



Address: Block - 263/03, Santej,
Ta-Kalol, Dis-Gandhinagar,
Gujarat-382721

Phone : 832 031 0672

Web: www.sbfpharma.com

E-mail: info@sbfpharma.com

CIN: U24230GJ2011PTC064654

Material Safety Data Sheet (MSDS)

Product Name: Magnesium Stearate IP/BP Grade

MSDS Generate Date: 20-05-2017

Revision Date: 30-12-2024

Manufacturer / Supplier:

SBF Pharma

Block - 263/03, Santej - Vadasar Road,

Ta - Kalol, Dis - Gandhinagar,

Gujarat, India - 382721

Contact No.: +91 832 031 0672

Email: info@sbfpharma.com

Website: www.sbfpharma.com

1. Identification of the Substance/Preparation and of the Company

- **Product Name:** Magnesium Stearate IP/BP Grade
- **Synonyms:** Octadecanoic acid magnesium salt, Magnesium distearate
- **Chemical Formula:** C₃₆H₇₀MgO₄
- **Molecular Weight:** 591.27 g/mol
- **Intended Use:** Pharmaceutical excipient, lubricant in tablet/capsule formulations

2. Hazard Identification

- **Classification (GHS):** Not classified as hazardous.
- **Physical Hazards:** Fine dust may form explosive mixtures in air.
- **Health Hazards:**
 - Inhalation of dust may cause respiratory irritation.
 - Prolonged contact may cause mild skin/eye irritation.

- **Environmental Hazards:** Not expected to be hazardous to the environment.
 - **Label Elements:**
 - **Signal Word:** None
 - **Hazard Statement:** Not hazardous under normal handling.
 - **Precautionary Statements:** Avoid inhalation of dust; use protective equipment.
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3. Composition / Information on Ingredients

- **Substance:** Magnesium Stearate
 - **CAS Number:** 557-04-0
 - **EC Number:** 209-150-3
 - **Concentration:** ≥ 95%
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4. First Aid Measures

- **Inhalation:** Move person to fresh air. Seek medical attention if irritation persists.
 - **Skin Contact:** Wash with soap and water. If irritation occurs, seek medical advice.
 - **Eye Contact:** Rinse thoroughly with water for several minutes. Seek medical help if irritation continues.
 - **Ingestion:** Non-toxic in small quantities. If discomfort occurs, seek medical advice.
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5. Fire Fighting Measures

- **Suitable Extinguishing Media:** Water spray, dry chemical, CO₂, foam.
 - **Special Hazards:** Dust may form combustible mixtures with air.
 - **Protective Equipment for Firefighters:** Wear self-contained breathing apparatus (SCBA).
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6. Accidental Release Measures

- **Personal Precautions:** Avoid dust formation; wear suitable PPE.
- **Environmental Precautions:** Prevent uncontrolled release into drains.

- **Cleanup Methods:** Sweep or vacuum without creating dust; dispose in compliance with local regulations.
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7. Handling and Storage

- **Handling:** Avoid dust generation and inhalation. Use local exhaust ventilation.
 - **Storage:** Store in a tightly closed container, in a cool, dry, and well-ventilated area. Protect from moisture and incompatible materials.
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8. Exposure Controls / Personal Protection

- **Occupational Exposure Limits (OEL):** Not established specifically; treat as nuisance dust (10 mg/m³ total dust).
 - **Engineering Controls:** Adequate ventilation, dust extraction.
 - **Personal Protection:**
 - **Respiratory Protection:** Dust mask or respirator (N95).
 - **Skin Protection:** Gloves.
 - **Eye Protection:** Safety goggles.
 - **General Hygiene:** Wash hands after handling.
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9. Physical and Chemical Properties

- **Appearance:** Fine, white, hydrophobic powder
 - **Odor:** Odorless or faint fatty odor
 - **Melting Point:** 88 – 150 °C (decomposition)
 - **Solubility:** Insoluble in water; soluble in hot ethanol and oils
 - **Density:** ~1.0 g/cm³
 - **pH:** Neutral
 - **Flash Point:** Not applicable (solid)
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10. Stability and Reactivity

- **Stability:** Stable under normal storage and handling conditions.
 - **Conditions to Avoid:** Heat, sparks, open flames, excessive dusting.
 - **Incompatible Materials:** Strong oxidizing agents, acids.
 - **Hazardous Decomposition Products:** Carbon oxides (CO, CO₂) and magnesium oxides under fire conditions.
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11. Toxicological Information

- **Acute Toxicity:** Practically non-toxic (LD₅₀ oral, rat > 10,000 mg/kg).
 - **Skin Corrosion/Irritation:** Non-irritant to skin.
 - **Eye Irritation:** May cause slight transient irritation.
 - **Respiratory Effects:** Dust may cause mechanical irritation.
 - **Carcinogenicity:** Not classified as carcinogenic.
 - **Other Effects:** Widely used as safe excipient in pharmaceuticals.
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12. Ecological Information

- **Ecotoxicity:** Not expected to be hazardous.
 - **Persistence/Degradability:** Biodegradable.
 - **Bioaccumulation Potential:** Low.
 - **Mobility in Soil:** Negligible due to insolubility in water.
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13. Disposal Considerations

- **Waste Disposal:** Dispose in accordance with local, regional, and national regulations.
 - **Packaging Disposal:** Rinse and recycle or dispose as per official guidelines.
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14. Transport Information (Detailed)

- **UN Number:** Not regulated (Non-hazardous material).
- **Proper Shipping Name:** Magnesium Stearate

- **Transport Hazard Class:** Not applicable (non-dangerous).
 - **Packing Group:** Not applicable.
 - **Label Requirements:** None required.
 - **Marine Pollutant:** No
 - **Special Precautions for Transport:**
 - Transport in tightly sealed bags or containers to avoid dust emission.
 - Avoid contamination with strong oxidizing agents or acids during transport.
 - Keep away from heat sources and ignition points (as fine dust can be combustible).
 - Ensure containers are secured against physical damage.
 - **Regulatory Status by Mode of Transport:**
 - **ADR/RID (Road/Rail):** Not classified as dangerous goods.
 - **IMDG (Sea):** Not classified as marine pollutant, safe for shipment.
 - **IATA/ICAO (Air):** Not restricted, can be shipped as general cargo.
 - **Domestic Transport (India):** Safe for local distribution as non-hazardous bulk/package cargo.
 - **Emergency Transport Guidance:** In case of accidental spillage during transport, avoid generating dust, sweep material into closed container, and prevent entry into waterways.
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15. Regulatory Information

- **India:** Complies with Indian Pharmacopoeia (IP) standards for pharmaceutical use.
 - **International Regulations:** Listed in US FDA Inactive Ingredient Database; recognized as safe excipient by EU and WHO.
 - **Chemical Inventory Status:**
 - TSCA: Listed
 - REACH (EU): Exempt (pharmaceutical excipient use)
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16. Other Information

- **Training Advice:** Workers should be trained in safe handling practices of pharmaceutical excipients.
- **Disclaimer:** Information provided is based on current knowledge and intended as guidance for safe handling, storage, and transport of the material. It does not constitute a legally binding assurance of product properties.
- **MSDS Generate Date:** 20-05-2017
- **Revision Date:** 30-12-2024
- **Website:** www.sbfpharma.com
- MSDS are based on the manufacturer's provided information