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

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
     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.
     H400 Very toxic to aquatic life.
     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).
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
     - EINECS: 201-039-8
dibutyltin dilaurate
     - STOT RE 2, H373; Aquatic Acute 1, H400; Aquatic Chronic 1, H410;
     - Skin Irrit. 2, H315; Eye Irrit. 2, H319
     - 25-50%
   - 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.
Safety data sheet
according to 1907/2006/EC, Article 31

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· **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.

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**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.

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**SECTION 8: Exposure controls/personal protection**

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

· **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
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 trough 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

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information
- Appearance: Fluid
- Form: Yellow
- Colour: Aromatic
- Smell: Odour threshold: Not determined.
- pH-value: Not determined.
- Change in condition
  - Melting point/Melting range: Not determined
  - Boiling point/Boiling range: 270 °C
- Flash point: 146 °C
- Inflammability (solid, gaseous): Not applicable
- Ignition temperature:
  - Decomposition temperature: Not determined
- Self-inflammability: Product is not selfigniting
- Danger of explosion: Product is not explosive
- Critical values for explosion:
  - Lower: Not determined
  - Upper: Not determined
- Steam pressure: Not determined
- Density at 20 °C: 0.900 g/cm³
  - Relative density: Not determined
  - Vapour density: Not determined
  - Evaporation rate: Not determined
**Trade name:** Xantopren function hardener 2

- **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.
- **Solvent content:**
  - **VOC EU**
  - **g/l**
- **9.2 Other information**
  - No further relevant information available.

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**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 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:**
  - **Skin corrosion/irritation**
    - 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**
  - Based on available data, the classification criteria are not met.
- **STOT-repeated exposure**
  - May cause damage to organs through prolonged or repeated exposure.
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

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
    - III

- **14.5 Environmental hazards:**
  - Marine pollutant: Yes
    - Symbol (fish and tree)
  - 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.
  - Transport/Additional information:
    - -

- **UN "Model Regulation":**
  - UN3082, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S., 9, III

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**SECTION 15: Regulatory information**

- **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, Schweiz (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
- Eye Irrit. 2: Serious eye damage/eye 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.