

SAFETY DATA SHEET

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1. Identification of the substance/mixture and the company/undertaking

Product Name: Silodosin Capsules 4 mg and 8 mg**Chemical Family:** Mixture**Intended use:** Pharmaceutical product used for treatment of the signs and symptoms of benign prostatic hyperplasia**Details of the manufacturer:**

MSN Laboratories Private Limited.

Formulation Division, Unit - II,

Sy No 1277 & 1319 to 1324

Nandigama Village & Mandal

Ranga Reddy Dist

Telangana State, India.

PIN 509228

Phone: +91 40 3044 9200

2. 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.

3. 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

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.

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5. Fire Fighting Measures

Extinguishing media: Extinguish fire with carbon dioxide, dry chemical, or water spray.

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

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

Fire / Explosion Hazards: Not applicable

6. 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.

7. 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. Wash hands and any exposed skin after removal of PPE. Refer to Section 13 - 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 below 25°C

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8. 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.

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.

9. Physical and Chemical Properties

Appearance:

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

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

10. 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

11. Toxicological Information

Silodosin not listed as a carcinogenic by ACGIH, IARC, NTP or CA Prop 65

12. Ecological Information

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided.

13. Disposal Considerations

Disposal Procedures: Dispose of in accordance with all applicable laws and regulations.

14. Transport Information

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

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15. Regulatory Information

D.O.T. Proper Shipping Name: Not Regulated

Hazard Class: N/A

Identification Number: N/A

Packing Group: N/A

Label: N/A

Emergency Response Guide Book: N/A

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.