

**Safety Data Sheet**  
according to WHS Regulations

Printing date 06.03.2020

Version number 1

Revision: 06.03.2020

Not classified as hazardous according to criteria of Australian Safety and Compensation Council.

## 1 Identification

- **Product identifier**
- **Trade name:** **OptraDam Plus**
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** Anatomically shaped rubber dam
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Ivoclar Vivadent AG  
Bendererstrasse 2  
9494 Schaan  
PRINCIPALITY OF LIECHTENSTEIN  
Tel: +423 235 35 35 / Fax: +423 235 33 60
- **Importer:**  
Ivoclar Vivadent Pty. Ltd.  
1- 5 Overseas Drive  
Noble Park North VIC 3174  
Tel: + 61 3 9795 9599 / Fax: + 61 3 9795 9645
- **Further information obtainable from:**  
Regulatory Affairs  
sds@ivoclarvivadent.com
- **Emergency telephone number:** 131 126 (Poisons Information Centre - 24 hours / 7 days)

## 2 Hazard(s) Identification

- **Classification of the substance or mixture**  
The product is not classified, according to the Globally Harmonised System (GHS).
- **Label elements**
- **GHS label elements** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

## 3 Composition and Information on Ingredients

- **Chemical characterisation:** Mixtures
- **Description:** OptraDam Plus is made of latex and powdered with corn starch.
- **Dangerous components:** Void

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### 4 First Aid Measures

- **Description of first aid measures**
- **General information:** No special measures required.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:** Mechanical effects only.
- **After swallowing:** Seek medical treatment.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### 5 Fire Fighting Measures

- **Extinguishing media**
- **Suitable extinguishing agents:**  
CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

### 6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **Reference to other sections**  
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

- **Handling:**
- **Precautions for safe handling**  
Only adequately trained personnel should handle this product.  
For use in dentistry only.
- **Information about fire - and explosion protection:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **Specific end use(s)** No further relevant information available.

### 8 Exposure controls and personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.

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- **Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**  
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** 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 and dental laboratories.  
Keep away from foodstuffs, beverages and feed.  
Wash hands before breaks and at the end of work.
- **Respiratory protection:** Not required.
- **Protection of hands:** Not required.
- **Eye protection:** Not required.

### 9 Physical and Chemical Properties

- |  |                 |
|--|-----------------|
| · <b>Information on basic physical and chemical properties</b>               |                 |
| · <b>General Information</b>   |                 |
| · <b>Appearance:</b>   |                 |
| Form:  | Solid           |
| Colour:  | Light blue      |
| Odour:   | Odourless       |
| Odour threshold:   | Not determined. |
| · <b>pH-value:</b> Not applicable.   |                 |
| · <b>Change in condition</b>   |                 |
| Melting point/freezing point:  | Undetermined.   |
| Initial boiling point and boiling range:                                     | Not applicable. |
| · <b>Flash point:</b> Not applicable.  |                 |
| · <b>Flammability (solid, gas):</b> Not determined.                          |                 |
| · <b>Auto-ignition temperature:</b> Product is not selfigniting.             |                 |
| · <b>Explosive properties:</b> Product does not present an explosion hazard. |                 |
| · <b>Vapour pressure:</b> Not applicable.                                    |                 |
| · <b>Density:</b> Not determined.  |                 |
| · <b>Relative density</b> Not determined.                                    |                 |
| · <b>Vapour density</b> Not applicable.                                      |                 |
| · <b>Evaporation rate</b> Not applicable.                                    |                 |
| · <b>Solubility in / Miscibility with water:</b> Insoluble.                  |                 |
| · <b>Partition coefficient: n-octanol/water:</b> Not determined.             |                 |
| · <b>Viscosity:</b>  |                 |
| Dynamic:   | Not applicable. |
| Kinematic:   | Not applicable. |
| · <b>Solvent content:</b>  |                 |
| Solids content:  | 100 %           |

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· **Other information** *No further relevant information available.*

### 10 Stability and Reactivity

- **Reactivity** *No further relevant information available.*
- **Chemical stability** *Stable under normal handling and storage conditions.*
- **Thermal decomposition / conditions to be avoided:** *No decomposition if used according to specifications.*
- **Possibility of hazardous reactions** *No dangerous reactions known.*
- **Conditions to avoid** *Keep away from heat and direct sunlight.*
- **Incompatible materials:** *No further relevant information available.*
- **Hazardous decomposition products:** *None under normal conditions of storage and use.*

### 11 Toxicological Information

- **Information on toxicological effects**
- **Acute toxicity**
- **Skin corrosion/irritation** *No irritant effect.*
- **Serious eye damage/irritation** *No irritating effect.*
- **Respiratory or skin sensitisation** *No sensitising effects known.*

### 12 Ecological Information

- **Toxicity**
- **Aquatic toxicity:** *No further relevant information available.*
- **Persistence and degradability** *No further relevant information available.*
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** *No further relevant information available.*
- **Mobility in soil** *No further relevant information available.*
- **Additional ecological information:**
- **General notes:** *Not hazardous for water.*
- **Results of PBT and vPvB assessment**
- **PBT:** *Not applicable.*
- **vPvB:** *Not applicable.*
- **Other adverse effects** *No further relevant information available.*

### 13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**  
*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**
- **ADG, ADN, IMDG, IATA** *Void*

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· <i>UN proper shipping name</i> · <i>ADG, ADN, IMDG, IATA</i>	<i>Void</i>
· <i>Transport hazard class(es)</i> · <i>ADG, ADN, IMDG, IATA</i> · <i>Class</i>	<i>Void</i>
· <i>Packing group</i> · <i>ADG, IMDG, IATA</i>	<i>Void</i>
· <i>Environmental hazards:</i> · <i>Marine pollutant:</i>	<i>No</i>
· <i>Special precautions for user</i>	<i>Not applicable.</i>
· <i>Transport in bulk according to Annex II of Marpol and the IBC Code</i>	<i>Not applicable.</i>
· <i>Transport/Additional information:</i>	<i>Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).</i>
· <i>UN "Model Regulation":</i>	<i>Void</i>

### 15 Regulatory information

· *Safety, health and environmental regulations/legislation specific for the substance or mixture*

· *Australian Inventory of Chemical Substances*

*All ingredients are listed.*

· *Standard for the Uniform Scheduling of Medicines and Poisons*

*None of the ingredients is listed.*

· *GHS label elements* *Void*

· *Hazard pictograms* *Void*

· *Signal word* *Void*

· *Hazard statements* *Void*

· *Directive 2012/18/EU*

· *Named dangerous substances - ANNEX I* *None of the ingredients is listed.*

· *National regulations:*

· *Other regulations, limitations and prohibitive regulations*

*The product is a medical device according to the Directive 93/42/EEC.*

· *Chemical safety assessment:* *A Chemical Safety Assessment has not been carried out.*

### 16 Other information

*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*

*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)*

*PBT: Persistent, Bioaccumulative and Toxic*

*vPvB: very Persistent and very Bioaccumulative*