



**Safety Data Sheet
according to WHS Regulations**

Printing date 01.02.2021

Version number 4

Revision: 01.02.2021

Hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

· Product identifier

· Trade name: **Xantopren Comfort**

· 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

· Details of the supplier of the safety data sheet

· Manufacturer/Supplier:

Kulzer Australia Pty Ltd
Unit 20, 53 Lorraine Street
Peakhurst, NSW 2210
Australia

Tel: +61 (0) 2 9153 0311

· Informing department: see above

· Emergency telephone number:

Poison Information Number: Australia 13 11 26 & New Zealand 0800 764 766

2 Hazard(s) Identification

· Classification of the substance or mixture

The product is not classified according to the Globally Harmonised System (GHS).

· Label elements

· GHS label elements Void

· Hazard pictograms Void

· Signal word Void

· Hazard statements Void

· Other hazards -

· Results of PBT and vPvB assessment

· PBT: Not applicable.

· vPvB: Not applicable.

3 Composition and Information on Ingredients

· Chemical characterisation: Mixtures

· Description: -

· Dangerous components:

CAS: 1344-95-2 EINECS: 215-710-8	Silicic acid, calcium salt		10-25%
CAS: 2768-02-7 EINECS: 220-449-8	trimethoxyvinylsilane	Flam. Liq. 3, H226; Acute Tox. 4, H332	0-5%

4 First Aid Measures

· Description of first aid measures

· General information No special measures required.

· After inhalation Supply fresh air; consult doctor in case of symptoms.

· After skin contact Instantly wash with water and soap and rinse thoroughly.

· 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.

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In case of persistent symptoms consult 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**

CO₂, extinguishing powder or water jet. Fight larger fires with water jet or alcohol-resistant foam. Use fire fighting measures that suit the environment.

· **Special hazards arising from the substance or mixture** *No further relevant information available.*

· **Advice for firefighters**

· **Protective equipment:** *No special measures required.*

· **Additional information -**

6 Accidental Release Measures

· **Personal precautions, protective equipment and emergency procedures** *Not required.*

· **Environmental precautions:** *No special measures required.*

· **Methods and material for containment and cleaning up:**

Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).

· **Reference to other sections**

No dangerous materials are released.

See Section 7 for information on safe handling

See Section 8 for information on personal protection equipment.

See Section 13 for information on disposal.

7 Handling and Storage

· **Handling**

· **Precautions for safe handling**

No special measures required.

Please observe the additional instructions in the product's instructions for use.

· **Information about protection against explosions and fires:** *No special measures required.*

· **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.*

· **Specific end use(s)** *No further relevant information available.*

8 Exposure controls and personal protection

· **Additional information about design of technical systems:** *No further data; see item 7.*

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· **Control parameters**

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

1344-95-2 Silicic acid, calcium salt

NES (Australia)	10 mg/m ³
PEL (USA)	15* 5** mg/m ³ *total dust **respirable fraction
REL (USA)	10* 5** mg/m ³ *total dust **respirable fraction
TLV (USA)	10 mg/m ³ synthetic nonfibrous, E

· **DNELs**

2768-02-7 trimethoxyvinylsilane

Oral	worker industr., lg.t., syst.	0.3 mg/Kg (nd)
Dermal	worker profess., acute, syst.	26.9 mg/Kg/d (nd)
	worker profess., l.te., syst.	0.3 mg/Kg/d (nd)
Inhalative	worker industr., acute, syst.	93.4 mg/m ³ (nd)
	worker profess., l.te., syst.	1.04 mg/m ³ (nd)

· **PNECs**

2768-02-7 trimethoxyvinylsilane

freshwater	0.34 mg/l (nd)
marine water	0.034 mg/l (nd)
STP	110 mg/l (nd)
sedim., dw, fre.wat.	0.27 mg/Kg (nd)

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

· **Exposure controls**

· **Personal protective equipment**

· **General protective and hygienic measures**

The usual precautionary measures should be adhered to in handling the chemicals.

· **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

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

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- **Eye protection:** Safety glasses
- **Body protection:** Light weight protective clothing

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9 Physical and Chemical Properties

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

· **General Information**

· **Appearance:**

- **Form:** Pasty
- **Colour:** Different according to colour
- **Smell:** Odourless
- **Odour threshold:** Not determined.

· **pH-value:** Not determined.

· **Change in condition**

- **Melting point/freezing point:** Not determined
- **Initial boiling point and boiling range:** Not determined

· **Flash point:** Not applicable

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

· **Ignition temperature:** Not applicable

· **Decomposition temperature:** Not determined.

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

· **Explosive properties:** Product is not explosive.

· **Critical values for explosion:**

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

· **Steam pressure:** Not determined.

· **Density** Not determined

- **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.

· **Viscosity:**

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

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

10 Stability and Reactivity

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

· **Chemical stability**

· **Conditions to be avoided:** No decomposition if used and stored according to specifications.

· **Possibility of hazardous reactions** No dangerous reactions known

· **Conditions to avoid** No further relevant information available.

· **Incompatible materials:** No further relevant information available.

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- **Hazardous decomposition products:** None
- **Additional information:** -

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11 Toxicological Information

- **Information on toxicological effects**

- **Acute toxicity**

- **LD/LC50 values that are relevant for classification:**

1344-95-2 Silicic acid, calcium salt

Oral	LD50	> 10000 mg/kg (rat)
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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	Sensib.	nicht sensibil. (guinea pig)

- **Primary irritant effect:**

- **Skin corrosion/irritation** No irritant effect.
- **Serious eye damage/irritation** No irritant effect.
- **Respiratory or skin sensitisation** No sensitizing effect known.

- **Additional toxicological information:**

The product is not subject to classification according to the calculation method of the General EC Classification Guidelines for Preparations as issued in the latest version.
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

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)

- **Persistence and degradability** No further relevant information available.

- **Behaviour in environmental systems:**

- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.

- **Additional ecological information:**

- **General notes:**

Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

- **Other adverse effects** No further relevant information available.

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13 Disposal considerations

- **Waste treatment methods**
 - **Recommendation** Smaller quantities can be disposed with household garbage.
- **Uncleaned packagings:**
 - **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- **UN-Number**
 - **ADG, ADN, IMDG, IATA** Void
- **UN proper shipping name**
 - **ADG, ADN, IMDG, IATA** Void
- **Transport hazard class(es)**
 - **ADG, ADN, IMDG, IATA** Void
 - **Class** Void
- **Packing group**
 - **ADG, IMDG, IATA** Void
- **Environmental hazards:**
 - **Marine pollutant:** No
- **Special precautions for user** Not applicable.
- **Transport in bulk according to Annex II of Marpol and the IBC Code** Not applicable.
- **Transport/Additional information:** -
- **UN "Model Regulation":** Void

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
 - **GHS label elements** Void
 - **Hazard pictograms** Void
 - **Signal word** Void
 - **Hazard statements** Void
- **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 vapour.
 - H332 Harmful if inhaled.
- **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
 - EINECS: European Inventory of Existing Commercial Chemical Substances

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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. 4: Acute toxicity – Category 4
*** Data compared to the previous version altered.**

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