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

· **1.1 Product identifier**

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

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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
Quartz (SiO2)
· **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:** -

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· **Dangerous components:**			
CAS: 14464-46-1 EINECS: 238-455-4	cristobalite	STOT RE 1, H372	≥50-≤75%
CAS: 14808-60-7 EINECS: 238-878-4	Quartz (SiO2)	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**
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.

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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.

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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/m3 (not defined)
	worker industrial, long term, local	73 mg/m3 (not defined)
	general population, long term, systemic	13 mg/m3 (not defined)
	general population, long term, local	13 mg/m3 (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

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calculated in advance and has therefore to be checked prior to the application.

· ***Penetration time of glove material***
The exact break trough 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:***	*Blue*
· ***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***	
· ***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/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.*

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· **Information with regard to physical hazard classes**	
· **Explosives**	Void
· **Flammable gases**	Void
· **Aerosols**	Void
· **Oxidising gases**	Void
· **Gases under pressure**	Void
· **Flammable liquids**	Void
· **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:** -

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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)
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)

· **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.

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· **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.

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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)
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	
Bioconcentration 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.

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· **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

· **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

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· **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.

· **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.**