



MSN Laboratories Private Limited
R&D Center, Formulation Division

MATERIAL SAFETY DATA SHEET		
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1. Product Information

Product Name: Silodosin Capsules 4 mg and 8 mg

2. Composition/Information on Ingredients

C.A.S. No : 160970-54-7
Molecular Formula : $C_{25}H_{32}F_3N_3O_4$
Molecular Weight : 495.53
Chemical Name : 1-(3-Hydroxypropyl)-5-[(2R)-2-({2-[2-(2,2,2trifluoroethoxy)phenoxy]ethyl}amino)propyl]-2,3-dihydro-1H-indole-7-carboxamide.

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.

6. Fire Fighting Measures

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

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Hazardous Combustion Products: Carbon monoxide, carbon dioxide, oxides of nitrogen, oxides of sulfur, hydrochloride, and other chlorine-containing compounds

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self contained breathing apparatus.

Fire / Explosion Hazards: Not applicable

7. Accidental Release Measures

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Measures for Environmental Protections:

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Additional Consideration for Large Spills:

Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

8. Handling and Storage

General Handling: Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls. Releases to the environment should be avoided.

Storage Conditions: Store as directed by product packaging.

9. Exposure Controls/Personal Protection

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

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Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

10. Physical and Chemical Properties

Appearance:

4 mg : White to off white colored powder filled in Size“3” hard gelatin capsules with White Opaque body imprinted “4 mg” and White Opaque cap imprinted “S” with black ink.

8 mg : White to off white colored powder filled in Size“1” hard gelatin capsules with White Opaque body imprinted “8 mg” and White Opaque cap imprinted “S” with black ink.

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:** none known
- **Primary irritant effect:**not known
- **On the skin:**none known
- **On the eye:**not known; may be an irritant

13. Ecological Information

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

14. Disposal Considerations

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



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15. Transport Information

DOT:

- **Proper shipping name:** none
- **Non-Hazardous for transport:** this substance is considered to be non-hazardous for transport.

IATA class:

- **Proper shipping name:** none
- **Non-Hazardous for transport:** this substance is considered to be non-hazardous for transport.

16. Regulatory Information

- S24/25: Avoid contact with skin and eyes
- S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
- S28: After contact with skin, wash immediately with plenty of water
- S36/37/39: Wear protective clothing, gloves and eye/face protection
- R28: Very toxic if swallowed
- R38: Irritating to skin
- R41: Risk of serious damages to eyes
- R48: Toxic; danger of serious damage to health by prolonged exposure
- **R62: Possible risk of impaired fertility**
- **R63: Possible risk of harm to unborn child**

17. 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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