

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

- **Product identifier**
- **Trade name: Ivostar, Gnathostar**
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** Manufacture of dental prosthesis
- **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** Avoid breathing sanding dust /swarf.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

## 3 Composition/Information on ingredients

- **Chemical characterisation: Mixtures**
- **Description:** Resin teeth based on polymethylmethacrylate
- **Dangerous components:** Void
- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

## 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.

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- **After eye contact:**  
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.  
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:** No special measures required.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **Reference to other sections**  
No dangerous substances are released.  
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:** No special requirements.
- **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.

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- **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.
- **Respiratory protection:** Use respiratory protective device against the effects of dust.
- **Protection of hands:**  
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.  
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.  
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
- **Material of gloves**  
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
- **Penetration time of glove material**  
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:**  
Always wear safety goggles during mechanical processing (grinding, sawing /cutting, drilling, milling).

### 9 Physical and chemical properties

- |  |                                    |
|--|------------------------------------|
| · <b>Information on basic physical and chemical properties</b>               |                                    |
| · <b>General Information</b>   |                                    |
| · <b>Appearance:</b>   |                                    |
| Form:  | Solid                              |
| Colour:  | According to product specification |
| · <b>Odour:</b> Odourless  |                                    |
| · <b>Odour threshold:</b> Not determined.                                    |                                    |
| · <b>pH-value:</b> Not applicable.   |                                    |
| · <b>Change in condition</b>   |                                    |
| Melting point/freezing point:  | Undetermined.                      |
| Initial boiling point and boiling range:                                     | Undetermined.                      |
| · <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>Explosion limits:</b>   |                                    |
| Lower:   | Not determined.                    |
| Upper:   | Not determined.                    |
| · <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.                                    |                                    |

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· <b>Solubility in / Miscibility with water:</b>	<i>Insoluble.</i>
· <b>Partition coefficient: n-octanol/water:</b>	<i>Not determined.</i>
· <b>Viscosity:</b>	
<b>Dynamic:</b>	<i>Not applicable.</i>
<b>Kinematic:</b>	<i>Not applicable.</i>
· <b>Solvent content:</b>	
<b>Solids content:</b>	<i>100.0 %</i>
· <b>Other information</b>	<i>No further relevant information available.</i>

### 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** *No further relevant information available.*
- **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**
- **Specific symptoms in biological assay:**
- **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.*

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

None of the ingredients is 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.

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

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### **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.*

· **Contact:**

· **Abbreviations and acronyms:**

*ADR: Accord relatif au transport international 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*

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