



**Safety data sheet  
according to 1907/2006/EC, Article 31**

Printing date 22.11.2022

Version number 4 (replaces version 3)

Revision: 22.11.2022

**SECTION 1: Identification of the substance/mixture and of the company/undertaking**

- **1.1 Product identifier**
  - Trade name: **Pala Lab Putty 90 Cat**
- **1.2 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
- **1.3 Details of the supplier of the safety data sheet**
  - **Manufacturer/Supplier:**  
Kulzer GmbH  
Leipziger Straße 2, 63450 Hanau (Germany) Tel.: +49 (0)800 4372522
  - **Informing department:** E-Mail: [msds@kulzer-dental.com](mailto:msds@kulzer-dental.com)
- **1.4 Emergency telephone number:** Emergency CONTACT (24-Hour-Number): +49 (0)6132-84463

**SECTION 2: Hazards identification**

- **2.1 Classification of the substance or mixture**
    - **Classification according to Regulation (EC) No 1272/2008**  
STOT RE 1 H372 Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.
  - **2.2 Label elements**
    - **Labelling according to Regulation (EC) No 1272/2008**

The product is classified and labelled according to the GB CLP regulation.

      - **Hazard pictograms**
- 

GHS08
- **Signal word** Danger
  - **Hazard-determining components of labelling:**  
cristobalite  
Quartz (SiO<sub>2</sub>)
  - **Hazard statements**  
H372 Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.
  - **Precautionary statements**  
P260 Do not breathe dust.  
P264 Wash thoroughly after handling.  
P314 Get medical advice/attention if you feel unwell.
- **2.3 Other hazards -**
    - **Results of PBT and vPvB assessment**
      - **PBT:** Not applicable.
      - **vPvB:** Not applicable.

**SECTION 3: Composition/information on ingredients**

- **3.2 Mixtures**
  - **Description:** -

(Contd. on page 2)

GB



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(Contd. of page 1)

**· Dangerous components:**

CAS: 14464-46-1 EINECS: 238-455-4	cristobalite	STOT RE 1, H372	≥25-≤50%
CAS: 14808-60-7 EINECS: 238-878-4	Quartz (SiO <sub>2</sub> )	STOT RE 1, H372	10-25%

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

**SECTION 4: First aid measures**

- **4.1 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.
- **4.2 Most important symptoms and effects, both acute and delayed**  
No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

**SECTION 5: Firefighting measures**

- **5.1 Extinguishing media**
  - **Suitable extinguishing agents**  
CO<sub>2</sub>, extinguishing powder or water jet. Fight larger fires with water jet or alcohol-resistant foam.  
Use fire fighting measures that suit the environment.
- **5.2 Special hazards arising from the substance or mixture**  
Formation of toxic gases is possible during heating or in case of fire.
- **5.3 Advice for firefighters**
  - **Protective equipment:** No special measures required.
  - **Additional information** -

**SECTION 6: Accidental release measures**

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Wear protective equipment. Keep unprotected persons away.  
Avoid contact with eyes and skin.
- **6.2 Environmental precautions:**  
Do not allow to enter drainage system, surface or ground water.  
Do not allow to enter the ground/soil.
- **6.3 Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).
- **6.4 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.

(Contd. on page 3)



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(Contd. of page 2)

**SECTION 7: Handling and storage**

- **7.1 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.
- **7.2 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.
- **7.3 Specific end use(s)** No further relevant information available.

**SECTION 8: Exposure controls/personal protection**

- **8.1 Control parameters**
  - **Components with critical values that require monitoring at the workplace:**  
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.  
Not required.

· **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 <sup>3</sup> (not defined)
	worker industrial, long term, local	73 mg/m <sup>3</sup> (not defined)
	general population, long term, systemic	13 mg/m <sup>3</sup> (not defined)
	general population, long term, local	13 mg/m <sup>3</sup> (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.

- **8.2 Exposure controls**
  - **Individual protection measures, such as personal protective equipment**
    - **General protective and hygienic measures**  
The usual precautionary measures should be adhered to in handling the chemicals.
    - **Breathing equipment:** Filter P3.
    - **Hand protection**  
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

(Contd. on page 4)



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Version number 4 (replaces version 3)

Revision: 22.11.2022

**Trade name: Pala Lab Putty 90 Cat**

(Contd. of page 3)

- 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/face protection** Safety glasses
- **Body protection:** Light weight protective clothing

**SECTION 9: Physical and chemical properties**

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

· **General Information**

- **Physical state** Fluid
- **Colour:** Grey
- **Smell:** Recognisable
  - **Odour threshold:** Not determined.
- **Melting point/freezing point:** Not determined
- **Boiling point or initial boiling point and boiling range** 2230 °C
- **Flammability** Not applicable.
- **Lower and upper explosion limit**
  - **Lower:** Not determined.
  - **Upper:** Not determined.
- **Flash point:** >130 °C
- **Decomposition temperature:** Not determined.
- **SADT** Not determined.
- **pH** Not determined.
- **Viscosity:**
  - **Kinematic viscosity** Not determined.
  - **dynamic:** Not determined.
- **Solubility**
  - **Water:** Not miscible or difficult to mix
- **Partition coefficient n-octanol/water (log value)** Not determined.
- **Steam pressure:** Not determined.
- **Density and/or relative density**
  - **Density at 20 °C** 1.77 g/cm<sup>3</sup>
  - **Relative density** Not determined.
  - **Vapour density** Not determined.

· **9.2 Other information**

No further relevant information available.

- **Appearance:**
  - **Form:** Pasty
- **Important information on protection of health and environment, and on safety.**
  - **Self-inflammability:** Product is not selfigniting.
  - **Explosive properties:** Product is not explosive.
- **Change in condition**
  - **Evaporation rate** Not determined.

(Contd. on page 5)



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Version number 4 (replaces version 3)

Revision: 22.11.2022

**Trade name: Pala Lab Putty 90 Cat**

(Contd. of page 4)

**Information with regard to physical hazard classes**

· <b>Explosives</b>	Void
· <b>Flammable gases</b>	Void
· <b>Aerosols</b>	Void
· <b>Oxidising gases</b>	Void
· <b>Gases under pressure</b>	Void
· <b>Flammable liquids</b>	Void
· <b>Flammable solids</b>	Void
· <b>Self-reactive substances and mixtures</b>	Void
· <b>Pyrophoric liquids</b>	Void
· <b>Pyrophoric solids</b>	Void
· <b>Self-heating substances and mixtures</b>	Void
· <b>Substances and mixtures, which emit flammable gases in contact with water</b>	Void
· <b>Oxidising liquids</b>	Void
· <b>Oxidising solids</b>	Void
· <b>Organic peroxides</b>	Void
· <b>Corrosive to metals</b>	Void
· <b>Desensitised explosives</b>	Void

**SECTION 10: Stability and reactivity**

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
  - **Conditions to be avoided:** No decomposition if used and stored according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** None
  - **Additional information:** -

**SECTION 11: Toxicological information**

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
  - **Acute toxicity** Based on available data, the classification criteria are not met.

**LD/LC50 values that are relevant for classification:**

**68083-19-2 Silopren U 1 dental**

Oral	LD50	>5,000 mg/kg (rat)
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**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)

**8042-47-5 White mineral oil, petroleum**

Oral	LD50	>5,000 mg/kg (rat) (OECD 401)
Dermal	LD50	>2,000 mg/kg (rabbit) (OECD 402)
Inhalative	LC0/4h	≥5 mg/L (rat) (OECD 403)

**556-67-2 octamethylcyclotetrasiloxane**

Oral	LD50	>4,800 mg/kg (rat) (OECD 401)
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(Contd. on page 6)



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Version number 4 (replaces version 3)

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**Trade name: Pala Lab Putty 90 Cat**

(Contd. of page 5)

Dermal	LD50	>2,375 mg/kg (rat) (OECD 402)
Inhalative	LC50/4 h	36 mg/l (rat) (OECD 403)

- **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**  
Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

**11.2 Information on other hazards**

- **Endocrine disrupting properties**

None of the ingredients is listed.

**SECTION 12: Ecological information**

**12.1 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)

**8042-47-5 White mineral oil, petroleum**

LL50/96h	>100 mg/L (fish) (OECD 203)
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**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)

**12.2 Persistence and degradability**

**556-67-2 octamethylcyclotetrasiloxane**

Biodegradation	3.7 % /29d (not defined) (OECD 310)
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**12.3 Bioaccumulative potential**

**556-67-2 octamethylcyclotetrasiloxane**

Bloconcentration factor (BCF)	12,400 (not defined)
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(Contd. on page 7)



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(Contd. of page 6)

- **12.4 Mobility in soil** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**
  - **PBT:** Not applicable.
  - **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**  
For information on endocrine disrupting properties see section 11.
- **12.7 Other adverse effects**
  - **Additional ecological information:**
    - **General notes:** Avoid transfer into the environment.

**SECTION 13: Disposal considerations**

- **13.1 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.  
Non contaminated packagings can be used for recycling.

**SECTION 14: Transport information**

- |   |                 |
|---|-----------------|
| · <b>14.1 UN number or ID number</b><br>· <b>ADR, ADN, IMDG, IATA</b>                       | Void            |
| · <b>14.2 UN proper shipping name</b><br>· <b>ADR, ADN, IMDG, IATA</b>                      | Void            |
| · <b>14.3 Transport hazard class(es)</b><br>· <b>ADR, ADN, IMDG, IATA</b><br>· <b>Class</b> | Void            |
| · <b>14.4 Packing group</b><br>· <b>ADR, IMDG, IATA</b>                                     | Void            |
| · <b>14.5 Environmental hazards:</b><br>· <b>Marine pollutant:</b>                          | No              |
| · <b>14.6 Special precautions for user</b>  | Not applicable. |
| · <b>14.7 Maritime transport in bulk according to IMO instruments</b>                       | Not applicable. |
| · <b>Transport/Additional information:</b>  | -               |
| · <b>UN "Model Regulation":</b>   | Void            |

**SECTION 15: Regulatory information**

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**  
No further relevant information available.

(Contd. on page 8)



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· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out. (Contd. of page 7)

**SECTION 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:**

SADT: Self Accelerating Decomposition Temperature

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

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

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 (UK REACH)

PNEC: Predicted No-Effect Concentration (UK 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.**