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

- **1.1 Product identifier**
  - Trade name: **ApexCal**

- **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 Corr. 1A H314 Causes severe skin burns and eye damage.
    - Eye Dam. 1 H318 Causes serious eye damage.
    - STOT SE 3 H335 May cause respiratory irritation.
    - Aquatic Chronic 3 H412 Harmful 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**
    - GHS05
    - GHS07

- **Signal word** Danger

- **Hazard-determining components of labelling:**
  - calcium dihydroxide

- **Hazard statements**
  - H314 Causes severe skin burns and eye damage.
  - H335 May cause respiratory irritation.
  - H412 Harmful to aquatic life with long lasting effects.

- **Precautionary statements**
  - P280 Wear protective gloves/protective clothing/eye protection/face protection.
  - P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
  - P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
  - P301 + P330 + P331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
Trade name: ApexCal

- **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.

<table>
<thead>
<tr>
<th>Dangerous components</th>
<th>CAS:</th>
<th>EINECS:</th>
<th>Description</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>calcium dihydroxide</td>
<td>1305-62-0</td>
<td>215-137-3</td>
<td>Eye Dam. 1, H318; Skin Irrit. 2, H315; STOT SE 3, H335</td>
<td>10-&lt;25%</td>
</tr>
<tr>
<td>glycerol</td>
<td>56-81-5</td>
<td>200-289-5</td>
<td>substance with a Community workplace exposure limit</td>
<td>5-&lt;10%</td>
</tr>
<tr>
<td>zinc oxide</td>
<td>1314-13-2</td>
<td>215-222-5</td>
<td>Aquatic Acute 1, H400; Aquatic Chronic 1, H410</td>
<td>1-&lt;2.5%</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; consult doctor in case of complaints.
    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:**
    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.
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

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.

7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace:

<table>
<thead>
<tr>
<th>CAS Number</th>
<th>Substance</th>
<th>WEL Long-term value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1305-62-0</td>
<td>calcium dihydroxide</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>56-81-5</td>
<td>glycerol</td>
<td>10 mg/m³</td>
</tr>
</tbody>
</table>

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: Not required.

Protection of hands:

Protective gloves

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

(Contd. on page 4)
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 cannot be calculated in advance and has therefore to be checked prior to the application.

- **Penetration time of glove material**
  The exact breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.

- **Eye protection**
  Tightly sealed goggles

## 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:** >12.5

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

- **Flash point:** Not applicable.

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

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

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

- **Vapour pressure:** Not determined.

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

- **Solubility in / Miscibility with water:** Soluble.

- **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.
- 10.3 Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- 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 under normal conditions of storage and use.

SECTION 11: Toxicological information

- 11.1 Information on toxicological effects
  - Acute toxicity:
    - LD/LC50 values relevant for classification:
      - 1314-13-2 zinc oxide
        - Oral: LD50 > 5000 mg/kg (rat)
    - Primary irritant effect:
      - on the skin: No irritant effect.
      - on the eye: Strong irritant with the danger of severe eye injury.
      - Sensitisation: No sensitising effects known.
    - Additional toxicological information: No further relevant information available.

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: Harmful to fish
- 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.
    - Harmful to aquatic organisms
- 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.
SECTION 14: Transport information

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

· 14.2 UN proper shipping name
  · ADR, ADN, IMDG, IATA
  Void

· 14.3 Transport hazard class(es)
  · ADR, ADN, IMDG, IATA
  Class
  Void

· 14.4 Packing group
  · ADR, 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 73/78 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":
  -

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
  H315 Causes skin irritation.
  H318 Causes serious eye damage.
  H335 May cause respiratory irritation.
  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) |
| LC50: Lethal concentration, 50 percent |
| LD50: Lethal dose, 50 percent |
| Skin Corr. 1A: Skin corrosion/irritation, Hazard Category 1A |
| Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2 |
| Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1 |
| STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3 |
| Aquatic Acute 1: Hazardous to the aquatic environment - Acute Hazard, Category 1 |
| Aquatic Chronic 1: Hazardous to the aquatic environment - Chronic Hazard, Category 1 |
| Aquatic Chronic 3: Hazardous to the aquatic environment - Chronic Hazard, Category 3 |

* Data compared to the previous version altered.