

# EU Safety Data Sheet

Helioseal



Date of issue / Reference

26.10.2010

liprt

Replaces version of

27.09.2007

lise / v4

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27.10.2010

**Sheet No. 1143**

Version 5

Page 1 of 5

Edited

Deleted

Company

Ivoclar Vivadent AG, Bendererstrasse 2, FL - 9494 Schaan  
Fürstentum Liechtenstein

## 1 Commercial product name and supplier

1.1 Commercial product name /  
Designation

**Helioseal**

1.2 Application / Use

Light-curing fissure sealant

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

Uncured material may cause slight, reversible irritation. Avoid contact with skin, mucous membrane, and eyes. The material is contraindicated if a person is known to be allergic to any of the ingredients of the product.

## 3 Composition

3.1 Chemical characterization

Mixture of Bis-GMA, dimethacrylate, titanium dioxide, initiators and stabilizers

3.2 Hazardous components

CAS No. 1565-94-2

< 60 % Bis-GMA

Xi: Irritant. R36: Irritating to eyes. R38: Irritating to skin.

CAS No. 109-16-0

< 40 % Triethylene glycoldimethacrylate

Xi: Irritant. R43: May cause sensitisation by skin contact. R36/37/38: Irritating to eyes, respiratory system and skin.

3.3 Further information

None.

## 4 First aid measures

4.1 Eye contact

Flush with plenty of water. Consult a physician if irritation persists.

4.2 Skin contact

Wash thoroughly with soap and water.

4.3 Ingestion

No hazards anticipated from swallowing small amounts incidentally to normal handling.

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Page 2 of 5

Edited

Deleted

4.4 Inhalation Remove to fresh air.

4.5 Further information If you feel unwell, seek medical advice (show this safety data sheet).

## 5 Fire-fighting measures

5.1 Suitable extinguishing media Water fog, carbon dioxide, foam, dry chemicals.

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.

## 7 Handling and storage

7.1 Handling Only adequately trained personnel should handle this product.

7.2 Industrial hygiene Usual hygienic measures for dental practice.

7.3 Storage Store at 2-28 °C / 36-82 °F

7.4 Place of storage Avoid exposure to light.

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 Not required.

8.3.2 Hand protection  
Gloves.  
Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates.  
Check penetration time for the specific gloves used with the glove manufacturer.

8.3.3 Eye protection Safety goggles.

8.3.4 Other None.

8.4 Environmental exposure controls

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**Sheet No. 1143**

Version 5

Page 3 of 5

Edited

Deleted

## 9 Physical and chemical properties

9.1	Appearance	liquid	
9.2	Colour	white	
9.3	Odour	practically odourless	
9.4	Change of physical state		Test method:
		---	
9.5	Density	1.25 g/cm <sup>3</sup> (20°C)	
9.6	Vapour pressure		
		not applicable	
9.7	Viscosity		
		not determined	
9.8	Solubility		
	Solubility in water	< 0.1 %	
9.9	pH		
		Not determined.	
9.10	Flash point	> 200 °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	Avoid exposure of product to light.

## 11 Toxicological information

11.1	Acute toxicity	Oral LD50 for rats: >5000 mg/kg
11.2	Subacute / Chronic toxicity	Uncured material: prolonged or frequently repeated skin contact may cause allergic skin reactions.

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**Sheet No. 1143**

Version 5

Page 4 of 5

Edited

Deleted

## 11.3 Further information

No hazards anticipated from swallowing small amounts incidentally to normal handling.

## 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.  
nearly insoluble

## 13 Disposal considerations

Take to a waste incineration plant, under conditions approved by the local authority.

### 13.1 EU waste key

20 01 39

## 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

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Version 5

Page 5 of 5

Edited

Deleted

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.	

## 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.

15.1	UN number	---
15.2	National regulations	
15.3	EINECS/ELINCS number	---
15.4	Hazard symbols	
15.5	Hazard designation	
15.6	Risk phrases	
15.7	Safety phrases	
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.*