

EU Safety Data Sheet

OptraDam / OptraDam Plus

Date of issue / Reference	13.10.2008	liprt		
Replaces version of	13.10.2008	liprt / Version 2		
Date of printing	23.02.2009	Sheet No. 1573	Version 3	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 | OptraDam / OptraDam Plus |
| 1.2 | Application / Use | Anatomically shaped rubber dam |
| 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 35 35 or 373 40 40
Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein |
-

2 Hazards identification

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 | OptraDam is made of latex and powdered with corn starch. |
| 3.2 | Hazardous components | None. |
| 3.3 | Further information | None. |
-

4 First aid measures

- | | | |
|-----|---------------------|---------------------------|
| 4.1 | Eye contact | No specific requirements. |
| 4.2 | Skin contact | No specific requirements. |
| 4.3 | Ingestion | No specific requirements. |
| 4.4 | Inhalation | No specific requirements. |
| 4.5 | Further information | None. |
-

5 Fire-fighting measures

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

EU Safety Data Sheet

OptraDam / OptraDam Plus

Date of issue / Reference	13.10.2008	liprt		
Replaces version of	13.10.2008	liprt / Version 2		
Date of printing	23.02.2009	Sheet No. 1573	Version 3	Page 2 of 5
	Edited		Deleted	

5.2 Extinguishing media to avoid None known

5.3 Further information None.

6 Accidental release measures Clean up mechanically.

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 Do not store in open sunshine.

7.5 Fire- and explosion-protection Not required.

8 Exposure controls / Personal protection

8.1 Exposure controls No specific requirements.

8.2 Exposure limit values ---

8.3 Occupational exposure controls

8.3.1 Respiratory protection Not necessary.

8.3.2 Hand protection Not required.

8.3.3 Eye protection Not required.

8.3.4 Other None.

8.4 Environmental exposure controls

9 Physical and chemical properties

9.1 Appearance Flexible Solid

9.2 Colour blue

9.3 Odour odourless

9.4 Change of physical state Test method:

9.5 Density

Not determined.

9.6 Vapour pressure

Not applicable.

EU Safety Data Sheet

OptraDam / OptraDam Plus

Date of issue / Reference	13.10.2008	liprt		
Replaces version of	13.10.2008	liprt / Version 2		
Date of printing	23.02.2009	Sheet No. 1573	Version 3	Page 3 of 5
	Edited		Deleted	

9.7 Viscosity
Not applicable.

9.8 Solubility
Not determined.

9.9 pH
Not determined.

9.10 Flash point

9.11 Ignition temperature

9.12 Explosion limits
Lower:
Upper:

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
Do not store in open sunshine.

11 Toxicological information

11.1 Acute toxicity

11.2 Subacute / Chronic toxicity

11.3 Further information
The use of OptraDam is contraindicated for patients with latex allergy.

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
None.

EU Safety Data Sheet

OptraDam / OptraDam Plus

Date of issue / Reference	13.10.2008	liprt		
Replaces version of	13.10.2008	liprt / Version 2		
Date of printing	23.02.2009	Sheet No. 1573	Version 3	Page 4 of 5
	Edited		Deleted	

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			
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

This product does not require classification according to the criteria of the Commission of the European Communities (Council Directive 67/548/EEC).
The product is a medical device according to the EC-directive 93/42/EEC.

15.1 UN number ---

15.2 National regulations

EU Safety Data Sheet

OptraDam / OptraDam Plus

Date of issue / Reference	13.10.2008	liprt		
Replaces version of	13.10.2008	liprt / Version 2		
Date of printing	23.02.2009	Sheet No. 1573	Version 3	Page 5 of 5
	Edited		Deleted	

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	--- ml/m ³ (ppm)
15.9	BVD classification (CH)	
15.10	VbF (D)	
15.11	Further information	None.
16	Other information	None.

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.

This safety data sheet has been generated with the safety database 'ChemManager',
© ASSiST Applied Software Solutions in Science and Technology AG,
Weiherweg 3, CH-4104 Oberwil, Switzerland

Regulation (EC) No 1907/2006 (REACH)