



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

Printing date 17.11.2022

Version number 5 (replaces version 4)

Revision: 17.11.2022

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

- **1.1 Product identifier**
  - Trade name: **Xantasil Cat. 1:1, Xantasil Dynamix Cat. 5:1**
- **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 the lung through prolonged or repeated exposure.  
Route of exposure: Inhalation.

Aquatic Chronic 3      H412 Harmful to aquatic life with long lasting effects.
- **2.2 Label elements**
  - **Labelling according to Regulation (EC) No 1272/2008**

The product is classified and labelled according to the GB CLP regulation.

    - **Hazard pictograms**

GHS08

  - **Signal word** Danger
  - **Hazard-determining components of labelling:**

Cristobalite
  - **Hazard statements**

H372 Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.

H412 Harmful to aquatic life with long lasting effects.
  - **Precautionary statements**

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

P264 Wash thoroughly after handling.

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

P314 Get medical advice/attention if you feel unwell.
- **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:** -

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**· Dangerous components:**

CAS: 14464-46-1	Cristobalite	STOT RE 1, H372	50-75%
EINECS: 238-878-4			

**· 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** 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:** Put on breathing apparatus.
  - **Additional information** -

**SECTION 6: Accidental release measures**

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Use breathing protection against the effects of fumes/dust/aerosol.  
Avoid contact with eyes and skin.
- **6.2 Environmental precautions:** Prevent material from reaching sewage system, holes and cellars.
- **6.3 Methods and material for containment and cleaning up:**  
Dispose of the material collected according to regulations.
- **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.

**SECTION 7: Handling and storage**

- **7.1 Precautions for safe handling**  
Please observe the additional instructions in the product's instructions for use.  
Keep containers tightly sealed.  
Ensure good ventilation/exhaustion at the workplace.
- **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**

- **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**
  - **Individual protection measures, such as 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:** 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

**SECTION 9: Physical and chemical properties**

- **9.1 Information on basic physical and chemical properties**
  - **General Information**

· <b>Physical state</b>	Fluid
· <b>Colour:</b>	White
· <b>Smell:</b>	Characteristic
· <b>Odour threshold:</b>	Not determined.
· <b>Melting point/freezing point:</b>	Not determined
· <b>Boiling point or initial boiling point and boiling range</b>	300 °C
· <b>Flammability</b>	Not applicable.

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· <b>Lower and upper explosion limit</b>	
· Lower:	Not determined.
· Upper:	Not determined.
· <b>Flash point:</b>	>130 °C
· <b>Decomposition temperature:</b>	Not determined.
· <b>SADT</b>	
· pH	Not determined.
· <b>Viscosity:</b>	
· Kinematic viscosity	Not determined.
· dynamic:	Not determined.
· <b>Solubility</b>	
· Water:	Fully miscible
· <b>Partition coefficient n-octanol/water (log value)</b>	Not determined.
· <b>Steam pressure:</b>	Not determined.
· <b>Density and/or relative density</b>	
· Density	Not determined
· Relative density	Not determined.
· Vapour density	Not determined.

· <b>9.2 Other information</b>	No further relevant information available.
· <b>Appearance:</b>	
· Form:	Fluid
· <b>Important information on protection of health and environment, and on safety.</b>	
· Self-inflammability:	Product is not selfigniting.
· Explosive properties:	Product is not explosive. Not determined.
· Solvent content:	
· Solids content:	0.0 %
· <b>Change in condition</b>	
· Evaporation rate	Not determined.

· <b>Information with regard to physical hazard classes</b>	
· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void

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· **Desensitised explosives**

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:**

**68083-19-2 Silopren U 1 dental**

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

- **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** 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 the lung through prolonged or repeated exposure. Route of exposure: Inhalation.
- **Aspiration hazard** Based on available data, the classification criteria are not met.
- **11.2 Information on other hazards**

· **Endocrine disrupting properties**

None of the ingredients is listed.

**SECTION 12: Ecological information**

- **12.1 Toxicity**
  - **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **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** No further relevant information available.

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**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.

· **Uncleaned packagings:**

· **Recommendation:**

Disposal must be made according to official regulations.

Non contaminated packagings can be used for recycling.

· **Recommended cleaning agent:** Water, if necessary with cleaning agent.

**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

· **14.3 Transport hazard class(es)**

· ADR, ADN, IMDG, IATA

· Class

Void

· **14.4 Packing group**

· ADR, IMDG, IATA

Void

· **14.5 Environmental hazards:**

Not applicable.

· **14.6 Special precautions for user**

Not applicable.

· **14.7 Maritime transport in bulk according to IMO instruments**

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.

· **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**

H372 Causes damage to organs through prolonged or repeated exposure.

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· **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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

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

Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

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

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