



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

Printing date 17.11.2022

Version number 4 (replaces version 1)

Revision: 17.11.2022

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

· **1.1 Product identifier**

· Trade name: **Xantopren Comfort Activator**

· **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 Sens. 1 H317 May cause an allergic skin reaction.

· **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

· **Signal word** Warning

· **Hazard-determining components of labelling:**

trimethoxyvinylsilane

· **Hazard statements**

H226 Flammable liquid and vapour.

H317 May cause an allergic skin reaction.

· **Precautionary statements**

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P240 Ground and bond container and receiving equipment.

P241 Use explosion-proof [electrical/ventilating/lighting] equipment.

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

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

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

· **2.3 Other hazards -**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.



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(Contd. of page 1)

SECTION 3: Composition/information on ingredients

· **3.2 Mixtures**

· **Description:** -

· **Dangerous components:**

CAS: 2768-02-7 EINECS: 220-449-8 Reg.nr.: 01-2119513215-52-xxxx	trimethoxyvinylsilane Flam. Liq. 3, H226 Acute Tox. 4, H332; Skin Sens. 1B, H317	10-25%
CAS: 870-08-6 EINECS: 212-791-1 Reg.nr.: 01-2119971268-27-xxxx	dioctyltin oxide STOT SE 2, H371 Aquatic Chronic 4, H413	0-5%
CAS: 681-84-5 EINECS: 211-656-4 Reg.nr.: 01-2119957658-18-0001	tetramethyl orthosilicate Flam. Liq. 3, H226 Acute Tox. 1, H330 Eye Dam. 1, H318 Skin Irrit. 2, H315	<1%

· **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. Then 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**

Alcohol-resistant foam

Carbon dioxide

· **For safety reasons unsuitable extinguishing agents** 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** -

IE
(Contd. on page 3)



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Version number 4 (replaces version 1)

Revision: 17.11.2022

Trade name: Xantopren Comfort Activator

(Contd. of page 2)

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 the ground/soil.
Do not allow to enter drainage system, surface or ground water.
Prevent material from reaching sewage system, holes and cellars.
- **6.3 Methods and material for containment and cleaning up:** Collect mechanically.
- **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**
Keep containers tightly sealed.
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
 - **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

· **8.1 Control parameters**

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

681-84-5 tetramethyl orthosilicate

OEL (Ireland) Long-term value: 6 mg/m³, 1 ppm

· **DNELs**

2768-02-7 trimethoxyvinylsilane

Oral	worker industrial, long term, systemic	0.3 mg/Kg (not defined)
Dermal	worker professional, acute, systemic	26.9 mg/Kg/d (not defined)
	worker professional, long term, local	0.3 mg/Kg/d (not defined)
Inhalative	worker industrial, acute, systemic	93.4 mg/m ³ (not defined)
	worker professional, long term, systemic	1.04 mg/m ³ (not defined)

· **PNECs**

2768-02-7 trimethoxyvinylsilane

freshwater	0.34 mg/l (not defined)
marine water	0.034 mg/l (not defined)
sewage treatment plant	110 mg/l (not defined)

(Contd. on page 4)



**Safety data sheet
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Trade name: Xantopren Comfort Activator

(Contd. of page 3)

sediment, dry weight, freshwater 0.27 mg/Kg (not defined)

· **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.

Do not inhale gases / fumes / aerosols.

· **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**

· **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**

123 °C

· **Flammability**

Not applicable.

· **Lower and upper explosion limit**

· **Lower:**

Not determined.

· **Upper:**

Not determined.

· **Flash point:**

24 °C (2768-02-7 trimethoxyvinylsilane)

· **Decomposition temperature:**

Not determined.

· **SADT**

· **pH**

Not determined.

· **Viscosity:**

· **Kinematic viscosity**

Not determined.

· **dynamic:**

Not determined.

· **Solubility**

· **Water:**

Not miscible or difficult to mix

(Contd. on page 5)



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Version number 4 (replaces version 1)

Revision: 17.11.2022

Trade name: Xantopren Comfort Activator

(Contd. of page 4)

· Partition coefficient n-octanol/water (log value)	Not determined.
· Steam pressure:	Not determined.
· Density and/or relative density	
· Density at 20 °C	0.994 g/cm ³
· 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. However, formation of explosive air/vapour mixtures is possible.
· 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	
Flammable liquid and vapour.	
· 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
· 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:** -

(Contd. on page 6)



**Safety data sheet
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Version number 4 (replaces version 1)

Revision: 17.11.2022

Trade name: Xantopren Comfort Activator

(Contd. of page 5)

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:**

2768-02-7 trimethoxyvinylsilane

Oral	LD50	7120-7236 mg/kg (rat)
Dermal	LD50	3200 mg/kg (rabbit)
Inhalative	LC50/4 h	16.8 mg/l (rat) 64000 mg/l (rat)
Sensitisation	sensitization	(guinea pig)

870-08-6 dioctyltin oxide

Oral	LD50	>4000 mg/kg (rat)
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681-84-5 tetramethyl orthosilicate

Oral	LD50	700 mg/kg (rat)
Inhalative	LC50/4 h	0.392 mg/l (not defined)

- **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**
May cause an allergic skin reaction.
- **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** Based on available data, the classification criteria are not met.
- **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:**

2768-02-7 trimethoxyvinylsilane

EC50/72h	>100 mg/l (algae)
EC50/48h	>100 mg/l (daphnia) (OECD 202)
LC50/96h	191 mg/l (fish)

870-08-6 dioctyltin oxide

EC50/48h	6.9 mg/l (daphnia)
LC50/96h	13 mg/l (fish)

- **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.

(Contd. on page 7)



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Trade name: Xantopren Comfort Activator

(Contd. of page 6)

- **12.6 Endocrine disrupting properties**
For information on endocrine disrupting properties see section 11.
- **12.7 Other adverse effects**
 - **Additional ecological information:**
 - **General notes:** Not known to be hazardous to water.

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.
Non contaminated packagings can be used for recycling.

SECTION 14: Transport information

- **14.1 UN number or ID number**
 - **ADR, IMDG, IATA** UN1993
- **14.2 UN proper shipping name**
 - **ADR** 1993 FLAMMABLE LIQUID, N.O.S.
(trimethoxyvinylsilane)
 - **IMDG, IATA** FLAMMABLE LIQUID, N.O.S.
(trimethoxyvinylsilane)
- **14.3 Transport hazard class(es)**
 - **ADR**

 - **Class** 3 (F1) Flammable liquids.
 - **Label** 3
 - **IMDG, IATA**

 - **Class** 3 Flammable liquids.
 - **Label** 3
- **14.4 Packing group**
 - **ADR, IMDG, IATA** III

(Contd. on page 8)



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Trade name: Xantopren Comfort Activator

(Contd. of page 7)

· 14.5 Environmental hazards:	Not applicable.
· 14.6 Special precautions for user	Warning: Flammable liquids.
· Kemler Number:	30
· EMS Number:	F-E, S-E
· Stowage Category	A
· 14.7 Maritime transport in bulk according to IMO instruments	Not applicable.
· Transport/Additional information:	-
· ADR	
· Limited quantities (LQ)	5L
· Excepted quantities (EQ)	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· Transport category	3
· Tunnel restriction code	D/E
· IMDG	
· Limited quantities (LQ)	5L
· Excepted quantities (EQ)	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· UN "Model Regulation":	UN 1993 FLAMMABLE LIQUID, N.O.S. (TRIMETHOXYVINYL SILANE), 3, III

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.

· **Seveso category** P5c FLAMMABLE LIQUIDS

· **Qualifying quantity (tonnes) for the application of lower-tier requirements** 5,000 t

· **Qualifying quantity (tonnes) for the application of upper-tier requirements** 50,000 t

· **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3, 20

· **Regulation (EU) No 649/2012**

870-08-6 dioctyltin oxide

Annex I Part 1

· **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.

(Contd. on page 9)



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

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Version number 4 (replaces version 1)

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Trade name: Xantopren Comfort Activator

(Contd. of page 8)

H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H330 Fatal if inhaled.
H332 Harmful if inhaled.
H371 May cause damage to organs.
H413 May cause long lasting harmful effects to aquatic life.

· **Date of previous version:** 17.11.2022

· **Version number of previous version:** 1

· **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 (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. 1: Acute toxicity – Category 1

Acute Tox. 4: Acute toxicity – Category 4

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

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

Skin Sens. 1: Skin sensitisation – Category 1

Skin Sens. 1B: Skin sensitisation – Category 1B

STOT SE 2: Specific target organ toxicity (single exposure) – Category 2

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

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