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

Printing date 28.04.2015

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Version number 4

Revision: 02.04.2015

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

· Dangerous components:		
CAS: 41637-38-1	ethyoxylated bisphenol A dimethacrylate	10-<25%
	Aquatic Chronic 4, H413	
	ytterbium trifluoride	3-<10%
EINECS: 237-354-2	Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	
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CAS: 1565-94-2	Bis-GMA	Contd. of page 1) 3-<10%
	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	
	1,4-butanediol dimethacrylate	3-<10%
EINECS: 218-218-1	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	

• 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.

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· 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:
- 13760-80-0 ytterbium trifluoride
- WEL Long-term value: 2.5 mg/m<sup>3</sup>

· Additional information: The lists valid during the making were used as basis.

· 8.2 Exposure controls

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- · 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	<i>H</i> 1, 1	
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.	
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· 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-octano	<i>l/water):</i> Not determined.	
· Viscosity:		
Dynamic:	Not applicable.	
Kinematic:	Not applicable.	
· Solvent content:		
Solids content:	100.0 %	
· 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.
- 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 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.

## **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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· 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.

<b>SECTION 14: Transport information</b>	<b>SECTION 1</b>	4: Transport	information
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· 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
<ul> <li>14.4 Packing group</li> <li>ADR, IMDG, IATA</li> </ul>	Void
<ul> <li>14.5 Environmental hazards:</li> <li>Marine pollutant:</li> </ul>	No
· 14.6 Special precautions for user	Not applicable.
· 14.7 Transport in bulk according to Annex MARPOL73/78 and the IBC Code	II of 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.

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(Contd. of page 5) · 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  $\cdot$  \* Data compared to the previous version altered.