

## Safety Data Sheet according to WHS Regulations

Printing date 04.08.2021

Version number 1

Revision: 04.08.2021

Hazardous according to criteria of Australian Safety and Compensation Council.

### 1 Identification

- **Product identifier**
- **Trade name:** EXAHIFLEX Injection Type (base)
- **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**  
Skin Irrit. 2 H315 Causes skin irritation.  
Eye Irrit. 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 skin irritation.  
Causes serious eye irritation.
- **Precautionary statements**  
Wash thoroughly after handling.  
Wear protective gloves / 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 skin irritation occurs: Get medical advice/attention.  
Take off contaminated clothing and wash it before reuse.

(Contd. on page 2)

# Safety Data Sheet

## according to WHS Regulations

Printing date 04.08.2021

Version number 1

Revision: 04.08.2021

**Trade name: EXAHIFLEX Injection Type (base)**

(Contd. of page 1)

If eye irritation persists: Get medical advice/attention.

- **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 STOT RE 1, H372	25-<50%
9016-45-9	Nonylphenol, ethoxylated Skin Irrit. 2, H315; Eye Irrit. 2A, H319	10-<25%
68037-59-2	Methylhydrogen dimethylpolysiloxane Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335	2.5-<5%

- **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:**  
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:**  
Immediately wash with water and soap and rinse thoroughly.  
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.

AU

(Contd. on page 3)

## Safety Data Sheet according to WHS Regulations

Printing date 04.08.2021

Version number 1

Revision: 04.08.2021

Trade name: EXAHIFLEX Injection Type (base)

(Contd. of page 2)

### 5 Fire Fighting Measures

- **Extinguishing media**
- **Suitable extinguishing agents:**  
CO<sub>2</sub>, 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 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.
- **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.

AU

(Contd. on page 4)

## Safety Data Sheet according to WHS Regulations

Printing date 04.08.2021

Version number 1

Revision: 04.08.2021

Trade name: EXAHIFLEX Injection Type (base)

(Contd. of page 3)

### 8 Exposure controls and 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 Long-term value: 0.1 mg/m<sup>3</sup>  
respirable dust

WES Long-term value: 0.05 mg/m<sup>3</sup>  
respirable dust

· **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.

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

### 9 Physical and Chemical Properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form: Pasty

Colour: Brown

· **Odour:** Odourless

· **Odour threshold:** Not determined.

(Contd. on page 5)

## Safety Data Sheet

### according to WHS Regulations

Printing date 04.08.2021

Version number 1

Revision: 04.08.2021

Trade name: EXAHIFLEX Injection Type (base)

(Contd. of page 4)

· <b>pH-value:</b>	Not determined.
· <b>Change in condition</b>	
Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	Undetermined.
· <b>Flash point:</b>	Not applicable.
· <b>Flammability (solid, gas):</b>	Not applicable.
· <b>Ignition temperature:</b>	Undetermined.
· <b>Decomposition temperature:</b>	Not determined.
· <b>Auto-ignition temperature:</b>	Product is not selfigniting.
· <b>Explosive properties:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
Lower:	Not determined.
Upper:	Not determined.
· <b>Vapour pressure:</b>	Not determined.
· <b>Density:</b>	Not determined. 2,56 g/cm <sup>3</sup> 1,18g/ml
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with water:</b>	Insoluble.
· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
· <b>Viscosity:</b>	
Dynamic:	Not determined.
Kinematic:	Not determined.
· <b>Solvent content:</b>	
VOC (EC)	0.0 g/l
· <b>Other information</b>	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.

-AU-

(Contd. on page 6)

# Safety Data Sheet

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Version number 1

Revision: 04.08.2021

Trade name: EXAHIFLEX Injection Type (base)

(Contd. of page 5)

### 11 Toxicological Information

- **Information on toxicological effects**
- **Acute toxicity**
- **LD/LC50 values relevant for classification:** No further relevant information available.
- **Primary irritant effect:**
- **Skin corrosion/irritation** Irritant to skin and mucous membranes.
- **Serious eye damage/irritation** Irritating effect.
- **Additional toxicological information:**  
The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:  
Irritant
- **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:**  
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

(Contd. on page 7)

-AU-

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Revision: 04.08.2021

Trade name: EXAHIFLEX Injection Type (base)

(Contd. of page 6)

· <b>UN proper shipping name</b>	
· <b>ADG, ADN, IMDG, IATA</b>	not regulated
· <b>Transport hazard class(es)</b>	
· <b>ADG, ADN, IMDG, IATA</b>	
· <b>Class</b>	not regulated
· <b>Packing group</b>	
· <b>ADG, IMDG, IATA</b>	not regulated
· <b>Environmental hazards:</b>	
· <b>Marine pollutant:</b>	No
· <b>Special precautions for user</b>	Not applicable.
· <b>Transport in bulk according to Annex II of Marpol and the IBC Code</b>	Not applicable.
· <b>UN "Model Regulation":</b>	not regulated

### 15 Regulatory information

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

· **Australian Inventory of Chemical Substances**

68083-19-2	Vinyldimethylpolysiloxane
9016-45-9	Nonylphenol, ethoxylated
68037-59-2	Methylhydrogen dimethylpolysiloxane
1309-37-1	Iron(III)oxide
40716-47-0	4,5,6,7-tetrachloro-3-[[[3-methyl-4-[[[4-[(4,5,6,7-tetrachloro-1-oxo-1H-isoindol-3-yl)amino]phenyl]azo]phenyl]amino]-1H-isoindol-1-one

· **Standard for the Uniform Scheduling of Medicines and Poisons**

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 skin irritation.

Causes serious eye irritation.

· **Precautionary statements**

Wash thoroughly after handling.

Wear protective gloves / 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 skin irritation occurs: Get medical advice/attention.

Take off contaminated clothing and wash it before reuse.

(Contd. on page 8)

AU

## Safety Data Sheet

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Version number 1

Revision: 04.08.2021

**Trade name: EXAHIFLEX Injection Type (base)**

(Contd. of page 7)

*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**

- 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 européen sur le transport 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 Irrit. 2: Skin corrosion/irritation – Category 2*
- Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A*
- STOT SE 3: Specific target organ toxicity (single exposure) – Category 3*
- STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1*

### · **Sources**

- ECHA (<http://echa.europa.eu/>)
- EnviChem ([www.echemportal.org](http://www.echemportal.org))

### · **\* Data compared to the previous version altered.**

*This version replaces all previous versions.*

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