

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 - base*
- **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	50-<75%
9016-45-9	Nonylphenol, ethoxylated	Skin Irrit. 2, H315; Eye Irritation 2A, H319	5-<10%

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1309-37-1	Iron(III)oxide	0.5-<1%
· SVHC		
9016-45-9	Nonylphenol, ethoxylated	

· **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:** 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:**
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:**
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.
- **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.
Avoid formation of dust.
Wear protective clothing.
- **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:**
Pick up mechanically.

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- Prevent formation of dust.
- 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**
- 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.
- **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/m³
respirable dust

WES Long-term value: 0.05 mg/m³
respirable dust

1309-37-1 Iron(III)oxide

WES Long-term value: 5 mg/m³

- **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.
- Do not inhale dust / smoke / mist.
- 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.

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· **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

9 Physical and Chemical Properties

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

· **General Information**

· **Appearance:**

· Form:	Pasty
· Colour:	Blue
· 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.

· **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:**

· Lower:	Not determined.
· Upper:	Not determined.

· **Vapour pressure:** Not applicable.

· **Density:** Not determined.

2,56 g/cm³
1,18g/ml

· **Relative density** Not determined.

· **Vapour density** Not applicable.

· **Evaporation rate** Not applicable.

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

Fully miscible.

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

· **Viscosity:**

· Dynamic:	Not applicable.
· Kinematic:	Not applicable.

· **Solvent content:**

VOC (EC) 0.0 g/l

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· **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.
- **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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- **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.

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- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

14 Transport information

· UN-Number · ADG, IMDG, IATA	<i>not regulated</i>
· UN proper shipping name · ADG, 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:	<i>Not applicable.</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	
14808-60-7	Quartz
68083-19-2	Vinyldimethylpolysiloxane
9016-45-9	Nonylphenol, ethoxylated
1309-37-1	Iron(III)oxide
1345-16-0	Cobalt aluminate blue spinel
68037-59-2	Methylhydrogen dimethylpolysiloxane
· Standard for the Uniform Scheduling of Medicines and Poisons	
<i>None of the ingredients is listed.</i>	
· Australia: Priority Existing Chemicals	
<i>None of the ingredients is listed.</i>	
· GHS label elements <i>Void</i>	
· Hazard pictograms <i>Void</i>	
· Signal word <i>Void</i>	
· Hazard statements <i>Void</i>	
· Directive 2012/18/EU	
· Named dangerous substances - ANNEX I <i>None of the ingredients is listed.</i>	

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· **Other regulations, limitations and prohibitive regulations**

· **Substances of very high concern (SVHC) according to REACH, Article 57**

9016-45-9	Nonylphenol, ethoxylated
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· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

· **Relevant phrases**

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H372 Causes damage to organs through prolonged or repeated exposure.

· **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

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

Skin Irrit. 2: Skin corrosion/irritation – Category 2

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

STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1

· **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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