or where the material may become airborne (as through grinding, etc.).
- Powder should be put into solution or a closed or covered container after handling.
- If using a ventilated enclosure that has not been validated, wear a half-mask respirator equipped with HEPA cartridges until the enclosure is validated for use.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE

Crystals; partly soluble in water.

PHYSICAL PROPERTIES

Solid.
Mixes with water.
State: Divided solid
Molecular Weight: 531.48
Melting Range (°C): 146
Viscosity: Not Applicable
Boiling Range (°C): Not available.
Solubility in water (g/L): Miscible
Flash Point (°C): Not Available

pH (1% solution): Not available
Decomposition Temp (°C): Not Available
pH (as supplied): Not applicable
Autoignition Temp (°C): Not available.
Vapour Pressure (kPa): Not applicable.
Upper Explosive Limit (%): Not available.
Specific Gravity (water=1): Not available.
Lower Explosive Limit (%): Not available.
Relative Vapour Density (air=1): Not applicable
Volatile Component (%vol): Not applicable.
Evaporation Rate: Not applicable

Section 10 - CHEMICAL STABILITY

CONDITIONS CONTRIBUTING TO INSTABILITY

- Presence of incompatible materials.
- Product is considered stable.
- Hazardous polymerisation will not occur.

For incompatible materials - refer to Section 7 - Handling and Storage.

Section 11 - TOXICOLOGICAL INFORMATION

TOXICITY

Oral (rat) LD50: 166 mg/kg

Section 12 - ECOLOGICAL INFORMATION

- Toxic to aquatic organisms may cause long-term adverse effects in the aquatic environment.
- Do NOT allow product to come in contact with surface waters or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash-waters. Wastes resulting from use of the product must be disposed of on site or at approved waste sites.
- **DO NOT discharge into sewer or waterways.**

Section 13 - DISPOSAL CONSIDERATIONS

- Containers may still present a chemical hazard/ danger when empty.
- Return to supplier for reuse/ recycling if possible.

Otherwise:

- If container can not be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, then puncture containers, to prevent re-use, and bury at an authorized landfill.
- Where possible retain label warnings and MSDS and observe all notices pertaining to the product.

Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.

A Hierarchy of Controls seems to be common - the user should investigate:

- Reduction
- Reuse
- Recycling
- Disposal (if all else fails)

Section 14 - TRANSPORTATION INFORMATION

Labels Required: TOXIC
HAZCHEM: 2X

Land Transport UNDG:

Class or division:	6.1	Subsidiary risk:	None
UN No.:	2811	UN packing group:	III

Shipping name: Toxic solid, organic, n.o.s. (Ketoconazole)

Air Transport IATA:

ICAO/IATA Class:	6.1	ICAO/IATA Sub risk:	None
UN/ID Number:	2811	Packing Group:	III

Shipping name: Toxic solid, organic, n.o.s. (Ketoconazole)

Maritime Transport IMDG:

IMDG Class:	6.1	IMDG Sub risk:	None
UN Number:	2811	Packing Group:	III

Shipping name: Toxic solid, organic, n.o.s. (Ketoconazole)

Section 15 - REGULATORY INFORMATION

REGULATIONS
No data for ketoconazole (CAS: , 65277-42-1)

Section 16 - OTHER INFORMATION

- Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

M)SDS revision date : 15/09/2017

- The (M) SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures