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_(Heavy_Body_base_types_-_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	50-<75%
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	1-<2.5%

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CAS: 8007-18-9 EINECS: 232-353-3	antimony nickel titanium oxide yellow	1-<2.5%

· **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.

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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
8007-18-9 antimony nickel titanium oxide yellow	
WES (New Zealand)	Long-term value: 0.02 0.005* mg/m³ sen, suspected carc.; as Ni; *respirable dust
BOELV (European Union)	Long-term value: 0.1* mg/m³ as Ni; sens. dermal/resp. *inhalable

· **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.
· **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.

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· ***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.*
· ***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*

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· **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**

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

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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)

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