

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 - 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**
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	50-<75%
EINECS: 238-878-4			

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CAS: 9016-45-9 NLP: 500-024-6	Nonylphenol, ethoxylated	Skin Irrit. 2, H315; Eye Irrit. 2, H319	5-<10%
CAS: 1309-37-1 EINECS: 215-168-2	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.

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Do not allow to penetrate the ground/soil.

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

Pick up mechanically.

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/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 (New Zealand)

Long-term value: 0.2 mg/m³
confirmed carcinogen; respirable dust

WES (New Zealand)

Long-term value: 0.2 mg/m³
confirmed carcinogen; respirable dust

BOELV (European Union)

Long-term value: 0.1* mg/m³
*respirable fraction

1309-37-1 Iron(III)oxide

WES (New Zealand)

Long-term value: 5 mg/m³
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.

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.

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- **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

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.

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Kinematic:	Not applicable.
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.
- **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.

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13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **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	
· NZS, IMDG, IATA	not regulated
· UN proper shipping name	
· NZS, IMDG, IATA	not regulated
· Transport hazard class(es)	
· NZS, ADN, IMDG, IATA	
· Class	not regulated
· Packing group	
· NZS, IMDG, IATA	not regulated
· Environmental hazards:	Not applicable.
· Special precautions for user	Not applicable.
· Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· UN "Model Regulation":	not regulated

15 Regulatory information

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

· New Zealand Inventory of 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	
· HSNO Approval numbers		
14808-60-7	Quartz	HSR003125

- **GHS label elements** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void

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- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **Other regulations, limitations and prohibitive regulations**

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

9016-45-9 Nonylphenol, ethoxylated

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

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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