1 Identification

· Product identifier
  · Trade name: **Xantopren function hardener 2**

· 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
  Skin Irrit. 2 H315 Causes skin irritation.
  Eye Irrit. 2A H319 Causes serious eye 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**

      GHS07 GHS08

· Signal word Warning

· Hazard-determining components of labeling:
  dibutyltin dilaurate

· **Hazard statements**
  Causes skin irritation.
  Causes serious eye irritation.
  May cause damage to organs through prolonged or repeated exposure.

· **Precautionary statements**
  Do not breathe dust/fume/gas/mist/vapors/spray.
  Wear protective gloves.
  Wear eye protection / face protection.
  If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
  Specific treatment (see on this label).
  If skin irritation occurs: Get medical advice/attention.

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

- Classification system
- NFPA ratings for USA (scale 0-4)
  - Health = 1
  - Fire = 1
  - Reactivity = 0

- HMIS-Ratings (Scale 0-4)
  - HEALTH
    - Health = *1
  - FIRE
    - Fire = 1
  - 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:
  - 77-58-7 dibutyltin dilaurate STOT RE 2, H373; Skin Irrit. 2, H315; Eye Irrit. 2A, H319 25-50%
- Additional information For the wording of the listed hazard phrases refer to section 16.

4 First-aid measures
- Description of first aid measures
  - After skin contact: Immediately wash with water and soap and rinse thoroughly.
  - 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.
    If symptoms persist consult doctor.
    Seek immediate medical advice.
- 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 spray. Fight larger fires with water spray or alcohol resistant foam.
  - Use fire fighting measures that suit the environment.
6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
  Wear protective equipment. Keep unprotected persons away.
- **Environmental precautions:**
  Inform respective authorities in case of seepage into water course or sewage system.
- **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. Send for recovery or disposal in suitable receptacles.
- **Reference to other sections**
  See Section 13 for disposal information.
  See Section 8 for information on personal protection equipment.

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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:** No special measures required.
- **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.

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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:**
    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 creation were used as basis.
**Trade name:** Xantopren function hardener 2

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**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

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**Physical and chemical properties**

**Information on basic physical and chemical properties**

**General Information**

- **Appearance:**
  - **Form:** Fluid
  - **Color:** Yellow
  - **Odor:** Aromatic
  - **Odor threshold:** Not determined.

- **pH-value:** Not determined.

**Change in condition**

- **Melting point/Melting range:** Undetermined
- **Boiling point/Boiling range:** 270 °C (518 °F)

- **Flash point:** 146 °C (295 °F)

- **Flammability (solid, gaseous):** Not applicable.
Trade name: Xantopren function hardener 2

- Ignition temperature:
  - Decomposition temperature: Not determined.
- Auto igniting: Product is not selfigniting.
- Danger of explosion: Product does not present an explosion hazard.
- Explosion limits:
  - Lower: Not determined.
  - Upper: Not determined.
- Vapor pressure: Not determined.
- Density at 20 °C (68 °F): 0.900 g/cm³ (7.511 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.
- 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:
      - 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:
  - on the skin: Irritant to skin and mucous membranes.
  - on the eye: Irritating effect.
12 Ecological information

- **Toxicity**
  - **Aquatic toxicity:** No further relevant information available.
  - **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.
- **Ecotoxicological effects**
  - **Remark:** Very toxic for fish
- **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.
    - Also poisonous for fish and plankton in water bodies.
    - Very toxic for aquatic organisms
  - **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.
- **Uncleaned packagings:**
  - **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- **UN-Number**
  - DOT: UN3082

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| · **ADR, IMDG, IATA**                  | 3082 |
| · **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) |
| · **Transport hazard class(es)**       |      |
|   · **DOT, IMDG, IATA**                |      |
|     · **Class**                        | 9 Miscellaneous dangerous substances and articles |
|     · **Label**                        | 9 |
| · **ADR**                              |      |
|     · **Class**                        | 9 (M6) Miscellaneous dangerous substances and articles |
|     · **Label**                        | 9 |
| · **Packing group**                    |      |
|   · **DOT, ADR, IMDG, IATA**           | III |
| · **Environmental hazards:**           |      |
|   · **Marine pollutant:**              | Yes |
|   · **Special marking (ADR):**         | Symbol (fish and tree) |
|   · **Special marking (IATA):**        | Symbol (fish and tree) |
| · **Special precautions for user**     | Warning: Miscellaneous dangerous substances and articles |
|   · **Danger code (Kemler):**          | 90 |
|   · **EMS Number:**                    | F-A,S-A |
| · **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). |
Trade name: Xantopren function hardener 2

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).
  - **Hazard pictograms**
    - GHS07
    - GHS08

- **Signal word** Warning
- **Hazard-determining components of labeling:**
  - dibutyltin dilaurate
- **Hazard statements**
  - Causes skin irritation.
  - Causes serious eye irritation.
  - May cause damage to organs through prolonged or repeated exposure.

- **Precautionary statements**
  - Do not breathe dust/fume/gas/mist/vapors/spray.
  - Wear protective gloves.
  - Wear eye protection / face protection.
  - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
  - Specific treatment (see on this label).
  - If skin irritation occurs: Get medical advice/attention.

- **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**
  - H315 Causes skin irritation.
  - H319 Causes serious eye irritation.
  - H373 May cause damage to organs through prolonged or repeated exposure.
Trade name: Xantopren function hardener 2

- **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
  - 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
  - Skin Irrit. 2: Skin corrosion/irritation – Category 2
  - Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A
  - STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2

* Data compared to the previous version altered.