



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

Printing date 08.04.2020

Version number 4

Revision: 08.04.2020

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

· **1.1 Product identifier**

· Trade name: **Xantopren M mucosa**

· **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**

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**



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.

P264 Wash thoroughly after handling.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

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.

· **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 EINECS: 238-455-4	cristobalite STOT RE 1, H372	10-25%
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	
541-02-6	2,2,4,4,6,6,8,8,10,10-decamethylcyclopentasiloxane	

· 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** 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** Not required.**· 6.2 Environmental precautions:** No special measures required.**· 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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· **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.

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SECTION 7: Handling and storage

· **7.1 Precautions for safe handling**

No special measures required.

Ensure good ventilation/exhaustion at the workplace.

· **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

· **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:**

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

Not required.

· **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**

Keep away from foodstuffs, beverages and food.

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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Trade name: Xantopren M mucosa· **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:**

Orange

· **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.

· **Ignition temperature:**

550 °C

· **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**1.12-1.52 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.

· **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.

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- **10.6 Hazardous decomposition products:** None
- **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 Dodecamethylcyclotetrasiloxane

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 Dodecamethylcyclotetrasiloxane

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 Dodecamethylcyclotetrasiloxane

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)

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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)

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

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-decamethylcyclopentasiloxane

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.

Do not allow product to reach ground water, water bodies or sewage system.

Danger to drinking water if even small quantities leak into soil.

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.

SECTION 14: Transport information

14.1 UN-Number

ADR, IMDG, IATA

Void

14.2 UN proper shipping name

ADR, IMDG, IATA

Void

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|--|-----------------|
| · 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 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**
 - **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**

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.
- 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)

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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

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

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