



**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 Comfort**
- **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
- **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**

The product is not classified, according to the CLP regulation.
- **2.2 Label elements**
 - **Labelling according to Regulation (EC) No 1272/2008** Void
 - **Hazard pictograms** Void
 - **Signal word** Void
 - **Hazard statements** Void
 - **Precautionary statements**
P302+P350 IF ON SKIN: Gently wash with plenty of soap and water.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
 - **Additional information:**

Safety data sheet available on request.
- **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:** -

· Dangerous components:		
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: 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%
CAS: 541-02-6	2,2,4,4,6,6,8,8,10,10-decamethylcyclopentasiloxane	<1%
· SVHC		
540-97-6	Dodecamethylcyclohexasiloxane	
556-67-2	octamethylcyclotetrasiloxane	

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

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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.
 - **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**
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**
Avoid contact with eyes and skin.
Wear protective clothing.
- **6.2 Environmental precautions:** Prevent material from reaching sewage system, holes and cellars.
- **6.3 Methods and material for containment and cleaning up:**
Collect mechanically.
Send for recovery or disposal in suitable containers.
- **6.4 Reference to other sections**
No dangerous materials are released.
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**
No special measures required.
Please observe the additional instructions in the product's instructions for use.
 - **Information about protection against explosions and fires:** No special measures required.

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- **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

- **Additional information about design of technical systems:** No further data; see item 7.

· **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 ³ *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**
The usual precautionary measures should be adhered to in handling the chemicals.
 - **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
 - **Body protection:** Light weight protective clothing

SECTION 9: Physical and chemical properties

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

· **General Information**

· **Appearance:**

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

· **pH-value:** Not determined.

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· 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	1.13 g/cm ³
· 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
 - **Additional information:** -

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:**

8042-47-5 White mineral oil, petroleum

Oral	LD50	>5,000 mg/kg (rat)
Dermal	LD50	>2,000 mg/kg (rabbit)

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540-97-6 Dodecamethylcyclohexasiloxane		
Oral	LD50	2,000 mg/kg (rat)
Dermal	LD50	2,000 mg/kg (rat)
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)
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)

- **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)

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

SECTION 12: Ecological information

· **12.1 Toxicity**

Aquatic toxicity:	
8042-47-5 White mineral oil, petroleum	
LC50/96h	>100 mg/l (fish)
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)
LC50/96h	>0.0016 mg/l (fish)
NOEC / 21d	>0.0015 mg/l (daphnia) (OECD 211)

· **12.2 Persistence and degradability**

556-67-2 octamethylcyclotetrasiloxane	
Biodegradation	3.7 % (nd)

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541-02-6 2,2,4,4,6,6,8,8,10,10-decamethylcyclotetrasiloxane

Biodegradation 0.14 % (nd)

· **12.3 Bioaccumulative potential**

556-67-2 octamethylcyclotetrasiloxane

Bloconcentration factor (BCF) 12.4 (fish)

541-02-6 2,2,4,4,6,6,8,8,10,10-decamethylcyclotetrasiloxane

Bloconcentration factor (BCF) 7,060 (fish)

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

· **Additional ecological information:**

· **General notes:**

Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.

· **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 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**

· **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.

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- | | |
|--|-----------------|
| · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code | 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**

- **National regulations**

- **Other regulations, limitations and prohibitive regulations**

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

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

- **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.

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

Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4

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