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

1.1 Product identifier

Trade name: **Apexit Plus (Activator)**

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

The product is not classified according to the CLP regulation.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 Void

Hazard pictograms Void
Signal word Void
Hazard statements Void

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: Void

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

General information: No special measures required.

After inhalation: Supply fresh air; consult doctor in case of complaints.
**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:**
  - No special measures required.

- **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: 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:
    - 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.

(Contd. on page 3)
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.
Keep away from foodstuffs, beverages and feed.

Respiratory protection:
Not required.

Protection of hands:
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 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.

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: Not determined.

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

Flash point: Not applicable.

Flammability (solid, gaseous): 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: Not determined.
Relative density Not determined.
Vapour density Not determined.
Evaporation rate Not determined.
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:
· Primary irritant effect:
  · on the skin: No irritant effect.
  · on the eye: No irritating effect.
· Sensitisation: No sensitising effects known.
· Additional toxicological information:
  When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

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: Generally not hazardous for water
· 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.
Trade name: Apexit Plus (Activator)

(Contd. of page 4)

· 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

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

· 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.

· 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
  · ELINCS: European List of Notified Chemical Substances
  · CAS: Chemical Abstracts Service (division of the American Chemical Society)
· * Data compared to the previous version altered.