

## **Safety Data Sheet according to WHS Regulations**

Printing date 08.01.2020

Version number 4

Revision: 08.01.2020

Not classified as hazardous according to criteria of Australian Safety and Compensation Council.

### **1 Identification**

- **Product identifier**
- **Trade name:** GC Reline (Extra) Soft 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**  
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 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:**

112926-00-8	silicon dioxide, amorphous
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25-<50%
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68037-59-2	Methylhydrogen dimethylpolysiloxane [Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335]	5-<10%

**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:**
  - 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

- **Extinguishing media**
- **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.
- **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.
- **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.

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See Section 13 for disposal information.

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### 7 Handling and Storage

- **Handling:**
- **Precautions for safe handling** No special precautions are necessary if used correctly.
- **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.

### 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:**

**112926-00-8 silicon dioxide, amorphous**

WES | Long-term value: 10 mg/m<sup>3</sup>

- **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.

Wash hands before breaks and at the end of work.

- **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

### 9 Physical and Chemical Properties

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

- **General Information**

- **Appearance:**

**Form:**

Pasty

**Colour:**

Pink

**Odour:**

Odourless

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· <b>Odour threshold:</b>	Not determined.
· <b>pH-value:</b>	Not determined.
· <b>Change in condition</b>	
<b>Melting point/freezing point:</b>	Undetermined.
<b>Initial boiling point and boiling range:</b>	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>	
<b>Lower:</b>	Not determined.
<b>Upper:</b>	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>	
<b>Dynamic:</b>	Not determined.
<b>Kinematic:</b>	Not determined.
· <b>Solvent content:</b>	
<b>VOC (EC)</b>	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.

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### 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** No irritant effect.
- **Serious eye damage/irritation** No irritating effect.
- **Respiratory or skin sensitisation** No sensitising effects known.
- **Additional toxicological information:**  
The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.
- **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:**  
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

· <b>UN-Number</b>	
· <b>ADG, ADN, IMDG, IATA</b>	not regulated
· <b>UN proper shipping name</b>	
· <b>ADG, ADN, IMDG, IATA</b>	not regulated

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

## 15 Regulatory information

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

· **Australian Inventory of Chemical Substances**

68083-19-2	Vinyldimethylpolysiloxane
68037-59-2	Methylhydrogen dimethylpolysiloxane
1309-37-1	Iron(III)oxide

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

None of the ingredients is listed.

· **Australia: Priority Existing Chemicals**

None of the ingredients is listed.

· **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.

· **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

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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

**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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