

**Safety Data Sheet**  
in accordance with HSNO

Printing date 06.03.2020

Version number 1

Revision: 06.03.2020

### 1 Identification of the substance or mixture and of the supplier

- **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 Ltd  
12 Omega St, Rosedale, Auckland  
New Zealand  
Tel: + 64 9 914 9999 / Fax: + 64 9 914 9990
- **Further information obtainable from:**  
Regulatory Affairs  
sds@ivoclarvivadent.com
- **Emergency telephone number:** 0800 764 766 (National Poison Centre - 24 hours / 7 days)

### 2 Hazards 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/Information on ingredients

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

### 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.

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- **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/personal protection

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

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- 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

#### · Information on basic physical and chemical properties

##### · General Information

##### · Appearance:

- |                           |                 |
|---------------------------|-----------------|
| · <b>Form:</b>            | Solid           |
| · <b>Colour:</b>          | Light blue      |
| · <b>Odour:</b>           | Odourless       |
| · <b>Odour threshold:</b> | Not determined. |

- |                    |                 |
|--------------------|-----------------|
| · <b>pH-value:</b> | Not applicable. |
|--------------------|-----------------|

##### · Change in condition

- |   |                 |
|---|-----------------|
| · <b>Melting point/freezing point:</b>            | Undetermined.   |
| · <b>Initial boiling point and boiling range:</b> | 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. |
|--|-----------------|

##### · Viscosity:

- |                     |                 |
|---------------------|-----------------|
| · <b>Dynamic:</b>   | Not applicable. |
| · <b>Kinematic:</b> | Not applicable. |

##### · Solvent content:

- |                            |  |
|----------------------------|--|
| · <b>Solids content:</b>   | 100 %                                      |
| · <b>Other information</b> | 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.

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- **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

- |                                       |      |
|---------------------------------------|------|
| · <b>UN-Number</b>                    |      |
| · <b>ADR/RID/ADN, ADN, IMDG, IATA</b> | Void |
| · <b>UN proper shipping name</b>      |      |
| · <b>ADR/RID/ADN, ADN, IMDG, IATA</b> | Void |
| · <b>Transport hazard class(es)</b>   |      |
| · <b>ADR/RID/ADN, ADN, IMDG, IATA</b> |      |
| · <b>Class</b>                        | Void |
| · <b>Packing group</b>                |      |
| · <b>ADR/RID/ADN, IMDG, IATA</b>      | Void |
| · <b>Environmental hazards:</b>       |      |
| · <b>Marine pollutant:</b>            | No   |

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· <b>Special precautions for user</b>	Not applicable.
· <b>Transport in bulk according to Annex II of Marpol and the IBC Code</b>	Not applicable.
· <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

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

· **New Zealand Inventory of Chemicals**

All ingredients are listed.

· **HSNO Approval numbers**

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