

## Safety Data Sheet according to WHS Regulations

Printing date 16.06.2020

Version number 2

Revision: 16.06.2020

Hazardous according to criteria of Australian Safety and Compensation Council.

### 1 Identification

- **Product identifier**
- **Trade name: GC Fuji II Capsule**
- **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 Irrit. 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**



GHS07

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

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· **vPvB:** Not applicable.

### 3 Composition and Information on Ingredients

· **Chemical characterisation:** Mixtures· **Description:**

Mixture of substances listed below with nonhazardous additions.

Mixture: consisting of the following components.

· **Dangerous components:**

9003-01-4	Polyacrylic acid	Eye Irrit. 2, H319	10-<25%
87-69-4	Tartaric acid	Eye Dam. 1, H318	≥2.5-<3%

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

### 4 First Aid Measures

· **Description of first aid measures**· **General information:** No special measures required.· **After inhalation:** Supply fresh air; consult doctor in case of complaints.· **After skin contact:** Generally the product does not irritate the skin.· **After eye contact:** Rinse opened eye for several minutes under running water.· **After swallowing:** 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

· **Extinguishing media**· **Suitable extinguishing agents:**CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.· **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.

· **Advice for firefighters**· **Protective equipment:** No special measures required.

### 6 Accidental Release Measures

· **Personal precautions, protective equipment and emergency procedures** Not required.· **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.· **Methods and material for containment and cleaning up:** Pick up mechanically.· **Reference to other sections**

No dangerous substances are released.

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

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See Section 13 for disposal information.

### 7 Handling and Storage

- **Handling:**
- **Precautions for safe handling** Prevent formation of dust.
- **Information about fire - and explosion protection:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **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 item 7.
- **Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**  
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists valid during the making were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** Suitable respiratory protective device recommended.
- **Protection of hands:**  
Protective gloves  
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.  
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
- **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:** Not required.

### 9 Physical and Chemical Properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**
- **Form:** Solid
- **Colour:** According to product specification

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· <b>Odour:</b>	Characteristic
· <b>Odour threshold:</b>	Not determined.
· <b>pH-value:</b>	Not applicable.
· <b>Change in condition</b>	
<b>Melting point/freezing point:</b>	> 1350°C
<b>Initial boiling point and boiling range:</b>	100 °C (212 °F)
· <b>Flash point:</b>	Not applicable.
· <b>Flammability (solid, gas):</b>	Not determined.
· <b>Decomposition temperature:</b>	Not determined.
· <b>Auto-ignition temperature:</b>	Product is not selfigniting.
· <b>Explosive properties:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
<b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.
· <b>Vapour pressure at 20 °C (68 °F):</b>	23 hPa (17.3 mm Hg)
· <b>Density:</b>	Not determined.
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not applicable.
· <b>Evaporation rate</b>	Not applicable.
· <b>Solubility in / Miscibility with water:</b>	Soluble.
· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
· <b>Viscosity:</b>	
<b>Dynamic:</b>	Not applicable.
<b>Kinematic:</b>	Not applicable.
· <b>Solvent content:</b>	
<b>Organic solvents:</b>	0.0 %
<b>Water:</b>	13.4 %
· <b>Other information</b>	No further relevant information available.

### 10 Stability and Reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **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.

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### 11 Toxicological Information

- **Information on toxicological effects**
- **Acute toxicity**
- **LD/LC50 values relevant for classification:** No further relevant information available.
- **Primary irritant effect:**
- **Skin corrosion/irritation**  
Irritant to skin and mucous membranes.  
No irritant effect.
- **Serious eye damage/irritation** No irritating effect.
- **Respiratory or skin sensitisation** No sensitising effects known.
- **Additional toxicological information:**  
The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.
- **CMR effects (carcinogenicity, 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:**  
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

### 13 Disposal considerations

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

### 14 Transport information

- |                                     |               |
|-------------------------------------|---------------|
| · <b>UN-Number</b>                  |               |
| · <b>ADG, ADN, IMDG, IATA</b>       | not regulated |
| · <b>UN proper shipping name</b>    |               |
| · <b>ADG, ADN, IMDG, IATA</b>       | not regulated |
| · <b>Transport hazard class(es)</b> |               |
| · <b>ADG, ADN, IMDG, IATA</b>       |               |
| · <b>Class</b>                      | not regulated |

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· <b>Packing group</b> · <b>ADG, IMDG, IATA</b>	not regulated
· <b>Environmental hazards:</b> · <b>Marine pollutant:</b>	No
· <b>Special precautions for user</b>	Not applicable.
· <b>Transport in bulk according to Annex II of Marpol and the IBC Code</b>	Not applicable.
· <b>UN "Model Regulation":</b>	not regulated

### 15 Regulatory information

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

· **Australian Inventory of Chemical Substances**

9003-01-4	Polyacrylic acid
87-69-4	Tartaric acid
20344-49-4	Iron hydroxide oxide
1317-61-9	triiron tetraoxide
1309-37-1	Iron(III)oxide
7732-18-5	Water

· **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**



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· **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.

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

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### 16 Other information

- **Relevant phrases**

*H318 Causes serious eye damage.*

*H319 Causes serious eye irritation.*

- **Department issuing SDS:** Regulatory affairs

- **Contact:** msds@gc.dental

- **Abbreviations and acronyms:**

*RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)*

*ICAO: International Civil Aviation Organisation*

*ADR: Accord européen sur le transport 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*

*ELINCS: European List of Notified Chemical Substances*

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

*LC50: Lethal concentration, 50 percent*

*LD50: Lethal dose, 50 percent*

*PBT: Persistent, Bioaccumulative and Toxic*

*vPvB: very Persistent and very Bioaccumulative*

*Eye Dam. 1: Serious eye damage/eye irritation – Category 1*

*Eye Irrit. 2: Serious eye damage/eye irritation – Category 2*

*Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A*

- **\* Data compared to the previous version altered.**