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

1.1 **Product identifier**
   - **Trade name**: Xantopren function hardener 2

1.2 **Relevant identified uses of the substance or mixture and uses advised against**
   - **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
   - **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**
     - Skin Irrit. 2  H315 Causes skin irritation.
     - Eye Irrit. 2  H319 Causes serious eye irritation.
     - STOT RE 2  H373 May cause damage to organs through prolonged or repeated exposure.
     - Aquatic Acute 1  H400 Very toxic to aquatic life.
     - Aquatic Chronic 1  H410 Very toxic to aquatic life with long lasting effects.

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**
       - GHS07
       - GHS08
       - GHS09
     - **Signal word** Warning
     - **Hazard-determining components of labelling**: dibutyltin dilaurate
     - **Hazard statements**
       - H315 Causes skin irritation.
       - H319 Causes serious eye irritation.
       - H373 May cause damage to organs through prolonged or repeated exposure.
       - H410 Very toxic to aquatic life with long lasting effects.
     - **Precautionary statements**
       - P260  Do not breathe dust/fume/gas/mist/vapours/spray.
       - P280  Wear protective gloves/protective clothing/eye protection/face protection.
       - P273  Avoid release to the environment.
       - P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
       - P321  Specific treatment (see on this label).

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

P362 Take off contaminated clothing and wash before reuse.

· 2.3 Other hazards -
  · Results of PBT and vPvB assessment
    · PBT: Not applicable.
    · vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

· 3.2 Chemical characterisation: Mixtures
  · Description: Activator for use with condensation curing silicone-based impression materials

· Dangerous components:
  · CAS: 77-58-7 dibutyltin dilaurate
  · EINECS: 201-039-8 STOT RE 2, H373; Aquatic Acute 1, H400; Aquatic Chronic 1, H410; Skin Irrit. 2, H315; Eye Irrit. 2, H319
  · 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
  · 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.
    In case of persistent symptoms consult doctor.
    Seek immediate medical advice.
  · 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
    CO2, extinguishing powder or water jet. Fight larger fires with water jet or alcohol-resistant foam.
    Use fire fighting measures that suit the environment.
  · 5.2 Special hazards arising from the substance or mixture
    Formation of toxic gases is possible during heating or in case of fire.
  · 5.3 Advice for firefighters
    · Protective equipment: No special measures required.
    · Additional information -

SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures
  Wear protective equipment. Keep unprotected persons away.
Trade name: Xantopren function hardener 2

6.2 Environmental precautions:
Inform respective authorities in case product reaches water or sewage system.

6.3 Methods and material for containment and cleaning up:
Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).
Dispose of contaminated material as waste according to item 13.
Send for recovery or disposal in suitable containers.

6.4 Reference to other sections
See Section 13 for information on disposal.
See Section 8 for information on personal protection equipment.

SECTION 7: Handling and storage

7.1 Precautions for safe handling
Keep containers tightly sealed.
Ensure good ventilation/exhaustion at the workplace.

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

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.

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

8.2 Exposure controls
Personal protective equipment
General protective and hygienic measures
Keep away from foodstuffs, beverages and food.
Instantly remove any soiled and impregnated garments.
Wash hands during breaks and at the end of the 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.
recommended

(Contd. of page 2)
### SECTION 9: Physical and chemical properties

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>General Information</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Appearance:</strong></td>
<td></td>
</tr>
<tr>
<td>Form</td>
<td>Fluid</td>
</tr>
<tr>
<td>Colour</td>
<td>Yellow</td>
</tr>
<tr>
<td>Smell</td>
<td>Aromatic</td>
</tr>
<tr>
<td>Odour threshold</td>
<td>Not determined</td>
</tr>
<tr>
<td><strong>pH-value:</strong></td>
<td>Not determined</td>
</tr>
<tr>
<td><strong>Change in condition</strong></td>
<td></td>
</tr>
<tr>
<td>Melting point/Melting range</td>
<td>Not determined</td>
</tr>
<tr>
<td>Boiling point/Boiling range</td>
<td>270 °C</td>
</tr>
<tr>
<td><strong>Flash point:</strong></td>
<td>146 °C</td>
</tr>
<tr>
<td><strong>Inflammability (solid, gaseous)</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Ignition temperature:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Decomposition temperature:</strong></td>
<td>Not determined</td>
</tr>
<tr>
<td><strong>Self-inflammability:</strong></td>
<td>Product is not selfigniting.</td>
</tr>
<tr>
<td><strong>Danger of explosion:</strong></td>
<td>Product is not explosive.</td>
</tr>
<tr>
<td><strong>Critical values for explosion:</strong></td>
<td></td>
</tr>
<tr>
<td>Lower</td>
<td>Not determined</td>
</tr>
<tr>
<td>Upper</td>
<td>Not determined</td>
</tr>
<tr>
<td><strong>Steam pressure:</strong></td>
<td>Not determined</td>
</tr>
<tr>
<td><strong>Density at 20 °C</strong></td>
<td>0.900 g/cm³</td>
</tr>
<tr>
<td>Relative density</td>
<td>Not determined</td>
</tr>
<tr>
<td>Vapour density</td>
<td>Not determined</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not determined</td>
</tr>
</tbody>
</table>
### SECTION 10: Stability and reactivity

- **10.1 Reactivity**: No further relevant information available.
- **10.2 Chemical stability**: 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**: 

### SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
  - **Acute toxicity**: Based on available data, the classification criteria are not met.
  - **LD/LC50 values that are relevant for classification**:
    - **Oral**: LD50 4735 mg/kg (rat)
    - **110-27-0 isopropyl myristate**
      - **Oral**: LD50 >10000 mg/kg (rat)
      - **Dermal**: LD50 >5000 mg/kg (rabbit)
    - **Primary irritant effect**: Causes skin irritation.
    - **Serious eye damage/irritation**: Causes serious eye irritation.
    - **Respiratory or skin sensitisation**: Based on available data, the classification criteria are not met.
    - **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
      - **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**: May cause damage to organs through prolonged or repeated exposure.
    - **STOT-repeated exposure**: 

(Contd. on page 6)
Trade name: Xantopren function hardener 2

Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- 12.1 Toxicity
  - Aquatic toxicity: No further relevant information available.
- 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.
  - Ecotoxicological effects:
    - Remark: Very toxic for fish
  - Additional ecological information:
    - General notes:
      - Do not allow product to reach groundwater, water bodies or sewage system.
      - Danger to drinking water if even small quantities leak into soil.
      - Also poisonous for fish and plankton in water bodies.
      - Very toxic for aquatic organisms
- 12.5 Results of PBT and vPvB assessment
  - PBT: Not applicable.
  - vPvB: Not applicable.
- 12.6 Other adverse effects No further relevant information available.

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.
- European waste catalogue
  - 18 01 06 chemicals consisting of or containing dangerous substances
  - Uncleaned packagings:
    - Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information

- 14.1 UN-Number
  - ADR, IMDG, IATA 3082
- 14.2 UN proper shipping name
  - ADR 2788 ORGANOTIN COMPOUND, LIQUID, N.O.S. (dibutyltin dilaurate)
  - IMDG, IATA ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (dibutyltin dilaurate)
Trade name: Xantopren function hardener 2

14.3 Transport hazard class(es)
- ADR
  - Class 9 (M6) Miscellaneous dangerous substances and articles.
  - Label 9
- IMDG, IATA
  - Class 9 Miscellaneous dangerous substances and articles.
  - Label 9

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

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

14.6 Special precautions for user
- Warning: Miscellaneous dangerous substances and articles
  - Kemler Number: 90
  - EMS Number: F-A, S-A

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
- Not applicable.

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3, 20

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
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H373 May cause damage to organs through prolonged or repeated exposure.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.

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
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)
VOCV: Lenkungsabgabe auf flüchtigen organischen Verbindungen, Schweis (Swiss Ordinance on volatile organic compounds)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Skin Irrit. 2: Skin corrosion/irritation – Category 2
STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2
Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

* Data compared to the previous version altered.