

EU Safety Data Sheet

Vivaglass CEM PL Powder



Date of issue / Reference	18.08.2011	liprt		
Replaces version of	01.10.2007	lise / v3		
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Company Ivoclar Vivadent AG, Bendererstrasse 2, FL - 9494 Schaan
Fürstentum Liechtenstein

1 Commercial product name and supplier

1.1	Commercial product name / Designation	Vivaglass CEM PL Powder
1.2	Application / Use	Glass ionomer cement
1.3	Producer	Ivoclar Vivadent AG, Bendererstrasse 2, FL - 9494 Schaan Fürstentum Liechtenstein msds@ivoclarvivadent.com
	Supplier	
1.4	TOX emergency number	
	Official	Emergency-Call: +423 / 235 33 13 Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein

2 **Hazards identification** Irritating to eyes, respiratory system and skin.

3 Composition

3.1	Chemical characterization	Mixture of polyacrylic acid, inorganic fillers and pigments
3.2	Hazardous components	
	CAS No. 9003-01-4	< 30 % Polyacrylic acid Xi: Irritant. R36/37/38: Irritating to eyes, respiratory system and skin.
3.3	Further information	None.

4 First aid measures

4.1	Eye contact	Flush eyes with plenty of water (10-15 min.). Call a physician.
4.2	Skin contact	Wash thoroughly with water.
4.3	Ingestion	Give large amounts of water. If you feel unwell, seek medical advice (show this safety data sheet).
4.4	Inhalation	Remove to fresh air.
4.5	Further information	None.

5 Fire-fighting measures

5.1	Suitable extinguishing media	Water fog, carbon dioxide, foam, dry chemicals.
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5.2 Extinguishing media to avoid None known

5.3 Further information None.

6 Accidental release measures
Clean up mechanically.
Dispose of according to local and national regulations.
Wash the area with soap and water.

7 Handling and storage

7.1 Handling Only adequately trained personnel should handle this product.
This product is intended for use in dentistry only.
Keep out of reach of children.

7.2 Industrial hygiene Usual hygienic measures for dental practice.
When using, do not eat, drink or smoke.

7.3 Storage Store at 12-28 °C / 54-82 °F.

7.4 Place of storage Protect from excessive heat and cold.

7.5 Fire- and explosion-protection Not required.

8 Exposure controls / Personal protection

8.1 Exposure controls Good general ventilation should be sufficient.

8.2 Exposure limit values None established.

8.3 Occupational exposure controls

8.3.1 Respiratory protection Respiratory Protection.

8.3.2 Hand protection Gloves.

8.3.3 Eye protection Safety goggles (patient).

8.3.4 Other None.

8.4 Environmental exposure controls

9 Physical and chemical properties

9.1 Appearance powder

9.2 Colour off-white to cream

9.3 Odour practically odourless

9.4 Change of physical state Test method:

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9.5 Density	Not determined.
9.6 Vapour pressure	not applicable
9.7 Viscosity	not determined
9.8 Solubility Solubility in water	partially miscible
9.9 pH	< 2
9.10 Flash point	> 150 °C
9.11 Ignition temperature	not determined
9.12 Explosion limits	Lower: Upper: not applicable
9.13 Further information Part. coeff. n-octanol/water Evaporat. rate	None.

10 Stability and reactivity

10.1 Thermal decomposition	None, if used in accordance to instructions.
10.2 Hazardous decomposition products	None under normal conditions of storage and use.
10.3 Conditions / materials to avoid	None.
10.4 Further information	None.

11 Toxicological information

11.1 Acute toxicity	Oral LD50 for rats: > 5'000 mg/kg Direct contact may cause eye irritation. Skin: repeated or prolonged exposure may cause slight irritations. Assessment based on actual testing or on data for similar material(s).
11.2 Subacute / Chronic toxicity	Uncured material: prolonged or frequently repeated skin contact may cause allergic skin reactions.
11.3 Further information	No hazards anticipated from swallowing small amounts incidentally to normal handling.

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12 Ecological information

12.1	Ecotoxicity	No data available.
12.2	Mobility	No data available.
12.3	Persistence and degradability	No data available.
12.4	Bioaccumulative potential	No data available.
12.5	Further information	No ecological problems to be anticipated if properly handled and used.

13 Disposal considerations

		Take to a special waste incineration plant, in line with local regulations.
13.1	EU waste key	18 01 07

14 Transport information

14.1	Transport at land	ADR	---	RID	---
		UN Number	---	Kemler Number	---
		Packing Group	---		
		Proper shipping name	---		
14.2	Transport at sea	ADNR	---	IMDG	---
		UN Number	---		
		EMS	---	MFAG	---
		Packing Group			
		Proper shipping name	---		
		Marine pollutant			
14.3	Air transport	ICAO / IATA-DGR	---		
		UN Number	---		
		Proper shipping name	---		
		Subsidiary Risk	---		
		Labels	---		
		Packing Group	---		
	Passenger airplane	Packing Instructions	---		
		max.	---		
	Cargo Airplane	Packing Instructions	---		
		max.	---		
14.4	Further information	Product is not classified as a dangerous good for transport.			

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15 Regulatory information

The product is a medical device according to the EC-directive 93/42/EEC.

This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada.

This product requires classification according to the criteria of the "Gefahrstoffverordnung".

15.1 UN number ---

15.2 National regulations

15.3 EINECS/ELINCS number ---

15.4 Hazard symbols

Xi



15.5 Hazard designation Xi: Irritant. Contains Polyacrylic acid.

15.6 Risk phrases

R: 36/37/38

36/37/38 Irritating to eyes, respiratory system and skin.

15.7 Safety phrases

S: 2-26-28

2 Keep out of the reach of children.

26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advise.

28 After contact with skin, wash immediately with plenty of water.

15.8 AGW value

15.9 BVD classification (CH)

15.10 VbF (D)

15.11 Further information None.

16 Other information

No other information.

The above mentioned data correspond to our present state of knowledge and experience. The safety data sheet serves as description of the products in regard to necessary safety measures. The indications do not have the meaning of guarantees on properties.