

## Safety Data Sheet according to WHS Regulations

Printing date 06.09.2022

Version number 1

Revision: 06.09.2022

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

### 1 Identification

- **Product identifier**
- **Trade name: GC EXA Advanced Monophase normal set - catalyst**
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** Auxiliary 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:**

14808-60-7	Quartz	STOT RE 1, H372	25-<50%
1309-37-1	Iron(III)oxide		0.5-<1%

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· **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.  
If symptoms persist consult doctor.
- **After inhalation:** Take affected persons into fresh air and keep quiet.
- **After skin contact:** 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

- **Extinguishing media**
- **Suitable extinguishing agents:**  
CO<sub>2</sub>, 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.
- **Advice for firefighters**
- **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.
- **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.

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### 7 Handling and Storage

- **Handling:**
- **Precautions for safe handling** No special precautions are necessary if used correctly.
- **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:** 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 item 7.
- **Control parameters**

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

#### 14808-60-7 Quartz

TWA Long-term value: 0.1 mg/m<sup>3</sup>  
respirable dust

WES Long-term value: 0.05 mg/m<sup>3</sup>  
respirable dust

#### 1309-37-1 Iron(III)oxide

WES Long-term value: 5 mg/m<sup>3</sup>

- **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.  
Wash hands before breaks and at the end of work.  
Keep away from foodstuffs, beverages and feed.
- **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:** Safety glasses

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### 9 Physical and Chemical Properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

· <b>Form:</b>	Pasty
· <b>Colour:</b>	Blue
· <b>Odour:</b>	Odourless
· <b>Odour threshold:</b>	Not determined.

· **pH-value:** Not determined.

· **Change in condition**

· <b>Melting point/freezing point:</b>	Undetermined.
· <b>Initial boiling point and boiling range:</b>	Undetermined.

· **Flash point:** Not applicable.

· **Flammability (solid, gas):** Not applicable.

· **Ignition temperature:** Undetermined.

· **Decomposition temperature:** Not determined.

· **Auto-ignition temperature:** Product is not selfigniting.

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

· **Explosion limits:**

· <b>Lower:</b>	Not determined.
· <b>Upper:</b>	Not determined.

· **Vapour pressure:** Not determined.

· **Density:** Not determined.  
2,56 g/cm<sup>3</sup>  
1,18g/ml

· **Relative density** Not determined.

· **Vapour density** Not determined.

· **Evaporation rate** Not determined.

· **Solubility in / Miscibility with water:**

Fully miscible.

· **Partition coefficient: n-octanol/water:** Not determined.

· **Viscosity:**

· <b>Dynamic:</b>	Not determined.
· <b>Kinematic:</b>	Not determined.

· **Solvent content:**

· **VOC (EC)** 0.0 g/l

· **Other information** 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.

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- **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**

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

**1309-37-1 Iron(III)oxide**

Oral	LD50	>5,000 mg/kg (rat (f+m))
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- **Primary irritant effect:**
- **Skin corrosion/irritation** No irritant effect.
- **Serious eye damage/irritation** No irritating effect.
- **Respiratory or skin sensitisation** No sensitising effects known.
- **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:** Not hazardous for water.
- **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.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

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### 14 Transport information

· <b>UN-Number</b> · <b>ADG, IMDG, IATA</b>	not regulated
· <b>UN proper shipping name</b> · <b>ADG, IMDG, IATA</b>	not regulated
· <b>Transport hazard class(es)</b> · <b>ADG, ADN, IMDG, IATA</b> · <b>Class</b>	not regulated
· <b>Packing group</b> · <b>ADG, IMDG, IATA</b>	not regulated
· <b>Environmental hazards:</b>	Not applicable.
· <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

· <b>Safety, health and environmental regulations/legislation specific for the substance or mixture</b>
· <b>Australian Inventory of Industrial Chemicals</b> All ingredients are listed.
· <b>Standard for the Uniform Scheduling of Medicines and Poisons</b> None of the ingredients is listed.
· <b>Australia: Priority Existing Chemicals</b> None of the ingredients is listed.
· <b>GHS label elements</b> Void
· <b>Hazard pictograms</b> Void
· <b>Signal word</b> Void
· <b>Hazard statements</b> Void
· <b>Directive 2012/18/EU</b>
· <b>Named dangerous substances - ANNEX I</b> None of the ingredients is listed.
· <b>Chemical safety assessment:</b> A Chemical Safety Assessment has not been carried out.

### 16 Other information

· <b>Relevant phrases</b> H372 Causes damage to organs through prolonged or repeated exposure.
· <b>Department issuing SDS:</b> Regulatory affairs
· <b>Contact:</b> msds@gc.dental
· <b>Abbreviations and acronyms:</b> 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

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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)  
VOC: Volatile Organic Compounds (USA, EU)  
LC50: Lethal concentration, 50 percent  
LD50: Lethal dose, 50 percent  
PBT: Persistent, Bioaccumulative and Toxic  
vPvB: very Persistent and very Bioaccumulative  
STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1

· **Sources**

- ECHA (<http://echa.europa.eu/>)
- EnviChem ([www.echemportal.org](http://www.echemportal.org))

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

*This version replaces all previous versions.*

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