

# Pola Professional 35% Powder

SDI (North America) Inc.

Version No: 8.1

Safety Data Sheet according to OSHA HazCom Standard (2012) requirements

Issue Date: 20/08/2021 Print Date: 21/11/2023 L.GHS.USA.EN

#### **SECTION 1 Identification**

#### **Product Identifier**

Product name	Pola Professional 35% Powder
Chemical Name	Not Applicable
Synonyms	Not Available
Chemical formula	Not Applicable
Other means of identification	Not Available

#### Recommended use of the chemical and restrictions on use

Relevant identified uses Professional Dental use: To medically bleach endodontically treated teeth, to be performed by a dentist.

#### Name, address, and telephone number of the chemical manufacturer, importer, or other responsible party

Registered company name	SDI (North America) Inc. SDI Limited		SDI HOLDINGS PTY LTD DO	
Address	1279 Hamilton Parkway Itasca IL 60143 United States	3-15 Brunsdon Street Bayswater VIC 3153 Australia	Rua Dr. Reinaldo Schmithausen 3141 – Cordeiros Itajaí – SC – CEP 88310-004 Brazil	
Telephone	+1 630 361 9200	+61 3 8727 7111	+55 11 3092 7100	
Fax	Not Available	+61 3 8727 7222	Not Available	
Website	www.sdi.com.au	www.sdi.com.au	http://www.sdi.com.au/	
Email	USA.Canada@sdi.com.au	info@sdi.com.au	Brasil@sdi.com.au	
Registered company name	SDI Germany GmbH			
Address	Hansestrasse 85 Cologne D-51149 Germany			
Telephone	+49 0 2203 9255 0			
Fax	+49 0 2203 9255 200			
Website	www.sdi.com.au			
Email	germany@sdi.com.au			

# Emergency phone number

Association / Organisation	SDI Limited	CHEMWATCH EMERGENCY RESPONSE (24/7)	
Emergency telephone numbers	131126 Poisons Information Centre	+1 855-237-5573	
Other emergency telephone numbers	+61 3 8727 7111	+61 3 9573 3188	

Once connected and if the message is not in your preferred language then please dial 01

Una vez conectado y si el mensaje no está en su idioma preferido, por favor marque 02

# SECTION 2 Hazard(s) identification

# Classification of the substance or mixture NFPA 704 diamond



Note: The hazard category numbers found in GHS classification in section 2 of this SDSs are NOT to be used to fill in the NFPA 704 diamond. Blue = Health Red = Fire Yellow = Reactivity White = Special (Oxidizer or water reactive substances)

Classification

Skin Corrosion/Irritation Category 2, Serious Eye Damage/Eye Irritation Category 2A, Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3

Version No: **8.1** Page **2** of **10** Issue Date: **20/08/2021** 

# Pola Professional 35% Powder

Print Date: 21/11/2023

# Hazard pictogram(s)



Signal word	Warnin
Sidilal Word	ı vvarnın

# Hazard statement(s)

H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

# Hazard(s) not otherwise classified

Not Applicable

# Precautionary statement(s) Prevention

P271	Use only outdoors or in a well-ventilated area.
P261	Avoid breathing dust/fumes.
P280 Wear protective gloves, protective clothing, eye protection and face protection.	
P264	Wash all exposed external body areas thoroughly after handling.

# Precautionary statement(s) Response

P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P312	Call a POISON CENTER/doctor/physician/first aider/if you feel unwell.
P337+P313	If eye irritation persists: Get medical advice/attention.
P302+P352	IF ON SKIN: Wash with plenty of water and soap.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P332+P313	If skin irritation occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.

# Precautionary statement(s) Storage

· · · · · · · · · · · · · · · · · · ·	
P405	Store locked up.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.

# Precautionary statement(s) Disposal

P501 Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation.

# **SECTION 3 Composition / information on ingredients**

# Substances

See section below for composition of Mixtures

# Mixtures

CAS No	%[weight]	Name
7631-86-9	70-75	silica amorphous

# **SECTION 4 First-aid measures**

# Description of first aid measures

Description of first aid measur	es
Eye Contact	If this product comes in contact with the eyes:  Wash out immediately with fresh running water.  Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.  Seek medical attention without delay; if pain persists or recurs seek medical attention.  Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	If skin contact occurs:  Immediately remove all contaminated clothing, including footwear.  Flush skin and hair with running water (and soap if available).  Seek medical attention in event of irritation.
Inhalation	<ul> <li>If fumes or combustion products are inhaled remove from contaminated area.</li> <li>Lay patient down. Keep warm and rested.</li> <li>Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures.</li> <li>Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary.</li> <li>Transport to hospital, or doctor, without delay.</li> </ul>
Ingestion	<ul> <li>If swallowed do NOT induce vomiting.</li> <li>If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.</li> <li>Observe the patient carefully.</li> </ul>

Version No: 8.1 Page 3 of 10 Issue Date: 20/08/2021

#### Pola Professional 35% Powder

Print Date: 21/11/2023

- ▶ Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious.
- Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink.
- Seek medical advice.

#### Most important symptoms and effects, both acute and delayed

See Section 11

#### Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

# **SECTION 5 Fire-fighting measures**

#### **Extinguishing media**

- Water spray or fog.
- Foam.
- Dry chemical powder.
- BCF (where regulations permit).
- Carbon dioxide.

#### Special hazards arising from the substrate or mixture

		,	

Fire Incompatibility None known.

Special protective equipment and precautions for fire-fighters		
Fire Fighting	<ul> <li>Alert Fire Brigade and tell them location and nature of hazard.</li> <li>Wear breathing apparatus plus protective gloves in the event of a fire.</li> <li>Prevent, by any means available, spillage from entering drains or water courses.</li> <li>Use fire fighting procedures suitable for surrounding area.</li> <li>DO NOT approach containers suspected to be hot.</li> <li>Cool fire exposed containers with water spray from a protected location.</li> <li>If safe to do so, remove containers from path of fire.</li> <li>Equipment should be thoroughly decontaminated after use.</li> </ul>	
Fire/Explosion Hazard	<ul> <li>Non combustible.</li> <li>Not considered a significant fire risk, however containers may burn.</li> <li>May emit poisonous fumes.</li> <li>May emit corrosive fumes.</li> <li>Decomposes on heating and produces:</li> <li>carbon dioxide (CO2)</li> <li>carbon monoxide (CO)</li> </ul>	

# **SECTION 6 Accidental release measures**

# Personal precautions, protective equipment and emergency procedures

sulfur oxides (SOx)

See section 8

# **Environmental precautions**

See section 12

# Methods and material for containment and cleaning up

	Clean up all spills immediately.
	Avoid breathing dust and contact with skin and eyes.
	Wear protective clothing, gloves, safety glasses and dust respirator.
	Use dry clean up procedures and avoid generating dust.
Minor Spills	► Sweep up, shovel up or

**Major Spills** 

- ▶ Vacuum up (consider explosion-proof machines designed to be grounded during storage and use).
- ▶ Place spilled material in clean, dry, sealable, labelled container.

# Moderate hazard.

- ► CAUTION: Advise personnel in area.
- Alert Emergency Services and tell them location and nature of hazard.
- Control personal contact by wearing protective clothing.
- Prevent, by any means available, spillage from entering drains or water courses.
- Recover product wherever possible. FIF DRY: Use dry clean up procedures and avoid generating dust. Collect residues and place in sealed plastic bags or other containers for
- disposal. IF WET: Vacuum/shovel up and place in labelled containers for disposal.
- ALWAYS: Wash area down with large amounts of water and prevent runoff into drains.
- ▶ If contamination of drains or waterways occurs, advise Emergency Services

Personal Protective Equipment advice is contained in Section 8 of the SDS.

# **SECTION 7 Handling and storage**

# Precautions for safe handling

#### Safe handling

- Avoid all personal contact, including inhalation.
- Wear protective clothing when risk of exposure occurs.
- Lise in a well-ventilated area.

Version No: **8.1** Page **4** of **10** Issue Date: **20/08/2021** 

#### Pola Professional 35% Powder

Print Date: 21/11/2023

- Prevent concentration in hollows and sumps.
- ▶ DO NOT enter confined spaces until atmosphere has been checked.
- ► DO NOT allow material to contact humans, exposed food or food utensils.
- Avoid contact with incompatible materials.
- ▶ When handling, **DO NOT** eat, drink or smoke.
- ▶ Keep containers securely sealed when not in use.
- Avoid physical damage to containers.
- Always wash hands with soap and water after handling.
- ▶ Work clothes should be laundered separately. Launder contaminated clothing before re-use.
- Use good occupational work practice.
- Observe manufacturer's storage and handling recommendations contained within this SDS.
- Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.

#### Other information

Store between 2 and 8 deg C.

Do not store in direct sunlight.

Store in a dry and well ventilated-area, away from heat and sunlight.

#### Conditions for safe storage, including any incompatibilities

Suitable container

- Polyethylene or polypropylene container.
- ▶ Check all containers are clearly labelled and free from leaks.

Storage incompatibility

Avoid strong acids, bases.

#### SECTION 8 Exposure controls / personal protection

#### Control parameters

#### Occupational Exposure Limits (OEL)

#### INGREDIENT DATA

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
US OSHA Permissible Exposure	silica	Particulates Not Otherwise Regulated (PNOR)-	5 mg/m3	Not	Not	Not
Limits (PELs) Table Z-1	amorphous	Respirable fraction		Available	Available	Available
US OSHA Permissible Exposure	silica	Particulates Not Otherwise Regulated (PNOR)-	15 mg/m3	Not	Not	Not
Limits (PELs) Table Z-1	amorphous	Total dust		Available	Available	Available
US OSHA Permissible Exposure	silica	Amorphous, including natural diatomaceous earth	80 (%SiO2) mg/m3 /	Not	Not	Not
Limits (PELs) Table Z-3	amorphous		20 mppcf	Available	Available	Available
US NIOSH Recommended Exposure Limits (RELs)	silica amorphous	Silica, amorphous	6 mg/m3	Not Available	Not Available	Not Available

### Emergency Limits

Ingredient	TEEL-1	TEEL-2	TEEL-3
silica amorphous	18 mg/m3	200 mg/m3	1,200 mg/m3
silica amorphous	18 mg/m3	100 mg/m3	630 mg/m3
silica amorphous	120 mg/m3	1,300 mg/m3	7,900 mg/m3
silica amorphous	45 mg/m3	500 mg/m3	3,000 mg/m3
silica amorphous	18 mg/m3	740 mg/m3	4,500 mg/m3

Ingredient	Original IDLH	Revised IDLH
silica amorphous	3,000 mg/m3	Not Available

#### MATERIAL DATA

### **Exposure controls**

Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection.

The basic types of engineering controls are:
Process controls which involve changing the way a job activity or process is done to reduce the risk.

Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment. Ventilation can remove or dilute an air contaminant if designed properly. The design of a ventilation system must match the particular process and chemical or contaminant in use.

Employers may need to use multiple types of controls to prevent employee overexposure.

- Local exhaust ventilation is required where solids are handled as powders or crystals; even when particulates are relatively large, a certain proportion will be powdered by mutual friction.
- If in spite of local exhaust an adverse concentration of the substance in air could occur, respiratory protection should be considered.

Appropriate engineering

Such protection might consist of:

(a): particle dust respirators if ne

controls

(a): particle dust respirators, if necessary, combined with an absorption cartridge;

(b): filter respirators with absorption cartridge or canister of the right type;

(c): fresh-air hoods or masks.

Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the contaminant.

Type of Contaminant:	Air Speed:
direct spray, spray painting in shallow booths, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)	/e 1-2.5 m/s (200-500 f/min.)
grinding, abrasive blasting, tumbling, high speed wheel generated dusts (released at high initial velocity into zor of very high rapid air motion).	ne 2.5-10 m/s (500-2000 f/min.)

Within each range the appropriate value depends on:

 Version No: 8.1
 Page 5 of 10
 Issue Date: 20/08/2021

 Print Date: 21/11/2023
 Print Date: 21/11/2023

#### Pola Professional 35% Powder

Lower end of the range

1: Room air currents minimal or favourable to capture

1: Disturbing room air currents

2: Contaminants of low toxicity or of nuisance value only.

3: Intermittent, low production.

4: Large hood or large air mass in motion

Upper end of the range

1: Disturbing room air currents

2: Contaminants of high toxicity

3: High production, heavy use

Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 4-10 m/s (800-2000 f/min) for extraction of crusher dusts generated 2 metres distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.

# Individual protection measures, such as personal protective equipment











# Eye and face protection

Safety glasses with side shields.

► Chemical goggles. [AS/NZS 1337.1, EN166 or national equivalent]

Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59].

#### Skin protection

See Hand protection below

The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice.

Personal hygiene is a key element of effective hand care. Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.

Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include:

- · frequency and duration of contact
- · chemical resistance of glove material,
- $\cdot$  glove thickness and
- dexterity

Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739, AS/NZS 2161.1 or national equivalent).

- · When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended.
- When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended.
   Some glove polymer types are less affected by movement and this should be taken into account when considering gloves for long-term use.

# Hands/feet protection

- · Contaminated gloves should be replaced.
- As defined in ASTM F-739-96 in any application, gloves are rated as:
- · Excellent when breakthrough time > 480 min
- Good when breakthrough time > 20 min • Fair when breakthrough time < 20 min
- Poor when glove material degrades
- For general applications, gloves with a thickness typically greater than 0.35 mm, are recommended.

It should be emphasised that glove thickness is not necessarily a good predictor of glove resistance to a specific chemical, as the permeation efficiency of the glove will be dependent on the exact composition of the glove material. Therefore, glove selection should also be based on consideration of the task requirements and knowledge of breakthrough times.

Glove thickness may also vary depending on the glove manufacturer, the glove type and the glove model. Therefore, the manufacturers technical data should always be taken into account to ensure selection of the most appropriate glove for the task.

Note: Depending on the activity being conducted, gloves of varying thickness may be required for specific tasks. For example:

- · Thinner gloves (down to 0.1 mm or less) may be required where a high degree of manual dexterity is needed. However, these gloves are only likely to give short duration protection and would normally be just for single use applications, then disposed of.
- · Thicker gloves (up to 3 mm or more) may be required where there is a mechanical (as well as a chemical) risk i.e. where there is abrasion or puncture potential

Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.

# Body protection

See Other protection below

#### Other protection

- Overalls.
- P.V.C apron.
- Barrier cream.Skin cleansing cream.
- Eye wash unit.

### Respiratory protection

Type -P Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

Required Minimum Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
up to 10 x ES	P1 Air-line*	-	PAPR-P1
up to 50 x ES	Air-line**	P2	PAPR-P2
up to 100 x ES	-	P3	-
		Air-line*	-

Version No: 8.1 Page 6 of 10 Issue Date: 20/08/2021 Print Date: 21/11/2023

#### Pola Professional 35% Powder

PAPR-P3 100+ x ES Air-line\*

\* - Negative pressure demand \*\* - Continuous flow

A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO2), G = Agricultural chemicals, K = Ammonia(NH3), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

- · Respirators may be necessary when engineering and administrative controls do not adequately prevent exposures.
- The decision to use respiratory protection should be based on professional judgment that takes into account toxicity information, exposure measurement data, and frequency and likelihood of the worker's exposure - ensure users are not subject to high thermal loads which may result in heat stress or distress due to personal protective equipment (powered, positive flow, full face apparatus may be an option).
- Published occupational exposure limits, where they exist, will assist in determining the adequacy of the selected respiratory protection. These may be government mandated or vendor recommended.
- · Certified respirators will be useful for protecting workers from inhalation of particulates when properly selected and fit tested as part of a complete respiratory protection program.
- · Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU)
- · Use approved positive flow mask if significant quantities of dust becomes airborne.
- · Try to avoid creating dust conditions.

# **SECTION 9 Physical and chemical properties**

#### Information on basic physical and chemical properties

Appearance	Fluffy white speckled powder, insoluble in water.		
Physical state	Divided Solid	Relative density (Water = 1)	Not Available
Odour	Not Available	Partition coefficient n-octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Available
pH (as supplied)	Not Available	Decomposition temperature (°C)	Not Available
Melting point / freezing point (°C)	Not Available	Viscosity (cSt)	Not Available
Initial boiling point and boiling range (°C)	Not Available	Molecular weight (g/mol)	Not Applicable
Flash point (°C)	Not Applicable	Taste	Not Available
Evaporation rate	Not Available	Explosive properties	Not Available
Flammability	Not Applicable	Oxidising properties	Not Available
Upper Explosive Limit (%)	Not Available	Surface Tension (dyn/cm or mN/m)	Not Applicable
Lower Explosive Limit (%)	Not Available	Volatile Component (%vol)	Not Available
Vapour pressure (kPa)	Not Available	Gas group	Not Available
Solubility in water	Immiscible	pH as a solution (1%)	Not Available
Vapour density (Air = 1)	Not Available	VOC g/L	Not Available

# **SECTION 10 Stability and reactivity**

Reactivity	See section 7
Chemical stability	<ul> <li>Unstable in the presence of incompatible materials.</li> <li>Product is considered stable.</li> <li>Hazardous polymerisation will not occur.</li> </ul>
Possibility of hazardous reactions	See section 7
Conditions to avoid	See section 7
Incompatible materials	See section 7
Hazardous decomposition products	See section 5

# **SECTION 11 Toxicological information**

# Information on toxicological effects

Inhaled	Evidence shows, or practical experience predicts, that the material produces irritation of the respiratory system, in a substantial number of individuals, following inhalation. In contrast to most organs, the lung is able to respond to a chemical insult by first removing or neutralising the irritant and then repairing the damage. The repair process, which initially evolved to protect mammalian lungs from foreign matter and antigens, may however, produce further lung damage resulting in the impairment of gas exchange, the primary function of the lungs. Respiratory tract irritation often results in an inflammatory response involving the recruitment and activation of many cell types, mainly derived from the vascular system.
Ingestion	The material has <b>NOT</b> been classified by EC Directives or other classification systems as "harmful by ingestion". This is because of the lack of corroborating animal or human evidence. The material may still be damaging to the health of the individual, following ingestion, especially where pre-existing organ (e.g liver, kidney) damage is evident. Present definitions of harmful or toxic substances are generally based on doses producing mortality rather than those producing morbidity (disease, ill-health). Gastrointestinal tract discomfort may produce nausea and vomiting. In an occupational setting however, ingestion of insignificant quantities is not thought to be cause for concern.
Skin Contact	Evidence exists, or practical experience predicts, that the material either produces inflammation of the skin in a substantial number of individuals following direct contact, and/or produces significant inflammation when applied to the healthy intact skin of animals, for up to four hours, such

Version No: **8.1** Page **7** of **10** Issue Date: **20/08/2021** 

#### Pola Professional 35% Powder

Print Date: 21/11/2023

inflammation being present twenty-four hours or more after the end of the exposure period. Skin irritation may also be present after prolonged or repeated exposure; this may result in a form of contact dermatitis (nonallergic). The dermatitis is often characterised by skin redness (erythema) and swelling (oedema) which may progress to blistering (vesiculation), scaling and thickening of the epidermis. At the microscopic level there may be intercellular oedema of the spongy layer of the skin (spongiosis) and intracellular oedema of the epidermis.

The material may accentuate any pre-existing dermatitis condition

Open cuts, abraded or irritated skin should not be exposed to this material

Entry into the blood-stream through, for example, cuts, abrasions, puncture wounds or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

Eve

Evidence exists, or practical experience predicts, that the material may cause eye irritation in a substantial number of individuals and/or may produce significant ocular lesions which are present twenty-four hours or more after instillation into the eye(s) of experimental animals. Repeated or prolonged eye contact may cause inflammation characterised by temporary redness (similar to windburn) of the conjunctiva (conjunctivitis); temporary impairment of vision and/or other transient eye damage/ulceration may occur.

# Chronic

SILICA AMORPHOUS

Long-term exposure to respiratory irritants may result in disease of the airways involving difficult breathing and related systemic problems. Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems.

Long term exposure to high dust concentrations may cause changes in lung function (i.e. pneumoconiosis) caused by particles less than 0.5 micron penetrating and remaining in the lung. A prime symptom is breathlessness. Lung shadows show on X-ray.

Pola Professional 35% Powder	TOXICITY	IRRITATION	
	Not Available	Not Available	
	TOXICITY	IRRITATION	
silica amorphous	dermal (rat) LD50: >2000 mg/kg <sup>[1]</sup>	Eye (rabbit): non-irritating ** [Grace]	
	Inhalation(Rat) LC50: >0.09<0.84 mg/l4h <sup>[1]</sup>	Eye: no adverse effect observed (not irritating) <sup>[1]</sup>	
	Oral (Rat) LD50: >1000 mg/kg <sup>[1]</sup>	Skin (rabbit): non-irritating *	
		Skin: no adverse effect observed (not irritating) <sup>[1]</sup>	
Legend:	Value obtained from Europe ECHA Registered Substances - Acute toxicity 2. Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances		

Reports indicate high/prolonged exposures to amorphous silicas induced lung fibrosis in experimental animals; in some experiments these effects were reversible. [PATTYS]

For silica amorphous:

Derived No Adverse Effects Level (NOAEL) in the range of 1000 mg/kg/d.

In humans, synthetic amorphous silica (SAS) is essentially non-toxic by mouth, skin or eyes, and by inhalation. Epidemiology studies show little evidence of adverse health effects due to SAS. Repeated exposure (without personal protection) may cause mechanical irritation of the eye and drying/cracking of the skin.

When experimental animals inhale synthetic amorphous silica (SAS) dust, it dissolves in the lung fluid and is rapidly eliminated. If swallowed, the vast majority of SAS is excreted in the faeces and there is little accumulation in the body. Following absorption across the gut, SAS is eliminated via urine without modification in animals and humans. SAS is not expected to be broken down (metabolised) in mammals.

After ingestion, there is limited accumulation of SAS in body tissues and rapid elimination occurs. Intestinal absorption has not been calculated, but appears to be insignificant in animals and humans. SASs injected subcutaneously are subjected to rapid dissolution and removal. There is no indication of metabolism of SAS in animals or humans based on chemical structure and available data. In contrast to crystalline silica, SAS is soluble in physiological media and the soluble chemical species that are formed are eliminated via the urinary tract without modification. Both the mammalian and environmental toxicology of SASs are significantly influenced by the physical and chemical properties, particularly those of solubility and particle size. SAS has no acute intrinsic toxicity by inhalation. Adverse effects, including suffocation, that have been reported were caused by the presence of high numbers of respirable particles generated to meet the required test atmosphere. These results are not representative of exposure to commercial SASs and should not be used for human risk assessment. Though repeated exposure of the skin may cause dryness and cracking, SAS is not a skin or eye irritant, and it is not a sensitiser.

Repeated-dose and chronic toxicity studies confirm the absence of toxicity when SAS is swallowed or upon skin contact.

Long-term inhalation of SAS caused some adverse effects in animals (increases in lung inflammation, cell injury and lung collagen content), all of which subsided after exposure.

Numerous repeated-dose, subchronic and chronic inhalation toxicity studies have been conducted with SAS in a number of species, at airborne concentrations ranging from 0.5 mg/m3 to 150 mg/m3. Lowest-observed adverse effect levels (LOAELs) were typically in the range of 1 to 50 mg/m3. When available, the no-observed adverse effect levels (NOAELs) were between 0.5 and 10 mg/m3. The difference in values may be explained by different particle size, and therefore the number of particles administered per unit dose. In general, as particle size decreases so does the NOAEL/I/OAEL

Neither inhalation nor oral administration caused neoplasms (tumours). SAS is not mutagenic in vitro. No genotoxicity was detected in in vivo assays. SAS does not impair development of the foetus. Fertility was not specifically studied, but the reproductive organs in long-term studies were not affected.

For Synthetic Amorphous Silica (SAS)

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.

Inhalation (rat), 13 weeks, Lowest Observed Effect Level (LOEL) =1.3 mg/m3 based on mild reversible effects in the lungs. Inhalation (rat), 90 days, LOEL = 1 mg/m3 based on reversible effects in the lungs and effects in the nasal cavity.

For silane treated synthetic amorphous silica:

Repeated dose toxicity: oral (rat), 28-d, diet, no significant treatment-related adverse effects at the doses tested.

There is no evidence of cancer or other long-term respiratory health effects (for example, silicosis) in workers employed in the manufacture of SAS. Respiratory symptoms in SAS workers have been shown to correlate with smoking but not with SAS exposure, while serial pulmonary function values and chest radiographs are not adversely affected by long-term exposure to SAS.

The substance is classified by IARC as Group 3:

NOT classifiable as to its carcinogenicity to humans.

Evidence of carcinogenicity may be inadequate or limited in animal testing.

Acute Toxicity	×	Carcinogenicity	×
Skin Irritation/Corrosion	✓	Reproductivity	×
Serious Eye Damage/Irritation	✓	STOT - Single Exposure	✓
Respiratory or Skin sensitisation	×	STOT - Repeated Exposure	×

Version No: **8.1** Page **8** of **10** Issue Date: **20/08/2021** 

Pola Professional 35% Powder Print Date: 21/11/2023

Mutagenicity X Aspiration Hazard X

X − Data either not available or does not fill the criteria for classification
✓ − Data available to make classification

# **SECTION 12 Ecological information**

#### **Toxicity**

	Endpoint	Test Duration (hr)	Species	Value	Source
Pola Professional 35% Powder Not Available	Not Available	Not Available	Not Available	Not Available	Not Available
	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50	72h	Algae or other aquatic plants	14.1mg/l	2
	EC50	48h	Crustacea	>86mg/l	2
silica amorphous	EC50	96h	Algae or other aquatic plants	217.576mg/l	2
	LC50	96h	Fish	1033.016mg/l	2
	EC0(ECx)	24h	Crustacea	>=10000mg/l	1
Legend:	Ecotox databa	n 1. IUCLID Toxicity Data 2. Europe ECHA Regis ise - Aquatic Toxicity Data 5. ECETOC Aquatic F ition Data 8. Vendor Data	•	,	

#### DO NOT discharge into sewer or waterways.

#### Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
silica amorphous	LOW	LOW

#### **Bioaccumulative potential**

Ingredient	Bioaccumulation
silica amorphous	LOW (LogKOW = 0.5294)

# Mobility in soil

Ingredient	Mobility
silica amorphous	LOW (KOC = 23.74)

# **SECTION 13 Disposal considerations**

### Waste treatment methods

Product / Packaging disposal

- ▶ DO NOT allow wash water from cleaning or process equipment to enter drains.
- It may be necessary to collect all wash water for treatment before disposal.
- In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first.
- Where in doubt contact the responsible authority.

Consult State Land Waste Management Authority for disposal.

Bury residue in an authorised landfill.

# **SECTION 14 Transport information**

# **Labels Required**

Marine Pollutant NO

Land transport (DOT): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

14.7.1. Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable

# 14.7.2. Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code

Product name	Group
silica amorphous	Not Available

### 14.7.3. Transport in bulk in accordance with the IGC Code

Product name	Ship Type
silica amorphous	Not Available

Version No: 8.1 Page 9 of 10 Issue Date: 20/08/2021

#### Pola Professional 35% Powder

Print Date: 21/11/2023

# **SECTION 15 Regulatory information**

#### Safety, health and environmental regulations / legislation specific for the substance or mixture

#### silica amorphous is found on the following regulatory lists

Chemical Footprint Project - Chemicals of High Concern List

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs - Not Classified as Carcinogenic

International WHO List of Proposed Occupational Exposure Limit (OEL) Values for Manufactured Nanomaterials (MNMS)

US - Alaska Air Quality Control - Concentrations Triggering an Air Quality Episode for Air Pollutants Other Than PM-2.5

US - California - Biomonitoring - Priority Chemicals

US - California Proposition 65 - Carcinogens

US - California Safe Drinking Water and Toxic Enforcement Act of 1986 - Proposition 65 List

US - Massachusetts - Right To Know Listed Chemicals

US DOE Temporary Emergency Exposure Limits (TEELs)

US NIOSH Carcinogen List

US NIOSH Recommended Exposure Limits (RELs)

US OSHA Carcinogens Listing

US OSHA Permissible Exposure Limits (PELs) Table Z-1

US OSHA Permissible Exposure Limits (PELs) Table Z-3

US Toxic Substances Control Act (TSCA) - Chemical Substance Inventory

# **Additional Regulatory Information**

Not Applicable

#### **Federal Regulations**

# Superfund Amendments and Reauthorization Act of 1986 (SARA)

#### Section 311/312 hazard categories

Flammable (Gases, Aerosols, Liquids, or Solids)	No
Gas under pressure	No
Explosive	No
Self-heating	No
Pyrophoric (Liquid or Solid)	No
Pyrophoric Gas	No
Corrosive to metal	No
Oxidizer (Liquid, Solid or Gas)	No
Organic Peroxide	No
Self-reactive	No
In contact with water emits flammable gas	No
Combustible Dust	No
Carcinogenicity	No
Acute toxicity (any route of exposure)	No
Reproductive toxicity	No
Skin Corrosion or Irritation	Yes
Respiratory or Skin Sensitization	No
Serious eye damage or eye irritation	Yes
Specific target organ toxicity (single or repeated exposure)	No
Aspiration Hazard	No
Germ cell mutagenicity	No
Simple Asphyxiant	No
Hazards Not Otherwise Classified	No

#### US. EPA CERCLA Hazardous Substances and Reportable Quantities (40 CFR 302.4)

None Reported

# **State Regulations**

# US. California Proposition 65



MARNING: This product can expose you to chemicals including silica amorphous, which is known to the State of California to cause cancer. For more information, go to

# **National Inventory Status**

National Inventory	Status
Australia - AIIC / Australia Non-Industrial Use	Yes
Canada - DSL	Yes
Canada - NDSL	Yes
China - IECSC	Yes

 Version No: 8.1
 Page 10 of 10
 Issue Date: 20/08/2021

 Print Date: 21/11/2023
 Print Date: 21/11/2023

#### Pola Professional 35% Powder

**National Inventory** Status Europe - EINEC / ELINCS / NLP Japan - ENCS Yes Korea - KECI Yes New Zealand - NZIoC Yes Philippines - PICCS Yes USA - TSCA Taiwan - TCSI Yes Mexico - INSQ Yes Vietnam - NCI Yes Russia - FBEPH Yes = All CAS declared ingredients are on the inventory Legend: No = One or more of the CAS listed ingredients are not on the inventory. These ingredients may be exempt or will require registration.

#### **SECTION 16 Other information**

Revision Date	20/08/2021
Initial Date	10/11/2015

#### **SDS Version Summary**

Version	Date of Update	Sections Updated
7.1	01/11/2019	One-off system update. NOTE: This may or may not change the GHS classification
8.1	20/08/2021	Classification change due to full database hazard calculation/update.

#### Other information

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by SDI Limited using available literature references.

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

#### **Definitions and abbreviations**

- ▶ PC TWA: Permissible Concentration-Time Weighted Average
- ▶ PC STEL: Permissible Concentration-Short Term Exposure Limit
- ▶ IARC: International Agency for Research on Cancer
- ► ACGIH: American Conference of Governmental Industrial Hygienists
- ▶ STEL: Short Term Exposure Limit
- ► TEEL: Temporary Emergency Exposure Limit,
- IDLH: Immediately Dangerous to Life or Health Concentrations
- ES: Exposure Standard
- OSF: Odour Safety Factor
- ► NOAEL: No Observed Adverse Effect Level
- LOAEL: Lowest Observed Adverse Effect Level
- ► TLV: Threshold Limit Value
- ▶ LOD: Limit Of Detection
- OTV: Odour Threshold Value
- ▶ BCF: BioConcentration Factors
- ▶ BEI: Biological Exposure Index
- ► DNEL: Derived No-Effect Level
- ► PNEC: Predicted no-effect concentration
- AIIC: Australian Inventory of Industrial Chemicals
- ► DSL: Domestic Substances List
- NDSL: Non-Domestic Substances List
- ► IECSC: Inventory of Existing Chemical Substance in China
- ► EINECS: European INventory of Existing Commercial chemical Substances
- ELINCS: European List of Notified Chemical Substances
- NLP: No-Longer Polymers
- ► ENCS: Existing and New Chemical Substances Inventory
- KECI: Korea Existing Chemicals Inventory
- ► NZIoC: New Zealand Inventory of Chemicals
- ▶ PICCS: Philippine Inventory of Chemicals and Chemical Substances
- TSCA: Toxic Substances Control Act
- ► TCSI: Taiwan Chemical Substance Inventory
- INSQ: Inventario Nacional de Sustancias Químicas
- NCI: National Chemical Inventory
- FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances

The information contained in the Safety Data Sheet is based on data considered to be accurate, however, no warranty is expressed or implied regarding the accuracy of the data or the results to be obtained from the use thereof.

#### Other information:

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