Safety Data Sheet
according to WHS Regulations

Printing date 03.06.2024 *Version number 2* *Revision: 03.06.2024*

Hazardous according to criteria of Australian Safety and Compensation Council.

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1 Identification

· **Product identifier**

· **Trade name: EXA_Advanced_(Injection_base_-_normal_set,_fast_set,_normal_set_(Tube_type))**
· **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**
Eye damage/irritation – Category 2A H319 Causes serious eye irritation.

· **Label elements**
· **GHS label elements** The product is classified and labelled according to the Globally Harmonised System (GHS).
· **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**

GHS07

· **Signal word** Warning
· **Hazard statements**
Causes serious eye irritation.
· **Precautionary statements**
Wash thoroughly after handling.
Wear eye protection / face protection.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.

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· **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 Specific target organ toxicity (repeated exposure) – Category 1, H372	25-<50%
68037-59-2	Methylhydrogen dimethylpolysiloxane Skin corrosion/irritation – Category 2, H315; Eye damage/irritation – Category 2A, H319; Specific target organ toxicity (single exposure) – Category 3, H335	2.5-<5%
68131-39-5	Alcohols, C12-15, ethoxylated Eye damage/irritation – Category 1, H318; Acute toxicity - oral – Category 4, H302; Skin corrosion/irritation – Category 2, H315	1-<2.5%

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

4 First Aid Measures

· **General information:**
Immediately remove any clothing soiled by the product.
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:**
Protect unharmed eye.
Rinse opened eye for several minutes under running water. Then 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

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· **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.
Avoid contact with the eyes and skin.
Wear protective clothing.
· **Environmental precautions:**
Do not allow product to reach sewage system or any water course.
Inform respective authorities in case of seepage into water course or sewage system.
Do not allow to penetrate the ground/soil.
In case of seepage into the ground inform responsible authorities.
· **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.

7 Handling and Storage

· **Handling:**
· **Precautions for safe handling**
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
Avoid contact with the eyes and skin.
· **Information about fire - and explosion protection:** No special measures required.
· **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:**	
14808-60-7 Quartz	
TWA	Long-term value: 0.1 mg/m³ respirable dust
WES	Long-term value: 0.05 mg/m³ respirable dust

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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.
Avoid contact with the eyes and skin.
Wash hands before breaks and at the end of work.
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing
· **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:**

Tightly sealed goggles

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9 Physical and Chemical Properties

· **General Information**	
· **Appearance:**	
· **Form:**	Pasty
· **Colour:**	Red-brown
· **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.
· **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 determined.
· **Density:**	Not determined.

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· **Relative density**	Not determined.
· **Vapour density**	Not determined.
· **Evaporation rate**	Not determined.
· **Solubility in / Miscibility with**	
· **water:**	Insoluble.
· **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.

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.

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11 Toxicological Information

· **Information on toxicological effects**
· **Acute toxicity** Based on available data, the classification criteria are not met.
· **LD/LC50 values relevant for classification:** No further relevant information available.
· **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
· **Serious eye damage/irritation** Causes serious eye irritation.
· **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 (carcinogenity, 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.

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· ***Additional ecological information:***
· ***General notes:***
Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water
Do not allow product to reach ground water, water course or sewage system.
Danger to drinking water if even small quantities leak into the ground.
· ***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.

· ***Uncleaned packaging:***
· ***Recommendation:*** *Disposal must be made according to official regulations.*

14 Transport information

· ***UN-Number***	
· ***ADG, ADN, IMDG, IATA***	*not regulated*
· ***UN proper shipping name***	
· ***ADG, ADN, IMDG, IATA***	*not regulated*
· ***Transport hazard class(es)***	
· ***ADG, ADN, IMDG, IATA***	
· ***Class***	*not regulated*
· ***Packing group***	
· ***ADG, IMDG, IATA***	*not regulated*
· ***Environmental hazards:***	
· ***Marine pollutant:***	*No*
· ***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***

· ***Australian Inventory of Industrial Chemicals***
All ingredients are listed.

· ***Standard for the Uniform Scheduling of Medicines and Poisons***
None of the ingredients is listed.

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· ***Australia: Priority Existing Chemicals***

None of the ingredients is listed.

· ***GHS label elements*** *The product is classified and labelled according to the Globally Harmonised System (GHS).*
· ***Hazard pictograms***

GHS07

· ***Signal word*** *Warning*
· ***Hazard statements***
Causes serious eye irritation.
· ***Precautionary statements***
Wash thoroughly after handling.
Wear eye protection / face protection.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.

· ***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***
H302 Harmful if swallowed.
H315 Causes skin irritation.
H318 Causes serious eye damage.
H319 Causes serious eye irritation.
H335 May cause respiratory 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
vPvB: very Persistent and very Bioaccumulative
Acute toxicity - oral – Category 4: Acute toxicity – Category 4
Skin corrosion/irritation – Category 2: Skin corrosion/irritation – Category 2
Eye damage/irritation – Category 1: Serious eye damage/eye irritation – Category 1
Eye damage/irritation – Category 2A: Serious eye damage/eye irritation – Category 2A
Specific target organ toxicity (single exposure) – Category 3: Specific target organ toxicity (single exposure) – Category 3
Specific target organ toxicity (repeated exposure) – Category 1: Specific target organ toxicity (repeated exposure) – Category 1

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· **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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