



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 USP 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/Undertaking

- **Product Name:** Magnesium Stearate
- **Synonyms:** Octadecanoic acid, magnesium salt; Stearic acid magnesium salt
- **Grade:** USP Grade
- **Recommended Use:** Pharmaceutical excipient, lubricant in tablet/capsule formulations.

2. Hazards Identification

- **Classification (GHS):** Not classified as hazardous.
- **Physical State:** White, fine, hydrophobic powder.
- **Potential Health Effects:**

- **Inhalation:** May cause mechanical irritation to respiratory tract.
- **Skin Contact:** Non-irritating to skin.
- **Eye Contact:** Dust may cause mechanical irritation.
- **Ingestion:** Low toxicity, considered safe in pharmaceutical use.

3. Composition / Information on Ingredients

- **Chemical Name:** Magnesium Stearate
- **Molecular Formula:** $C_{36}H_{70}MgO_4$
- **Molecular Weight:** 591.27 g/mol
- **CAS Number:** 557-04-0
- **EC Number:** 209-150-3
- **Purity:** Conforms to USP grade specifications

4. First Aid Measures

- **Inhalation:** Move to fresh air. Seek medical attention if symptoms persist.
- **Skin Contact:** Wash with water and soap. No irritation expected.
- **Eye Contact:** Rinse thoroughly with water for at least 15 minutes. If irritation persists, seek medical advice.
- **Ingestion:** Rinse mouth with water. Material is of low toxicity.

5. Firefighting Measures

- **Suitable Extinguishing Media:** Water spray, dry chemical powder, foam, CO_2 .
- **Special Hazards:** Product is combustible; dust may form explosive mixtures with air.
- **Protective Equipment:** Firefighters should wear self-contained breathing apparatus and protective clothing.

6. Accidental Release Measures

- **Personal Precautions:** Avoid creating dust, provide ventilation, wear protective mask.

- **Environmental Precautions:** Prevent uncontrolled release to environment.
 - **Methods for Cleaning Up:** Sweep or vacuum without generating dust. Dispose in accordance with local regulations.
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7. Handling and Storage

- **Handling:** Avoid dust generation, handle with adequate ventilation.
 - **Storage:** Store in tightly closed containers in a cool, dry place. Protect from moisture and ignition sources.
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8. Exposure Controls / Personal Protection

- **Engineering Controls:** Local exhaust ventilation if dust levels exceed exposure limits.
 - **Personal Protection:**
 - **Respiratory Protection:** Dust mask if airborne dust exceeds limits.
 - **Eye Protection:** Safety glasses.
 - **Skin Protection:** Protective gloves not generally required.
 - **Exposure Limits:** Not established (use occupational dust limits as guidance: 10 mg/m³ for nuisance dust).
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9. Physical and Chemical Properties

- **Appearance:** White, fine, hydrophobic powder
 - **Odor:** Odorless or faint fatty odor
 - **Melting Point:** ~130–150 °C
 - **Solubility:** Practically insoluble in water, soluble in hot ethanol and chloroform
 - **Bulk Density:** ~0.15–0.30 g/cm³
 - **Flash Point:** Not applicable (solid, combustible)
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10. Stability and Reactivity

- **Stability:** Stable under normal conditions.

- **Conditions to Avoid:** Excessive heat, sparks, open flame.
 - **Incompatible Materials:** Strong oxidizing agents.
 - **Hazardous Decomposition Products:** Carbon oxides, magnesium oxides.
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11. Toxicological Information

- **Acute Toxicity:** LD₅₀ oral (rat): >10,000 mg/kg (low toxicity)
 - **Skin & Eye Irritation:** Non-irritant
 - **Carcinogenicity/Mutagenicity:** Not listed as carcinogenic (IARC, NTP, OSHA).
 - **Pharmaceutical Safety:** Widely used excipient in oral dosage forms.
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12. Ecological Information

- **Ecotoxicity:** Not expected to be harmful to aquatic or terrestrial organisms.
 - **Persistence & Degradability:** Biodegradable.
 - **Bioaccumulative Potential:** Not expected to bioaccumulate.
 - **Mobility in Soil:** Low mobility due to insolubility.
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13. Disposal Considerations

- Dispose of in accordance with local, regional, and national regulations.
 - Product is not hazardous waste; can be landfilled in compliance with environmental regulations.
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14. Transport Information (Detailed)

- **UN Number:** Not applicable (non-hazardous material)
- **UN Proper Shipping Name:** Not regulated for transport
- **Transport Hazard Class(es):** Not classified as hazardous under ADR/RID, IMDG, IATA/ICAO, DOT regulations.
- **Packing Group:** Not applicable
- **Environmental Hazards:** Not a marine pollutant

- **Special Precautions for User:** Avoid generating airborne dust during handling or transfer. Keep containers tightly sealed to prevent moisture ingress.
 - **Transport in Bulk (Annex II of MARPOL 73/78 and IBC Code):** Not applicable
 - **Regulatory Status:**
 - **ADR/RID (Road/Rail Transport in EU):** Not restricted.
 - **IMDG (Sea Transport):** Not restricted.
 - **IATA/ICAO (Air Transport):** Not restricted.
 - **DOT (US Transport):** Not restricted.
 - **Remarks:** Magnesium Stearate USP Grade is safe for transport and does not require special labeling, placarding, or hazard communication.
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15. Regulatory Information

- **GHS Classification:** Not hazardous
 - **Regulation Compliance:** USP, FDA, EU Pharmacopeia, local excipient regulations
 - **Other Regulations:** Not listed as hazardous under OSHA, REACH, TSCA
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16. Other Information

- **Abbreviations:** GHS = Globally Harmonized System, ADR = European Agreement on Road Transport, IMDG = International Maritime Dangerous Goods Code, IATA = International Air Transport Association.
- **Disclaimer:** The information provided is based on current knowledge and is intended to describe the product for safety, health, and environmental requirements only. It should not be construed as guaranteeing specific 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.