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

· 1.1 Product identifier
  · Trade name: SpeedCem Plus (Base)

· 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.

· 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
  · Signal word Warning
  · Hazard-determining components of labelling:
    · urethane dimethacrylate
    · triethylene glycol dimethacrylate

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

· Precautionary statements
  · P280 Wear protective gloves/protective clothing/eye protection/face protection.
  · P302+P352 IF ON SKIN: Wash with plenty of water.
  · P333+P313 IF skin irritation or rash occurs: Get medical advice/attention.
  · P337+P313 IF eye irritation persists: Get medical advice/attention.

(Contd. on page 2)
Trade name: SpeedCem Plus (Base)

41.2.21

· Additional information:
  Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

· 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: Mixture of substances listed below with nonhazardous additions.

· Dangerous components:
  
<table>
<thead>
<tr>
<th>CAS:</th>
<th>Chemical name</th>
<th>Percentages</th>
</tr>
</thead>
<tbody>
<tr>
<td>72869-86-4</td>
<td>urethane dimethacrylate</td>
<td>10-&lt;25%</td>
</tr>
<tr>
<td>276-957-5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>109-16-0</td>
<td>triethylene glycol dimethacrylate</td>
<td>2.5-&lt;10%</td>
</tr>
<tr>
<td>25852-47-5</td>
<td>polyethylene glycol dimethacrylate</td>
<td>2.5-&lt;10%</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 to be sure call for a doctor.
    In case of unconsciousness place patient stably in side position for transportation.
  · After skin contact:
    Rinse with water.
    If skin irritation continues, consult a doctor.
  · After eye contact:
    Rinse opened eye for several minutes under running water. Then consult a doctor.
  · After swallowing:
    Rinse out mouth and then drink plenty of water.
    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.

· 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.
- 7.2 Conditions for safe storage, including any incompatibilities
  - Storage:
    - Requirements to be met by storerooms and receptacles: Store only in the original receptacle.
    - Information about storage in one common storage facility: Not required.
    - Further information about storage conditions:
      - Protect from exposure to the light.
      - Protect from heat and direct sunlight.
      - Keep container tightly sealed.
- 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

- Additional information about design of technical facilities: No further data; see item 7.
- 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.
    - Respiratory protection:
      - In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
  - Protection of hands:
    - Protective gloves
      - The glove material has to be impermeable and resistant to the product/substance/preparation.
      - After use of gloves apply skin-cleaning agents and skin cosmetics.
41.2.21

- **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.

- **Not suitable are gloves made of the following materials:**
  Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates.

- **Eye protection:** Safety glasses

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### SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
  - **General Information**
    - **Appearance:** 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:** Not determined.
    - **Vapour density:** Not determined.
    - **Evaporation rate:** Not determined.
    - **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.

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### SECTION 10: Stability and reactivity

- **10.1 Reactivity**
  No further relevant information available.
### SECTION 6: Exposition / Transport Information

- **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** May cause an allergic skin reaction.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **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.
- **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.
- **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:** 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**
    - Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

(Contd. on page 6)
Trade name: SpeedCem Plus (Base)

- 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
  - Directive 2012/18/EU
  - Named dangerous substances - ANNEX I: None of the ingredients is listed.
- 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
  - 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

(Contd. on page 7)
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
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