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CIN: U24230GJ2011PTC064654

Material Safety Data Sheet (MSDS)

Product Name: Colloidal Silicon Dioxide IP Grade

MSDS Generate Date: 20-05-2017

Revision Date: 30-12-2024

Manufacturer / Supplier:

SBF Pharma

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1. Identification of the Substance and Company

- **Product Name:** Colloidal Silicon Dioxide – IP Grade
- **Synonyms:** Silica, Synthetic Amorphous Silica, Light Silica
- **Chemical Formula:** SiO₂
- **Intended Use:** Pharmaceutical excipient, food additive, anti-caking agent, glidant in tablet formulations.

2. Hazards Identification

- **GHS Classification:** Not classified as hazardous under normal conditions.
- **Routes of Exposure:** Inhalation, skin contact, eye contact.
- **Potential Health Effects:**

- Inhalation: May cause respiratory irritation if inhaled in dust form.
 - Skin: Non-irritating.
 - Eyes: May cause temporary mechanical irritation.
 - Ingestion: Non-toxic; widely used as food and pharma additive.
 - **Precautionary Statement:** Avoid dust generation. Use in well-ventilated areas.
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3. Composition / Information on Ingredients

- **Substance:** Silicon Dioxide, Synthetic Amorphous (Colloidal)
 - **CAS Number:** 7631-86-9
 - **Content:** ≥ 99% SiO₂
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4. First Aid Measures

- **Inhalation:** Move to fresh air. Seek medical attention if irritation persists.
 - **Skin Contact:** Wash with water. No special treatment required.
 - **Eye Contact:** Rinse thoroughly with water for at least 15 minutes. Seek medical help if irritation persists.
 - **Ingestion:** Rinse mouth. No adverse effects expected.
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5. Fire Fighting Measures

- **Flammability:** Non-flammable, non-combustible.
 - **Suitable Extinguishing Media:** Use water, CO₂, foam or dry chemical for surrounding fire.
 - **Protective Equipment:** Use standard protective gear; substance itself does not burn.
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6. Accidental Release Measures

- Avoid dust formation. Sweep up or vacuum using equipment fitted with HEPA filter.
- Place in suitable containers for disposal.
- Ventilate area and prevent airborne dust.

7. Handling and Storage

- **Handling:** Avoid inhaling dust. Use local exhaust ventilation. Handle in accordance with GMP guidelines.
- **Storage:** Store in tightly closed containers in a cool, dry place away from moisture.

8. Exposure Controls / Personal Protection

- **Occupational Exposure Limits (OEL):**
 - OSHA PEL (Total dust): 20 mppcf or 80 mg/m³ / % SiO₂
 - ACGIH TLV: 10 mg/m³ (inhalable particles, amorphous silica)
- **Personal Protective Equipment:**
 - Respiratory: Dust mask/respirator if dust is generated.
 - Eye: Safety glasses.
 - Skin: Protective gloves if handling bulk quantities.

9. Physical and Chemical Properties

- **Appearance:** White, very light, fluffy powder
- **Odor:** Odorless
- **Molecular Weight:** 60.08 g/mol
- **Melting Point:** > 1600 °C
- **Boiling Point:** Not applicable
- **Solubility:** Insoluble in water & solvents
- **Bulk Density:** 30 – 60 g/L

10. Stability and Reactivity

- **Stability:** Stable under recommended storage conditions.
- **Reactivity:** Inert material.

- **Conditions to Avoid:** Avoid excessive dust and strong acids/alkalis.
 - **Hazardous Decomposition Products:** None known.
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11. Toxicological Information

- **Acute Toxicity:** Non-toxic (LD50 oral rat > 5000 mg/kg).
 - **Irritation:** Minimal mechanical irritation possible.
 - **Chronic Effects:** No evidence of carcinogenicity (different from crystalline silica).
 - **Mutagenicity / Teratogenicity:** Not reported.
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12. Ecological Information

- **Environmental Fate:** Inert, not biodegradable, persists as insoluble material.
 - **Aquatic Toxicity:** No known adverse effects on aquatic organisms.
 - **Bioaccumulation:** Not expected.
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13. Disposal Considerations

- Dispose of in accordance with local, state, and federal regulations.
 - Can be landfilled in compliance with environmental laws.
 - Avoid release into drains or waterways.
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14. Transport Information (Detailed)

Colloidal Silicon Dioxide is **not classified as dangerous goods** by transport regulations (ADR, RID, IMDG, IATA).

- **UN Number:** Not applicable (Non-hazardous)
- **Proper Shipping Name:** Not regulated / Colloidal Silicon Dioxide
- **Transport Hazard Class:** Not applicable
- **Packing Group:** Not applicable
- **Label Requirements:** None required

- **Marine Pollutant:** No
- **Special Precautions:**
 - Ensure containers are tightly sealed to avoid dust release.
 - Use clean, dry, covered transport vehicles.
 - Avoid contamination with food or feed during transportation.
 - Handle with care to prevent mechanical damage to packaging.
- **Regulatory References:**
 - ADR (European Road Transport): Not classified
 - RID (Rail Transport): Not classified
 - IMDG (Sea Transport): Not classified
 - IATA/ICAO (Air Transport): Not classified

Thus, **Colloidal Silicon Dioxide** can be transported safely worldwide as a non-hazardous, non-dangerous material.

15. Regulatory Information

- Listed in major pharmacopeias (IP, BP, USP, EP, JP).
- Complies with food and pharma excipient standards.
- OSHA Hazard Communication: Non-hazardous.

16. Other Information

- **Training Advice:** Personnel should be trained in handling fine powders safely.
- **Disclaimer:** Information provided is accurate to the best of knowledge as of the revision date. The user is responsible for ensuring suitability for intended use.
- **MSDS Generate Date:** 20-05-2017
- **Revision Date:** 30-12-2024
- **Website:** www.sbfpharma.com

- MSDS are based on the manufacturer's provided information.