SAFETY DATA SHEET

Prepared in accordance with the Australian National model Code of Practice for the Preparation of Safety Data Sheets for Hazardous Chemicals (2018)

According to the Model Work Health and Safety Regulation (WHS) of March 21, 2016, a Safety Data Sheet (SDS) must be provided for substances or mixtures that are classified as hazardous according to the Globally Harmonized System (GHS). This product does not meet the classification criteria of GHS. Therefore such document is outside the scope of Chapter 7.1 article 330 of WHS Regulation and the requirements for content in each section do not apply.

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product name: CAB-O-SIL® Untreated Fumed Silica - Pharmaceutical Grade

Product code: M5P

Synonyms: Untreated Fumed Silica, Silicon Dioxide, Synthetic Amorphous Silica, Pyrogenic (Fumed) Amorphous Silica, Colloidal Silicon Dioxide, Colloidal Anhydrous Silica, Light Anhydrous Silicic Acid

This SDS is valid for the following grades: CAB-O-SIL® Untreated Fumed Silica: M5P, M5DP.

Recommended use: Multifunctional excipient for pharmaceutical solid, semi-solid, and liquid forms, Free flow agent, Anti-caking agent, Spray aid, Anti-blocking agent, Anti-settling agent, Thickening agent, Stabilization agent, Carrier, Other

Restrictions on use: Not Applicable.

Supplier:

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International CHEMTREC: +1 703-741-5970 or +1-703-527-3887
CHINA: CHEMTREC 4001 - 204937
GERMANY: CHEMTREC 0800-181-7059
UK: CHEMTREC: (+44)-870-8200418
US: CHEMTREC: +1-703-527-3887 or 1-800-424-9300

2. HAZARDS IDENTIFICATION

Classification
Not a hazardous substance or mixture according to the Globally Harmonized System (GHS) Rev. 3 referred in Australia Model Work Health and Safety Regulation (WHS).

**Pictogram:**
None

**Signal Word:**
None

**Hazard statements:**
None

**Precautionary statements:**
None

**Hazards not otherwise classified (HNOC)**
None.

**Potential health effects**

**Principle Routes of Exposure:** Inhalation, Skin Contact, Eye contact

**Eye Contact:** May cause mechanical irritation. Avoid contact with eyes.

**Skin Contact:** May cause mechanical irritation and skin drying. Avoid contact with skin. No cases of sensitization in humans have been reported.

**Inhalation:** Dust may be irritating to respiratory tract. Provide appropriate exhaust ventilation at machinery and at places where dust can be generated. See also Section 8.

**Ingestion:** Adverse health effects are not expected. See Section 11.

**Carcinogenicity:** Does not contain any substances greater than 0.1% listed by IARC (International Agency for Research on Cancer), NTP (National Toxicology Program), OSHA (Occupational Safety and Health Administration), ACGIH (American Conference for Governmental Industrial Hygienists) or EU (European Union). See also Section 11.

**Target Organ Effects:** Lungs, See Section 11

**Medical Conditions Aggravated by** Asthma, Respiratory disorder
Exposure:

Potential Environmental Effects: None known. See Section 12.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Synonyms: Untreated Fumed Silica, Silicon Dioxide, Synthetic Amorphous Silica, Pyrogenic (Fumed) Amorphous Silica, Colloidal Silicon Dioxide, Colloidal Anhydrous Silica, Light Anhydrous Silicic Acid.

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS No</th>
<th>weight-%</th>
<th>Trade secret</th>
</tr>
</thead>
<tbody>
<tr>
<td>Synthetic Amorphous, Pyrogenic Silica</td>
<td>112945-52-5</td>
<td>&gt; 99.9</td>
<td>-</td>
</tr>
</tbody>
</table>

Regulatory information is found under the general silica: CAS RN 7631-86-9, EINECS RN 231-545-4

Other Information:
The hyphen (-) means "not applicable"

4. FIRST AID MEASURES

FIRST AID MEASURES

Skin Contact: Wash thoroughly with soap and water. Seek medical attention if symptoms develop.

Eye contact: Flush eyes immediately with large amounts of water for 15 minutes. Seek medical attention if symptoms develop.

Inhalation: If cough, shortness of breath or other breathing problems occur, move to fresh air. Seek medical attention if symptoms persist. If necessary, restore normal breathing through standard first aid measures.

Ingestion: Do not induce vomiting. If conscious, give several glasses of water. Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed

Symptoms: The most important known symptoms and effects are described in Section 2 and/or in Section 11.

Indication of any immediate medical attention and special treatment needed

Note to physicians: Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media: Silica is non-combustible, therefore no extinguishing media needs to be identified.

Unsuitable Extinguishing Media: None.

Specific hazards arising from the chemical: None.

Hazardous combustion products: None.
Protective equipment and precautions for firefighters: Wear suitable protective equipment. In the event of fire, wear self-contained breathing apparatus.

Risk of Dust Explosion: Not Applicable

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal precautions: Avoid dust formation. Ensure adequate ventilation. Use personal protective equipment. See also Section 8.

For emergency responders: Use personal protection recommended in Section 8.

Environmental Precautions:

Environmental Precautions: Contain spilled product on land, if possible. Local authorities should be advised if significant spillages cannot be contained.

Methods and material for containment and cleaning up

Methods for containment: Prevent further leakage or spillage if safe to do so.

Methods for cleaning up: Clean up promptly by vacuum. Use of a vacuum with high efficiency particulate air (HEPA) filtration is recommended. Do not create a dust cloud by using a brush or compressed air. Pick up and transfer to properly labelled containers. See Section 13.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on safe handling: Avoid contact with skin and eyes. Avoid dust formation. Do not breathe dust. Provide appropriate exhaust ventilation at machinery and at places where dust can be generated. Do not create a dust cloud by using a brush or compressed air.

Take precautionary measures against static discharges. All metal parts of the mixing and processing equipment must be earthed/grounded. Ensure all equipment is electrically earthed/grounded before beginning transfer operations. Fine dust is capable of penetrating electrical equipment and may cause electrical shorts.

General hygiene considerations: Handle in accordance with good industrial hygiene and safety practice

Conditions for safe storage, including any incompatibilities

Storage Conditions: Keep containers tightly closed in a dry and well-ventilated place. Do not store together with volatile chemicals as they may be adsorbed onto product. Store at ambient conditions. Keep in properly labeled containers.

Incompatible materials: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure guidelines: The table below is a summary. Please see the specific legislation for complete information.
<table>
<thead>
<tr>
<th>Region</th>
<th>Amorphous Silica</th>
<th>Dust, or Particulates Not Otherwise Specified</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>2 mg/m³, TWA, Respirable</td>
<td>10 mg/m³, TWA, Inhalable</td>
</tr>
<tr>
<td>Austria MAK</td>
<td>4 mg/m³, TWA, Inhalable fraction</td>
<td>3 mg/m³ TWA, Respirable</td>
</tr>
<tr>
<td>Finland</td>
<td>5 mg/m³</td>
<td>China: 8 mg/m³, TWA</td>
</tr>
<tr>
<td>Germany TRGS 900</td>
<td>4 mg/m³, TWA, Inhalable fraction</td>
<td>10 mg/m³, STEL</td>
</tr>
<tr>
<td>India</td>
<td>10 mg/m³, TWA</td>
<td>France: 10 mg/m³, TWA Inhalable dust</td>
</tr>
<tr>
<td>Ireland</td>
<td>2.4 mg/m³, TWA, Respirable dust</td>
<td>5 mg/m³, TWA Respirable dust</td>
</tr>
<tr>
<td>Norway</td>
<td>1.5 mg/m³, TWA, Respirable dust</td>
<td>Italy: 10 mg/m³, TWA, Inhalable</td>
</tr>
<tr>
<td>Switzerland</td>
<td>4 mg/m³, TWA</td>
<td>3 mg/m³, TWA, Respirable</td>
</tr>
<tr>
<td>UK WEL</td>
<td>6 mg/m³, TWA, Inhalable fraction</td>
<td>Malaysia: 10 mg/m³, TWA, Inhalable</td>
</tr>
<tr>
<td></td>
<td>2.4 mg/m³, TWA, Respirable fraction</td>
<td>3 mg/m³, TWA, Respirable</td>
</tr>
<tr>
<td>US OSHA PEL</td>
<td>6 mg/m³ (54 FR2701)</td>
<td>Spain: 10 mg/m³, VLA, Inhalable</td>
</tr>
</tbody>
</table>

**NOTE:**

In its facilities globally, Cabot Corporation manages silica to the Germany TRGS 900 occupational exposure limit of 4 mg/m³, TWA, Inhalable fraction.

**MAK:** Maximale Arbeitsplatzkonzentration (Maximum Workplace Concentration)

**PEL:** Permissible Exposure Limit

**PNOS:** Particulate Not Otherwise Specified

**STEL:** Short Term Exposure Limit

**TRGS:** Technische Regeln für Gefahrstoffe (Technical Rule for Hazardous Materials)

**TWA:** Time Weighted Average

**US ACGIH:** United States American Conference of Governmental Industrial Hygienists

**US OSHA:** United States Occupational Safety and Health Administration

**VLA:** Valore Límite Ambientales (Environmental Limit Value)

**WEL:** Workplace Exposure Limit

**Engineering Controls:**

Ensure adequate ventilation to maintain exposures below occupational limits. Provide
appropriate local exhaust ventilation at machinery and at places where dust can be generated.

**Personal protective equipment [PPE]**

**Respiratory Protection:**Approved respirator may be necessary if local exhaust ventilation is not adequate.

**Hand Protection:**Wear protective gloves to prevent skin drying. Use protective barrier cream before handling the product. Wash hands and other exposed skin with mild soap and water.

**Eye/face Protection:**Wear eye/face protection. Wear safety glasses with side shields (or goggles).

**Skin and Body Protection:**Wear suitable protective clothing. Wash clothing daily. Work clothing should not be allowed out of the workplace.

**Other:**Handle in accordance with good industrial hygiene and safety practice. Emergency eyewash and safety shower should be located nearby.

**Environmental exposure controls:**In accordance with all local legislation and permit requirements as applicable for dusts.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Values</th>
<th>Remarks • Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State:</td>
<td>Solid</td>
<td></td>
</tr>
<tr>
<td>Appearance:</td>
<td>Powder</td>
<td></td>
</tr>
<tr>
<td>Color:</td>
<td>White</td>
<td></td>
</tr>
<tr>
<td>pH:</td>
<td>3.6-4.5</td>
<td>In-house testing</td>
</tr>
<tr>
<td>Melting point/freezing point:</td>
<td>1700 °C</td>
<td>NIOSH Pocket Guide to Chemical Hazards</td>
</tr>
<tr>
<td>Boiling point / boiling range:</td>
<td>2230 °C</td>
<td>NIOSH Pocket Guide to Chemical Hazards</td>
</tr>
<tr>
<td>Evaporation Rate:</td>
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<td></td>
</tr>
<tr>
<td>Vapor pressure:</td>
<td>Not Applicable</td>
<td></td>
</tr>
<tr>
<td>Vapor Density:</td>
<td>Not Applicable</td>
<td></td>
</tr>
<tr>
<td>Density:</td>
<td>2.2 g/cm³</td>
<td>@ 20 °C</td>
</tr>
<tr>
<td>Bulk Density:</td>
<td>30 - 150 kg/m³</td>
<td>DIN/ISO 787:11</td>
</tr>
<tr>
<td>Specific Gravity at 20°C:</td>
<td>2.2</td>
<td></td>
</tr>
<tr>
<td>Water solubility:</td>
<td>Slightly soluble</td>
<td>According to OECD 105</td>
</tr>
<tr>
<td>Solubility(ies):</td>
<td></td>
<td>No information available</td>
</tr>
<tr>
<td>Partition Coefficient (n-octanol/water):</td>
<td></td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Decomposition temperature:</td>
<td></td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Viscosity:</td>
<td></td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Kinematic viscosity:</td>
<td></td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Dynamic viscosity:</td>
<td></td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Oxidizing Properties:</td>
<td></td>
<td>No oxidizing properties</td>
</tr>
<tr>
<td>Softening point:</td>
<td></td>
<td>Not Applicable</td>
</tr>
<tr>
<td>VOC content (%):</td>
<td></td>
<td>Not Applicable</td>
</tr>
<tr>
<td>% Volatile (by Volume):</td>
<td></td>
<td>Not Applicable</td>
</tr>
<tr>
<td>% Volatile (by Weight):</td>
<td></td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Surface Tension:</td>
<td></td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>
**10. STABILITY AND REACTIVITY**

- **Reactivity:** Not reactive. Substance is an inert inorganic solid.
- **Stability:** Stable under recommended handling and storage conditions.
- **Possibility of hazardous reactions:** None under normal processing.
- **Hazardous polymerization:** Hazardous polymerization does not occur.
- **Conditions to avoid:** None known.
- **Incompatible materials:** None known.

**Explosion data**

- **Sensitivity to Mechanical Impact:** None.
- **Sensitivity to Static Discharge:** This material is an inorganic dust and will not create nor support conditions that would result in a dust explosion or fire. Take precautionary measures against static discharges. Avoid dust formation. All metal parts of the mixing and processing equipment must be earthed/grounded. Ensure all equipment is electrically earthed/grounded before beginning transfer operations.

- **Hazardous decomposition products:** None known.

**11. TOXICOLOGICAL INFORMATION**

- **Acute toxicity**
  - **Oral LD50:** LD50/oral/rat = > 5000 mg/kg. No deaths occurred and no signs of toxicity were seen.
Product code: M5P  
Product name: CAB-O-SIL® Untreated Fumed Silica - Pharmaceutical Grade  
Revision date: 02-Dec-2018

during the observation periods after single oral administration of silica (OECD 401).

Inhalation LC50:  
Due to the product's physical characteristics, no suitable testing procedure is available.

Dermal LD50:  
LD50/dermal/rabbit = > 2000 mg/kg. Very slight transient erythema in one animal. No signs of systemic or organ toxicity (OECD 402).

Skin corrosion/irritation:  
Primary irritation index = 0/8 @ 24 hr. Not classified as an irritant (OECD 404)

Serious eye damage/eye irritation:  
Draize score 1.0/110 @ 24 hr. Not classified as an irritant in rabbit studies (OECD 405). High dust concentrations may cause mechanical irritation.

Sensitization:  
No experimental animal data are available. No cases of sensitization in humans have been reported.

Mutagenicity:  
Not mutagenic in Ames test. Negative in the unscheduled DNA synthesis assay. Negative in the chromosome aberration test in Chinese hamster ovary (CHO) cells.

Carcinogenicity:  
No evidence of carcinogenicity was observed in multiple animal species following repeated oral or inhalation exposure to amorphous silica. Similarly, epidemiology studies show no evidence of carcinogenicity in workers who manufacture amorphous silica.

Reproductive Toxicity:  
No effects on reproductive organs or fetal development have been reported in animal toxicity studies.

STOT - single exposure:  
Based on available data, specific target organ toxicity is not expected after single oral, single inhalation, or single dermal exposure.

STOT - repeated exposure:  
Repeated dose toxicity: oral (rat), 2 weeks to 6 months, no significant treatment-related adverse effects at doses of up to 8% silica in the diet.  
Repeated dose toxicity: inhalation (rat), 13 weeks, Lowest Observed Effect Level (LOEL) = 1.3 mg/m³ based on mild reversible effects in the lungs.  
Repeated dose toxicity: inhalation (rat), 90 days, LOEL = 1 mg/m³ based on reversible effects in the lungs and effects in the nasal cavity.

Based on available data, a STOT-RE classification is not warranted.

Aspiration Hazard:  
Based on industrial experience and available data, no aspiration hazard is expected.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity:  
Fish (Brachydanio rerio) LC50 (96 h): > 10,000 mg/l; (Method: OECD 203)  
No acute toxicity to Daphnia with EL and EL₅₀ ranging from >1000 to 10,000 mg/L (OECD 202)

ENVIRONMENTAL FATE
Persistence and degradability  
The methods for determining biodegradability are not applicable to inorganic substances

Bioaccumulation  
Not expected due to physicochemical properties of the substance.
Mobility: Not expected to migrate.

Distribution to Environmental Compartments: No information available.

PBT and vPvB Assessment: This substance is not considered to be persistent, bioaccumulating nor toxic (PBT). This substance is not considered to be very persistent nor very bioaccumulating (vPvB).

Other adverse effects: No information available.

13. DISPOSAL CONSIDERATIONS

Disclaimer: Information in this section pertains to the product as shipped in its intended composition as described in Section 3 of this SDS. Contamination or processing may change waste characteristics and requirements. Regulations may also apply to empty containers, liners or rinsate. State/provincial and local regulations may be different from federal regulations.

Disposal considerations: Disposal should be in accordance with applicable regional, national and local laws and regulations.

14. TRANSPORT INFORMATION

DOT

| UN/ID no    | Not regulated |
| Proper Shipping Name | Not regulated |
| Hazard Class    | Not regulated |
| Packing group  | Not regulated |

ICAO (air)

| UN/ID no    | Not regulated |
| Proper Shipping Name | Not regulated |
| Hazard Class    | Not regulated |
| Packing group  | Not regulated |

IATA

| UN/ID no    | Not regulated |
| Proper Shipping Name | Not regulated |
| Hazard Class    | Not regulated |
| Packing group  | Not regulated |

IMDG

| UN/ID no    | Not regulated |
| Proper Shipping Name | Not regulated |
| Hazard Class    | Not regulated |
| Packing group  | Not regulated |

RID
15. REGULATORY INFORMATION

*Regulatory information is found under the general silica: CAS RN 7631-86-9, EINECS RN 231-545-4.
Classification

Not a hazardous substance or mixture according to the Globally Harmonized System (GHS) Rev. 3 referred in Australia Model Work Health and Safety Regulation (WHS).

International Inventories

- **TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory
  Complies
- **DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List
  Complies
- **EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
  Complies
- **ENCS** - Japan Existing and New Chemical Substances
  Complies
- **IECSC** - China Inventory of Existing Chemical Substances
  Complies
- **KECL** - Korean Existing and Evaluated Chemical Substances
  Complies
- **PICCS** - Philippines Inventory of Chemicals and Chemical Substances
  Complies
- **AICS** - Australian Inventory of Chemical Substances
  Complies
- **NZIoC** - New Zealand Inventory of Chemicals
  Complies
- **TCSI** - Taiwan Chemical Substance Inventory
  Complies

16. OTHER INFORMATION

**Pharmaceutical Use:**
Designed for pharmaceutical applications. Please refer to Pharma Grade Statement and Application Guide available on www.cabotcorp.com for further information

**Food Additive Use:**
Not recommended

**References:**

**Contacts:**