1 Identification

- **Product identifier**
  - Trade name: Xantopren function hardener 1

- **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)
    GBK/Infotrac ID 105860: (domestic) 1 800 535 5053 or international (001) 352 323 3500

2 Hazard(s) identification

- **Classification of the substance or mixture**
  - Flam. Liq. 3 H226 Flammable liquid and vapor.
  - Skin Irrit. 2 H315 Causes skin irritation.
  - Eye Irrit. 2A 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.

- **Label elements**
  - GHS label elements
    The product is classified and labeled according to the Globally Harmonized System (GHS).
  - Hazard pictograms
    ![GHS02](image1) ![GHS07](image2) ![GHS08](image3)
    GHS02  GHS07  GHS08

- **Signal word** Warning

- **Hazard-determining components of labeling:**
  - dibutyltin dilaurate
tetraethyl orthosilicate

- **Hazard statements**
  - Flammable liquid and vapor.
  - Causes skin irritation.
  - Causes serious eye irritation.
  - May cause respiratory irritation.
  - May cause damage to organs through prolonged or repeated exposure.

- **Precautionary statements**
  - Keep away from heat/sparks/open flames/hot surfaces. No smoking.
  - Use explosion-proof electrical/ventilating/lighting/equipment.
  - Do not breathe dust/fume/gas/mist/vapors/spray.

(Contd. on page 2)
Trade name: Xantopren function hardener 1

If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Store locked up.

 Classification system

 - NFPA ratings for USA (scale 0-4)
   - Health = 2
   - Fire = 3
   - Reactivity = 0

 - HMIS-Ratings (Scale 0-4)
   - HEALTH
     - Health = *2
   - FIRE
     - Fire = 3
   - REACTIVITY
     - Reactivity = 0

Results of PBT and vPvB assessment:

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

3 Composition/information on ingredients

 - Chemical characterization: Mixtures
 - Description: Activator for use with condensation curing silicone-based impression materials
 - Dangerous components:

<table>
<thead>
<tr>
<th>Chemical</th>
<th>CAS Number</th>
<th>Purity</th>
<th>Hazards</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tetraethyl orthosilicate</td>
<td>78-10-4</td>
<td>25-50%</td>
<td>Flamm. Liq. 3, H226; Acute Tox. 4, H332; Eye Irrit. 2A, H319; STOT SE 3, H335</td>
</tr>
<tr>
<td>Dibutyltin dilaurate</td>
<td>77-58-7</td>
<td>25-50%</td>
<td>Skin Irrit. 2, H315; Eye Irrit. 2A, H319</td>
</tr>
</tbody>
</table>

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.
     - After eye contact: Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
     - After swallowing: Rinse out mouth and then drink plenty of water. Immediately call a doctor. If symptoms persist consult doctor.
5 Fire-fighting measures

- **Extinguishing media**
  - Suitable extinguishing agents: CO2, sand, extinguishing powder. Do not use water.
  - For safety reasons unsuitable extinguishing agents
    - Water.
    - 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 enter sewers/surface or ground water.
  - Do not allow to penetrate the ground/soil.

- **Methods and material for containment and cleaning up:**
  - Absorb with liquid binding material (diatomite, universal binders, for small amounts tissues).
  - Dispose contaminated material as waste according to item 13.
  - Do not flush with water or aqueous cleansing agents.

- **Reference to other sections**
  - See Section 8 for information on personal protection equipment.

7 Handling and storage

- **Handling**
  - Precautions for safe handling
    - Keep receptacles 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.

- **Conditions for safe storage, including any incompatibilities**
  - Storage
    - Requirements to be met by storerooms and receptacles: No special requirements.
Trade name: Xantopren function hardener 1

- 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

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

#### Control parameters

- **Components with limit values that require monitoring at the workplace:**

<table>
<thead>
<tr>
<th>Component</th>
<th>PEL (mg/m³)</th>
<th>REL (mg/m³)</th>
<th>TLV (mg/m³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>78-10-4 tetraethyl orthosilicate</td>
<td>850, 100 ppm</td>
<td>85, 10 ppm</td>
<td>85, 10 ppm</td>
</tr>
</tbody>
</table>

- **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.
    - Immediately remove all soiled and contaminated clothing.
    - Wash hands before breaks and at the end of 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.
    - **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 protection:** Safety glasses
    - **Body protection:** Light weight protective clothing
9 Physical and chemical properties

9.1 Information on basic physical and chemical properties
9.1.1 General Information
   · Appearance: Fluid
   · Form: Fluid
   · Color: Light red
   · Odor: Aromatic
   · Odor threshold: Not determined.
   · pH-value: Not determined.

9.1.2 Change in condition
   · Melting point/Melting range: Undetermined
   · Boiling point/Boiling range: 170 °C (338 °F)

9.1.3 Flash point: 36 °C (97 °F)

9.1.4 Flammability (solid, gaseous) Not applicable.

9.1.5 Ignition temperature: 265 °C (509 °F)

9.1.6 Decomposition temperature: Not determined.

9.1.7 Auto igniting: Product is not selfigniting.

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

9.1.9 Explosion limits:
   · Lower: Not determined.
   · Upper: Not determined.

9.1.10 Vapor pressure at 20 °C (68 °F): 10 hPa (8 mm Hg)

9.1.11 Density at 20 °C (68 °F):
   · Relative density: Not determined.
   · Vapor density: Not determined.
   · Evaporation rate: Not determined.

9.1.12 Solubility in / Miscibility with
   · Water: Not miscible or difficult to mix

9.1.13 Partition coefficient (n-octanol/water): Not determined.

9.1.14 Viscosity:
   · Dynamic: Not determined.
   · Kinematic: Not determined.

9.1.15 Other information
   · No further relevant information available.

10 Stability and reactivity

10.1 Reactivity
   No further relevant information available.

10.2 Possibility of hazardous reactions
   No dangerous reactions known.

10.3 Conditions to avoid
   No further relevant information available.

10.4 Incompatible materials
   No further relevant information available.
**Trade name:** Xantopren function hardener 1

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

### 11 Toxicological information

#### Information on toxicological effects

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

<table>
<thead>
<tr>
<th></th>
<th>Oral LD50 (rat)</th>
<th>Dermal LD50</th>
</tr>
</thead>
<tbody>
<tr>
<td>78-10-4 tetraethyl orthosilicate</td>
<td>6270 mg/kg (rat)</td>
<td>5870 mg/kg (can)</td>
</tr>
</tbody>
</table>

- **Primary irritant effect:
  - on the skin: Irritant to skin and mucous membranes.
  - on the eye: Irritating effect.
  - Sensitization: No sensitizing effects known.

- **Additional toxicological information:
  The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
  - Harmful
  - Irritant

- **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.

### 12 Ecological information

- **Toxicity:
  - Aquatic toxicity:
    78-10-4 tetraethyl orthosilicate
    EC50/48h >844 mg/l (daphnia)

- **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:
    Do not allow product to reach ground water, water course or sewage system.
    Danger to drinking water if even small quantities leak into the ground.
13 Disposal considerations

- Waste treatment methods
  - Recommendation
    Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

- Uncleaned packagings:
  - Recommendation: Disposal must be made according to official regulations.

14 Transport information

- UN-Number
  - DOT, ADR, IMDG, IATA: UN1993

- 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)

- Transport hazard class(es)
  - DOT
    - Class: 3 Flammable liquids
      - Label: 3
  - ADR
    - Class: 3 (F1) Flammable liquids
Safety Data Sheet
acc. to OSHA HCS

Printing date 06/03/2017
Reviewed on 06/03/2017

Trade name: Xantopren function hardener 1

- Label 3
- IMDG

- Class 3 Flammable liquids
- Label 3

- IATA

- Class 3 Flammable liquids
- Label 3

- Packing group
  - DOT, ADR, IMDG, IATA
  III

- Environmental hazards:
  - Marine pollutant: Yes
    Symbol (fish and tree)
  - Special marking (ADR): Symbol (fish and tree)

- Special precautions for user
  - Warning: Flammable liquids
  - Danger code (Kemler): 30

- Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code
  Not applicable.

- Transport/Additional information:
  - DOT
  - Remarks: Special marking with the symbol (fish and tree).

- UN "Model Regulation": UN1993, FLAMMABLE LIQUID, N.O.S., 3, III

* 15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
  - SARA Section 355 (extremely hazardous substances)
  None of the ingredients is listed.

- Cancerogenity categories
  - TLV (Threshold Limit Value established by ACGIH)
    77-58-7 dibutyltin dilaurate A4

- GHS label elements
  The product is classified and labeled according to the Globally Harmonized System (GHS).
(Contd. on page 9)
Trade name: Xantopren function hardener 1

Hazard pictograms

- GHS02
- GHS07
- GHS08

Signal word: Warning

Hazard-determining components of labeling:
- dibutyltin dilaurate
- tetraethyl orthosilicate

Hazard statements
- Flammable liquid and vapor.
- Causes skin irritation.
- Causes serious eye irritation.
- May cause respiratory irritation.
- May cause damage to organs through prolonged or repeated exposure.

Precautionary statements
- Keep away from heat/sparks/open flames/hot surfaces. No smoking.
- Use explosion-proof electrical/ventilating/lighting/equipment.
- Do not breathe dust/fume/gas/mist/vapors/spray.
- If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
- If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- Store locked up.

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.
- 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.

Date of preparation / last revision: 06/03/2017 / 2

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
- DOT: US Department of Transportation
- IATA: International Air Transport Association
- ACGIH: American Conference of Governmental Industrial Hygienists
- 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)
- HMIS: Hazardous Materials Identification System (USA)
- LC50: Lethal concentration, 50 percent
<table>
<thead>
<tr>
<th>Trade name: Xantopren function hardener 1</th>
</tr>
</thead>
</table>

LD50: Lethal dose, 50 percent  
PBT: Persistent, Bioaccumulative and Toxic  
vPvB: very Persistent and very Bioaccumulative  
OSHA: Occupational Safety & Health  
TLV: Threshold Limit Value  
PEL: Permissible Exposure Limit  
REL: Recommended Exposure Limit  
Flam. Liq. 3: Flammable liquids – Category 3  
Acute Tox. 4: Acute toxicity – Category 4  
Skin Irrit. 2: Skin corrosion/irritation – Category 2  
Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A  
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3  
STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2

* Data compared to the previous version altered.

USA