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_(Injection_catalyst_-_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** 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%

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

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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.

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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.

7 Handling and storage

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

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· ***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:***	*Yellow*
· ***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.*

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· ***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.*
· ***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.*

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· ***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.*

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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.
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.*
· ***Special precautions for user***	*Not applicable.*
· ***Transport in bulk according to Annex II of Marpol and the IBC Code***	*Not applicable.*

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