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

· 1.1 Product identifier
  · Trade name: SpeedCEM (Catalyst)

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

· 1.3 Details of the supplier of the safety data sheet
  · Manufacturer/Supplier:
    Ivoclar Vivadent AG
    Bendererstrasse 2
    FL-9494 Schaan
    PRINCIPALITY OF LIECHTENSTEIN

  · Tel: +423 235 35 35
  · Fax: +423 235 33 60

· 1.4 Emergency telephone number:
  · +423 / 235 33 13 (Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein)

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.
    · Skin Sens. 1 H317 May cause an allergic skin reaction.
    · STOT SE 3 H335 May cause respiratory irritation.

· 2.2 Label elements
  · Labelling according to Regulation (EC) No 1272/2008
    The product is classified and labelled according to the CLP regulation.

· 2.3 Hazard pictograms
  · GHS07

· 2.4 Signal word
  · Warning

· 2.5 Hazard-determining components of labelling:
  · Urethane dimethacrylate
  · Ytterbium trifluoride
  · Triethylene glycol dimethacrylate
  · Methacrylated phosphoric acid ester

· 2.6 Hazard statements
  · H315 Causes skin irritation.
  · H319 Causes serious eye irritation.
  · H317 May cause an allergic skin reaction.
  · H335 May cause respiratory irritation.

· 2.7 Precautionary statements
  · P280 Wear protective gloves/protective clothing/eye protection/face protection.
## SECTION 3: Composition/information on ingredients

### 3.2 Chemical characterisation: Mixtures

**Description:** Mixture of substances listed below with nonhazardous additions.

<table>
<thead>
<tr>
<th>CAS</th>
<th>EINECS</th>
<th>Substance</th>
<th>% in mixture</th>
</tr>
</thead>
<tbody>
<tr>
<td>13760-80-0</td>
<td>237-354-2</td>
<td>ytterbium trifluoride</td>
<td>25-50%</td>
</tr>
<tr>
<td>72869-86-4</td>
<td>276-957-5</td>
<td>urethane dimethacrylate</td>
<td>10-&lt;25%</td>
</tr>
<tr>
<td>109-16-0</td>
<td></td>
<td>triethylene glycol dimethacrylate</td>
<td>≤10%</td>
</tr>
<tr>
<td>85590-00-7</td>
<td></td>
<td>Methacrylated phosphoric acid ester</td>
<td>3-&lt;10%</td>
</tr>
<tr>
<td>25852-47-5</td>
<td></td>
<td>polyethylene glycol dimethacrylate</td>
<td>1-&lt;2.5%</td>
</tr>
<tr>
<td>94-36-0</td>
<td>202-327-6</td>
<td>dibenzoyl peroxide</td>
<td>0.3-&lt;1%</td>
</tr>
</tbody>
</table>

**Additional information:** For the wording of the listed risk phrases refer to section 16.

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

After inhalation:
Supply fresh air and be sure call for a doctor.
In case of unconsciousness place patient stably in side position for transportation.

After skin contact:
Rinse with water.

After eye contact:
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

After swallowing:
If symptoms persist consult doctor.

### 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, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

(Contd. on page 3)
Safety data sheet
according to 1907/2006/EC, Article 31

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Version number 4
Revision: 12.03.2015

Trade name: SpeedCEM (Catalyst)

- 5.2 Special hazards arising from the substance or mixture: No further relevant information available.
- 5.3 Advice for firefighters
  - Protective equipment: No special measures required.

SECTION 6: Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures: Not required.
- 6.2 Environmental precautions: Do not allow to enter sewers/surface or ground water.
- 6.3 Methods and material for containment and cleaning up: Pick up mechanically.
- 6.4 Reference to other sections
  - See Section 7 for information on safe handling.
  - See Section 8 for information on personal protection equipment.
  - See Section 13 for disposal information.

SECTION 7: Handling and storage

- 7.1 Precautions for safe handling
  - Only adequately trained personnel should handle this product.
  - For use in dentistry only.
  - Information about fire - and explosion protection: No special measures required.
- 7.2 Conditions for safe storage, including any incompatibilities
- 7.3 Specific end use(s): No further relevant information available.
- 7.4 Reference to other sections
  - See Section 8 for information on personal protection equipment.

SECTION 8: Exposure controls/personal protection

- 8.1 Control parameters
  - Ingredients 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 valid during the making were used as basis.
- 8.2 Exposure controls
  - Personal protective equipment:
  - General protective and hygienic measures:
    Usual hygienic measures for dental practice.
    Wash hands before breaks and at the end of work.
    Avoid contact with the eyes and skin.
    Keep away from foodstuffs, beverages and feed.
- 8.3 Protection of hands:
  - Protective gloves

(Contd. on page 4)
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

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 through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection**: Safety glasses

### SECTION 9: Physical and chemical properties

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

- **General Information**
  - **Appearance:**
    - **Form:** Pasty
    - **Colour:** According to product specification
    - **Odour:** Characteristic
    - **Odour threshold:** Not determined.
  - **pH-value:** Not determined.

- **Change in condition**
  - Melting point/Melting range: Undetermined.
  - Boiling point/Boiling range: Undetermined.

- **Flash point:** Not applicable.

- **Self-igniting:** Product is not selfigniting.

- **Danger of explosion:** Product does not present an explosion hazard.

- **Explosion limits:**
  - Lower: Not determined.
  - Upper: Not determined.

- **Vapour pressure:** Not determined.

- **Density:** Not determined.
- **Relative density**
- **Vapour density**
- **Evaporation rate**

- **Solubility in / Miscibility with water:** Nearly insoluble.

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

- **Viscosity:**
  - Dynamic: Not determined.
  - Kinematic: Not determined.

#### 9.2 Other information
No further relevant information available.
SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
  Stable under normal handling and storage conditions.
  Photoreactive (Danger of polymerization).
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid**
  Protect from exposure to the light.
  Keep away from heat and direct sunlight.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** None under normal conditions of storage and use.

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
  - **Acute toxicity** Based on available data, the classification criteria are not met.
  - **Skin corrosion/irritation** Causes skin irritation.
  - **Serious eye damage/irritation** Causes serious eye irritation.
  - **Respiratory or skin sensitisation** May cause an allergic skin reaction.
  - **Additional toxicological information:** No further relevant information available.
  - **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 respiratory irritation.
  - **STOT-repeated exposure** Based on available data, the classification criteria are not met.
  - **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.
  - **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:**
    Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
    Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
  - **12.5 Results of PBT and vPvB assessment**
    | PBT | vPvB |
    |-----|------|
    | Not applicable | Not applicable |
- **12.6 Other adverse effects** No further relevant information available.
SECTION 13: Disposal considerations

- 13.1 Waste treatment methods
  - Recommendation
    Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
  - Uncleaned packaging:
    - Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information

- 14.1 UN-Number
  - ADR, RID, ADN, ADN, IMDG, IATA Void

- 14.2 UN proper shipping name
  - ADR, RID, ADN, ADN, IMDG, IATA Void

- 14.3 Transport hazard class(es)
  - ADR, RID, ADN, ADN, IMDG, IATA Void

- 14.4 Packing group
  - ADR, RID, ADN, IMDG, IATA Void

- 14.5 Environmental hazards:
  - Marine pollutant: No

- 14.6 Special precautions for user
  - Not applicable.

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

- Transport/Additional information:
  - Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).

- UN "Model Regulation": Void

SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
  - National regulations:
  - Other regulations, limitations and prohibitive regulations
    The product is a medical device according to the Directive 93/42/EEC.

- 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- Relevant phrases
  - H241 Heating may cause a fire or explosion.
  - H315 Causes skin irritation.
  - H317 May cause an allergic skin reaction.
  - H319 Causes serious eye irritation.
  - H335 May cause respiratory irritation.
H412 Harmful 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)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Org. Perox. B: Organic Peroxides, Type B
Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2
Skin Sens. 1: Sensitisation - Skin, Hazard Category 1
STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3
Aquatic Chronic 3: Hazardous to the aquatic environment - Chronic Hazard, Category 3

* Data compared to the previous version altered.