

Safety Data Sheet according to WHS Regulations

Printing date 22.05.2023

Version number 4

Revision: 22.05.2023

Not classified as hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

- **Product identifier**
- **Trade name: GC Fuji IX GP EXTRA Powder**
- **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**
The product is not classified, according to the Globally Harmonised System (GHS).
- **Label elements**
- **GHS label elements** Void
- **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** Void
- **Signal word** Void
- **Hazard statements** Void
- **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:**

9003-01-4	Polyacrylic acid	Serious eye damage/irritation – Category 2A, H319	5-<10%
13463-67-7	titanium dioxide	Carc. 2, H351	0.2-<0.5%

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

4 First Aid Measures

· **General information:**

No special measures required.

If symptoms persist consult doctor.

· **After inhalation:** Take affected persons into fresh air and keep quiet.

· **After skin contact:**

Generally the product does not irritate the skin.

Immediately rinse with water.

· **After eye contact:**

Rinse opened eye for several minutes under running water. If symptoms persist, 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

· **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.

· **Environmental precautions:**

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

Do not allow to penetrate the ground/soil.

Do not allow to enter sewers/ surface or ground water.

· **Methods and material for containment and cleaning up:**

Pick up mechanically.

Dispose of the material collected according to regulations.

· **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.

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7 Handling and Storage

- **Handling:**
- **Precautions for safe handling**
Prevent formation of dust.
Any unavoidable deposit of dust must be regularly removed.
- **Information about fire - and explosion protection:** Dust can combine with air to form an explosive mixture.
- **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.

- **Ingredients with limit values that require monitoring at the workplace:**

13463-67-7 titanium dioxide

WES	Long-term value: 10 mg/m ³ inhalable dust
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- **DNELs**

13463-67-7 titanium dioxide

Inhalative	DNEL inhalation	10 mg/m ³ (m)
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- **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.
Do not inhale dust / smoke / mist.
Wash hands before breaks and at the end of work.
- **Respiratory protection:**
Suitable respiratory protective device recommended.
Suitable respiratory protective device recommended.
- **Protection of hands:**
Protective gloves
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:** Safety glasses

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9 Physical and Chemical Properties

· General Information

· Appearance:

· Form:

Powder

· Colour:

According to product specification

· Odour:

Odourless

· Odour threshold:

Not determined.

· pH-value:

Not applicable.

· Change in condition

· Melting point/freezing point:

Undetermined.

· Initial boiling point and boiling range:

Undetermined.

· Flash point:

Not applicable.

· Flammability (solid, gas):

Not determined.

· Auto-ignition temperature:

Undetermined.

· Decomposition temperature:

Not determined.

· Ignition temperature:

Product is not selfigniting.

· Explosive properties:

Product does not present an explosion hazard.

· Explosion limits:

· Lower:

Not determined.

· Upper:

Not determined.

· Vapour pressure:

Not applicable.

· Density:

Not determined.

· Relative density

Not determined.

· Vapour density

Not applicable.

· Evaporation rate

Not applicable.

· Solubility in / Miscibility with

· water:

Insoluble.

· Partition coefficient: n-octanol/water:

Not determined.

· Viscosity:

· Dynamic:

Not applicable.

· Kinematic:

Not applicable.

· 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.

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· **LD/LC50 values relevant for classification:**

13463-67-7 titanium dioxide

Oral	LD50	>5,000 mg/kg (mouse) (OECD 420)
Inhalative	LC50/4 h	>6.82 mg/l (rat male)

- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **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.
- **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

- **Waste treatment methods**
- **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
Contact waste processors for recycling information.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- **UN-Number**
- **ADG, ADN, IMDG, IATA** not regulated

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· UN proper shipping name · ADG, ADN, IMDG, IATA	<i>not regulated</i>
· Transport hazard class(es) · ADG, ADN, IMDG, IATA · Class	<i>not regulated</i>
· Packing group · ADG, IMDG, IATA	<i>not regulated</i>
· Environmental hazards: · Marine pollutant:	<i>No</i>
· Special precautions for user	<i>Not applicable.</i>
· Transport in bulk according to Annex II of Marpol and the IBC Code	<i>Not applicable.</i>
· UN "Model Regulation":	<i>not regulated</i>

15 Regulatory information

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

· **Australian Inventory of Industrial Chemicals**

65997-17-3	Glass, oxide, chemicals
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9003-01-4	Polyacrylic acid
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1309-37-1	Iron(III)oxide
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1317-61-9	triiron tetraoxide
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13463-67-7	titanium dioxide
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20344-49-4	Iron hydroxide oxide
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· **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** *Void*

· **Hazard pictograms** *Void*

· **Signal word** *Void*

· **Hazard statements** *Void*

· **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.*

16 Other information

· **Relevant phrases**

H319 Causes serious eye irritation.

H351 Suspected of causing cancer.

· **Department issuing SDS:** *Regulatory affairs*

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· **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 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

ELINCS: European List of Notified Chemical Substances

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

DNEL: Derived No-Effect Level (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Serious eye damage/irritation – Category 2A: Serious eye damage/eye irritation – Category 2A

Carc. 2: Carcinogenicity – Category 2

· **Sources**

• *ECHA (<http://echa.europa.eu/>)*

• *EnviChem (www.echemportal.org)*

· *** Data compared to the previous version altered.**

This version replaces all previous versions.

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