



**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 GB 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.

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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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** -

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

· 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)

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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

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· 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	
<i>Flammable liquid and vapour.</i>	
· 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:** -

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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.

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- **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.
 - **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
- **14.5 Environmental hazards:** Not applicable.
- **14.6 Special precautions for user**
 - **Kemler Number:** 30

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· 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
- 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.
- 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.

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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)

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

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.**

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