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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.
- $\cdot$  Application of the substance / the preparation Denture base material
- $\cdot$  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

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• 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:
- CO2, 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.

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• Information about fire - and explosion protection: No special measures required.

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• 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

General Information Appearance:		
Form:	Powder	
Colour: Odour:	According to product specification Characteristic	
Odour threshold:	Not determined.	
pH-value:	Not applicable.	

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Undetermined. Undetermined.	
Not applicable.	
Not determined.	
Product is not selfigniting.	
Product does not present an explosion hazard.	
Not determined. Not determined.	
Not applicable.	
Not determined. Not determined. Not applicable. Not applicable.	
Nearly insoluble.	
ter): Not determined.	
Not applicable. Not applicable. No further relevant information available.	
	Undetermined. Not applicable. Not determined. Product is not selfigniting. Product does not present an explosion hazard. Not determined. Not determined. Not applicable. Not determined. Not determined. Not determined. Not applicable. Not applicable. Not applicable. ter): Not determined.

#### **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:
- $\cdot$  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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#### **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

· UN-Number	
· ADR, ADN, IMDG, IATA	Void
· UN proper shipping name · ADR, ADN, IMDG, IATA	Void
· Transport hazard class(es)	
· ADR, ADN, IMDG, IATA · Class	Void
· Packing group · ADR, IMDG, IATA	Void
· Environmental hazards: · Marine pollutant:	No
· Special precautions for user	Not applicable.
• Transport in bulk according to Annex II MARPOL73/78 and the IBC Code	of Not applicable.

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## **15 Regulatory information**

 $\cdot$  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.