



**Safety Data Sheet
acc. to OSHA HCS**

Printing date 11/17/2022

Reviewed on 11/17/2022

1 Identification

· **Product identifier**

· **Trade name:** Xantopren Comfort Activator

· -

· **Application of the substance / the mixture** Activator for dental impression material

· **Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**

Kulzer GmbH

Leipziger Straße 2, 63450 Hanau (Germany) Tel.: +49 (0)800 4372522

· **Information department:**

Tel. +1 (800) 431-1785 Fax: +1 (800) 522-1545

e-mail: customer.servicehkna@kulzer-dental.com

· **Emergency telephone number:**

Emergency CONTACT (24-Hour-Number)

ID 105860: (domestic) 1 800 535 5053 or international (001) 352 323 3500

2 Hazard(s) identification

· **Classification of the substance or mixture**

Flammable Liquids 3

H226 Flammable liquid and vapor.

Sensitization - Skin 1

H317 May cause an allergic skin reaction.

Specific Target Organ Toxicity - Single Exposure 2 H371 May cause damage to organs.

· **Label elements**

· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**



GHS02 GHS07 GHS08

· **Signal word** Warning

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

trimethoxyvinylsilane

dioctyltin oxide

· **Hazard statements**

Flammable liquid and vapor.

May cause an allergic skin reaction.

May cause damage to organs.

· **Precautionary statements**

Keep away from heat/sparks/open flames/hot surfaces. - No smoking.

Keep container tightly closed.

Ground/bond container and receiving equipment.

Use explosion-proof electrical/ventilating/lighting/equipment.

Use only non-sparking tools.

Take precautionary measures against static discharge.

Do not breathe dust/fume/gas/mist/vapors/spray.

Wash thoroughly after handling.

Do not eat, drink or smoke when using this product.

Contaminated work clothing must not be allowed out of the workplace.

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

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If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

IF exposed or concerned: Call a poison center/doctor.

If skin irritation or rash occurs: Get medical advice/attention.

Specific treatment (see on this label).

Wash contaminated clothing before reuse.

In case of fire: Use CO₂, powder or water spray to extinguish.

Store in a well-ventilated place. Keep cool.

Store locked up.

Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Classification system**

· **NFPA ratings for USA (scale 0-4)**



· **HMIS-Ratings (Scale 0-4)**



· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**

· **Description:** -

· **Dangerous components:**

2768-02-7	trimethoxyvinylsilane Flammable Liquids 3, H226 Acute Toxicity - Inhalation 4, H332; Sensitization - Skin 1B, H317	10-25%
870-08-6	dioctyltin oxide Specific Target Organ Toxicity - Single Exposure 2, H371	0-5%
681-84-5	tetramethyl orthosilicate Flammable Liquids 3, H226 Acute Toxicity - Inhalation 1, H330 Eye Damage 1, H318 Skin Irritation 2, H315	<1%

· **Additional information** For the wording of the listed hazard phrases refer to section 16.

4 First-aid measures

· **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 complaints.

· **After skin contact** If skin irritation continues, consult a doctor.

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- **After eye contact**
Rinse opened eye for several minutes under running water. Then consult a doctor.
- **Information for doctor**
 - **Most important symptoms and effects, both acute and delayed**
No further relevant information available.
 - **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire-fighting measures

- **Extinguishing media**
 - **Suitable extinguishing agents**
Alcohol resistant foam
Carbon dioxide
 - **For safety reasons unsuitable extinguishing agents** Water with full jet.
- **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.
- **Advice for firefighters**
 - **Protective equipment:** Mount respiratory protective device.
- **Additional information** -

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
- **Environmental precautions:**
Do not allow to penetrate the ground/soil.
Do not allow to enter sewers/ surface or ground water.
Prevent seepage into sewage system, workpits and cellars.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **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 disposal information.
-
- **Protective Action Criteria for Chemicals**

· PAC-1:		
2768-02-7	trimethoxyvinylsilane	9.5 ppm
65-85-0	Benzoic acid	13 mg/m ³
681-84-5	tetramethyl orthosilicate	0.083 ppm
· PAC-2:		
2768-02-7	trimethoxyvinylsilane	100 ppm
65-85-0	Benzoic acid	140 mg/m ³
681-84-5	tetramethyl orthosilicate	0.91 ppm
· PAC-3:		
2768-02-7	trimethoxyvinylsilane	120 ppm
65-85-0	Benzoic acid	830 mg/m ³

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681-84-5 tetramethyl orthosilicate

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1.4 ppm

7 Handling and storage

- **Handling**
 - **Precautions for safe handling**
Keep receptacles 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.
- **Conditions for safe storage, including any incompatibilities**
 - **Storage**
 - **Requirements to be met by storerooms and receptacles:** No special requirements.
 - **Information about storage in one common storage facility:** Not required.
 - **Further information about storage conditions:** None.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Control parameters**
 - **Components with limit values that require monitoring at the workplace:**
The following constituent is the only constituent of the product which has a PEL, TLV or other recommended exposure limit.
At this time, the other constituents have no known exposure limits.

681-84-5 tetramethyl orthosilicate

REL Long-term value: 6 mg/m³, 1 ppm

TLV Long-term value: 6 mg/m³, 1 ppm

· **Additional information:** The lists that were valid during the creation were used as basis.

- **Exposure controls**
 - **Personal protective equipment**
 - **General protective and hygienic measures**
Keep away from foodstuffs, beverages and feed.
Wash hands before breaks and at the end of work.
Do not inhale gases / fumes / aerosols.
 - **Breathing equipment:** Not required.
 - **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.

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- **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

9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

- **Form:** Pasty
- **Color:** Blue
- **Odor:** Odorless
- **Odor threshold:** Not determined.

· **pH-value:** Not determined.

· **Change in condition**

- **Melting point/Melting range:** undetermined
- **Boiling point/Boiling range:** 123 °C (253.4 °F)

· **Flash point:** 24 °C (75.2 °F)

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

· **Decomposition temperature:** Not determined.

· **Auto igniting:** Product is not selfigniting.

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

· **Explosion limits:**

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

· **Vapor pressure:** Not determined.

· **Density at 20 °C (68 °F):** 0.994 g/cm³ (8.29493 lbs/gal)

- **Relative density** Not determined.
- **Vapor 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.

· **Other information** No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Possibility of hazardous reactions** No dangerous reactions known

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- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** none
- **Additional information:** -

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**

· **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)
Sensitization	Sensibilisierung	(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)

- **Primary irritant effect:**
 - **on the skin:** No irritant effect.
 - **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:** Harmful

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

· **NTP (National Toxicology Program)**

None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

· **Reproductive toxicity** Based on available data, the classification criteria are not met.

12 Ecological information

- **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)

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- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
 - **Bioaccumulative potential** No further relevant information available.
 - **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
 - **General notes:** Not known to be hazardous to water.
- **Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **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.

14 Transport information

- | | |
|-------------------------------------|--|
| · UN-Number | |
| · DOT | NA1993 |
| · ADR, IMDG, IATA | UN1993 |
| · UN proper shipping name | |
| · DOT | Flammable liquids, n.o.s. (trimethoxyvinylsilane) |
| · ADR | 1993 FLAMMABLE LIQUID, N.O.S.
(trimethoxyvinylsilane) |
| · IMDG, IATA | FLAMMABLE LIQUID, N.O.S.
(trimethoxyvinylsilane) |
| · Transport hazard class(es) | |
| · DOT | |
| | |
| · Class | 3 Flammable liquids |
| · Label | 3 |
| · ADR | |
| | |
| · Class | 3 (F1) Flammable liquids |

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· Label	3
· IMDG, IATA	
	
· Class	3 Flammable liquids
· Label	3
· Packing group	
· DOT, ADR, IMDG, IATA	III
· Environmental hazards:	Not applicable.
· Special precautions for user	Warning: Flammable liquids
· Hazard identification number (Kemler code):	30
· EMS Number:	F-E, S-E
· Stowage Category	A
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
· Transport/Additional information:	-
· ADR	
· Excepted quantities (EQ)	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· 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. (TRIMETHOXYVINYLSILANE), 3, III

15 Regulatory information

· Safety, health and environmental regulations/legislation specific for the substance or mixture
No further relevant information available.

· Sara

· SARA Section 355 (extremely hazardous substances)

None of the ingredients is listed.

· SARA Section 313 (specific toxic chemical listings)

None of the ingredients is listed.

· Hazardous Air Pollutants

None of the ingredients is listed.

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· Proposition 65

· Prop 65 - Chemicals known to cause cancer
None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for females:
None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for males:
None of the ingredients is listed.

· Chemicals known to cause developmental toxicity:
None of the ingredients is listed.

· Cancerogenity categories

· EPA (Environmental Protection Agency)
65-85-0 Benzoic acid D

· TLV (Threshold Limit Value)
870-08-6 dioctyltin oxide A4

· NIOSH-Ca (National Institute for Occupational Safety and Health)
None of the ingredients is listed.

· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

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 vapor.
- 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.

· Date of preparation / last revision 11/17/2022

· Abbreviations and acronyms:

- 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
- DOT: US Department of Transportation
- IATA: International Air Transport Association
- 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)
- NFPA: National Fire Protection Association (USA)
- HMS: Hazardous Materials Identification System (USA)
- LC50: Lethal concentration, 50 percent
- LD50: Lethal dose, 50 percent
- PBT: Persistent, Bioaccumulative and Toxic
- vPvB: very Persistent and very Bioaccumulative
- NIOSH: National Institute for Occupational Safety
- OSHA: Occupational Safety & Health
- TLV: Threshold Limit Value
- PEL: Permissible Exposure Limit
- REL: Recommended Exposure Limit
- Flammable Liquids 3: Flammable liquids – Category 3
- Acute Toxicity - Inhalation 1: Acute toxicity – Category 1
- Acute Toxicity - Inhalation 4: Acute toxicity – Category 4
- Skin Irritation 2: Skin corrosion/irritation – Category 2

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Eye Damage 1: Serious eye damage/eye irritation – Category 1

Sensitization - Skin 1: Skin sensitisation – Category 1

Sensitization - Skin 1B: Skin sensitisation – Category 1B

Specific Target Organ Toxicity - Single Exposure 2: Specific target organ toxicity (single exposure) – Category 2

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

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