



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

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

- **1.1 Product identifier**
 - **Trade name: Xantopren function hardener 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** Activator for 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**

Flam. Liq. 3	H226 Flammable liquid and vapour.
Skin Irrit. 2	H315 Causes skin irritation.
Eye Irrit. 2	H319 Causes serious eye irritation.
STOT SE 3	H335 May cause respiratory irritation.
STOT RE 2	H373 May cause damage to organs through prolonged or repeated exposure.
Aquatic Acute 1	H400 Very toxic to aquatic life.
Aquatic Chronic 1	H410 Very toxic 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 CLP regulation.

 - **Hazard pictograms**

GHS02 GHS07 GHS08 GHS09
 - **Signal word** Warning
 - **Hazard-determining components of labelling:**
dibutyltin dilaurate
tetraethyl orthosilicate
 - **Hazard statements**
H226 Flammable liquid and vapour.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H373 May cause damage to organs through prolonged or repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.

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· Precautionary statements

- P210 *Keep away from heat/sparks/open flames/hot surfaces. - No smoking.*
- P241 *Use explosion-proof electrical/ventilating/lighting/equipment.*
- P260 *Do not breathe dust/fume/gas/mist/vapours/spray.*
- P303+P361+P353 *IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.*
- P305+P351+P338 *IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.*
- P405 *Store locked up.*

· 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:** Activator for use with condensation curing silicone-based impression materials

· Dangerous components:

CAS: 78-10-4 EINECS: 201-083-8 Reg.nr.: 01-2119496195-28-0003	tetraethyl orthosilicate Flam. Liq. 3, H226; Acute Tox. 4, H332; Eye Irrit. 2, H319; STOT SE 3, H335	25-50%
CAS: 77-58-7 EINECS: 201-039-8	dibutyltin dilaurate STOT RE 2, H373; Aquatic Acute 1, H400; Aquatic Chronic 1, H410; Skin Irrit. 2, H315; Eye Irrit. 2, H319	25-50%

- **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

· General information

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

- **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. If symptoms persist, consult doctor.

· After swallowing

Rinse out mouth and then drink plenty of water.

Instantly call for doctor.

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.

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SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
 - **Suitable extinguishing agents** CO₂, sand, extinguishing powder. Do not use water.
 - **For safety reasons unsuitable extinguishing agents**
Water.
Water with a full water jet.
- **5.2 Special hazards arising from the substance or mixture**
Can form explosive gas-air mixtures.
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**
Wear protective equipment. Keep unprotected persons away.
- **6.2 Environmental precautions:**
Do not allow to enter drainage system, surface or ground water.
Do not allow to enter the ground/soil.
- **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).
Dispose of contaminated material as waste according to item 13.
Do not flush with water or aqueous cleansing agents
- **6.4 Reference to other sections**
See Section 8 for information on personal protection equipment.
-

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
Keep containers tightly sealed.
Ensure good ventilation/exhaustion at the workplace.
 - **Information about protection against explosions and fires:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
- **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.

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· 8.1 Control parameters

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

78-10-4 tetraethyl orthosilicate

OELV () Short-term value: 255 mg/m³, 30 ppm
Long-term value: 85 mg/m³, 10 ppm

· DNELs

78-10-4 tetraethyl orthosilicate

Dermal	worker industr., acute, syst.	12.1 mg/Kg/d (human)
	worker industr., l.te., syst.	12.1 mg/Kg/d (human)
	ge.pop., acu., syst.	8.4 mg/Kg/d (human)
	ge.pop., l.te, syst.	8.4 mg/Kg/d (human)
Inhalative	worker industr., acute, syst.	85 mg/m ³ (human)
	worker industr., l.te., syst.	85 mg/m ³ (human)
	ge.pop., l.te, syst.	25 mg/m ³ (human)

· PNECs

78-10-4 tetraethyl orthosilicate

freshwater	0.192 mg/l (aqua)
marine water	0.0192 mg/l (aqua)
interm. wat. release	10 mg/l (aqua)
sedim., dw, fre.wat.	0.18 mg/Kg (sediment)
soil,dw	0.05 mg/Kg (soil)

· 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.
Instantly remove any soiled and impregnated garments.
Wash hands during breaks and at the end of the work.
Avoid contact with the eyes and skin.

· Breathing equipment: Not required.

· Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
Solvent resistant gloves
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.

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- **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:** Fluid
- **Colour:** Light red
- **Smell:** Aromatic
- **Odour threshold:** Not determined.

· **pH-value:** Not determined.

· **Change in condition**

- **Melting point/Melting range:** Not determined
- **Boiling point/Boiling range:** 170 °C

· **Flash point:** 36 °C

· **Inflammability (solid, gaseous)** Not applicable.

· **Ignition temperature:** 265 °C

· **Decomposition temperature:** Not determined.

· **Self-inflammability:** Product is not selfigniting.

· **Danger of explosion:** Product is not explosive. However, formation of explosive air/vapour mixtures is possible.

· **Critical values for explosion:**

- **Lower:** Not determined.
- **Upper:** Not determined.

· **Steam pressure at 20 °C:** 10 hPa

· **Density at 20 °C** 0.974 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.

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- **Viscosity:**
 - **dynamic:** Not determined.
 - **kinematic:** Not determined.

- **Solvent content:**
 - **VOC EU** g/l
- **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:**

Oral	LD50	(rat)
------	------	-------

78-10-4 tetraethyl orthosilicate

Oral	LD50	6270 mg/kg (rat)
Dermal	LD50	5878 mg/kg (can)

- **Primary irritant effect:**
 - **Skin corrosion/irritation** Causes skin irritation.
 - **Serious eye damage/irritation** Causes serious eye irritation.
- **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** Based on available data, the classification criteria are not met.
- **STOT-single exposure** May cause respiratory irritation.
- **STOT-repeated exposure** May cause damage to organs through prolonged or repeated exposure.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

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SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**

78-10-4 tetraethyl orthosilicate

EC50/48h >844 mg/l (daphnia)

· **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.

· **Additional ecological information:**

· **General notes:**

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.

· **European waste catalogue**

18 01 06 chemicals consisting of or containing dangerous substances

· **Uncleaned packagings:**

· **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

· **14.1 UN-Number**

· **ADR, IMDG, IATA**

UN1993

· **14.2 UN proper shipping name**

· **ADR**

1993 FLAMMABLE LIQUID, N.O.S., special provision 640E (TETRAETHYL SILICATE, dibutyltin dilaurate)

· **IMDG**

FLAMMABLE LIQUID, N.O.S. (TETRAETHYL SILICATE, dibutyltin dilaurate), MARINE POLLUTANT

· **IATA**

FLAMMABLE LIQUID, N.O.S. (TETRAETHYL SILICATE, dibutyltin dilaurate)

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· 14.3 Transport hazard class(es)

· ADR



· Class
· Label

3 (F1) Flammable liquids.
3

· IMDG



· Class
· Label

3 Flammable liquids.
3

· IATA



· Class
· Label

3 Flammable liquids.
3

· 14.4 Packing group
· ADR, IMDG, IATA

III

· 14.5 Environmental hazards:

· Marine pollutant:

Yes
Symbol (fish and tree)

· Special marking (ADR):

Symbol (fish and tree)

· 14.6 Special precautions for user

· Kemler Number:

Warning: Flammable liquids.
30

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

Not applicable.

· Transport/Additional information:

-

· ADR

· Limited quantities (LQ)

5L

· Transport category

3

· Tunnel restriction code

D/E

· UN "Model Regulation":

UN1993, FLAMMABLE LIQUID, N.O.S., 3, III

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SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
 - **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3, 20
- **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.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

H335 May cause respiratory irritation.

H373 May cause damage to organs through prolonged or repeated exposure.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

· **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)

VOCV: Lenkungsabgabe auf flüchtigen organischen Verbindungen, Schweiz (Swiss Ordinance on volatile organic compounds)

DNEL: Derived No-Effect Level (REACH)

PNEC: Predicted No-Effect Concentration (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

Acute Tox. 4: Acute toxicity – Category 4

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

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

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