

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 20.05.2015

Version number 2

Revision: 11.04.2015

**SECTION 1: Identification of the substance/mixture and of the company/undertaking**

- **1.1 Product identifier**
- **Trade name: IPS d.SIGN Shade, Stains, Glaze**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** Auxiliary for manufacture of dental prothesis
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Ivoclar Vivadent AG  
Bendererstrasse 2  
FL-9494 Schaan  
PRINCIPALITY OF LIECHTENSTEIN
- 
- Tel: +423 235 35 35  
Fax: +423 235 33 60
- **Further information obtainable from:**  
Regulatory Affairs  
sds@ivoclarvivadent.com
- **1.4 Emergency telephone number:** +423 / 235 33 13 (Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein)

**SECTION 2: Hazards identification**

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
The product is not classified according to the CLP regulation.

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- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Additional information:**  
Safety data sheet available on request.
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

**SECTION 3: Composition/information on ingredients**

- **3.2 Chemical characterisation: Mixtures**
- **Description:** dental ceramic

· **Dangerous components:**

|                                      |             |   |         |
|--------------------------------------|-------------|---|---------|
| CAS: 56-81-5<br>EINECS: 200-289-5    | glycerol    | substance with a Community workplace exposure limit | 25-50%  |
| CAS: 18282-10-5<br>EINECS: 242-159-0 | tin dioxide | substance with a Community workplace exposure limit | 2.5-<3% |

- **Additional information:** For the wording of the listed risk phrases refer to section 16.

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#### **SECTION 4: First aid measures**

- **4.1 Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:**  
Supply fresh air; consult doctor in case of complaints.  
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:**  
Rinse with water.  
Generally the product does not irritate the skin.
- **After eye contact:**  
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.  
Mechanical effects only.
- **After swallowing:**  
Rinse out mouth and then drink plenty of water.  
If symptoms persist consult doctor.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

#### **SECTION 5: Firefighting measures**

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

#### **SECTION 6: Accidental release measures**

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:** Pick up mechanically.
- **6.4 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.

#### **SECTION 7: Handling and storage**

- **7.1 Precautions for safe handling**  
No special measures required.  
Only adequately trained personnel should handle this product.  
For use in dentistry only.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 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:**  
This product is hygroscopic.

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Store in dry conditions.

· **7.3 Specific end use(s)** No further relevant information available.

**SECTION 8: Exposure controls/personal protection**

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

· **8.1 Control parameters**

· **Ingredients with limit values that require monitoring at the workplace:**

**56-81-5 glycerol**

WEL Long-term value: 10 mg/m<sup>3</sup>

**18282-10-5 tin dioxide**

WEL Short-term value: 4 mg/m<sup>3</sup>  
Long-term value: 2 mg/m<sup>3</sup>  
as Sn

· **Additional information:** The lists valid during the making were used as basis.

· **8.2 Exposure controls**

· **Personal protective equipment:**

· **General protective and hygienic measures:**

Usual hygienic measures for dental practice.

Keep away from foodstuffs, beverages and feed.

Wash hands before breaks and at the end of work.

· **Respiratory protection:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

· **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:** Safety glasses

**SECTION 9: Physical and chemical properties**

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

**Form:** Pasty

**Colour:** According to product specification

· **Odour:** Characteristic

· **Odour threshold:** Not determined.

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|   |  |
|---|--|
| · <b>pH-value:</b>                                | <i>Not determined.</i>                               |
| · <b>Change in condition</b>                      |  |
| <b>Melting point/Melting range:</b>               | <i>Undetermined.</i>                                 |
| <b>Boiling point/Boiling range:</b>               | <i>Undetermined.</i>                                 |
| · <b>Flash point:</b>                             | <i>Undetermined.</i>                                 |
| · <b>Flammability (solid, gaseous):</b>           | <i>Not applicable.</i>                               |
| · <b>Self-igniting:</b>                           | <i>Product is not selfigniting.</i>                  |
| · <b>Danger of explosion:</b>                     | <i>Product does not present an explosion hazard.</i> |
| · <b>Explosion limits:</b>                        |  |
| <b>Lower:</b>                                     | <i>Not determined.</i>                               |
| <b>Upper:</b>                                     | <i>Not determined.</i>                               |
| · <b>Vapour pressure:</b>                         | <i>Not determined.</i>                               |
| · <b>Density:</b>                                 | <i>Not determined.</i>                               |
| · <b>Relative density</b>                         | <i>Not determined.</i>                               |
| · <b>Vapour density</b>                           | <i>Not determined.</i>                               |
| · <b>Evaporation rate</b>                         | <i>Not determined.</i>                               |
| · <b>Solubility in / Miscibility with water:</b>  | <i>Not miscible or difficult to mix.</i>             |
| · <b>Partition coefficient (n-octanol/water):</b> | <i>Not determined.</i>                               |
| · <b>Viscosity:</b>                               |  |
| <b>Dynamic:</b>                                   | <i>Not determined.</i>                               |
| <b>Kinematic:</b>                                 | <i>Not determined.</i>                               |
| · <b>9.2 Other information</b>                    | <i>No further relevant information available.</i>    |

### **SECTION 10: Stability and reactivity**

- **10.1 Reactivity** *No further relevant information available.*
- **10.2 Chemical stability** *Stable under normal handling and storage conditions.*
- **Thermal decomposition / conditions to be avoided:** *No decomposition if used according to specifications.*
- **10.3 Possibility of hazardous reactions** *No dangerous reactions known.*
- **10.4 Conditions to avoid** *No further relevant information available.*
- **10.5 Incompatible materials:** *No further relevant information available.*
- **10.6 Hazardous decomposition products:** *None under normal conditions of storage and use.*

### **SECTION 11: Toxicological information**

- **11.1 Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** *No irritant effect.*
- **on the eye:** *No irritating effect.*
- **Sensitisation:** *No sensitising effects known.*
- **Additional toxicological information:** *No further relevant information available.*

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### SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**  
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water  
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

### SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
  - **Recommendation**  
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
  - **European waste catalogue**
- |          |                                |
|----------|--------------------------------|
| 08 02 99 | wastes not otherwise specified |
|----------|--------------------------------|
- **Uncleaned packaging:**
  - **Recommendation:** Disposal must be made according to official regulations.

### SECTION 14: Transport information

- |   |  |
|---|--|
| · <b>14.1 UN-Number</b>   |  |
| · <b>ADR, ADN, IMDG, IATA</b>   | Void   |
| · <b>14.2 UN proper shipping name</b>   |  |
| · <b>ADR, ADN, IMDG, IATA</b>   | Void   |
| · <b>14.3 Transport hazard class(es)</b>  |  |
| · <b>ADR, ADN, IMDG, IATA</b>   |  |
| · <b>Class</b>  | Void   |
| · <b>14.4 Packing group</b>   |  |
| · <b>ADR, IMDG, IATA</b>  | Void   |
| · <b>14.5 Environmental hazards:</b>  |  |
| · <b>Marine pollutant:</b>  | No   |
| · <b>14.6 Special precautions for user</b>  | Not applicable.  |
| · <b>14.7 Transport in bulk according to Annex II of MARPOL73/78 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). |

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· **UN "Model Regulation":** -

### **SECTION 15: Regulatory information**

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**  
The product is a medical device according to the Directive 93/42/EEC.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

### **SECTION 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:**

*RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)*

*ICAO: International Civil Aviation Organisation*

*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*

*GHS: Globally Harmonised System of Classification and Labelling of Chemicals*

*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)*

- **\* Data compared to the previous version altered.**

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