



MSN Laboratories Private Limited
R&D Center, Formulation Division

SAFETY DATA SHEET

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1. Product Information

Product Name: Darunavir Tablets 600 mg and 800 mg

2. Composition/Information on Ingredients

C.A.S. No : 206361-99-1
Molecular Formula : $C_{27}H_{37}N_3O_7S$
Molecular Weight : 547.66
Chemical Name : [(1S,2R)-3-[[[4-aminophenyl)sulfonyl](2-methylpropyl)amino]-2-hydroxy-1(phenylmethyl)propyl]-carbamic acid (3R,3aS,6aR)-hexahydrofuro[2,3-b]furan-3-yl ester

3. Hazards Identification

Handling should only be performed by personnel trained and familiar with handling of potent active pharmaceutical ingredients. Moderate to severe irritant to the skin and eyes.

4. First Aid Measures

Eye Contact: Check for and remove contact lenses and flush with copious amounts of water; assure adequate flushing by separating the eyelids with fingers; call a physician.

Skin Contact: flush with copious amounts of water; remove contaminated clothing and shoes; call a physician.

Ingestion: If swallowed, wash out mouth with copious amounts of water; call a physician.

Inhalation: If inhaled, remove to fresh air; if breathing is difficult, give oxygen; if breathing stops, give artificial respiration.

5. Emergency Overview

Major Health Hazards: No major health hazards are known.

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6. Fire Fighting Measures

Suitable extinguishing media:	Carbon dioxide, dry chemical powder. Water spray. Avoid spill into drains, surface and groundwater and soil.
Special protective equipment:	Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

7. Accidental Release Measures

Personal precautions: Use personal protective equipment. Avoid dust formation. Avoid breathing dust. Ensure adequate ventilation. Evacuate personnel to safe areas.

Environmental precautions: Prevent further leakage or spillage. Do not let product enter into drains.

Methods and materials for containment and cleaning up: Pick up and arrange disposal without creating dust. Keep in suitable, closed containers for disposal

8. Handling and Storage

Precautions for safe handling:

Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection.

Storage Conditions: Store as directed by product packaging.

9. Exposure Controls/Personal Protection

Personal protective equipment: Glasses, Gloves, Respirator, Particulate etc

Respiratory protection:

Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N99 (US) or type P2 (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).

Hand protection: The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it. Handle with gloves.

Eye protection: Wear protective chemical safety goggles.

Skin and body protection:

Choose body protection according to the amount and concentration of the

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dangerous substance at the work place.

Hygiene measures: Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.

10. Physical Properties

Appearance:

600 mg : Beige colored, oval shaped, biconvex, film coated tablets, debossed with "M" on one side and "600" on other side and free from physical defects

800 mg : Brown colored, oval shaped, biconvex, film coated tablets, debossed with "M" on one side and "800" on other side and free from physical defects

11. Stability and Reactivity

Stability: Stable under normal conditions of use.

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

Hazardous Decomposition Products: None known

12. Toxicological Information

- **Acute toxicity:**
- Lethal Dose Ld_{50} Rat {Oral} : 2000 mg/kg.
- **Skin corrosion/irritation:**
- No data available.
- **Serious eye damage/eye irritation:**
- No data available.
- **Respiratory or skin sensitization:**
- No data available.
- **Carcinogenicity:** Darunavir was non-carcinogenic.
- **Mutagenicity:** Darunavir is considered not to be genotoxic.
- **Reproductive toxicology & Teratology:** In rats, no effects on male and female fertility were seen with Darunavir
- **Specific target organ toxicity - single exposure:** Not available



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- **Specific target organ toxicity - repeated exposure:** No data available
- **Aspiration hazard:** No data available
- **Potential health effects:**
 - **Inhalation:** May be harmful if inhaled. May cause respiratory tract irritation.
 - **Ingestion:** May be harmful if swallowed
 - **Skin:** May be harmful if absorbed through skin. May cause skin irritation.
 - **Eyes:** May cause eye irritation.
- **Additional Information**

RTECS: Not available

13. Disposal Considerations

Dispose of in accordance with prevailing country, federal, state and local regulations.

14. Transport Information

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations

15. Regulatory Information

- This safety data sheet complies with the requirements of Regulation (EC) No. 1272/2008.

16. Other Information

While the information herein is believed to be reliable, it is furnished without warranty of any kind. It shall be used only as a guide. We assume no liabilities from the use of this product or information contained herein.

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