

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

Printing date 29.04.2015

Version number 6

Revision: 18.04.2015

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

- **1.1 Product identifier**
- **Trade name: SR Spectrasit Dentin, Incisal**
- **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** Crowns- and bridges material
- **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**  
Eye Irrit. 2            H319 Causes serious eye irritation.  
Skin Sens. 1            H317 May cause an allergic skin reaction.  
Aquatic Chronic 3    H412 Harmful to aquatic life with long lasting effects.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
The product is classified and labelled according to the CLP regulation.

- **Hazard pictograms**



GHS07

- **Signal word** Warning
- **Hazard-determining components of labelling:**  
urethane dimethacrylate  
1,10-decandiol dimethacrylate
- **Hazard statements**  
H319 Causes serious eye irritation.  
H317 May cause an allergic skin reaction.  
H412 Harmful to aquatic life with long lasting effects.
- **Precautionary statements**  
P280            Wear protective gloves/protective clothing/eye protection/face protection.  
P363            Wash contaminated clothing before reuse.  
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.  
P337+P313 If eye irritation persists: Get medical advice/attention.

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- **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:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 72869-86-4	urethane dimethacrylate	≤25%
EINECS: 276-957-5	Eye Irrit. 2, H319; Skin Sens. 1, H317; Aquatic Chronic 3, H412	
CAS: 6701-13-9	1,10-decandiol dimethacrylate	3-<10%
EINECS: 229-745-1	Eye Irrit. 2, H319; Skin Sens. 1, H317	

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

### SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **After inhalation:**  
Supply fresh air and to be sure call for a doctor.  
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:** Rinse with water.
- **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.
- **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.

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See Section 13 for disposal information.

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### SECTION 7: Handling and storage

- **7.1 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.
- **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:**  
Protect from exposure to the light.  
Protect from heat and direct sunlight.  
Keep container tightly sealed.
- **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:**  
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.
- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
Usual hygienic measures for dental practice.  
Wash hands before breaks and at the end of work.  
Keep away from foodstuffs, beverages and feed.  
Avoid contact with the eyes and skin.
- **Respiratory protection:** Not required.
- **Protection of hands:**



Protective gloves

- After use of gloves apply skin-cleaning agents and skin cosmetics.
- **Material of gloves**  
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
- **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.
- **Not suitable are gloves made of the following materials:**  
Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates.

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· **Eye protection:** Safety glasses

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### SECTION 9: Physical and chemical properties

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

· **General Information**

· **Appearance:**

· <b>Form:</b>	Pasty
· <b>Colour:</b>	Cream coloured
· <b>Odour:</b>	Characteristic
· <b>Odour threshold:</b>	Not determined.

· **pH-value:** Not applicable.

· **Change in condition**

· <b>Melting point/Melting range:</b>	Undetermined.
· <b>Boiling point/Boiling range:</b>	Undetermined.

· **Flash point:** Not applicable.

· **Flammability (solid, gaseous):** Not applicable.

· **Self-igniting:** Product is not selfigniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Explosion limits:**

· <b>Lower:</b>	Not determined.
· <b>Upper:</b>	Not determined.

· **Vapour pressure:** Not determined.

· **Density:** Not determined.

· **Relative density** Not determined.

· **Vapour density** Not determined.

· **Evaporation rate** Not determined.

· **Solubility in / Miscibility with water:** Nearly insoluble.

· **Partition coefficient (n-octanol/water):** Not determined.

· **Viscosity:**

· <b>Dynamic:</b>	Not determined.
· <b>Kinematic:</b>	Not determined.

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

### SECTION 10: Stability and reactivity

· **10.1 Reactivity** No further relevant information available.

· **10.2 Chemical stability**

Stable under normal handling and storage conditions.

Photoreactive (Danger of polymerization).

· **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**

Protect from exposure to the light.

Keep away from heat and direct sunlight.

· **10.5 Incompatible materials:** No further relevant information available.

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· **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:** Irritating effect.
- **Sensitisation:** Sensitisation possible through skin contact.
- **Additional toxicological information:** No further relevant information available.

**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 2 (German Regulation) (Self-assessment): hazardous for water  
Do not allow product to reach ground water, water course or sewage system.  
Danger to drinking water if even small quantities leak into the ground.
- **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.
- **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 |

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· <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).
· <b>UN "Model Regulation":</b>	-

### 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.

- **Relevant phrases**  
H317 May cause an allergic skin reaction.  
H319 Causes serious eye irritation.  
H412 Harmful to aquatic life with long lasting effects.
- **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  
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)  
Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2  
Skin Sens. 1: Sensitisation - Skin, Hazard Category 1  
Aquatic Chronic 3: Hazardous to the aquatic environment - Chronic Hazard, Category 3
- **\* Data compared to the previous version altered.**

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