

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

Printing date 21.05.2015


Version number 9

Revision: 04.05.2015

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

- **1.1 Product identifier**
- **Trade name:** ***SR Ivolen 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** Custom tray 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.

(Contd. on page 2)

## Safety data sheet

### according to 1907/2006/EC, Article 31

Printing date 21.05.2015

Version number 9

Revision: 04.05.2015

**Trade name: SR Ivolen Polymer**

 · **vPvB:** Not applicable.

(Contd. of page 1)

### 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	I-<2.5%
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

 · **After inhalation:** Supply fresh air and to be sure call for a doctor.

 · **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 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.

GB

(Contd. on page 3)

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

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Version number 9

Revision: 04.05.2015

Trade name: **SR Ivolen Polymer**

(Contd. of page 2)

### 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:**

<b>94-36-0 dibenzoyl peroxide</b>
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WEL	Long-term value: 5 mg/m <sup>3</sup>
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- **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**

Nitrile rubber, NBR

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

GB

(Contd. on page 4)

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

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Version number 9

Revision: 04.05.2015

Trade name: **SR Ivolen Polymer**

(Contd. of page 3)

### SECTION 9: Physical and chemical properties

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

##### · General Information

##### · Appearance:

Form: Powder

Colour: Beige

· Odour: Characteristic

· Odour threshold: Not determined.

· pH-value: Not applicable.

##### · Change in condition

Melting point/Melting range: Undetermined.

Boiling point/Boiling range: 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:

Lower: Not determined.

Upper: Not determined.

· Vapour pressure: Not applicable.

· Density: Not determined.

· Relative density: Not determined.

· Vapour density: Not applicable.

· Evaporation rate: Not applicable.

· Solubility in / Miscibility with water:

Nearly insoluble.

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

##### · Viscosity:

Dynamic: Not applicable.

Kinematic: 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.

GB

(Contd. on page 5)

## Safety data sheet

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(Contd. of page 4)

#### 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:** 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 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.
- **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   |

(Contd. on page 6)

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

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Version number 9

Revision: 04.05.2015

**Trade name: SR Ivolen Polymer**

(Contd. of page 5)

· <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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