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

1.1 Product identifier

Trade name: FRC Postec Plus

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 Glass-fibre reinforced composite root canal post

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: Glass-fibre reinforced composite root canal post

<table>
<thead>
<tr>
<th>Dangerous components:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS: 41637-38-1</td>
<td>ethyoxylated bisphenol A dimethacrylate</td>
</tr>
<tr>
<td>Aquatic Chronic 4, H413</td>
<td>10-&lt;25%</td>
</tr>
<tr>
<td>CAS: 13760-80-0</td>
<td>ytterbium trifluoride</td>
</tr>
<tr>
<td>EINECS: 237-354-2</td>
<td>Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335</td>
</tr>
<tr>
<td>3-&lt;10%</td>
<td></td>
</tr>
</tbody>
</table>

(Contd. on page 2)
Trade name: FRC Postec Plus

40.1.5

<table>
<thead>
<tr>
<th>CAS: 1565-94-2</th>
<th>Bis-GMA</th>
<th>Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317</th>
<th>3-&lt;10%</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS: 2082-81-7</td>
<td>1,4-butanediol dimethacrylate</td>
<td>Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335</td>
<td>3-&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.

After eye contact:
Seek medical treatment.

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: 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.

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: Store only in the original receptacle.

Information about storage in one common storage facility: Not required.

Further information about storage conditions: None.
SECTION 8: Exposure controls/personal protection

- Additional information about design of technical facilities: No further data; see item 7.
- 8.1 Control parameters

<table>
<thead>
<tr>
<th>Ingredients with limit values that require monitoring at the workplace:</th>
</tr>
</thead>
<tbody>
<tr>
<td>13760-80-0 ytterbium trifluoride</td>
</tr>
<tr>
<td>WEL: Long-term value: 2.5 mg/m³ as F</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:
    - Wash hands before breaks and at the end of work.
    - Usual hygienic measures for dental practice.
    - Keep away from foodstuffs, beverages and feed.
  - Respiratory protection: Not required.
  - Protection of hands: Not required.
- 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: Not required.

SECTION 9: Physical and chemical properties

- 9.1 Information on basic physical and chemical properties

- General Information

- Appearance:
  - Form: Solid
  - Colour: Whitish
  - Odour: Odourless
  - Odour threshold: Not determined.
- pH-value: Not applicable.

- Change in condition
  - Melting point/Melting range: Undetermined.
  - Boiling point/Boiling range: Undetermined.
- Flash point: Not applicable.
- Flammability (solid, gaseous): Not determined.
- Self-igniting: Product is not selfigniting.
- Danger of explosion: Product does not present an explosion hazard.
40.1.5

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

- **Vapour pressure:** Not applicable.

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

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

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

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

- **Solvent content:**
  - Solids content: 100.0 %

9.2 Other information

**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 Possibility of hazardous reactions:** No dangerous reactions known.
- **10.5 Conditions to avoid:** No further relevant information available.
- **10.6 Incompatible materials:** No further relevant information available.
- **10.7 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.

**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.

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Safety data sheet
according to 1907/2006/EC, Article 31

Trade name: FRC Postec Plus

- 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.
  - European waste catalogue
    - 07 02 13 waste plastic
- 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:
  - 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.
Trade name: **FRC Postec Plus**

- **Relevant phrases**
  - H315 Causes skin irritation.
  - H317 May cause an allergic skin reaction.
  - H319 Causes serious eye irritation.
  - H335 May cause respiratory irritation.
  - H413 May cause long lasting harmful effects to aquatic life.

- **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 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 4: Hazardous to the aquatic environment - Chronic Hazard, Category 4

- * Data compared to the previous version altered.