

Preparation Date 2021/01/28

## Safety Data Sheet (SDS)

### Section 1 – CHEMICALS AND COMPANY IDENTIFICATION

Chemical Identifier EPITEX  
 Product Code 201218-5  
 Name of Supplier GC Corporation  
 Address 76-1 Hasunuma-Cho, Itabashi-Ku, Tokyo, Japan, Postal code 174-8585  
 Company Contact Quality Assurance department  
 Phone Number 81-3-3965-1388  
 Fax Number 81-3-3965-1276  
 Restriction on Use Prohibit use by anyone other than qualified dentistry.

Use for purposes other than those stated in the [Performance, Purpose of use, Efficacy or Effect] of the package insert is prohibited.

Prohibition of use of glass ionomer cement, methacrylate-based polymers, and methacrylate-based monomers in patients with a history of hypersensitivity symptoms such as rash and dermatitis.

Surgeons / patients who have a rash, dermatitis, or other hypersensitivity to this product should discontinue use and seek medical attention immediately.

### Section 2 – HAZARDS IDENTIFICATION

#### GHS Classification of the Chemical

Health Hazards Carcinogenicity Category 1B  
 Specific target organ toxicity (single exposure) Category 1 (respiratory system)  
 Specific target organ toxicity (repeated exposure) Category 1 (lung)  
 Other hazards than mentioned above are Not classified or Classification not possible.

#### GHS Label Elements

#### Pictograms



Signal Word Danger  
 Hazard Statements H350 May cause cancer  
 H370 Causes damage to respiratory system  
 H372 Causes damage to lung through prolonged or repeated exposure

#### Precautionary Statements

Prevention Obtain special instructions before use.(P201)  
 Do not handle until all safety precautions have been read and understood.(P202)  
 Do not breathe dust/fume/gas/mist/vapours/spray.(P260)  
 Wash hand thoroughly after handling.(P264)  
 Do not eat, drink or smoke when using this product.(P270)

Wear protective gloves/protective clothing/eye protection/face protection.(P280)

Response IF exposed or concerned: Call a doctor.(P308+P311)

IF exposed or concerned: Get medical advice/attention.(P308+P313)

Get medical advice and attention if you feel unwell.(P314)

Storage Specific treatment.(P321)

Store locked up.(P405)

Disposal Dispose of contents and container in accordance with local, regional and national regulations (to be specified).(P501)

Section 3 – COMPOSITION / INFORMATION ON INGREDIENTS

Distinction of Substance or Mixture Mixture

Chemical Name or Generic Name	Concentration or Its Ranges	Formula	ENCS No./ISHL No.		CAS RN
			ENCS No.	ISHL No.	
Polyethylene Terephthalate	Confidential	Confidential	Confidential	Confidential	Confidential
Silicon carbide	Confidential	Confidential	Confidential	Confidential	Confidential

Section 4 – FIRST AID MEASURES

Inhalation Call a doctor if you feel unwell.  
IF exposed or concerned: Call a doctor.

Skin Contact IF ON SKIN: Wash with plenty of soap and water.  
  
If skin irritation occurs: Get medical advice and attention.

Eye Contact IF exposed or concerned: Call a doctor.  
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Ingestion IF exposed or concerned: Call a doctor.  
Rinse mouth.  
IF SWALLOWED: Call a doctor if you feel unwell.  
  
IF exposed or concerned: Call a doctor.

Section 5 – FIRE FIGHTING MEASURES

Suitable Extinguishing Media Use extinguishing agent suitable for type of surrounding fire.  
When dust occurs, use dry sand.

Unsuitable Extinguishing Media No information available

Specific Hazards in Case of Fire Risk of producing harmful gases such as carbon monoxide. Avoid inhalation of smoke or gases.

Specific Fire Fighting Fight fire from upwind position if possible  
Keep away from sources of ignition and use appropriate extinguishing media.  
Prohibit unauthorized staff from entering the area around the fire.  
Keep unnecessary people away.

Special Protective Equipment and Precautions for Fire Use goggles in combination with dust mask, and another protections as appropriate to situation.

Section 6 – ACCIDENTAL RELEASE MEASURES

Personal Precautions,  
Protective Equipment and  
Emergency Procedures

Use goggles in combination with dust mask, and another protections as appropriate to situation.

Environmental  
Precautions  
Methods and Equipment  
for Containment and  
Cleaning Up  
Prevention Measures for  
Secondary Accidents

Large spills :Evacuate area.  
Ensure adequate ventilation.  
Do not discharge into the drains, surface waters or  
ground water directly.  
Sweep or vacuum spills to drums or containers.  
  
Keep away from sources of ignition and prepare  
extinguishing media.

Section 7 – HANDLING AND STORAGE

Handling

Technical Measures Provide ventilation system and use necessary personal protective equipment as described in “Section 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION”.

Use local exhaust ventilation in case of production of fume or mist.  
Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.

Precautions for  
Safe Handling

Do not eat, drink or smoke when using this product.  
  
Wash hands thoroughly after handling.  
Wear protective gloves/protective clothing/eye protection/face protection.  
Do not breathe dust/fume/gas/mist/vapours/spray.

Storage

Prevents Handling  
of Incompatible  
Substances or  
Conditions for Safe  
Storage

Refer to “Section 10 – STABILITY AND REACTIVITY”.  
  
Refer to “Section 10 – STABILITY AND REACTIVITY”.  
  
Store locked up.

Section 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

	Exposure Limits (ACGIH)
Silicon carbide	TWA 0.1 f/cc (F), STEL – (Fibrous (including whiskers));TWA 10 mg/m3 (I, E), 3 mg/m3 (R, E), STEL – (Nonfibrous)

Engineering Controls

Use local exhaust ventilation in case of production of fume or mist.  
Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.

Personal Protective  
Equipment

Respiratory  
Protection  
Hand Protection  
Eye/Face  
Skin and Body  
Protection

If necessary, wear respiratory protection.  
  
Wear protective gloves.  
Wear eye protection/face protection.  
Wear protective clothing.

Section 9 – PHYSICAL AND CHEMICAL PROPERTIES

Physical State		solid
Form		solid (sheet)
Colour		Blue(Coarse), Green(Medium), Gray(fine), Pink(Ultrafine)
Odour		odorless
Melting Point/Freezing Point		No data available
Boiling Point or Initial Boiling Point and Boiling Ranges		No data available
Flammability		No data available
Lower and Upper Explosion Limit / Flammability Limit	Lower Limit	No data available
	Upper Limit	No data available
Flash Point		No data available
Auto-Ignition Temperature		No data available
Decomposition Temperature		No data available
pH		No data available
Kinematic Viscosity		No data available
Solubility		No data available
Partition Coefficient : n-Octanol/Water		No data available
Vapour Pressure		No data available
Density and/or Relative Density		No data available
Relative Gas Density		No data available
Particle Characteristics		No data available

Section 10 – STABILITY AND REACTIVITY

Reactivity		No information available
Chemical Stability		No information available
Possibility of Hazardous Reaction		No information available
Conditions to Avoid		No information available
Incompatible Substances or Mixtures		No information available
Hazardous Decomposition Products		No information available

Section 11 – TOXICOLOGICAL INFORMATION

Acute Toxicity	Oral	Unable to classify
	Dermal	Unable to classify
	Inhalation	(gas) Does not fall under gas based on GHS definitions.
		(vapour) Unable to classify
		(dust and mist) Unable to classify
Skin Corrosion/Irritation		Unable to classify
Serious Eye Damage/Eye Irritation		Unable to classify
Respiratory Sensitization		Unable to classify

Skin Sensitization	Unable to classify
Germ Cell Mutagenicity	Unable to classify
Carcinogenicity	Category 1B
Reproductive Toxicity	(Reproductive toxicity) Unable to classify (Reproductive toxicity, effects on or via lactation) Unable to classify
Specific Target Organ Toxicity (Single Exposure)	Category 1(respiratory system)
Specific Target Organ Toxicity (Repeated Exposure)	Category 1(lung)
Aspiration Hazard	Classification not possible

**Section 12 – ECOLOGICAL INFORMATION**

Hazardous to the Aquatic Environment, Short-Term (Acute)	Classification not possible
Hazardous to the Aquatic Environment, Long-Term (Chronic)	Classification not possible
Ecotoxicity	No data available
Persistence	No data available
Bioaccumulative Potential	No data available
Mobility in Soil	No data available
Hazardous to the Ozone Layer	Unable to classify

**Section 13 – DISPOSAL CONSIDERATIONS**

Residual Waste	Before disposal, make the wastes harmless, stabilized, and neutralized, and minimize danger and toxicity of the wastes. Dispose of waste in accordance with local, state and federal regulations.
Contaminated Container and Packaging	Passed to a licensed waste contractor.  In case of disposal of empty containers, remove the content thoroughly.

**Section 14 – TRANSPORT INFORMATION**

International Regulations	Regulatory Information by Sea	Not regulated
	Marine Pollutant	Not applicable
	Liquid Substance	Not applicable
	Transported in Bulk	
	According to MARPOL 73/78, Annex II, the IBC Code	
	Regulatory Information by Air	Not regulated
Regulations in Japan	Regulatory Information by Road	Not regulated
	Regulatory Information by Sea	Not regulated
	Marine Pollutant	Not applicable

	Liquid Substance Transported in Bulk According to MARPOL 73/78, Annex II, the IBC Code	Not applicable
	Regulatory Information by Air	Not regulated
Emergency Response Guide Number		None

**Section 15 – REGULATORY INFORMATION**

It is recommended to consult the local regulations of the state/region to determine the identification as hazardous material.

**Section 16 – OTHER INFORMATION**

Information Contact	Described in item 1
Other Property	The information herein is given in good faith, but no warranty expressed or implied, is made.