



**Safety Data Sheet
according to WHS Regulations**

Printing date 22.11.2022

Version number 4

Revision: 22.11.2022

Hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

· **Product identifier**

· **Trade name: Pala Lab Putty 90 Base**

· **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 manufacture of dental prothesis

· **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.

· **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:**

crystalite
Quartz (SiO₂)

· **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.
Get medical advice/attention if you feel unwell.

· **Other hazards -**

· **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%
14808-60-7	Quartz (SiO ₂)	STOT RE 1, H372	10-25%

· **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.

· **After inhalation** Supply fresh air; consult doctor in case of symptoms.

· **After skin contact**

Instantly wash with water and soap and rinse thoroughly.

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**

Formation of toxic gases is possible during heating or in case of fire.

· **Advice for firefighters**

· **Protective equipment:** No special measures required.

· **Additional information** -

6 Accidental Release Measures

· **Personal precautions, protective equipment and emergency procedures**

Wear protective equipment. Keep unprotected persons away.

Avoid contact with eyes and skin.

· **Environmental precautions:**

Do not allow to enter drainage system, surface or ground water.

Do not allow to enter the ground/soil.

· **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

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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**
Wear protective equipment. Keep unprotected persons away.
Ensure good ventilation/exhaustion at the workplace.
Provide suction extractors if dust is formed.
 - **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 (Australia)	Long-term value: 0.05 mg/m ³ respirable dust
PEL (USA)	Long-term value: 0.05* mg/m ³ *resp. dust; ½ value from resp.dust formulae Quartz
REL (USA)	Long-term value: 0.05* mg/m ³ *respirable dust; See Pocket Guide App. A
TLV (USA)	Long-term value: 0.025* mg/m ³ *as respirable fraction

· **DNELs**

556-67-2 octamethylcyclotetrasiloxane

Oral	general population, long term, systemic	3.7 mg/Kg (not defined)
Inhalative	worker industrial, long term, systemic	73 mg/m ³ (not defined)
	worker industrial, long term, local	73 mg/m ³ (not defined)
	general population, long term, systemic	13 mg/m ³ (not defined)
	general population, long term, local	13 mg/m ³ (not defined)

· **PNECs**

556-67-2 octamethylcyclotetrasiloxane

freshwater	0.0015 mg/l (not defined)
marine water	0.00015 mg/l (not defined)
sewage treatment plant	10 mg/l (not defined)
sediment, dry weight, freshwater	3 mg/Kg (not defined)
sediment, dry weight, marine water	0.3 mg/Kg (not defined)

· **Additional information:** The lists that were valid during the compilation were used as basis.

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- **Exposure controls**
 - **Personal protective equipment**
 - **General protective and hygienic measures**
The usual precautionary measures should be adhered to in handling the chemicals.
 - **Breathing equipment:** Filter P3.
 - **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

9 Physical and Chemical Properties

- **Information on basic physical and chemical properties**
 - **General Information**
 - **Appearance:**
 - **Form:** Pasty
 - **Colour:** Blue
 - **Smell:** Recognisable
 - **Odour threshold:** Not determined.
 - **pH-value:** Not determined.
 - **Change in condition**
 - **Melting point/freezing point:** Not determined
 - **Initial boiling point and boiling range:** 2230 °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.
 - **Critical values for explosion:**
 - **Lower:** Not determined.
 - **Upper:** Not determined.
 - **Steam pressure:** Not determined.
 - **Density at 20 °C** 1.77 g/cm³
 - **Relative density** Not determined.
 - **Vapour density** Not determined.

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

11 Toxicological Information

- **Information on toxicological effects**
 - **Acute toxicity**

· LD/LC50 values that are relevant for classification:		
68083-19-2 Silopren U 1 dental		
Oral	LD50	>5,000 mg/kg (rat)
1317-65-3 calcium carbonate		
Oral	LD50	>2,000 mg/kg (rat) (OECD 420)
Dermal	LD50	>2,000 mg/kg (rat) (OECD 402)
Inhalative	LC0/4h	>3 mg/L (rat) (OECD 403)
556-67-2 octamethylcyclotetrasiloxane		
Oral	LD50	>4,800 mg/kg (rat) (OECD 401)
Dermal	LD50	>2,375 mg/kg (rat) (OECD 402)
Inhalative	LC50/4 h	36 mg/l (rat) (OECD 403)

- **Primary irritant effect:**
 - **Skin corrosion/irritation** No irritant effect.
 - **Serious eye damage/irritation** No irritant effect.
 - **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.

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12 Ecological Information

· Toxicity

· Aquatic toxicity:

1317-65-3 calcium carbonate

EC50/72h	>200 mg/l (algae)
EC50/48h	>1,000 mg/l (daphnia)
LC50/96h	>10,000 mg/l (fish)
ErC50 / 72 h	>14 mg/l (algae) (OECD 201)
NOEC / 72h	14 mg/l (algae) (OECD 201)
ErC10/72h	>14 mg/L (algae) (OECD 201)

556-67-2 octamethylcyclotetrasiloxane

EC50/21d	>0.015 mg/L (daphnia) (EPA OTS 797.1330)
EC50/48h	>0.015 mg/l (daphnia) (EPA OTS 797.1300)
LC50/96h	>0.022 mg/l (fish) (EPA OTS 797.1400)
NOEC / 91d	≥0.0044 mg/l (fish)
NOEC / 21d	≥0.015 mg/l (daphnia) (EPA OTS 797.1330)
NOEC / 96h	<0.022 mg/l (algae) (EPA OTS 797.1050)
	≥0.022 mg/l (fish) (EPA OTS 797.1400)
NOEC / 48h	≥0.015 mg/l (daphnia) (EPA OTS 797.1300)
ErC50/ 96h	>0.022 mg/L (algae) (EPA OTS 797.1050)

· Persistence and degradability

556-67-2 octamethylcyclotetrasiloxane

Biodegradation	3.7 % /29d (not defined) (OECD 310)
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· Behaviour in environmental systems:

· Bioaccumulative potential

556-67-2 octamethylcyclotetrasiloxane

Bloconcentration factor (BCF)	12,400 (not defined)
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· Mobility in soil No further relevant information available.

· Additional ecological information:

- **General notes:** Avoid transfer into the environment.
- **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

Disposal must be made according to official regulations.
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

· Uncleaned packagings:

· Recommendation:

Disposal must be made according to official regulations.

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Non contaminated packagings can be used for recycling.

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14 Transport information

· UN-Number · ADG, ADN, IMDG, IATA	Void
· UN proper shipping name · ADG, ADN, IMDG, IATA	Void
· Transport hazard class(es) · ADG, ADN, IMDG, IATA · Class	Void
· Packing group · ADG, IMDG, IATA	Void
· Environmental hazards: · Marine pollutant:	No
· 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**
No further relevant information available.

· Australian Inventory of Industrial Chemicals	
14464-46-1	crystalobalite
14808-60-7	Quartz (SiO ₂)
68083-19-2	Silopren U 1 dental
1317-65-3	calcium carbonate
8042-47-5	White mineral oil, petroleum
540-97-6	Dodecamethylcyclohexasiloxane
541-02-6	Decamethylcyclopentasiloxane
556-67-2	octamethylcyclotetrasiloxane
2082-79-3	n-octadecyl 3-(4'-hydroxy-3',5'-di-t-butylphenyl) propionate

· **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.

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· **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)

DNEL: Derived No-Effect Level (REACH)

PNEC: Predicted No-Effect Concentration (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1

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

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