



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

Printing date 14.04.2020

Version number 4

Revision: 14.04.2020

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

- **1.1 Product identifier**
  - Trade name: **Optosil P Plus**
- **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** Dental impression material
- **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 organs through prolonged or repeated exposure.
  - **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**
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GHS08
- **Signal word** Danger
  - **Hazard-determining components of labelling:**  
Cristobalite
  - **Hazard statements**  
H372 Causes damage to organs through prolonged or repeated exposure.
  - **Precautionary statements**  
P260 Do not breathe dust/fume/gas/mist/vapours/spray.  
P264 Wash thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P314 Get medical advice/attention if you feel unwell.  
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
  - **2.3 Other hazards -**
    - **Results of PBT and vPvB assessment**
      - **PBT:** Not applicable.
      - **vPvB:** Not applicable.

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

- **3.2 Chemical characterisation: Mixtures**
  - **Description:** -

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**· Dangerous components:**

CAS: 14464-46-1	Cristobalite STOT RE 1, H372	25-50%
CAS: 540-97-6 EINECS: 208-762-8 Reg.nr.: 01-2119717435-42-xxxx	Dodecamethylcyclohexasiloxane Acute Tox. 4, H302; Acute Tox. 4, H312	<1%
CAS: 541-02-6	2,2,4,4,6,6,8,8,10,10-decamethylcyclopentasiloxane	<1%
CAS: 556-67-2 EINECS: 209-136-7 Reg.nr.: 2119529238-36-xxxx	octamethylcyclotetrasiloxane Flam. Liq. 3, H226 Repr. 2, H361f Aquatic Chronic 4, H413	<1%

**· SVHC**

540-97-6	Dodecamethylcyclohexasiloxane
541-02-6	2,2,4,4,6,6,8,8,10,10-decamethylcyclopentasiloxane
556-67-2	octamethylcyclotetrasiloxane

**· 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**

**· 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** 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.

**· 6.2 Environmental precautions:** Prevent material from reaching sewage system, holes and cellars.

**· 6.3 Methods and material for containment and cleaning up:**

Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).

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Send for recovery or disposal in suitable containers.

**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**

Please observe the additional instructions in the product's instructions for use.

· **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:**

**9005-25-8 Starch**

WEL (Great Britain)	Long-term value: 10* 4** mg/m <sup>3</sup> *total inhalable **respirable
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· **Additional information:** The lists that were valid during the compilation were used as basis.

**8.2 Exposure controls**

· **Personal protective equipment**

· **General protective and hygienic measures**

Wash hands during breaks and at the end of the work.

· **Breathing equipment:** Use breathing protection against the effects of fumes/dust/aerosol.

· **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

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· **Body protection:** Light weight protective clothing

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**SECTION 9: Physical and chemical properties**

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

· **General Information**

· **Appearance:**

- **Form:** Pasty
- **Colour:** Yellow
- **Smell:** Odourless
- **Odour threshold:** Not determined.

· **pH-value:** Not determined.

· **Change in condition**

- **Melting point/freezing point:** Not determined
- **Initial boiling point and boiling range:** Not determined

· **Flash point:** Not applicable

· **Inflammability (solid, gaseous)** Not applicable.

· **Decomposition temperature:** Not determined.

· **Self-inflammability:** Product is not selfigniting.

· **Explosive properties:** Product is not explosive.  
Not determined.

· **Critical values for explosion:**

- **Lower:** Not determined.
- **Upper:** Not determined.

· **Steam pressure:** Not determined.

- **Density at 20 °C** 1.5 g/cm<sup>3</sup>
- **Relative density** Not determined.
- **Vapour density** Not determined.
- **Evaporation rate** Not determined.

· **Solubility in / Miscibility with**

- **Water:** Not miscible or difficult to mix

· **Partition coefficient: n-octanol/water:** Not determined.

· **Viscosity:**

- **dynamic:** Not determined.
- **kinematic:** Not determined.

· **9.2 Other information** No further relevant information available.

**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

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· **Additional information:** -

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**SECTION 11: Toxicological information**

· **11.1 Information on toxicological effects**

· **Acute toxicity** Based on available data, the classification criteria are not met.

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

**540-97-6 Dodecamethylcyclohexasiloxane**

Oral	LD50	2,000 mg/kg (rat)
Dermal	LD50	2,000 mg/kg (rat)

**541-02-6 2,2,4,4,6,6,8,8,10,10-decamethylcyclopentasiloxane**

Dermal	LD50	>2,000 mg/kg (rab)
Inhalative	LC50/4 h	8.67 mg/l (rat) 8.67 mg/l (rabbit)

**556-67-2 octamethylcyclotetrasiloxane**

Oral	LD50	1,700 mg/kg (mouse) 4,800 mg/kg (rat)
Dermal	LD50	>2,400 mg/kg (rat)
Inhalative	LC50/4 h	36 mg/l (rat)

· **Primary irritant effect:**

· **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.

· **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**

· **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**

**540-97-6 Dodecamethylcyclohexasiloxane**

Oral	NOAEL(C)	1,000 mg/kg (rat)
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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 organs through prolonged or repeated exposure.

· **Aspiration hazard** Based on available data, the classification criteria are not met.

**SECTION 12: Ecological information**

· **12.1 Toxicity**

· **Aquatic toxicity:**

**540-97-6 Dodecamethylcyclohexasiloxane**

EC50/72h	>0.002 mg/l (algae) (OECD 201)
NOEC / 21d	0.0046 mg/l (daphnia)
NOEC / 72h	>0.002 mg/l (algae) (OECD 201)

**541-02-6 2,2,4,4,6,6,8,8,10,10-decamethylcyclopentasiloxane**

EC50/48h	>0.0029 mg/l (daphnia) (OECD 202)
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LC50/96h	>0.0016 mg/l (fish)
NOEC / 21d	>0.0015 mg/l (daphnia) (OECD 211)

**12.2 Persistence and degradability**

**541-02-6 2,2,4,4,6,6,8,8,10,10-decamethylcyclopentasiloxane**

Biodegradation 0.14 % (nd)

**556-67-2 octamethylcyclotetrasiloxane**

Biodegradation 3.7 % (nd)

**12.3 Bioaccumulative potential**

**541-02-6 2,2,4,4,6,6,8,8,10,10-decamethylcyclopentasiloxane**

Bioconcentration factor (BCF) 7,060 (fish)

**556-67-2 octamethylcyclotetrasiloxane**

Bioconcentration factor (BCF) 12.4 (fish)

**12.4 Mobility in soil** No further relevant information available.

**Additional ecological information:**

**General notes:** Not known to be hazardous to water.

**12.5 Results of PBT and vPvB assessment**

**PBT:** Not applicable.

**vPvB:** Not applicable.

**12.6 Other adverse effects** No further relevant information available.

**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 07 chemicals other than those mentioned in 18 01 06

**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**

**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

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· <b>14.5 Environmental hazards:</b>	Not applicable.
· <b>14.6 Special precautions for user</b>	Not applicable.
· <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</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**

· **Directive 2012/18/EU**

- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3

· **National regulations**

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

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

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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**

H226 Flammable liquid and vapour.

H302 Harmful if swallowed.

H312 Harmful in contact with skin.

H361f Suspected of damaging fertility.

H372 Causes damage to organs through prolonged or repeated exposure.

H413 May cause long lasting harmful effects to aquatic life.

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport 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)

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

Flam. Liq. 3: Flammable liquids – Category 3

Acute Tox. 4: Acute toxicity - oral – Category 4

Repr. 2: Reproductive toxicity – Category 2

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

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*Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4* (Contd. of page 7)  
· \* **Data compared to the previous version altered.**

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