

## Safety Data Sheet in accordance with HSNO

Printing date 06.09.2022

Version number 1

Revision: 06.09.2022

### 1 Identification of the substance or mixture and of the supplier

- **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**  
Henry Schein Dental  
23 William Pickering Drive, Albany  
Auckland 0632, NEW ZEALAND  
  
PO Box 101140, NSMC  
Auckland 0745, NEW ZEALAND  
  
Free Phone: 0800 808 855
- **Further information obtainable from:** Regulatory affairs
- **Emergency telephone number:** 0800 764 766 (National Poisons Centre)

### 2 Hazards 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/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:**

CAS: 14808-60-7	Quartz	STOT RE 1, H372	25-<50%
EINECS: 238-878-4			

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CAS: 1309-37-1	Iron(III)oxide		
EINECS: 215-168-2			0,5-<1%

· **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.

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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/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:**

<b>14808-60-7 Quartz</b>	
TWA (New Zealand)	Long-term value: 0.2 mg/m <sup>3</sup> confirmed carcinogen; respirable dust
WES (New Zealand)	Long-term value: 0.2 mg/m <sup>3</sup> confirmed carcinogen; respirable dust
BOELV (European Union)	Long-term value: 0.1* mg/m <sup>3</sup> *respirable fraction
<b>1309-37-1 Iron(III)oxide</b>	
WES (New Zealand)	Long-term value: 5 mg/m <sup>3</sup> as Fe

· **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.

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· Eye protection: Safety glasses

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### 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 determined.

#### · Change in condition

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

· Lower:	Not determined.
· Upper:	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:

· Dynamic:	Not determined.
· Kinematic:	Not determined.

#### · Solvent content:

VOC (EC) 0.0 g/l

· Other information: No further relevant information available.

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### 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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- **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.

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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

· <b>UN-Number</b> · <b>NZS, IMDG, IATA</b>	<i>not regulated</i>
· <b>UN proper shipping name</b> · <b>NZS, IMDG, IATA</b>	<i>not regulated</i>
· <b>Transport hazard class(es)</b> · <b>NZS, ADN, IMDG, IATA</b> · <b>Class</b>	<i>not regulated</i>
· <b>Packing group</b> · <b>NZS, IMDG, IATA</b>	<i>not regulated</i>
· <b>Environmental hazards:</b>	<i>Not applicable.</i>
· <b>Special precautions for user</b>	<i>Not applicable.</i>
· <b>Transport in bulk according to Annex II of Marpol and the IBC Code</b>	<i>Not applicable.</i>
· <b>UN "Model Regulation":</b>	<i>not regulated</i>

### 15 Regulatory information

· <b>Safety, health and environmental regulations/legislation specific for the substance or mixture</b>	
· <b>New Zealand Inventory of Chemicals</b>	
<i>All ingredients are listed.</i>	
· <b>HSNO Approval numbers</b>	
14808-60-7 Quartz	HSR003125
· <b>GHS label elements</b> <i>Void</i>	
· <b>Hazard pictograms</b> <i>Void</i>	
· <b>Signal word</b> <i>Void</i>	
· <b>Hazard statements</b> <i>Void</i>	
· <b>Directive 2012/18/EU</b>	
· <b>Named dangerous substances - ANNEX I</b> <i>None of the ingredients is listed.</i>	
· <b>Chemical safety assessment:</b> <i>A Chemical Safety Assessment has not been carried out.</i>	

### 16 Other information

- **Relevant phrases**  
*H372 Causes damage to organs through prolonged or repeated exposure.*
- **Department issuing SDS:** *Regulatory affairs*
- **Contact:** *msds@gc.dental*

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· **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

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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