

 SMS pharmaceuticals ltd Unit-II	<b>SAFETY DATA SHEET OF</b> <b>Itraconazole</b>	DOC. No : SDS/FP/5043
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**Revision History:**

Rev. No.	DCR. No.	Reason for revision	Eff. Date
00	--	First issue	09 NOV 2016

<b>1. Material Identification:</b>	
Name of the product	: <b>Itraconazole</b>
Trade Name	: <b>Itraconazole</b>
Chemical name	: 4-[4-[4-[4-[[Cis-2-(2,4-dichlorophenyl)-2-(1H-1,2,4-triazol-1-ylmethyl)-1,3-dioxolan-4-yl]methoxy]phenyl]piperazin-1-yl]phenyl]-2-[(1RS)-1-methylpropyl]-2,4-dihydro-3H-1,2,4-triazol-3-one.
Synonym (s)	: --
Manufacturer :	
<b>Registered &amp; Corporate office :</b>	<b>Manufacturing Facility:</b>
SMS Pharmaceuticals Limited, Plot No .19-III, Road No 71, Opp. Bharatiya Vidya Bhavan Public School, Jubilee Hills, Hyderabad, Telangana - 500 096, INDIA. Tel: 91-40-6628 8888. Fax: 91-40-2355 1401/1402.	SMS Pharmaceuticals Limited, Unit-II, Plot No. 24 & 24B and 36 & 37, S.V. Co-Operative Industrial Estate, Bachupally, Ranga Reddy District Hyderabad, Telangana - 500 090, INDIA. Tel: 91-40-6598 6692. Email : <a href="mailto:qa_unit2@smspharma.com">qa_unit2@smspharma.com</a> , Website: <a href="http://www.smspharma.com">www.smspharma.com</a> . <b>Emergency Telephone Number:91-40-6598 6692</b>
Therapeutic Category	: Anti-fungal agent
<b>2. Hazard(s) Identification:</b>	
Hazard symbol(s)	: 
Signal word	: Warning.
classification of product	: Skin Irritation : cat. 2 Eye Irritation : cat. 2A Specific target organ toxicity : cat. 3 Acute Oral toxicity : cat. 4.
Hazard phrases	: H302 Harmful if swallowed. : H315 Cause skin irritation. : H319 Causes serious eye irritation. : H335 May cause respiratory irritation.
Precaution phrases	: <b>PREVENTION</b> P261: Avoid breathing dust/fume/gas/mist. P270: Do not eat, drink or smoke when using this product. P271: Use only outdoors or in well-ventilated area. P280 - Wear protective gloves/protective clothing/eye protection/face protection.

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**Response phrases** : P301+ P312 - IF SWALLOWED: Call a POISON CENTRE or physician if you feel unwell.  
 P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove Contact lenses, if present and easy to do. Continue rinsing.  
 P337+P313-If eye irritation persists get medical advice/attention.  
 P302+P352-If on skin wash the plenty water or soap.  
 P304+P340-If inhaled remove person to fresh air and keep comfortable for breathing.  
 P362+P364 – Take off contaminated clothing and wash it before reuse.  
 P330 - Rinse mouth.

**Specific target organs** : Liver, Heart.

**3. Composition/information on ingredients:**

Formula :  $C_{35}H_{38}Cl_2N_8O_4$   
 M.Wt. : 705.63.

Name	*CAS No.	*EINECS No.	Composition
<b>Itraconazole</b>	84625-61-6.	Unlisted	Pure material

Hazard symbol (s) : Xi  
 Risk Phrase : R22, R36/37/38.  
 Hazard Statements : H302; H315, H319, H335.  
 Precautionary Statements : P261, P264, P270, P271, P280, P301 + P312P302+P352, P304+P340, P305 + P351+P338, P310, P330, P362+364.

**4. First aid measures:**

**Inhalation:** Remove to fresh air. If not breathing, give artificial respiration .call a physician.  
**Skin contact:** Immediately wash skin for at least 20min. Flush area with large amounts of water. Use soap. Remove contaminated clothes Call a physician/Doctor.  
**Eye contact:** Hold eyelids apart and flush eyes with plenty of water for at least 20 minute's. Have eyes **examined** and tested by medical personnel.  
**Ingestion:** Wash out mouth with water provided person is consciousness. Call a physician. Do NOT induce vomiting unless directed to do so by medical personnel.

**5. Firefighting measures:**

**Extinguishing Media:** Use alcohol-resistant foam, dry chemical spray, or carbon dioxide.  
**Hazardous Combustion Products:** Emits oxidizing agents i.e. nitrates, oxidizing acids, chlorine beaches, pool chlorine.  
**Fire Fighting Procedures:** Wear approved positive pressure, self-contained breathing apparatus pressure-demand (NIOSH) approved and full protective turn out gear.

**6 Accidental release measures:**

**Health and Safety Precautions:** Personnel involved in clean-up should wear appropriate personal protective equipment like rubber boots, safety goggles, and heavy rubber gloves.  
**Measures for Cleaning / Collecting:** Contain spill and collect, as appropriate. Transfer to a chemical for disposal in accordance with local regulations.  
**Measures for Environmental Protections:**  
 Care should be taken to avoid environmental release.

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### 7. Handling and storage:

**Handling:** Avoid breathing dust/fume/gas/mist/spray. Avoid prolonged or repeated exposure.

**Storage :** Preserve in tight, light-resistance containers. Store below 30°C.

**Hazard label information:** Avoid contact with skin and eyes, don't reuse this container. Wash thoroughly after handling.

### 8. Exposure controls/ personal protection:

**Exposure Limits:**

**Lower exposure limits:** 30g/m<sup>3</sup>

**Upper exposure limits:** Not available.

**Personal protective equipment:**

**General protective and hygienic measures:** Immediately remove all soiled and contaminated clothing. Wash hands before breaks and at the end of work. Avoid contact with the eyes.

**Respiratory protection:** NIOSH approved respirator, as conditions warrant.

**Protection of hands:** wash thoroughly after handling.

**Other protection:** Facilities storing or utilizing this material should be equipped with an eye wash and safety shower.

**Material of gloves:** The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

Penetration time of glove material: The exact break through time has to be found out by the manufacturer of the protective gloves and has to be Observed

**Eye protection:** Safety goggles.

### 9. Physical and Chemical Properties:

**Basic chemical and physical information:**

Appearance	: A crystalline solid.
Solubility	: Soluble in DMSO and DMF.
Melting point	: 163°C
Boiling point	: No data available.
Chemical name	: 4-[4-[4-[4-[[Cis-2-(2,4-dichlorophenyl)-2-(1H-1,2,4-triazol-1-yl)methyl]-1,3-dioxolan-4-yl]methoxy]phenyl]piperazin-1-yl]phenyl]-2-[(1RS)-1-methylpropyl]-2,4-dihydro-3H-1,2,4-triazol-3-one.
Molecular weight	: 705.63.

### 10. Stability and reactivity:

**Chemical stability:** Unstable in the presence of incompatible materials.

Product is considered stable.

**Conditions to avoid:** No data available.


**Hazardous combustion or decomposition products:** Carbon dioxide (CO<sub>2</sub>), Carbon monoxide, Hydrogen chloride gas, nitrogen oxides.

### 11. Toxicological information:

**Toxicity** : Oral LD<sub>50</sub> >320 mg/Kg<sup>[2]</sup>

### 12. Ecological information:

Avoid release into the environment. Runoff from fire control or dilution water may cause pollution.

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**13. Disposal considerations:**


**Waste Treatment Methods:** Dissolve or mix the material with a combustible solvent. and waste chemicals of Reduction, Reuse, Recycling, Disposal.

**14. Transport information:**

The product can be transport by Land transport, Air transport, and Sea transport.  
**Additional transport information:** Transport in accordance with Local, State and federal regulations.

**15. Regulatory information:**

**Classification and labeling:**

Hazard Symbol (s) : 

Danger classification of product : Xi  
 Xn Harmful.

Risk (R-)phrases : R22- Harmful if swallowed.  
 R36/37/38 Irritating eyes, respiratory system and skin.

Safety (S-) phrases : S22- Do not breathes dust.  
 S24/25 –avoid contact with skin and eyes clothing.  
 S36/S37/S39-Wear suitable protective clothing, gloves and eye/face protection.

**Classification REGULATION (EC) No 1272/2008 and European Directive/EEC 67/548:**

Acute toxicity, category .4 : H302 : Harmful if swallowed  
 Skin Corrosion/Irritation, Category.2 : H315: causes skin irritation.  
 Skin Eye damage/ Eye irritation, Category.2A : H319: causes serious eye irritation.  
 Target organ systemic toxicity- category.3 : H335: May cause respiratory irritation.


**Label elements:**

Hazard Pictogram : 

Single word : Warning

Hazard statement(s) : H302 : Harmful if inhaled  
 H319 : Causes eye irritation  
 H335 : May cause respiratory irritation  
 H315 : Causes skin irritation

Precautionary statement(s) : **PREVENTION**  
 P261: Avoid breathing dust/fume/gas/mist.  
 P270: Do not eat, drink or smoke when using this product.  
 P271: Use only outdoors or in well-ventilated area.  
 P280 - Wear protective gloves/protective clothing/eye protection/face protection.

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**Other Regulatory information**

\*DSCL (EEC): : Unlisted  
\*HMIS (U.S.A.): : Unlisted

**16. Other Information**

The above information believed to be correct but does not support to be all inclusive and shall be used only as a guide. SMS Pharmaceuticals Limited (Unit-II) shall not be held liable for any damages resulting from handling or from contact with above product.

**Abbreviations:**

- \* CAS No.: Chemical abstracts service registration number.
- \* EINECS No: European inventory of existing chemical substances number.
- \* OEL: Occupational Exposure Limit
- \* NIOSH: National institute for occupational safety and health.
- \* MSHA: Mine safety and health administration.
- \* HMIS: Hazardous material identification system.
- \* DSCL(EEC): Dangerous substances classification and labeling (European Economic Community)
- \* LEL: Lower exposure limit
- \* UEL: Upper exposure limit.