

Preparation Date 2021/02/18

## Safety Data Sheet (SDS)

### Section 1 – CHEMICALS AND COMPANY IDENTIFICATION

Chemical Identifier	EXAFLEX Injection Type Base
Product Code	201221-7
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.

Prohibit use for purposes other than those written in this product IFU.

Prohibition of use of silicone 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	Skin corrosion/irritation Category 2 Serious eye damage/eye irritation Category 2A Carcinogenicity Category 1A Reproductive toxicity Category 2 Specific target organ toxicity (single exposure) Category 3 (respiratory tract irritation) Specific target organ toxicity (repeated exposure) Category 1 (respiratory apparatus kidney immunological system)
Environmental Hazards	Hazardous to the aquatic environment, short-term (acute) Category 2 Hazardous to the aquatic environment, long-term (chronic) Category 3 Other hazards than mentioned above are Not classified or Classification not possible.

#### GHS Label Elements

#### Pictograms



Signal Word	Danger
Hazard Statements	H315 Causes skin irritation H319 Causes serious eye irritation H335 May cause respiratory irritation H350 May cause cancer H361 Suspected of damaging fertility or the unborn child H372 Causes damage to respiratory apparatus, kidney, immunological system through prolonged or repeated exposure H401 Toxic to aquatic life

H412 Harmful to aquatic life with long lasting effects

## Precautionary Statements

Prevention	<p>Obtain special instructions before use.(P201)</p> <p>Do not handle until all safety precautions have been read and understood.(P202)</p> <p>Do not breathe dust/fume/gas/mist/vapours/spray.(P260)</p> <p>Avoid breathing dust/fume/gas/mist/vapours/spray.(P261)</p> <p>Wash hand thoroughly after handling.(P264)</p> <p>Wash eye thoroughly after handling.(P264)</p> <p>Do not eat, drink or smoke when using this product.(P270)</p> <p>Use only outdoors or in a well-ventilated area.(P271)</p>
Response	<p>Avoid release to the environment.(P273)</p> <p>Wear protective gloves/protective clothing/eye protection/face protection.(P280)</p> <p>IF ON SKIN: Wash with plenty of soap and water.(P302+P352)</p> <p>IF INHALED: Remove person to fresh air and keep comfortable for breathing.(P304+P340)</p> <p>IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.(P305+P351+P338)</p> <p>IF exposed or concerned: Get medical advice/attention.(P308+P313)</p> <p>Call a doctor if you feel unwell.(P312)</p> <p>Get medical advice and attention if you feel unwell.(P314)</p> <p>Specific treatment.(P321)</p> <p>If skin irritation occurs: Get medical advice/attention.(P332+P313)</p> <p>If eye irritation persists: Get medical advice/attention.(P337+P313)</p> <p>Take off contaminated clothing and wash it before reuse.(P362+P364)</p>
Storage	<p>Store in a well-ventilated place. Keep container tightly closed.(P403+P233)</p> <p>Store locked up.(P405)</p>
Disposal	<p>Dispose of contents and container in accordance with local, regional and national regulations (to be specified).(P501)</p>

## 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.	
Silicon dioxide	30–40%	Confidential	Confidential	Confidential	Confidential
Vinylpolysiloxane	Confidential	Confidential	Confidential	Confidential	Confidential
Polyoxyethylene nonylphenyl ether	10%	Confidential	Confidential	Confidential	Confidential
Hydrogen polysiloxane	Confidential	Confidential	Confidential	Confidential	Confidential

Pigment Yellow	Confidential	Confidential	Confidential	Confidential	Confidential
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## Section 4 – FIRST AID MEASURES

Inhalation	IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing. IF exposed or concerned: Get medical advice and attention.
Skin Contact	IF ON SKIN: Wash with plenty of soap and water.  Take of contaminated clothing and wash before re-use. If skin irritation occurs: Get medical advice and attention. IF exposed or concerned: Get medical advice and attention. Specific treatment.
Eye Contact	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. IF exposed or concerned: Get medical advice and attention.
Ingestion	Rinse mouth. IF SWALLOWED: Call a doctor if you feel unwell.  IF exposed or concerned: Get medical advice and attention.

## 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	Large spills :Evacuate area. Ensure adequate ventilation. Do not discharge into the drains, surface waters or ground water directly.

Methods and Equipment for Containment and Cleaning Up	Sweep or vacuum spills to drums or containers.
Prevention Measures for Secondary Accidents	Keep away from sources of ignition and prepare extinguishing media.

## Section 7 – HANDLING AND STORAGE

Handling	Technical Measures	Please comply with this section and the contents of this product IFU. 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. Use only outdoors or in a well-ventilated area.  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".  Store locked up.  Refer to "Section 10 – STABILITY AND REACTIVITY". Store container tightly closed in well-ventilated place.

## Section 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

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	If necessary, wear respiratory protection.
	Hand Protection	Wear protective gloves.
	Eye/Face Protection	Wear eye protection/face protection.
	Skin and Body Protection	Wear protective clothing.

## Section 9 – PHYSICAL AND CHEMICAL PROPERTIES

Physical State	the others
Form	paste
Colour	Light-yellow
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		Insoluble
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		Stable under normal conditions of use.
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	Classification not possible
	Dermal	Classification not possible
	Inhalation	(gas) Unable to classify (vapour) Unable to classify (dust and mist) Unable to classify
Skin Corrosion/Irritation		Classified as Category 2
Serious Eye Damage/Eye		Classified as Category 2A
Respiratory Sensitization		Unable to classify
Skin Sensitization		Unable to classify
Germ Cell Mutagenicity		Unable to classify
Carcinogenicity		Classified as Category 1A
Reproductive Toxicity		(Reproductive toxicity) Classified as Category 2 (Reproductive toxicity, effects on or via lactation)
		Unable to classify

Specific Target Organ Toxicity (Single Exposure)	Classified as Category 3(respiratory tract irritation)
Specific Target Organ	Classified as Category 1(respiratory apparatus) Classified as Category 1(kidney) Classified as Category 1(immunological system)
Aspiration Hazard	Classification not possible

## Section 12 – ECOLOGICAL INFORMATION

Hazardous to the Aquatic Environment, Short-Term (Acute)	Classified as Category 2
Hazardous to the Aquatic Environment, Long-Term (Chronic)	Classified as Category 3
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 Liquid Substance Transported in Bulk According to MARPOL 73/78, Annex II, the IBC Code	Not applicable applicable
Regulations in Japan	Regulatory Information by Air	Not regulated
	Regulatory Information by Road	Not regulated
	Regulatory Information by Sea	Not regulated
	Marine Pollutant Liquid Substance Transported in Bulk According to MARPOL 73/78, Annex II, the IBC Code	Not applicable 該当
	Regulatory Information by Air	Not regulated

Emergency Response Guide Number	None
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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	No information available
Other Property	The information herein is given in good faith, but no warranty expressed or implied, is made.