Safety Data Sheet
in accordance with HSNO

Printing date 03.06.2024 Version number 2 Revision: 03.06.2024

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1 Identification of the substance or mixture and of the supplier

· **Product identifier**

· **Trade name: EXA_Advanced_(Regular_base_-_normal_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** Auxiliary for dental technology

· **Details of the supplier of the safety data sheet**
Henry Schein Dental

243-249 Bush Road, Rosedale
Auckland 0632, 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 EINECS: 238-878-4	Quartz Specific target organ toxicity - repeated exposure Category 1, H372	25-<50%
CAS: 68037-59-2	Methylhydrogen dimethylpolysiloxane Skin irritation Category 2, H315; Eye irritation Category 2, H319; Specific target organ toxicity - single exposure Category 3, H335	2.5-<5%

(Contd. on page 2)

Safety Data Sheet
in accordance with HSNO

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

Trade name: EXA_Advanced_(Regular_base_-_normal_set,_normal_set_(Tube_type))

(Contd. of page 1)

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

4 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

· ***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.
· ***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.

(Contd. on page 3)

Safety Data Sheet
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Printing date 03.06.2024 *Version number 2* *Revision: 03.06.2024*

Trade name: EXA_Advanced_(Regular_base_-_normal_set,_normal_set_(Tube_type))

(Contd. of page 2)

7 Handling and storage

· ***Handling:***
· ***Precautions for safe handling***
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
· ***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/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 (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

· ***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.
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

· ***General Information***
· ***Appearance:***
· ***Form:*** *Pasty*
· ***Colour:*** *Blue*
· ***Odour:*** *Odourless*

(Contd. on page 4)

Safety Data Sheet
in accordance with HSNO

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

Trade name: EXA_Advanced_(Regular_base_-_normal_set,_normal_set_(Tube_type))

(Contd. of page 3)

· **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.
· **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** Based on available data, the classification criteria are not met.
· **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.

(Contd. on page 5)

Safety Data Sheet
in accordance with HSNO

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

Trade name: EXA_Advanced_(Regular_base_-_normal_set,_normal_set_(Tube_type))

(Contd. of page 4)

· ***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.*
· ***Additional ecological information:***
· ***General notes:***
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
· ***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.*

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.*

(Contd. on page 6)

Safety Data Sheet
in accordance with HSNO

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Trade name: EXA_Advanced_(Regular_base_-_normal_set,_normal_set_(Tube_type))

(Contd. of page 5)

· **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**

All ingredients are listed.

· **HSNO Approval numbers**

14808-60-7	Quartz	HSR003125

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

· **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**
H315 Causes skin irritation.
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
Skin irritation Category 2: Skin corrosion/irritation – Category 2
Eye irritation Category 2: Serious eye damage/eye irritation – Category 2
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
· **Sources**
• ECHA (http://echa.europa.eu/)
• EnviChem (www.echemportal.org)

(Contd. on page 7)

Safety Data Sheet
in accordance with HSNO

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

Trade name: EXA_Advanced_(Regular_base_-_normal_set,_normal_set_(Tube_type))

(Contd. of page 6)

· **** Data compared to the previous version altered.***
This version replaces all previous versions.
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