



**Safety Data Sheet
according to WHS Regulations**

Printing date 06.03.2023

Version number 6

Revision: 06.03.2023

Hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

· **Product identifier**

· **Trade name:** **Memoreg 2 Base**

· **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.

· **Application of the substance / the mixture** Dental impression material

· **Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**

Kulzer Australia Pty Ltd
Unit 20, 53 Lorraine St
PEAKHURST NSW 2210
Australia

Tel: +61 (02) 9153 0311

· **Informing department:** see above

· **Emergency telephone number:**

Poison Information Number: Australia 13 11 26 & New Zealand 0800 764 766

2 Hazard(s) Identification

· **Classification of the substance or mixture**

STOT RE 1 H372 Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.

· **Additional information:**

Since the product is a medical device in the sense of Directive 93/42/EEC (MDD) or the Regulation (EU) 2017/745 (MDR), that is intended for the end user and is used invasively or with physical contact, it is exempted from the classification and labeling obligation according to Regulation (EC) 1272/2008.

· **Label elements**

· **GHS label elements**

The product is classified and labelled according to the Globally Harmonised System (GHS).

· **Hazard pictograms**



GHS08

· **Signal word** Danger

· **Hazard-determining components of labelling:**

cristobalite

· **Hazard statements**

Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.

· **Precautionary statements**

Do not breathe dust.

Wash thoroughly after handling.

Avoid release to the environment.

Wear protective gloves / eye protection.

Wear protective clothing.

Get medical advice/attention if you feel unwell.

· **Additional information:** see 2.1

· **Other hazards** -

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- **Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.

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3 Composition and Information on Ingredients

- **Chemical characterisation: Mixtures**
 - **Description:** -

- **Dangerous components:**

14464-46-1 cristobalite

STOT RE 1, H372

50-75%

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

4 First Aid Measures

- **Description of first aid measures**
 - **After inhalation** Supply fresh air; consult doctor in case of symptoms.
 - **After skin contact** If skin irritation continues, consult a doctor.
 - **After eye contact**
Rinse opened eye for several minutes under running water. Then consult doctor.
 - **After swallowing**
Rinse out mouth and then drink plenty of water.
In case of persistent symptoms 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, extinguishing powder or water jet. Fight larger fires with water jet or alcohol-resistant foam.
Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
 - **Protective equipment:** No special measures required.
- **Additional information** -

6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures**
Avoid contact with eyes and skin.
- **Environmental precautions:** Prevent material from reaching sewage system, holes and cellars.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).
- **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 information on disposal.

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7 Handling and Storage

- **Handling**
 - **Precautions for safe handling**
Store in cool, dry place in tightly closed containers.
No special precautions necessary if used correctly.
 - **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
 - **Storage**
 - **Requirements to be met by storerooms and containers:** No special requirements.
 - **Information about storage in one common storage facility:** Not required.
 - **Further information about storage conditions:** None.
 - **Specific end use(s)** No further relevant information available.

8 Exposure controls and personal protection

- **Control parameters**

- **Components with critical values that require monitoring at the workplace:**

14464-46-1 cristobalite

WES	Long-term value: 0.05 mg/m ³ respirable dust
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- **Additional information:** The lists that were valid during the compilation were used as basis.

- **Exposure controls**

- **Personal protective equipment**

- **General protective and hygienic measures**

- Wash hands during breaks and at the end of the work.

- **Breathing equipment:** Not required.

- **Protection of hands:**

- Check protective gloves prior to each use for their proper condition.
recommended

- **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.

- **For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:**

- Butyl rubber, BR

- Nitrile rubber, NBR

- **Eye protection:** Safety glasses

- **Body protection:** Light weight protective clothing

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9 Physical and Chemical Properties**· Information on basic physical and chemical properties****· General Information****· Appearance:**

· Form:	Pasty
· Colour:	Pink
· Smell:	Characteristic
· Odour threshold:	Not determined.

· pH-value: Not determined.**· Change in condition**

· Melting point/freezing point:	Not determined
· Initial boiling point and boiling range:	>300 °C

· Flash point: >130 °C**· Inflammability (solid, gaseous)** Not applicable.**· Decomposition temperature:** Not determined.**· Self-inflammability:** Product is not selfigniting.**· Explosive properties:** Product is not explosive.
Not determined.**· Critical values for explosion:**

· Lower:	Not determined.
· Upper:	Not determined.

· Steam pressure at 1732 °C: 13.5 hPa**· Density** Not determined

· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.

· Solubility in / Miscibility with**· Water:** Not miscible or difficult to mix**· Partition coefficient: n-octanol/water:** Not determined.**· Viscosity:**

· dynamic:	Not determined.
· kinematic:	Not determined.

· Other information No further relevant information available.**10 Stability and Reactivity****· Reactivity** No further relevant information available.**· Chemical stability**

- **Conditions to be avoided:** No decomposition if used and stored 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:** None
- **Additional information:** -

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11 Toxicological Information

- **Information on toxicological effects**
 - **Acute toxicity**
 - **Primary irritant effect:**
 - **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
 - **Respiratory or skin sensitisation** No sensitizing effect known.
 - **Additional toxicological information:**
 - **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
 - **Reproductive toxicity** Based on available data, the classification criteria are not met.

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:** Not known to be hazardous to water.
- **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 of together with household garbage. Do not allow product to reach sewage system.
Disposal must be made according to official regulations.
- **Uncleaned packagings:**
 - **Recommendation:**
Disposal must be made according to official regulations.
Non contaminated packagings can be used for recycling.

14 Transport information

- | | |
|----------------------------------------------------------------------------------------|------|
| · UN-Number
· ADG, IMDG, IATA | Void |
| · UN proper shipping name
· ADG, IMDG, IATA | Void |
| · Transport hazard class(es)
· ADG, ADN, IMDG, IATA
· Class | Void |
| · Packing group
· ADG, IMDG, IATA | Void |

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- | | |
|-----------------------------------------------------------------------------|-----------------|
| · 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. |
| · Transport/Additional information: | - |
| · UN "Model Regulation": | Void |

15 Regulatory information

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

· **Australian Inventory of Industrial Chemicals**

14464-46-1	cristobalite
68909-20-6	hochdisperse Kieselsäure
1047-16-1	C.I. Pigment violet 19
556-67-2	octamethylcyclotetrasiloxane
540-97-6	Dodecamethylcyclohexasiloxane

· **Australia: Priority Existing Chemicals**

None of the ingredients is listed.

· **Directive 2012/18/EU**

-
- Named dangerous substances - ANNEX I**
- None of the ingredients is listed.

· **National regulations**

The product is subject to classification in accordance with the prevailing version of the regulations on hazardous materials.

· **Other regulations, limitations and prohibitive regulations**· **AICS - Australian Inventory of Chemical Substances**

14464-46-1	cristobalite
68909-20-6	hochdisperse Kieselsäure
556-67-2	octamethylcyclotetrasiloxane
540-97-6	Dodecamethylcyclohexasiloxane

-
- Chemical safety assessment:**
- A Chemical Safety Assessment has not been carried out.

16 Other information

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Relevant phrases**

H372 Causes damage to organs through prolonged or repeated exposure.

· **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)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative

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STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1
· *** Data compared to the previous version altered.**

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