1 Identification

- **Product identifier**
  - Trade name: Xantopren function Activator 2 Plus

- **Relevant identified uses of the substance or mixture and uses advised against**
  - No further relevant information available.

- **Application of the substance / the mixture**
  - Activator for dental impression material

- **Details of the supplier of the safety data sheet**
  - **Manufacturer/Supplier:**
    - Heraeus Kulzer GmbH
    - Grüner Weg 11, D-63450 Hanau
    - Tel.: 0800 4372522
  - **Information department:**
    - Marc Henn
    - Tel. +1 (574) 2995444 / Fax: +1 (574) 2912542
    - e-mail: marc.henn@kulzer-dental.com
  - **Emergency telephone 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 vapour.
  - Eye Irrit. 2A H319 Causes serious eye irritation.

- **Label elements**
  - **GHS label elements**
    - The product is classified and labeled according to the Globally Harmonized System (GHS).
  - **Hazard pictograms**
    - GHS02
    - GHS07

- **Signal word** Warning
- **Hazard statements**
  - Flammable liquid and vapour.
  - Causes serious eye irritation.
- **Precautionary statements**
  - Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
  - Use explosion-proof electrical/ventilating/lighting/equipment.
  - Wear protective gloves/protective clothing/eye protection/face protection.
  - IF ON SKIN (or hair): Remove/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.
  - Dispose of contents/container in accordance with local/regional/national/international regulations.

- **Classification system**
  - **NFPA ratings for USA (scale 0-4)**
    - Health = 2
    - Fire = 2
    - Reactivity = 0

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

3 Composition/information on ingredients

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

- Dangerous components:
  - 78-10-4 tetraethyl orthosilicate 5-10%
  - 870-08-6 dioctyltin oxide 5-10%
  - 681-84-5 tetramethyl orthosilicate < 1%

4 First-aid measures

- Description of first aid measures
  - After inhalation: Supply fresh air; consult doctor in case of complaints.
  - After skin contact: Immediately wash with water and soap and rinse thoroughly. 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. Seek immediate medical advice.
  - 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.
  - For safety reasons unsuitable extinguishing agents: 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: No special measures required.
  - Additional information:

6 Accidental release measures

- Personal precautions, protective equipment and emergency procedures:
  - Wear protective equipment. Keep unprotected persons away.
Trade name: Xantopren function Activator 2 Plus

- **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.
  - 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.

### 7 Handling and storage

- **Precautions for safe handling**
  - Wear protective equipment. Keep unprotected persons away.
  - Keep receptacles tightly sealed.
  - Ensure good ventilation/exhaustion at the workplace.
  - Please observe the additional instructions in the product’s instructions for use.

- **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.
    - **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:**

    | Compound                        | PEL  | REL  | TLV  |
    |---------------------------------|------|------|------|
    | 78-10-4 tetraethyl orthosilicate | 850 mg/m³, 100 ppm | 85 mg/m³, 10 ppm | 85 mg/m³, 10 ppm |
    | 681-84-5 tetramethyl orthosilicate | REL 6 mg/m³, 1 ppm | TLV 6 mg/m³, 1 ppm |

- **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.
      - Wash hands before breaks and at the end of work.
      - Do not inhale gases / fumes / aerosols.
    - **Breathing equipment:**
      - Not necessary with efficient local exhaust. If exposition to vapours is possible, use breathing protective mask (filter A).
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
- 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 in work areas without heightened risk of injury (e.g. Laboratory) gloves made of the following material are suitable:
  Butyl rubber, BR
  Fluorocarbon rubber (Viton)
  Nitrile rubber, NBR
  Natural rubber, NR
  Chloroprene rubber, CR
- For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:
  PVC or PE gloves
- Eye protection: Safety glasses
- Body protection: Light weight protective clothing

9 Physical and chemical properties
- Information on basic physical and chemical properties
  - General Information
    - Form: Liquid
    - Color: Light yellow
    - Odor: Aromatic
  - Change in condition
    - Melting point/Melting range: undetermined
    - Boiling point/Boiling range: > 110 °C (> 230 °F)
  - Flash point: > 48 °C (> 118 °F)
  - Auto igniting: Product is not selfigniting.
  - Danger of explosion: Product is not explosive. However, formation of explosive air/vapor mixtures are possible.
  - Density at 20 °C (68 °F): 0.920 g/cm³ (7.677 lbs/gal)
  - Solubility in / Miscibility with
    - Water: Not miscible or difficult to mix
    - Other information: No further relevant information available.

10 Stability and reactivity
- 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
Trade name: Xantopren function Activator 2 Plus

11 Toxicological information

· Information on toxicological effects
  · Acute toxicity:
    · LD/LC50 values that are relevant for classification:
      110-27-0 isopropyl myristate
      Oral LD50 >10000 mg/kg (rat)
      Dermal LD50 >5000 mg/kg (rabbit)
      78-10-4 tetraethyl orthosilicate
      Oral LD50 6270 mg/kg (rat)
      Dermal LD50 5878 mg/kg (can)
      870-08-6 dioctyltin oxide
      Oral LD50 >4000 mg/kg (rat)
      681-84-5 tetramethyl orthosilicate
      Oral LD50 700 mg/kg (rat)
  · Primary irritant effect:
    · on the skin: No irritant effect.
    · on the eye: No irritating effect.
  · Additional toxicological information: Harmful

· Carcinogenic categories
  None of the ingredients is listed.

· 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)
    870-08-6 dioctyltin oxide
    EC50/48h 6.9 mg/l (daphnia)
    LC50/96h 13 mg/l (fish)
  · Persistence and degradability
    No further relevant information available.
  · Bioaccumulative potential
    No further relevant information available.
  · Mobility in soil
    No further relevant information available.
  · Additional ecological information:
    · General notes: Avoid transfer into the environment.

· Results of PBT and vPvB assessment
  · PBT: Not applicable.
  · vPvB: Not applicable.

(Contd. on page 6)
Safety Data Sheet
acc. to OSHA HCS

Trade name: Xantopren function Activator 2 Plus

Other adverse effects No further relevant information available.

13 Disposal considerations

· Waste treatment methods
  · Recommendation
  Small quantities can be polymerized with the matching system component(s) and the cured solid material can be disposed of with the regular garbage. Larger quantities must be disposed of following the regulations of the local authorities.
  · Uncleaned packagings:
    · Recommendation: Disposal must be made according to official regulations.

14 Transport information

· UN-Number
  · DOT NA1993
  · ADR, IMDG, IATA UN1993

· UN proper shipping name
  · DOT COMBUSTIBLE LIQUID, N.O.S. (TETRAETHYL SILICATE, METHYL ORTHOSILICATE)
  · ADR 1993 FLAMMABLE LIQUID, N.O.S., special provision 640E (TETRAETHYL SILICATE, METHYL ORTHOSILICATE)
  · IMDG, IATA FLAMMABLE LIQUID, N.O.S. (TETRAETHYL SILICATE, METHYL ORTHOSILICATE)

· Transport hazard class(es)
  · DOT
    · Class 3
    · Label 3 Combustible liquids
  · ADR
    · Class 3 (F1)
    · Label 3 Combustible liquids
  · IMDG, IATA
    · Class 3
    · Label 3 Combustible liquids
Trade name: Xantopren function Activator 2 Plus

- Packing group
  - DOT, ADR, IMDG, IATA III
- Environmental hazards:
  - Marine pollutant: No
- Special precautions for user
  - Danger code (Kemler): Warning: Combustible liquids 30
  - EMS Number: F-E,S-E
- Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code
  - Not applicable.
- Transport/Additional information:
  - UN "Model Regulation": UN1993, Flammable liquids, n.o.s., special provision 640E (Tetraethyl silicate, Methyl orthosilicate), 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.
  - TSCA (Toxic Substances Control Act) Medical devices are exempted from TSCA.
  - Cancerogenity categories

- TLV (Threshold Limit Value established by ACGIH)
  - 870-08-6 dioctyltin oxide A4

- GHS label elements
  - The product is classified and labeled according to the Globally Harmonized System (GHS).
  - Hazard pictograms
    - GHS02
    - GHS07

- Signal word Warning
- Hazard statements
  - Flammable liquid and vapour. Causes serious eye irritation.
- Precautionary statements
  - Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Use explosion-proof electrical/ventilating/lighting/equipment. Wear protective gloves/protective clothing/eye protection/face protection. IF ON SKIN (or hair): Remove/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. Dispose of contents/container in accordance with local/regional/national/international regulations.
- 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.

- Date of preparation / last revision 05/12/2015 /
- 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
  - Flam. Liq. 3: Flammable liquids, Hazard Category 3
  - Eye Irrit. 2A: Serious eye damage/eye irritation, Hazard Category 2A
- * Data compared to the previous version altered.