



**Safety Data Sheet
according to WHS Regulations**

Printing date 14.04.2020

Version number 4

Revision: 14.04.2020

Not classified as hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

· **Product identifier**

· **Trade name:** **Optosil Comfort**

· **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

· **Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**

Kulzer Australia Pty Ltd
Unit 20, 53 Lorraine St
PEAKHURST NSW 2210
Australia

Tel: +61 (0) 2 9764 5222

· **Informing department:** see above

· **Emergency telephone number:**

Poison Information Number: Australia 13 11 26 & New Zealand 0800 764 766

2 Hazard(s) Identification

· **Classification of the substance or mixture**

The product is not classified, according to the Globally Harmonised System (GHS).

· **Label elements**

· **GHS label elements** Void

· **Hazard pictograms** Void

· **Signal word** Void

· **Hazard statements** Void

· **Precautionary statements**

Wear protective gloves / eye protection / face protection.

IF ON SKIN: Gently wash with plenty of soap and water.

Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Other hazards -**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

3 Composition and Information on Ingredients

· **Chemical characterisation: Mixtures**

· **Description: -**

· **Dangerous components:**

CAS: 9005-25-8 EINECS: 232-679-6	Starch	25-50%
CAS: 540-97-6 EINECS: 208-762-8	Dodecamethylcyclohexasiloxane Acute Tox. 4, H302; Acute Tox. 4, H312	<1%
CAS: 556-67-2 EINECS: 209-136-7	octamethylcyclotetrasiloxane Flam. Liq. 3, H226 Repr. 2, H361	<1%
CAS: 541-02-6	2,2,4,4,6,6,8,8,10,10-decamethylcyclopentasiloxane	<1%

· **SVHC**

540-97-6	Dodecamethylcyclohexasiloxane
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(Contd. on page 2)

AUS



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Printing date 14.04.2020

Version number 4

Revision: 14.04.2020

Trade name: Optosil Comfort

(Contd. of page 1)

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

4 First Aid Measures

- **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.
- **Information for doctor**
 - **Most important symptoms and effects, both acute and delayed**
No further relevant information available.
 - **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire Fighting Measures

- **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.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
 - **Protective equipment:** No special measures required.
- **Additional information** -

6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures**
Avoid contact with eyes and skin.
Wear protective clothing.
- **Environmental precautions:** Prevent material from reaching sewage system, holes and cellars.
- **Methods and material for containment and cleaning up:**
Collect mechanically.
Send for recovery or disposal in suitable containers.
- **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.

7 Handling and Storage

- **Handling**
 - **Precautions for safe handling**
No special measures required.

(Contd. on page 3)

AUS



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Version number 4

Revision: 14.04.2020

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(Contd. of page 2)

- Please observe the additional instructions in the product's instructions for use.
- **Information about protection against explosions and fires:** No special measures required.
- **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.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls and personal protection

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

· **Components with critical values that require monitoring at the workplace:**

9005-25-8 Starch

WES (Australia)	Long-term value: 10 mg/m ³
PEL (USA)	Long-term value: 15* 5** mg/m ³ *total dust **respirable fraction
REL (USA)	Long-term value: 10* 5** mg/m ³ *total dust **respirable fraction
TLV (USA)	Long-term value: 10 mg/m ³

556-67-2 octamethylcyclotetrasiloxane

WEEL (USA)	Long-term value: 10* ppm *OARS WEEL
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· **Additional information:** The lists that were valid during the compilation were used as basis.

- **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

AUS

(Contd. on page 4)



**Safety Data Sheet
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Printing date 14.04.2020

Version number 4

Revision: 14.04.2020

Trade name: Optosil Comfort

(Contd. of page 3)

9 Physical and Chemical Properties

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

· **General Information**

· **Appearance:**

· Form:	Pasty
· Colour:	Yellow
· Smell:	Peppermint
· 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** 1.13 g/cm³

· 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.

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

10 Stability and Reactivity

· **Reactivity** No further relevant information available.

· **Chemical stability**

· **Conditions to be avoided:** No decomposition if used and stored according to specifications.

· **Possibility of hazardous reactions** No dangerous reactions known

· **Conditions to avoid** No further relevant information available.

· **Incompatible materials:** No further relevant information available.

· **Hazardous decomposition products:** None

· **Additional information:** -

AUS

(Contd. on page 5)



**Safety Data Sheet
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Version number 4

Revision: 14.04.2020

Trade name: Optosil Comfort

(Contd. of page 4)

11 Toxicological Information

· Information on toxicological effects

· Acute toxicity

· 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)

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)

· Respiratory or skin sensitisation No sensitizing effect known.

· Additional toxicological information:

The product is not subject to classification according to the calculation method of the General EC Classification Guidelines for Preparations as issued in the latest version.

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

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

· Reproductive toxicity

540-97-6 Dodecamethylcyclohexasiloxane

Oral	NOAEL(C)	1,000 mg/kg (rat)
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12 Ecological Information

· Toxicity

· Aquatic toxicity:

8042-47-5 White mineral oil, petroleum

LC50/96h	>100 mg/l (fish)
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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)

(Contd. on page 6)

AUS



**Safety Data Sheet
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Trade name: Optosil Comfort

(Contd. of page 5)

· **Persistence and degradability**

556-67-2 octamethylcyclotetrasiloxane

Biodegradation 3.7 % (nd)

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

Biodegradation 0.14 % (nd)

· **Behaviour in environmental systems:**

· **Bioaccumulative potential**

556-67-2 octamethylcyclotetrasiloxane

Bioconcentration factor (BCF) 12.4 (fish)

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

Bioconcentration factor (BCF) 7,060 (fish)

· **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.

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

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

13 Disposal considerations

· **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.

· **Uncleaned packagings:**

· **Recommendation:**

Disposal must be made according to official regulations.

Non contaminated packagings can be used for recycling.

14 Transport information

· **UN-Number**

· **ADG, ADN, IMDG, IATA**

Void

· **UN proper shipping name**

· **ADG, ADN, IMDG, IATA**

Void

· **Transport hazard class(es)**

· **ADG, ADN, IMDG, IATA**

· **Class**

Void

· **Packing group**

· **ADG, IMDG, IATA**

Void

· **Environmental hazards:**

· **Marine pollutant:**

No

(Contd. on page 7)

AUS



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(Contd. of page 6)

- | | |
|---|-----------------|
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · Transport/Additional information: | - |
| · UN "Model Regulation": | Void |

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **Australia: Priority Existing Chemicals**

None of the ingredients is listed.

· **National regulations**

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

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

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

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

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.

H361 Suspected of damaging fertility or the unborn child.

· **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

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

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