

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

Printing date 21.05.2015

Version number 4

Revision: 12.03.2015

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

- **1.1 Product identifier**
- **Trade name: SR Ivocap High Impact Monomer**
- **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** Denture base 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**  
Flam. Liq. 2 H225 Highly flammable liquid and vapour.  
Skin Irrit. 2 H315 Causes skin irritation.  
Skin Sens. 1 H317 May cause an allergic skin reaction.  
STOT SE 3 H335 May cause respiratory irritation.
- 
- **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**



GHS02 GHS07

- **Signal word** Danger
- **Hazard-determining components of labelling:**  
methyl methacrylate  
ethylene glycol dimethacrylate

- **Hazard statements**  
H225 Highly flammable liquid and vapour.  
H315 Causes skin irritation.  
H317 May cause an allergic skin reaction.  
H335 May cause respiratory irritation.

· **Precautionary statements**

- P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
- P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
- P262 Do not get in eyes, on skin, or on clothing.

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- P280 Wear protective gloves/protective clothing/eye protection/face protection.  
 P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.  
 P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- **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: 80-62-6 EINECS: 201-297-1	methyl methacrylate Flam. Liq. 2, H225; Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	50-100%
CAS: 97-90-5 EINECS: 202-617-2	ethylene glycol dimethacrylate Skin Sens. 1, H317; STOT SE 3, H335	3-<10%

- **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**
- **General information:** Immediately remove any clothing soiled by the product.
- **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:** Immediately 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.  
Do not induce vomiting; call for medical help immediately.
- **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>, sand, extinguishing powder. Do not use water.
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **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.
- **Additional information** Cool endangered receptacles with water spray.

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### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Wear protective equipment. Keep unprotected persons away.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).  
Ensure adequate ventilation.  
Do not flush with water or aqueous cleansing agents
- **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**  
Only adequately trained personnel should handle this product.  
Ensure good ventilation/exhaustion at the workplace.
- **Information about fire - and explosion protection:**  
Keep ignition sources away - Do not smoke.  
Protect against electrostatic charges.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**  
Store only in the original receptacle.  
Store in a cool location.
- **Information about storage in one common storage facility:** Store away from oxidising agents.
- **Further information about storage conditions:**  
Store receptacle in a well ventilated area.  
Keep container tightly sealed.  
Store in cool, dry conditions in well sealed receptacles.
- **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:**

**80-62-6 methyl methacrylate**

WEL	Short-term value: 416 mg/m <sup>3</sup> , 100 ppm
	Long-term value: 208 mg/m <sup>3</sup> , 50 ppm

- **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.  
Immediately remove all soiled and contaminated clothing  
Avoid contact with the eyes and skin.

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· **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.*

· **Recommended filter device for short term use:**

Filter A1

Filter A2

Filter A3

· **Protection of hands:**



Protective gloves

*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**

Butyl rubber, BR

*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.*

· **Eye protection:**



Tightly sealed goggles

## SECTION 9: Physical and chemical properties

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

· **General Information**

· **Appearance:**

**Form:** Fluid

**Colour:** Colourless

· **Odour:** Pungent

· **Odour threshold:** Not determined.

· **pH-value:** Not determined.

· **Change in condition**

**Melting point/Melting range:** -48 °C

**Boiling point/Boiling range:** 101 °C

· **Flash point:** 10 °C

· **Ignition temperature:** 430 °C

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

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· <b>Danger of explosion:</b>	<i>Product is not explosive. However, formation of explosive air/vapour mixtures are possible.</i>
· <b>Explosion limits:</b>	
<b>Lower:</b>	2.1 Vol %
<b>Upper:</b>	12.5 Vol %
· <b>Vapour pressure at 20 °C:</b>	47 hPa
· <b>Density at 20 °C:</b>	0.943 g/cm <sup>3</sup>
· <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 at 20 °C:</b>	1.6 g/l
· <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**  
*Forms explosive gas mixture with air.*  
*Reacts with strong oxidising agents.*  
*Exothermic polymerisation.*
- **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:**

· **LD/LC50 values relevant for classification:**

**80-62-6 methyl methacrylate**

Oral	LD50	7872 mg/kg (rat)
------	------	------------------

- **Primary irritant effect:**
- **on the skin:** *Irritant to skin and mucous membranes.*
- **on the eye:** *No irritating effect.*
- **Sensitisation:** *Sensitisation possible through skin contact.*
- **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**  
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
  - **European waste catalogue**
- |           |  |
|-----------|--|
| 18 01 06* | chemicals consisting of or containing dangerous substances |
|-----------|--|
- **Uncleaned packaging:**
  - **Recommendation:** Disposal must be made according to official regulations.

### SECTION 14: Transport information

- **14.1 UN-Number**
  - **ADR, IMDG, IATA** UN1247
  - **14.2 UN proper shipping name**
  - **ADR** 1247 METHYL METHACRYLATE MONOMER,  
STABILIZED
  - **IMDG, IATA** METHYL METHACRYLATE MONOMER, STABILIZED
  - **14.3 Transport hazard class(es)**
  - **ADR**
- 
  - **Class** 3 (F1) Flammable liquids.
  - **Label** 3

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· **IMDG, IATA**

· **Class** 3 Flammable liquids.  
· **Label** 3

· **14.4 Packing group**  
· **ADR, IMDG, IATA** II

· **14.5 Environmental hazards:**  
· **Marine pollutant:** No

· **14.6 Special precautions for user** Warning: Flammable liquids.  
· **Danger code (Kemler):** 339  
· **EMS Number:** F-E,S-D

· **14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.

· **Transport/Additional information:**

· **ADR**  
· **Limited quantities (LQ)** 1L  
· **Excepted quantities (EQ)** Code: E2  
Maximum net quantity per inner packaging: 30 ml  
Maximum net quantity per outer packaging: 500 ml  
· **Transport category** 2  
· **Tunnel restriction code** D/E

· **IMDG**  
· **Limited quantities (LQ)** 1L  
· **Excepted quantities (EQ)** Code: E2  
Maximum net quantity per inner packaging: 30 ml  
Maximum net quantity per outer packaging: 500 ml

· **UN "Model Regulation":** UN1247, METHYL METHACRYLATE MONOMER, STABILIZED, 3, II

### 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**  
H225 Highly flammable liquid and vapour.  
H315 Causes skin irritation.

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*H317 May cause an allergic skin reaction.*

*H335 May cause respiratory irritation.*

**· 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)*

*LC50: Lethal concentration, 50 percent*

*LD50: Lethal dose, 50 percent*

*Flam. Liq. 2: Flammable liquids, Hazard Category 2*

*Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2*

*Skin Sens. 1: Sensitisation - Skin, Hazard Category 1*

*STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3*

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

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

- **1.1 Product identifier**
- **Trade name: SR Ivocap High Impact Polymer**
- **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** Denture base 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**  
Skin Sens. 1 H317 May cause an allergic skin reaction.
- **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:**  
dibenzoyl peroxide
- **Hazard statements**  
H317 May cause an allergic skin reaction.
- **Precautionary statements**  
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.  
P262 Do not get in eyes, on skin, or on clothing.  
P280 Wear protective gloves/protective clothing/eye protection/face protection.  
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- **2.3 Other hazards**  
Dust generation  
Particular danger of slipping on leaked/spilled product.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.

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· **vPvB:** Not applicable.

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

- **3.2 Chemical characterisation: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 94-36-0	dibenzoyl peroxide	0.3-<1%
EINECS: 202-327-6	Org. Perox. B, H241; 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**
- **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.
- **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**  
Avoid formation of dust.  
Particular danger of slipping on leaked/spilled product.
- **6.2 Environmental precautions:**  
Do not allow product to reach sewage system or any water course.  
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 heat and direct sunlight.

· **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:**

**94-36-0 dibenzoyl peroxide**

WEL Long-term value: 5 mg/m<sup>3</sup>

· **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.

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**

Butyl rubber, BR

Chloroprene rubber, CR

Natural rubber, NR

Nitrile rubber, NBR

Fluorocarbon rubber (Viton)

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.

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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>	Powder
· <b>Colour:</b>	According to product specification
· <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 determined.

· **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 applicable.

· <b>Density:</b>	Not determined.
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not applicable.
· <b>Evaporation rate</b>	Not applicable.

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

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

· **Viscosity:**

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

· **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.

· **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.

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**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.

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

**SECTION 14: Transport information**

- |   |      |
|---|------|
| · <b>14.1 UN-Number</b><br>· <b>ADR, ADN, IMDG, IATA</b>                                    | Void |
| · <b>14.2 UN proper shipping name</b><br>· <b>ADR, ADN, IMDG, IATA</b>                      | Void |
| · <b>14.3 Transport hazard class(es)</b><br>· <b>ADR, ADN, IMDG, IATA</b><br>· <b>Class</b> | Void |
| · <b>14.4 Packing group</b><br>· <b>ADR, IMDG, IATA</b>                                     | Void |

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

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

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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**  
H241 Heating may cause a fire or explosion.  
H317 May cause an allergic skin reaction.  
H319 Causes serious eye irritation.
- **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)  
Org. Perox. B: Organic Peroxides, Type B  
Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2  
Skin Sens. 1: Sensitisation - Skin, Hazard Category 1
- **\* Data compared to the previous version altered.**

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