



**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 65 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
- **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			

(Contd. on page 2)



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Trade name: Pala Lab Putty 65 Cat

(Contd. of page 1)
· **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**
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.
-

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.

(Contd. on page 3)



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Revision: 22.11.2022

Trade name: Pala Lab Putty 65 Cat

(Contd. of page 2)

- **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

(Contd. on page 4)



**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

Trade name: Pala Lab Putty 65 Cat

(Contd. of page 3)

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** 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

(Contd. on page 5)



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

Trade name: Pala Lab Putty 65 Cat

(Contd. of page 4)

· 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.

(Contd. on page 6)



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Version number 4 (replaces version 3)

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Trade name: Pala Lab Putty 65 Cat

(Contd. of page 5)

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

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.

European waste catalogue

18 01 06* chemicals consisting of or containing hazardous substances

(Contd. on page 7)



**Safety data sheet
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Trade name: Pala Lab Putty 65 Cat

(Contd. of page 6)

- **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.

(Contd. on page 8)



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Trade name: Pala Lab Putty 65 Cat

(Contd. of page 7)

· **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.

· **REGULATION (EC) No 1005/2009 on substances that deplete the ozone layer – ANNEX I (Ozone-depleting potential)**

· **Other regulations, limitations and prohibitive regulations**

· **Substances of very high concern (SVHC) according to REACH, Article 57**

556-67-2 octamethylcyclotetrasiloxane

· **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

SVHC: Substances of Very High Concern

vPvB: very Persistent and very Bioaccumulative

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

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