



Printing date 16.08.2024 Version number 3 Revision: 16.08.2024

Hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

- · Product identifier
- · Trade name: GC_Fuji_TEMP_LT_Paste_B
- Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
- · Application of the substance / the mixture Auxillary for dental technology
- · Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

GC Australasia Dental Pty Ltd 1753 Botany Road Banksmeadow, NSW 2019 Tel: +61 2 9301 8200

- · Further information obtainable from: Regulatory affairs
- · Emergency telephone number: 24 hours Emergency: 13 11 26.

2 Hazard(s) Identification

· Classification of the substance or mixture

Eye damage/irritation - Category 2A H319 Causes serious eye irritation.

- · Label elements
- · GHS label elements The product is classified and labelled according to the Globally Harmonised System (GHS).
- · Exemptions

The product, regulated as an invasive medical device by the Regulation (EC) 2017/745, is exempted from labelling requirements for substances and mixtures (according to the provision of the Art 1.5).

· Hazard pictograms



- · Signal word Warning
- · Hazard statements

Causes serious eye irritation.

· Precautionary statements

Wash thoroughly after handling.

Wear eye protection / face protection.

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.

(Contd. on page 2)

Printing date 16.08.2024 Version number 3 Revision: 16.08.2024

Trade name: GC_Fuji_TEMP_LT_Paste_B

(Contd. of page 1)

- · Other hazards
- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.

3 Composition and Information on Ingredients

- · Chemical characterisation: Mixtures
- · Description:

Only substances required to be mentioned according to Annex II of regulation 1907/2006 are listed. Information on the other substances that may be present can be obtained upon request.

· Dangerous components:			
7727-43-7 barium sulfat	е		25-<50%
9003-01-4 Polyacrylic a	cid	Eye damage/irritation – Category 2A, H319	10-<25%
56-81-5 glycerol			5-<10%
7631-86-9 silicon dioxid	e		1-<2.5%
. SVHC		·	

·SVHO

4247-02-3 Isobutyl 4-hydroxybenzoate

4 First Aid Measures

· General information:

Immediately remove any clothing soiled by the product.

If symptoms persist consult doctor.

· After inhalation:

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist. Take affected persons into fresh air and keep quiet.

- · After skin contact: If skin irritation continues, consult a doctor.
- · After eye contact:

Protect unharmed eye.

Rinse opened eye for several minutes under running water. Then consult a doctor.

· After swallowing:

Rinse out mouth and then drink plenty of water.

If symptoms persist consult doctor.

- · Information for doctor:
- · Most important symptoms and effects, both acute and delayed No further relevant information available.
- · Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Fire Fighting Measures

· Suitable extinguishing agents:

CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam. Use fire extinguishing methods suitable to surrounding conditions.

· For safety reasons unsuitable extinguishing agents: Water with full jet

(Contd. on page 3)

[·] Additional information: For the wording of the listed hazard phrases refer to section 16.

Printing date 16.08.2024 Version number 3 Revision: 16.08.2024

Trade name: GC Fuji TEMP LT Paste B

(Contd. of page 2)

· Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

No further relevant information available.

- · Protective equipment: Wear self-contained respiratory protective device.
- · Additional information

Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

6 Accidental Release Measures

· Personal precautions, protective equipment and emergency procedures

Remove persons from danger area.

Avoid contact with the eyes and skin.

Wear protective clothing.

· Environmental precautions:

Do not allow product to reach sewage system or any water course.

Inform respective authorities in case of seepage into water course or sewage system.

Do not allow to penetrate the ground/soil.

In case of seepage into the ground inform responsible authorities.

· Methods and material for containment and cleaning up:

Absorb liquid components with liquid-binding material.

Dispose of the material collected according to regulations.

· 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.

7 Handling and Storage

- · Handling:
- · Precautions for safe handling Avoid contact with the eyes and skin.
- · Information about fire and explosion protection: No special measures required.
- · Storage:
- · Requirements to be met by storerooms and receptacles: Store only in unopened original receptacles.
- Information about storage in one common storage facility: Store away from foodstuffs.
- · Further information about storage conditions: None.
- · Specific end use(s) No further relevant information available.

8 Exposure controls and personal protection

· Additional information about design of technical facilities: No further data; see section 7.

	· · · · · · · · · · · · · · · · · · ·
· Ingre	dients with limit values that require monitoring at the workplace:
7727-	43-7 barium sulfate
TWA	Long-term value: 10 mg/m³
WES	Long-term value: 10 mg/m³
	inhalable dust

56-81-5 glycerol

TWA Long-term value: 10 mg/m³

(Contd. on page 4)

Printing date 16.08.2024 Version number 3 Revision: 16.08.2024

Trade name: GC Fuji TEMP LT Paste B

(Contd. of page 3)

WES Long-term value: 10 mg/m³

inhalable dust

7631-86-9 silicon dioxide

TWA Long-term value: 2 mg/m³

- · Additional information: The lists valid during the making were used as basis.
- · Personal protective equipment:
- General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

Avoid contact with the eyes and skin.

Wash hands before breaks and at the end of work.

Immediately remove all soiled and contaminated clothing

- · Respiratory protection: Suitable respiratory protective device recommended.
- · Protection of hands:



Protective gloves

· Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product 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.

· Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye protection:



Tightly sealed goggles

9 Physical and Chemical Properties

- · General Information
- · Appearance:

· Form: Pasty · Colour: White **Odourless** Odour: Not determined. · Odour threshold: 2.5

· pH-value at 20 °C (68 °F):

· Change in condition

· Melting point/freezing point: Undetermined. · Initial boiling point and boiling range: Undetermined. >150 °C (>302 °F) · Flash point: · Flammability (solid, gas): Not applicable. · Auto-ignition temperature: Undetermined.

Not determined. · Decomposition temperature:

· Ignition temperature: Product is not selfigniting.

· Explosive properties: Product does not present an explosion hazard.

(Contd. on page 5)

Printing date 16.08.2024 Version number 3 Revision: 16.08.2024

Trade name: GC_Fuji_TEMP_LT_Paste_B

(Contd. of page 4)

· Explosion limits:

Lower: Not determined.
Upper: Not determined.
Vapour pressure: Not determined.
Density: Not determined.
Relative density Not determined.
Vapour density Not determined.
Evaporation rate Not determined.

· Solubility in / Miscibility with

• water: Insoluble.
• Partition coefficient: n-octanol/water: Not determined.

· Viscosity:

Dynamic: Not determined.Kinematic: Not determined.

· Solvent content:

• Organic solvents: 8.0 %
 • Water: 21.5 %
 • VOC (EC) 0.0 g/l

• Other information No further relevant information available.

10 Stability and Reactivity

- · Reactivity No further relevant information available.
- · Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: No dangerous decomposition products known.

11 Toxicological Information

- · Information on toxicological effects
- · Acute toxicity Based on available data, the classification criteria are not met.
- · LD/LC50 values relevant for classification:

7631-86-9 silicon dioxide

Oral LD50 10,000 mg/kg (rat (f+m))

- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- · Serious eye damage/irritation Causes serious eye irritation.
- Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- · Reproductive toxicity Based on available data, the classification criteria are not met.
- · STOT-single exposure Based on available data, the classification criteria are not met.
- · STOT-repeated exposure Based on available data, the classification criteria are not met.
- · Aspiration hazard Based on available data, the classification criteria are not met.
- · Additional toxicological information:
- · Repeated dose toxicity No further relevant information available.

(Contd. on page 6)

Version number 3 Printing date 16.08.2024 Revision: 16.08.2024

Trade name: GC_Fuji_TEMP_LT_Paste_B

(Contd. of page 5)

· CMR effects (carcinogenity, mutagenicity and toxicity for reproduction) No further relevant information available.

12 Ecological Information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- Behaviour in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes:

Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water

Do not allow product to reach ground water, water course or sewage system.

Danger to drinking water if even small quantities leak into the ground.

- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · **vPvB**: Not applicable.
- · Other adverse effects No further relevant information available.

13 Disposal considerations

- · Waste treatment methods
- · Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- Uncleaned packaging:
- **Recommendation:** Disposal must be made according to official regulations.

UN-Number		
ADG, ADN, IMDG, IATA	not regulated	
UN proper shipping name		
ADG, ADN, IMDG, IATA	not regulated	
Transport hazard class(es)		
ADG, ADN, IMDG, IATA		
Class	not regulated	
Packing group		
ADG, IMDG, IATA	not regulated	
Environmental hazards:		
Marine pollutant:	No	
Special precautions for user	Not applicable.	
Transport in bulk according to Annex I.	I of Marpol	
and the IBC Code	Not applicable.	

(Contd. on page 7)

Printing date 16.08.2024 Version number 3 Revision: 16.08.2024

Trade name: GC_Fuji_TEMP_LT_Paste_B

(Contd. of page 6)

· UN "Model Regulation":

not regulated

15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Australian Inventory of Industrial Chemicals

All ingredients are listed.

· Standard for the Uniform Scheduling of Medicines and Poisons

None of the ingredients is listed.

· Australia: Priority Existing Chemicals

None of the ingredients is listed.

- · GHS label elements The product is classified and labelled according to the Globally Harmonised System (GHS).
- · Hazard pictograms



- · Signal word Warning
- · Hazard statements

Causes serious eye irritation.

· Precautionary statements

Wash thoroughly after handling.

Wear eye protection / face protection.

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.

- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.
- · Other regulations, limitations and prohibitive regulations
- · Substances of very high concern (SVHC) according to REACH, Article 57

4247-02-3 Isobutyl 4-hydroxybenzoate

· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other information

· Relevant phrases

H319 Causes serious eye irritation.

- · Department issuing SDS: Regulatory affairs
- · Contact: msds@gc.dental
- · Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial Chemical Substances

(Contd. on page 8)

Printing date 16.08.2024 Version number 3 Revision: 16.08.2024

Trade name: GC_Fuji_TEMP_LT_Paste_B

(Contd. of page 7)

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

VOC: Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic SVHC: Substances of Very High Concern vPvB: very Persistent and very Bioaccumulative

Eye damage/irritation - Category 2A: Serious eye damage/eye irritation - Category 2A

· Sources

- ECHA (http://echa.europa.eu/)
- EnviChem (www.echemportal.org)
- * * Data compared to the previous version altered.

This version replaces all previous versions.

Disclaimer:

The information contained herein is believed to be true and accurate. However, all statements, recommendations or suggestions are made without any guarantee, representation or warranty, express or implied, on our part. Therefore, no warranty is made or to be implied that the information set out in this document is accurate or complete, and we accordingly exclude all liability in connection with the use of this information or the products referred to herein. All such risks are assumed by the purchaser/user. The information contained herein is also subject to change without notice. For the avoidance of doubt, however, nothing in this document excludes or limits our liability for death or personal injury caused by our negligence or for fraudulent misrepresentation.

ΔΙΙ