

# EU Safety Data Sheet

Helioseal Clear



Date of issue / Reference

18.03.2005 hot

Replaces version of

24.01.2001

Date of printing

18.03.2005 **Sheet No. 1358**

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Company

Ivoclar Vivadent AG, Bendererstrasse 2, FL - 9494 Schaan  
Principality of Liechtenstein

## 1 Commercial product name and supplier

1.1 Commercial product name /  
Designation

**Helioseal Clear**

1.2 Application / Use

Light-curing fissure sealant

1.3 Producer

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

1.4 Supplier

1.5 TOX emergency number

Emergency-Call: +423 / 235 35 35 or 373 40 40  
Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein

## 2 Composition

2.1 Chemical characterization

Mixture of Bis-GMA, dimethacrylate, initiators and stabilizers

2.2 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. R36/37/38: Irritating to eyes, respiratory system and skin.

2.3 Further information

None.

## 3 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.

## 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.

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.

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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.

## 7 Handling and storage

7.1 Handling Only adequately trained personnel should handle this product.  
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 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 Technical measures Good general ventilation should be sufficient.

8.2 Control of threshold limits None established.

8.3 Personal protective equipment

8.3.1 Respiratory protection Respiratory Protection.

8.3.2 Hand protection Gloves.

8.3.3 Eye protection Safety goggles.

8.3.4 Other None.

## 9 Physical and chemical properties

9.1 Appearance liquid

9.2 Colour transparent

9.3 Odour Practically odourless

9.4 Change of physical state Test method:  
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9.5 Density 1.14 g/cm<sup>3</sup> (20°C)

9.6 Vapour pressure  
not applicable

9.7 Viscosity  
not determined

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## 9.8 Solubility

Solubility in < 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

None.

## 10 Stability and reactivity

### 10.1 Thermal decomposition

None, if used in accordance with instructions.

### 10.2 Hazardous decomposition products

None under normal conditions of storage and use.

### 10.3 Hazardous reactions

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 in some individuals.

### 11.3 Further information

In the aqueous medium formation of insoluble and chemically inert polyureas will occur.

## 12 Ecological 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

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RID

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	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	---		
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 for any mode of transportation.		

## 15 Regulatory information

The product is a medical device according to the EC-directive 93/42.  
This product does not require classification according to the criteria of the EC.

15.1 UN number

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15.2 National regulations

15.3 EU number

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15.4 Hazard symbols

15.5 Hazard designation

15.6 Risk phrases

15.7 Safety phrases

15.8 MAK value

--- ml/m<sup>3</sup> (ppm)

15.9 BVD classification (CH)

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15.10 VbF (D)

15.11 Further information

None.

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## 16 Other information

Version: 3

Changes: 2.2 / 13.1

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*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.*

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This safety data sheet has been generated with the safety database 'ChemManager',  
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91/155/EEC
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