

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

Printing date 17.01.2013

Version number 3

Revision: 17.01.2013

### 1 Identification of the substance/mixture and of the company/undertaking

- **Product identifier**
- **Trade name:** ***SR Ivocap High Impact Polymer***
- **Relevant identified uses of the substance or mixture and uses advised against**  
*No further relevant information available.*
- **Application of the substance / the preparation** *Denture base material*
- **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  
msds@ivoclarvivadent.com*
- **Emergency telephone number:** *+423 / 235 33 13 (Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein)*

### 2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC** *Not applicable.*
- **Information concerning particular hazards for human and environment:**  
*The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.*
- **Classification system:**  
*The classification is according to the latest editions of the EU-lists, and extended by company and literature data.*
- **Label elements**
- **Labelling according to EU guidelines:**  
*The product is not subject to identification regulations under EU Directives and the Ordinance on Hazardous Materials (German GefStoffV).*
- **Special labelling of certain preparations:**  
*Contains dibenzoyl peroxide. May produce an allergic reaction.*
- **Other hazards**  
*Dust generation  
Particular danger of slipping on leaked/spilled product.*
- **Results of PBT and vPvB assessment**
- **PBT:** *Not applicable.*
- **vPvB:** *Not applicable.*

### 3 Composition/information on ingredients

- **Chemical characterization:** *Mixtures*
- **Description:** *Mixture of substances listed below with nonhazardous additions.*
- **Dangerous components:** *Void*

(Contd. on page 2)

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(Contd. of page 1)

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

#### 4 First aid measures

- **Description of first aid measures**
- **General information:** No special measures required.
- **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.  
If skin irritation continues, consult a doctor.
- **After eye contact:**  
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing:**  
Rinse out mouth and then drink plenty of water.  
If symptoms persist consult doctor.
- **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 Firefighting 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**  
Avoid formation of dust.  
Particular danger of slipping on leaked/spilled product.
- **Environmental precautions:**  
Do not allow product to reach sewage system or any water course.  
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.

(Contd. on page 3)

**Safety data sheet**  
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Revision: 17.01.2013

**Trade name: SR Ivocap High Impact Polymer**

(Contd. of page 2)

- **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:** Protect from heat and direct sunlight.
- **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.  
Keep away from foodstuffs, beverages and feed.  
Wash hands before breaks and at the end of work.  
Avoid contact with the skin.
- **Respiratory protection:** Use respiratory protective device against the effects of dust.
- **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.
- **Eye protection:** Safety glasses

## 9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**
- **Form:** Powder
- **Colour:** According to product specification
- **Odour:** Characteristic
- **Odour threshold:** Not determined.
- **pH-value:** Not applicable.

(Contd. on page 4)

**Safety data sheet**  
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Revision: 17.01.2013

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(Contd. of page 3)

· <b>Change in condition</b>	
<b>Melting point/Melting range:</b>	Undetermined.
<b>Boiling point/Boiling range:</b>	Undetermined.
· <b>Flash point:</b>	Not applicable.
· <b>Flammability (solid, gaseous):</b>	Not determined.
· <b>Self-igniting:</b>	Product is not selfigniting.
· <b>Danger of explosion:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
<b>Lower:</b>	Not determined.
<b>Upper:</b>	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.
· <b>Solubility in / Miscibility with water:</b>	Nearly insoluble.
· <b>Partition coefficient (n-octanol/water):</b>	Not determined.
· <b>Viscosity:</b>	
<b>Dynamic:</b>	Not applicable.
<b>Kinematic:</b>	Not applicable.
· <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** 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:**
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**  
The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.

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(Contd. on page 5)

**Safety data sheet**  
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Revision: 17.01.2013

**Trade name: SR Ivocap High Impact Polymer**

(Contd. of page 4)

### 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:**  
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.
- **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.
  - **European waste catalogue**
- |          |          |
|----------|----------|
| 20 01 39 | plastics |
|----------|----------|
- **Uncleaned packaging:**
  - **Recommendation:** Disposal must be made according to official regulations.

### 14 Transport information

- |  |                 |
|--|-----------------|
| · <b>UN-Number</b>   | Void            |
| · <b>ADR, ADN, IMDG, IATA</b>  | Void            |
| · <b>UN proper shipping name</b>   | Void            |
| · <b>ADR, ADN, IMDG, IATA</b>  | Void            |
| · <b>Transport hazard class(es)</b>  | Void            |
| · <b>ADR, ADN, IMDG, IATA</b>  | Void            |
| · <b>Class</b>   | Void            |
| · <b>Packing group</b>   | Void            |
| · <b>ADR, 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 MARPOL73/78 and the IBC Code</b> | Not applicable. |

GB

(Contd. on page 6)

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(Contd. of page 5)

### **15 Regulatory information**

- **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 EC-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.*

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