

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	SILICON DIOXIDE (Syloid® 244 FP)
PRODUCT CODE	3089
SUPPLIER	MEDISCA Inc. Tel.: 1.800.932.1039 Fax.: 1.855.850.5855 626 Tom Miller Road, Plattsburgh, NY, 12901 MEDISCA Pharmaceutique Inc. Tel.: 1.800.665.6334 Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 MEDISCA Australia PTY LTD Tel.: 1.300.786.392 Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020
EMERGENCY PHONE	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126 National Chemical Emergency Centre 44(0)1235239670
RECOMMENDED USES	Pharmaceutical Manufacturing
RESTRICTIONS ON USE	Not applicable

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION	Based on available data, the classification criteria are not met.		
PICTOGRAM	Not Applicable		
SIGNAL WORD	Not Applicable.		
HAZARD STATEMENT(S)	Not Applicable.		
ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS	Repeated exposure may cause skin dryness or cracking.		
PRECAUTIONARY STATEMENT(S)	Prevention	Not Applicable.	
	Response	Not Applicable.	
	Storage	Not Applicable.	
	Disposal	Not Applicable.	
HMS CLASSIFICATION	Health Hazard	1	Flammability 0
	Reactivity	0	Personal Protection E

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME	Silicon Dioxide
BOTANICAL NAME	Not applicable
SYNONYM	Not applicable
CHEMICAL FORMULA	SiO ₂
CHEMICAL FAMILY	Not applicable
CAS NUMBER	7631-86-9
ALTERNATE CAS NUMBER	Not applicable
MOLECULAR WEIGHT	60.084 (anhydrous)
COMPOSITION	

CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
SILICON DIOXIDE	7631-86-9	231-545-4	> 97

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

NOTES

SYLOID® 244 FP is a fine-sized, high pore volume silica gel with a large internal surface area.

SECTION 4: FIRST-AID MEASURES

IN CASE OF EYE CONTACT	Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.
IN CASE OF SKIN CONTACT	Wash with soap & water for 15 minutes. If irritation persists seek medical aid.
IF SWALLOWED	Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.
IF INHALED	Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician
MEDICAL ATTENTION AND SPECIAL TREATMENT	Get emergency medical help.
SYMPTOMS CAUSED BY EXPOSURE	Not expected to present a significant hazard under anticipated conditions of normal use.

SECTION 5: FIREFIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL	Not applicable
FLAMMABLE PROPERTIES	Non combustible
HAZARDOUS COMBUSTION PRODUCTS	Under fire conditions, hazardous fumes will be present.
SUITABLE & UNSUITABLE EXTINGUISHING MEDIA	Small fire: dry chemical, CO ₂ or water spray. Large fire: dry chemical, CO ₂ , alcohol resistant foam or water spray. Do not get water inside containers.
PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS	Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

**METHODS & MATERIAL FOR
CONTAINMENT**

On land, sweep or shovel into suitable containers. Minimize generation of dust.

CLEANUP PROCEDURE

Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

**REFERENCE TO OTHER
SECTIONS**

See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

SECTION 7: HANDLING AND STORAGE
**PRECAUTIONS FOR SAFE
HANDLING**

Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

**CONDITIONS FOR SAFE
STORAGE**

Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

STORAGE CONDITIONS

Store in original container, tightly sealed, protected from direct sunlight and moisture.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: SILICON DIOXIDE CAS #: 7631-86-9

	Country	Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes
		ppm	mg/m ³	ppm	mg/m ³				
OSHA	USA	N/L	80% SiO ₂	N/L	N/L	N/L	N/L	N/A	inhalable dust containing no asbestos and < 1% crystalline silica.
ACGIH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
NIOSH	USA	N/L	80% SiO ₂	N/L	N/L	3000	N/L	N/A	N/A
WEEL	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSIS	Australia	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSE	UK	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Australia	N/L	2	N/L	N/L	N/L	N/L	N/A	inhalable dust containing no asbestos and < 1% crystalline silica.
GESTIS	Austria	N/L	4	N/L	N/L	N/L	N/L	N/A	inhalable aerosol
GESTIS	Belgium	N/L	10	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Canada - Ontario	N/L	10	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Canada - Québec	N/L	6	N/L	N/L	N/L	N/L	N/A	N/A

GESTIS	Denmark	N/L	2	N/L	4	N/L	N/L	N/A	inhalable aerosol
GESTIS	Finland	N/L	5	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Germany (AGS)	N/L	4	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Germany (DFG)	N/L	4	N/L	N/L	N/L	N/L	N/A	inhalable aerosol
GESTIS	Ireland	N/L	6	N/L	N/L	N/L	N/L	N/A	Inhalable fraction
GESTIS	Latvia	N/L	1	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	New Zealand	N/L	1	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	China	N/L	2	N/L	N/L	N/L	N/L	N/A	Inhalable fraction
GESTIS	Singapore	N/L	10	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	South Korea	N/L	10	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Switzerland	N/L	4	N/L	N/L	N/L	N/L	N/A	inhalable aerosol
GESTIS	United Kingdom	N/L	6	N/L	N/L	N/L	N/L	N/A	inhalable aerosol

N/L = Not listed ; N/A = Not Available

PELs are 8-hour TWAs = Limit value - Eight hours

Ceiling or Short-Term TWA = STEL = Limit value - Short term

EXPOSURE GUIDELINES

Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³

PERSONAL PROTECTIVE EQUIPMENT

Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Wear appropriate gloves to prevent skin exposure. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. **Respirators:** Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. **Thermal Hazards:** For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

SPECIFIC ENGINEERING CONTROLS

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

BIOLOGICAL MONITORING

Not available

CONTROL BANDING

Not available

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE

Solid

DESCRIPTION

Fine, white, hygroscopic, odorless, amorphous powder.

SOLUBILITY

Insoluble in water, in alcohol, in other organic solvents; soluble in hot solutions of alkali hydroxides.

ODOR

Odorless

FLAMMABILITY

Non combustible solid

AUTO-IGNITION TEMPERATURE

Not available

BOILING POINT

2230 °C, 4046 °F

DECOMPOSITION TEMPERATURE

Not available

EVAPORATION RATE

Not available

EXPLOSIVE LIMIT

Non-explosive

FLASH POINT

Not available

log P (OCTANOL-WATER)	0.53 (25°C) (pH 7)	LOWER FLAMMABLE/ EXPLOSIVE LIMIT(S)	Not available	MELTING/FREEZING POINT	1710°C, 3110°F
PARTICLE CHARACTERISTICS	Not available	OXIDIZING PROPERTY	No (100%)	pH	4.0 - 7.0 (5 %)
RELATIVE DENSITY (WATER = 1)	2.2 (20°C)	SPECIFIC GRAVITY	2.20	UPPER FLAMMABLE/ EXPLOSIVE LIMIT(S)	Not available
VAPOR DENSITY (AIR = 1)	Not available	VAPOR PRESSURE	13.3 hPa (1732°C)	VISCOSITY	Not available

The physical data presented above are typical values and should not be construed as a specification.

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY	Not established
CHEMICAL STABILITY	Stable under recommended storage conditions
INCOMPATIBLE MATERIALS	Strong oxidants
HAZARDOUS DECOMPOSITION PRODUCTS	Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur
HAZARDOUS POLYMERIZATION	Will not occur
POSSIBILITY OF HAZARDOUS REACTION	Not established
CONDITIONS TO AVOID	Moisture, sunlight and extreme temperatures Hygroscopic - Avoid exposure to moisture

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY	Oral: Rat: LD50: (mg/kg): Not available Dermal: Rabbit: LD50: (mg/kg): 2 000 - 5 000 Inhalation: Rat: LC50: (mg/L/4hr): 140 - 58 800
SKIN CORROSION/IRRITATION	Due to lack of data the classification is not possible.
SERIOUS EYE DAMAGE/EYE IRRITATION	Due to lack of data the classification is not possible.
RESPIRATORY SENSITIZATION	Due to lack of data the classification is not possible.
SKIN SENSITIZATION	Due to lack of data the classification is not possible.
GERM CELL MUTAGENICITY	Due to lack of data the classification is not possible. Toxicity - InVitro: No adverse effect observed (negative)
CARCINOGENICITY	OSHA SILICA GEL is listed. NTP SILICA GEL is not listed. IARC SILICA GEL is listed in group 3 (not classifiable as to its carcinogenicity to humans).

ADDITIONAL CARCINOGENICITY INFORMATION
California Proposition

This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

Based on available data, the classification criteria are not met.

REPRODUCTIVE TOXICITY

Due to lack of data the classification is not possible.

SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE

Due to lack of data the classification is not possible.

SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE

Due to lack of data the classification is not possible.

ASPIRATION HAZARDS

Based on the available data the classification is not possible.

SIGNS AND SYMPTOMS OF EXPOSURE
ROUTES OF EXPOSURE:

Oral, Dermal, Inhalation, Eye contact

EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:

Not available

DELAYED HEALTH EFFECT FROM EXPOSURE:

Not available

Not expected to present a significant hazard under anticipated conditions of normal use.

Prolonged inhalation of some forms of silica dust may be associated with the development of fibrosis of lung.

POTENTIAL HEALTH EFFECTS
Inhalation

May be harmful if inhaled. May cause mechanic respiratory tract irritation.

Ingestion

May be harmful if swallowed.

Skin

May be harmful if absorbed through skin. May cause skin irritation. May dry skin.

Eyes

May cause mechanic eye irritation.

SECTION 12: ECOLOGICAL INFORMATION

ECOTOXICITY

EC50: 48 Hr: Crustacea: (mg/L): > 10,000

LC50: 96 Hr: Fish: (mg/L): > 10,000

EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available

PERSISTENCE AND DEGRADABILITY

No hazard identified

BIOACCUMULATIVE POTENTIAL

No bioaccumulation potential

MOBILITY IN SOIL

Insoluble in water

15 - 439.52 mg/L (20 - 37°C) (pH 5.5 - 7.4)

OTHER ADVERSE EFFECTS

No hazard identified

This product is not intended to be released into the environment

SECTION 13: DISPOSAL CONSIDERATIONS

DISPOSAL METHODS

Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.

SECTION 14: TRANSPORT INFORMATION

UN PROPER SHIPPING NAME Not dangerous good
 UN NUMBER Not applicable
 CLASS Not applicable
 PACKING GROUP Not applicable

AUSTRALIA

HAZCHEM Not applicable

EU

TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE Not Listed

ENVIRONMENTAL HAZARDS Not available

SPECIAL SHIPPING INFORMATION Not applicable

SECTION 15: REGULATORY INFORMATION
UNITED STATES REGULATIONS

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR	EPA 40 CFR Part 355 Appendix A	EPA 40 CFR Part 355 Appendix B	Pennsylvania	Right-to-know New Jersey	Massachusetts	California Prop 65
SILICA GEL 7631-86-9	N/L	N/L	N/L	N/L	X	N/L	X	N/L

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

Chemical Name & CAS	Poisons and Therapeutic Goods	Therapeutic Goods Act	Code of Practices - Illicit Drug	Poisons Standard	Work Health and Safety Regulations	Inventory of Industrial Chemicals
SILICA GEL 7631-86-9	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed

EU REGULATIONS

Chemical Name & CAS	REACH ANNEX XVII	REACH ANNEX XIV	EC 1005/2009	EC 850/2004	EC 1107/2009	PIC - Prior Informed Consent Regulation	EC 2012/18
SILICA GEL 7631-86-9	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

Any EU regulation not listed above is not applicable to this product.

SUBJECT TO INTERNATIONAL AGREEMENT Not applicable

SECTION 16: OTHER INFORMATION

REFERENCES

Available upon request

ABBREVIATIONS AND ACRONYMS

ACGIH - American Conference of Governmental Industrial Hygienists; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **CAESAR** – Computer Assisted Evaluation of industrial chemical Substances According to Regulations; **CAS** – Chemical Abstract Service; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **EC50** – Effective Concentration, 50%; **EPA** – Environmental Protection Agency; **GHS** – Global Harmonized System; **HMIS** – Hazardous Materials Information System; **HSE** – Health and Safety Executive; **HSIS** – Hazardous Substances Information System; **IARC** – International Agency for Research on Cancer; **IDLH** - Immediately Dangerous to Life or Health; **IRFMN** – Ready Biodegradability Model; **ISS** – Istituto Superiore Sanità; **LC50** – Lethal Concentration, 50%; **LD50** – Lethal Dose, 50%; **MSHA** - Mine Safety and Health Administration; **NIOSH** – National Institute for Occupational Safety and Health; **NTP** – National Toxicology Program; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **QSAR** – Quantitative Structure-activity relationship; **REL** - Recommended Exposure Limit; **SARA** – Superfund Amendments and Reauthorization Act; **STEL** – Short Term Exposure Limit; **TLV** – Threshold Limit Value; **TWA** – Time Weighted Average; **WHMIS** – Workplace Hazardous Materials Information System

LAST REVISION

09/2023

SUPERSEDES

05/2020

For a list of changes to the SDS since the last version, please communicate with MEDISCA at www.medisca.com

DISCLAIMER

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.

SUPPLEMENTARY INFORMATION

For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.