

**SAFETY DATA SHEET (GHS)**

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**1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE/PRODUCT AND MANUFACTURER/IMPORTER****1.1 Product identifier:-**

**Product name:** Vivaglass CEM PL - Liquid  
**Product number:** Void

**1.2 Other means of identification:-**

Not applicable.

**1.3 Recommended use of the chemical and restrictions on use:-**

Not applicable.

**Identified uses:** Self-curing glass ionomer based radiopaque luting cement

**1.4 Details of the manufacturer and importer:-**

**Manufacturer:** Ivoclar Vivadent AG  
 Bendererstrasse 2  
 FL-9494 Schaan  
 PRINCIPALITY OF LIECHTENSTEIN

**Importer:** Ivoclar Vivadent Ltd  
 12 Omega St, Rosedale, Auckland, New Zealand  
 Phone +64 9 914 9999 Fax +64 9 914 9990  
 www.ivoclarvivadent.co.nz

**Emergency phone number:** 0800 764 766 (National Poison Centre)  
 Poisons Hotline (24 hours / 7 days)

**2. HAZARD(S) IDENTIFICATION****2.1 GHS Classification:-**

Eye Irrit. 2 H319 Causes serious eye irritation.

**2.2 GHS Label elements, including precautionary statements:-****Hazard Pictogram:**

GHS07

**Signal word:**

Warning

**Hazard-determining components of labelling:**

Void

**Hazard statements:**

H319 Causes serious eye irritation

**Precautionary statements:**

P280 Wear protective gloves/protective clothing/eye protection/face protection.  
 P337+P313 If eye irritation persists: Get medical advice/attention.

**2.3 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.

**Other hazards:-**

Void

**Results of PBT and vPvB assessment;**

**PBT:** Not applicable.

**vPvB:** Not applicable.

### 3 COMPOSITION/INFORMATION ON INGREDIENTS

Mixture of substances listed below with nonhazardous additions.

Ingredient name	CAS No.	Classification	Concentration
(+)-tartaric acid	87-69-4	Eye Irrit. 2, H319	10-<25%

### 4. FIRST AID MEASURES

#### 4.1 Description of necessary first aid measures:-

**If inhaled:**

Supply fresh air and to be sure call for a doctor.  
In case of unconsciousness place patient stably in side position for transportation.

**In case of skin contact:**

Rinse with water. Generally the product does not irritate the skin

**In case of eye contact:**

Rinse opened eye for several minutes under running water. Then consult a doctor.

**If swallowed:**

Rinse out mouth and then drink plenty of water

#### 4.2 Symptoms caused by exposure:-

No further relevant information available

#### 4.3 Medical attention and special treatment:-

No further relevant information available.

### 5. FIRE FIGHTING MEASURES

#### 5.1 Suitable extinguishing equipment:-

**Suitable extinguishing media:**

CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam

**Unsuitable extinguishing media:**

No further relevant information available

#### 5.2 Specific hazards arising from the substance/mixture/product:-

No further relevant information available

#### 5.3 Special protective equipment and precautions for fire fighters:-

**Special personal protective equipment:**

No further relevant information available.

**Precautions:**

No further relevant information available.

### 6. ACCIDENTAL RELEASE MEASURES

#### 6.1 Personal precautions, protective equipment and emergency procedures:-

Not required.

#### 6.2 Environmental precautions:-

Dilute with plenty of water.

Do not allow to enter sewers/ surface or ground water

#### 6.3 Methods and materials for containment and cleaning up:-

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

### 7. HANDLING AND STORAGE

#### 7.1 Precautions for safe handling:-

For use in dentistry only.

#### 7.2 Conditions for safe storage, including any incompatibilities:-

Store only in the original receptacle.

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1 Exposure control measures:-

**Occupational exposure limits:**

Component	CAS No.	Value	Parameters	Basis
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**Ingredients with biological limit values:**

**8.2 Biological monitoring:-**

The lists valid during the making were used as basis.

**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.

**8.3 Control banding:-**

Void

**8.4 Engineering controls:-**

Void

**8.5 Individual protection measures include PPE:-**

**Eye/face protection:**



**Safety glasses**

Required Use tightly fitting safety glasses as per Australian Standard AS 1336 and AS/NZS 1337.

**Skin protection:**



**Protection of hands:**

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. After use of gloves apply skin-cleaning agents and skin cosmetics.

**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 break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

**Respiratory protection:**

Not Required



**9. PHYSICAL/CHEMICAL PROPERTIES**

**9.1 Information on physical/chemical properties:-**

a) **Appearance/Form:** | Liquid

b)	<b>Colour:</b>	White
c)	<b>Odour:</b>	Colourless
d)	<b>Odour threshold:</b>	Odourless
e)	<b>pH-value (10 g/l) at 20 °C:</b>	Not determined.
f)	<b>Melting point/melting range:</b>	Not determined.
g)	<b>Boiling point/boiling range:</b>	Not determined.
h)	<b>Flash point:</b>	Not determined.
i)	<b>Ignition temperature:</b>	Not determined.
j)	<b>Self-igniting:</b>	Product is not self-igniting.
k)	<b>Danger of explosion:</b>	Product does not present an explosion hazard.
l)	<b>Upper/lower flammability or explosive limits:</b>	Lower   Not determined.
		Upper   Not determined.
m)	<b>Vapour pressure 20°C:</b>	Not determined.
n)	<b>Density at 20°C:</b>	Not determined.
o)	<b>Relative density:</b>	Not determined.
p)	<b>Vapour density:</b>	Not determined.
q)	<b>Evaporation rate:</b>	Not determined.
r)	<b>Solubility in / Miscibility with water:</b>	Fully miscible
s)	<b>Partition coefficient: n- octanol/water:</b>	Not determined.
t)	<b>Viscosity:</b>	Dynamic   Not applicable.
		Kinematic   Not applicable.
u)	<b>Solids content:</b>	Not determined.

## 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 further relevant information available.

### 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.

## 11. TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects:-

#### **Acute toxicity / Values relevant for classification:**

#### **Skin corrosion/irritation:**

No irritant effect

#### **Serious eye damage/eye irritation:**

No irritating effect.

#### **Respiratory or skin sensitization:**

No sensitising effects known

#### **Germ cell mutagenicity:**

No further relevant information available.

#### **Carcinogenicity:**

No further relevant information available.

#### **Reproductive toxicity:**

No further relevant information available.

#### **Specific target organ toxicity - single exposure:**

No further relevant information available.

#### **Specific target organ toxicity - repeated exposure:**

No further relevant information available.

#### **Aspiration hazard:**

No further relevant information available.

**Additional information:**

**11.2 Information on possible routes of exposure:-**

**Short Term (Acute) Exposure:**

**Swallowed:**

**Eyes:**

**Skin:**

**Inhaled:**

**Long Term (Chronic) Exposure:**

**Swallowed:**

**Eyes:**

**Skin:**

**Inhaled:**

**11.3 Early onset symptoms related to exposure:-**

**11.4 Delayed health effects from exposure:-**

**11.5 Exposure levels and health effects:-**

**11.6 Interactive effects:-**

**11.7 Other:-**

No further relevant information available.  
 No further relevant information available.  
 No further relevant information available.  
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**12. ECOLOGICAL INFORMATION**

**12.1 Ecotoxicity:-**

No further relevant information available

**12.2 Persistence/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.

**12.5 Other adverse effects:-**

No further relevant information available.

**Additional ecological information / General notes:-**

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

**12.6 Other adverse effects:-**

No further relevant information available.

**13. DISPOSAL CONSIDERATIONS**

**13.1 Disposal methods:-**

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.

**14. TRANSPORT INFORMATION**

**UN number ADR / IMDG / IATA:-**

Void

**UN proper shipping name or technical name:-**

**ADR:**

Void

**IMDG, IATA:**

Void

**Transport hazard class(es):**

Void

**Label:**

Void

**Packaging group:**

Void

**Environmental hazards:**

Void

**Special precautions for user:**

Void

**Danger code:**

Void

**EMS Number:**

Void

<b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:</b>	Void
<b>Transport/Additional information:</b>	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
<b>UN "Model Regulation":</b>	Void

## 15. REGULATORY INFORMATION

### 15.1 Safety, health and environmental regulations/legislation specific for the substance/mixture/product:-

Void

### 15.2 Chemical safety assessment:

A Chemical Safety Assessment has not been carried out.

## 16. OTHER INFORMATION

### Key to abbreviations/acronyms used in SDS:-

H319 Causes serious eye irritation.

### Key literature references/data sources used to compile SDS:-

Void

### Copyright statement:-

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.

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).

LC50: Lethal concentration, 50 percent.

LD50: Lethal dose, 50 percent.

Flam. Liq. 2: Flammable liquids, Hazard Category 2.

Flam. Liq. 3: Flammable liquids, Hazard Category 3.

Acute Tox. 4: Acute toxicity, Hazard Category 4.

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2.

Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2.

Repr. 2: Reproductive toxicity, Hazard Category 2.

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3.

STOT RE 2: Specific target organ toxicity - Repeated exposure, Hazard Category 2.

Asp. Tox. 1: Aspiration hazard, Hazard Category 1.

**\* Data compared to the previous version altered**

### Disclaimer:-

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