



SAFETY DATA SHEET

Prepared in accordance with the United States Hazard Communication Standard: 29 CFR 1910.1200 (2012)

Revision date: 20-May-2015

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:

Cabot Corporation 4400 North Point Parkway Suite 200 Alpharetta, Georgia 30022 United States Tel: +1 678 297 1300	Cabot Corporation 157 Concord Road Billerica, MA 01821 UNITED STATES Tel: 1-978-663-3455 Fax: 1-978-670-6955
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Emergency Telephone Number: 24H/7d service
Canada: CANUTEC 1-613-996-6666
US: CHEMTREC 1-800-424-9300 or 1-703-527-3887
Germany: CHEMTREC 0800-181-7059
UK: CHEMTREC: (+44)-870-8200418
CHEMTREC China: 4001-204937
International CHEMTREC: +1 703-741-5970 or +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification

OSHA Regulatory Status: This chemical is not considered hazardous by the United States 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).

Label Elements

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 Exposure: Asthma, Respiratory disorder

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.

Chemical name	CAS No	weight-%	Trade secret
Synthetic Amorphous, Pyrogenic Silica	112945-52-5	> 99.9	-

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

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.

Amorphous Silica, The regulatory exposure limits are found under the general silica, CAS RN 7631-86-9:	Australia:	2 mg/m ³ , TWA, Respirable
	Austria MAK	4 mg/m ³ , TWA, Inhalable fraction
	Finland:	5 mg/m ³
	Germany TRGS 900:	4 mg/m ³ , TWA, Inhalable fraction
	India:	10 mg/m ³ , TWA
	Ireland:	2.4 mg/m ³ , TWA, Respirable dust
	Norway:	1.5 mg/m ³ , TWA, Respirable dust
	Switzerland:	4 mg/m ³ , TWA
	UK WEL:	6 mg/m ³ , TWA, Inhalable fraction 2.4 mg/m ³ , TWA, Respirable fraction
	US OSHA PEL:	6mg/m ³ (54 FR2701)

Dust, or Particulates Not Otherwise Specified:	Belgium:	10 mg/m ³ , TWA, Inhalable 3 mg/m ³ TWA, Respirable
	China:	8 mg/m ³ , TWA 10 mg/m ³ , STEL
	France:	10 mg/m ³ , TWA Inhalable dust 5 mg/m ³ , TWA Respirable dust
	Italy:	10 mg/m ³ , TWA, Inhalable 3 mg/m ³ , TWA, Respirable
	Malaysia:	10 mg/m ³ , TWA, Inhalable 3 mg/m ³ , TWA, Respirable
	Spain:	10 mg/m ³ , VLA, Inhalable 3 mg/m ³ , VLA, Respirable
	US ACGIH - PNOS:	10 mg/m ³ , TWA, Inhalable 3 mg/m ³ , TWA, Respirable
	US OSHA - PEL:	15 mg/m ³ , TWA, Total dust 5 mg/m ³ , TWA, Respirable

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 Limite 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

Physical State:	Solid	Odor:	None.
Appearance:	Powder	Odor threshold:	Not Applicable
Color:	White		

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH:	3.6-4.5	In-house testing
Melting point/freezing point:	1700 °C	NIOSH Pocket Guide to Chemical Hazards
Boiling point / boiling range:	2230 °C	NIOSH Pocket Guide to Chemical Hazards
Evaporation Rate:		Not Applicable
Vapor pressure:		Not Applicable
Vapor Density:		Not Applicable
Density:	2.2 g/cm ³	@ 20 °C
Bulk Density:	30 - 150 kg/m ³	DIN/ISO 787:11
Specific Gravity at 20°C:	2.2	
Water solubility:	Slightly soluble	According to OECD 105
Solubility(ies):		No information available
Partition Coefficient (n-octanol/water):		Not Applicable
Decomposition temperature:		Not Applicable
Viscosity:		Not Applicable
Kinematic viscosity:		Not Applicable
Dynamic viscosity:		Not Applicable
Oxidizing Properties:		No oxidizing properties
Softening point:		Not Applicable
VOC content (%):		Not Applicable
% Volatile (by Volume):		Not Applicable
% Volatile (by Weight):		Not Applicable
Surface Tension:		Not Applicable
Explosive properties:		Non-explosible
Flash Point:		Not combustible
Flammability (solid, gas):		Not flammable. Product resists ignition and does not promote flame spread
Flammability Limit in Air:		Not Applicable
Explosion Limits in Air - Upper (g/m ³):		Not Applicable
Explosion Limits in Air - Lower (g/m ³):		Not Applicable
Autoignition Temperature:		Not Applicable
Minimum Ignition Temperature:		Not Applicable

Minimum Ignition Energy:	Not Applicable
Ignition Energy:	Not Applicable
Maximum Absolute Explosion Pressure:	Not Applicable
Maximum Rate of Pressure Rise:	Not Applicable
Burn Velocity:	Not combustible
Kst Value:	Not Applicable
Dust Explosion Classification:	Not Applicable

End point is listed "not applicable" due to the inherent properties of the substance
"No information available" indicates testing has not been performed

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	Will not cause dust explosion. See also Section 9.
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 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/m ³ based on mild reversible effects in the lungs. Repeated dose toxicity: inhalation (rat), 90 days, LOEL = 1 mg/m ³ 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 EL ₅₀ ranging from >1000 to 10,000 mg/L (OECD 202)
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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.
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 MSDS. 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.

RCRA: Unused product is not a hazardous waste under U.S. RCRA, 40 CFR 261.

Disposal considerations: Dispose in accordance with applicable legislations.

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

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

ADR

UN/ID no	Not regulated
Proper Shipping Name	Not regulated

Hazard Class	Not regulated
Packing group	Not regulated

15. REGULATORY INFORMATION

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

Hazard Classification

United States - OSHA (29 CFR 1910.1200): Not Hazardous

Mexico - NOM-018-STPS-2000: Not hazardous

Canada - WHMIS Classification (CPR, SOR/88-66): Not controlled

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the M/SDS contains all the information required by the Controlled Products Regulations.

Chemical name	WHMIS - Ingredient Disclosure
Synthetic Amorphous, Pyrogenic Silica 112945-52-5	General silica CAS RN 7631-86-9, is listed

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

US Federal Regulations

TSCA Section 12(b) Export Regulations:

This product does not contain any components that are subject to TSCA 12(b) Export Notification

SARA Section 302 (40 CFR 355) Extremely Hazardous Substances:

No components are listed as extremely hazardous substances under SARA Section 302.

SARA 311/312 Hazard Categories

Acute Health Hazard	NO
Chronic Health Hazard	NO
Fire hazard	NO
Sudden release of pressure hazard	NO
Reactive Hazard	NO

SARA Section 313 (40 CFR 372) Toxics Release Inventory

Does not contain any of the substances identified under Section 313 as toxic chemicals in excess of the de minimis concentrations necessary to be subject to the supplier notification requirements.

Clean Air Act Amendments of 1990(CAA, Section 112, 40 CFR 82):

This product does not contain any components listed as a Hazardous Air Pollutant, Flammable Substance, Toxic Substance, or Class 1 or 2 Ozone Depletor

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

*US State Regulations*California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

Chemical name	New Jersey	Massachusetts	Pennsylvania	Louisiana:
Silica 7631-86-9	X	X	X	

16. OTHER INFORMATION

Pharmaceutical Use:

See Section 1.

References:

NIOSH Pocket Guide to Chemical Hazards, September 2005. "Silica, amorphous". DHHS (NIOSH) Publication No. 2005-149. National Technical Information Service, Springfield, VA. p. 277

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End of Safety Data Sheet