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

1.1 Product identifier

Trade name: Apexit Plus (Base)

1.2 Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

Application of the substance / the mixture: Root canal sealer

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

Further information obtainable from:

Regulatory Affairs

sds@ivoclarvivadent.com

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. 1B  H314  Causes severe skin burns and eye damage.

Eye Dam. 1   H318  Causes serious eye damage.

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

Signal word Danger

Hazard-determining components of labelling:
calcium oxide
calcium dihydroxide

Hazard statements

H314 Causes severe skin burns and eye damage.

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.

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.
EUH014 Reacts violently with water.

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 characterisation</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>1305-62-0</td>
<td>calcium dihydroxide</td>
<td>10-&lt;25%</td>
</tr>
<tr>
<td>215-137-3</td>
<td>Eye Dam. 1, H318; Skin Irrit. 2, H315; STOT SE 3, H335</td>
<td></td>
</tr>
<tr>
<td>1305-78-8</td>
<td>calcium oxide</td>
<td>10-&lt;25%</td>
</tr>
<tr>
<td>215-138-9</td>
<td>Skin Corr. 1B, H314</td>
<td></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.

4.3 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.
**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.
- **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:
    - **1305-62-0 calcium dihydroxide**
      WEL Long-term value: 5 mg/m³
    - **1305-78-8 calcium oxide**
      WEL Long-term value: 2 mg/m³
  - **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
  - **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**
    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:
Tightly sealed goggles

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- General Information
  - Appearance:
    - Form: Pasty
    - Colour: Whitish
  - Odour: Characteristic
  - Odour threshold: Not determined.
  - pH-value at 20 °C: ~8.5

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

- Flash point: Not applicable.

- Flammability (solid, gaseous): 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: Partly miscible.

- 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.
SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity:
- 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.
- 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.
- Uncleaned packaging:
  - Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information

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

14.2 UN proper shipping name
- ADR, ADN, IMDG, IATA Void
**Trade name: Apexit Plus (Base)**

- **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 MARPOL73/78 and the IBC Code**
  - Not applicable.

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

**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**
  - H314 Causes severe skin burns and eye damage.
  - H315 Causes skin irritation.
  - H318 Causes serious eye damage.
  - H335 May cause respiratory irritation.

- **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)
  - Skin Corr. 1B: Skin corrosion/irritation, Hazard Category 1B
  - 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

- * Data compared to the previous version altered.