



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

Printing date 06.04.2023

Version number 6 (replaces version 5)

Revision: 06.04.2023

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

· **1.1 Product identifier**

· Trade name: **Xantopren Comfort Light, Xantopren Comfort Medium**

· **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**

The product is not classified, according to the GB CLP regulation.

· **Additional information:**

Since the product is a medical device in the sense of Directive 93/42/EEC (MDD) or the Regulation (EU) 2017/745 (MDR), that is intended for the end user and is used invasively or with physical contact, it is exempted from the classification and labeling obligation according to Regulation (EC) 1272/2008.

· **2.2 Label elements**

· **Labelling according to Regulation (EC) No 1272/2008** Void

· Hazard pictograms Void

· Signal word Void

· Hazard statements Void

· **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: 1344-95-2 EINECS: 215-710-8 Reg.nr.: 01-2119427745-34-XXXX	Silicic acid, calcium salt substance with a Community workplace exposure limit	10-25%
CAS: 556-67-2 EINECS: 209-136-7 Reg.nr.: 01-2119529238-36-xxxx	octamethylcyclotetrasiloxane Flam. Liq. 3, H226 Repr. 2, H361f Aquatic Chronic 1, H410 (M=10) PBT; vPvB	≥0.025-<0.25%

**SECTION 4: First aid measures**

· **4.1 Description of first aid measures**

· General information No special measures required.

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- **After inhalation** Supply fresh air; consult doctor in case of symptoms.
- **After skin contact** The product is not skin irritating.
- **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**  
CO<sub>2</sub>, 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** Not required.
- **6.2 Environmental precautions:**  
No special measures required.  
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).
- **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.
  - **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:**

**1344-95-2 Silicic acid, calcium salt**

WEL (Great Britain) Long-term value: 10\* 4\*\* mg/m<sup>3</sup>  
\*inhalable dust, \*\*respirable

**DNELs**

**540-97-6 Dodecamethylcyclohexasiloxane**

Oral	general population, acute, systemic	1.7 mg/Kg (not defined)
	general population, long term, systemic	1.7 mg/Kg (not defined)
Inhalative	worker industrial, acute, local	6.1 mg/m <sup>3</sup> (not defined)
	worker industrial, long term, systemic	11 mg/m <sup>3</sup> (not defined)
	worker industrial, long term, local	1.22 mg/m <sup>3</sup> (not defined)
	general population, acute, local	1.5 mg/m <sup>3</sup> (not defined)
	general population, long term, systemic	2.7 mg/m <sup>3</sup> (not defined)
	general population, long term, local	0.3 mg/m <sup>3</sup> (not defined)

**PNECs**

**540-97-6 Dodecamethylcyclohexasiloxane**

sewage treatment plant	1 mg/l (not defined)
sediment, dry weight, freshwater	13 mg/Kg (not defined)
sediment, dry weight, marine water	1.3 mg/Kg (not defined)

**Additional information:** The lists that were valid during the compilation were used as basis.

**8.2 Exposure controls**

**Appropriate engineering controls** No further data; see section 7.

**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:** Not required.

**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

Nitrile rubber, NBR

**Eye/face protection** Safety glasses

**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**

· Physical state	Fluid
· Colour:	Blue
· Smell:	Odourless
· 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:	>160 °C
· Decomposition temperature:	Not determined.
· SADT	
· pH	Not determined.
· Viscosity:	
· Kinematic viscosity	Not determined.
· Kinematic viscosity	
· dynamic:	Not determined.
· Solubility	
· Water:	Not miscible or difficult to mix
· Partition coefficient n-octanol/water (log value)	Not determined.
· Steam pressure:	Not determined.
· Vapour pressure:	
· Density and/or relative density	
· Density at 20 °C	1.12-1.52 g/cm <sup>3</sup>
· 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.  
Not determined.

**· Solvent content:**

· Water: 0.5 %  
· Solids content: 22.9 %

**· 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

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· <b>Flammable solids</b>	Void
· <b>Self-reactive substances and mixtures</b>	Void
· <b>Pyrophoric liquids</b>	Void
· <b>Pyrophoric solids</b>	Void
· <b>Self-heating substances and mixtures</b>	Void
· <b>Substances and mixtures, which emit flammable gases in contact with water</b>	Void
· <b>Oxidising liquids</b>	Void
· <b>Oxidising solids</b>	Void
· <b>Organic peroxides</b>	Void
· <b>Corrosive to metals</b>	Void
· <b>Desensitised explosives</b>	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:**

**1344-95-2 Silicic acid, calcium salt**

Oral LD50 >10000 mg/kg (rat)

**540-97-6 Dodecamethylcyclhexasiloxane**

Oral LD50 >2000 mg/kg (rat) (OECD 423)

Dermal LD50 >2000 mg/kg (rat) (OECD 402)

- **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**

**540-97-6 Dodecamethylcyclhexasiloxane**

Oral NOAEL(C) 1000 mg/kg (rat)

- **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.

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**· 11.2 Information on other hazards****· Endocrine disrupting properties**

None of the ingredients is listed.

**SECTION 12: Ecological information****· 12.1 Toxicity****· Aquatic toxicity:****540-97-6 Dodecamethylcyclohexasiloxane**

NOEC / 91d	≥0.014 mg/l (fish) (OECD 210)
NOEC / 21d	0.0046 mg/l (daphnia) (OECD 211)
ErC50 / 72 h	>0.002 mg/l (algae) (OECD 201)
NOEC / 72h	≥0.002 mg/l (algae) (OECD 201)

**· 12.2 Persistence and degradability****540-97-6 Dodecamethylcyclohexasiloxane**

Biodegradation	4.47 % /28d (not defined) (OECD 310)
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**· 12.3 Bioaccumulative potential****540-97-6 Dodecamethylcyclohexasiloxane**

Bloconcentration factor (BCF)	1160 (not defined)
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**· 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:**

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

**SECTION 13: Disposal considerations****· 13.1 Waste treatment methods****· Recommendation** Contact waste processors for recycling information.**· 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, IMDG, IATA** Void**· 14.2 UN proper shipping name****· ADR, IMDG, IATA** Void

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· <b>14.3 Transport hazard class(es)</b>	
· <b>ADR, ADN, IMDG, IATA</b>	
· <b>Class</b>	Void
· <b>14.4 Packing group</b>	
· <b>ADR, IMDG, IATA</b>	Void
· <b>14.5 Environmental hazards:</b>	
· <b>Marine pollutant:</b>	No
· <b>14.6 Special precautions for user</b>	Not applicable.
· <b>14.7 Maritime transport in bulk according to IMO instruments</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.
- **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.

H361f Suspected of damaging fertility.

H410 Very toxic to aquatic life with long lasting effects.

- **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 (UK REACH)

PNEC: Predicted No-Effect Concentration (UK REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Flam. Liq. 3: Flammable liquids – Category 3

Repr. 2: Reproductive toxicity – Category 2

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

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