



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

Printing date 08.03.2023

Version number 4 (replaces version 3)

Revision: 08.03.2023


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

- **1.1 Product identifier**
 - Trade name: **Pala Lab Putty 65 Base**
- **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
- **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 CLP regulation.
 - **Hazard pictograms**
- 

GHS08
- **Signal word** Danger
 - **Hazard-determining components of labelling:**
cristobalite
 - **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:** -

· **Dangerous components:**

CAS: 14464-46-1	cristobalite	STOT RE 1, H372	≥50-≤75%
EINECS: 238-455-4			

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· **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.
 - **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**
CO₂, 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**
No further relevant information available.
- **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.
-

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.

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- **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:**

14464-46-1 cristobalite

OEL (Ireland) Long-term value: 0.1 mg/m³

· **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.

· **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 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

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- 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:** Pink
- **Smell:** Recognisable
 - **Odour threshold:** Not determined.
- **Melting point/freezing point:** Not determined
- **Boiling point or initial boiling point and boiling range** 300 °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** 1.57 g/cm³
 - **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.

· **Information with regard to physical hazard classes**

- **Explosives** Void
- **Flammable gases** Void
- **Aerosols** Void
- **Oxidising gases** Void
- **Gases under pressure** Void
- **Flammable liquids** Void

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· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	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:**

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)
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.

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· **11.2 Information on other hazards**

· **Endocrine disrupting properties**

None of the ingredients is listed.

SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**

8042-47-5 White mineral oil, petroleum

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

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)

· **12.3 Bioaccumulative potential**

556-67-2 octamethylcyclotetrasiloxane

Bloconcentration factor (BCF) 12,400 (not defined)

· **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.

· **European waste catalogue**

18 01 06* chemicals consisting of or containing hazardous substances

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- **Uncleaned packagings:**
- **Recommendation:**
Disposal must be made according to official regulations.
Non contaminated packagings can be used for recycling.

SECTION 14: Transport information

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

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
No further relevant information available.
 - **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3, 70
 - **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**
None of the ingredients is listed.
 - **REGULATION (EU) 2019/1148**
 - **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**
no information available
 - **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**
no information available
 - **Regulation (EC) No 273/2004 on drug precursors**
None of the ingredients is listed.
 - **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**
None of the ingredients is listed.

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

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.

· **Date of previous version:** 22.11.2022

· **Version number of previous version:** 3

· **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 (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.**