

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

Printing date 27.11.2012

Version number 8

Revision: 26.11.2012

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

- **Product identifier**
- **Trade name:** **SR Ivolen Monomer**
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the preparation** Custom tray 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 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.
- **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
- **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/sparks/open flames/hot surfaces. - No smoking.
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.

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P303+P361+P353 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- **Other hazards**
- **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:**

CAS: 80-62-6	methyl methacrylate	50-100%
EINECS: 201-297-1	Flam. Liq. 2, H225; Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	
CAS: 8002-74-2	Paraffin waxes and Hydrocarbon waxes	2.5-10%
EINECS: 232-315-6		

4 First aid measures

- **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.
If skin irritation continues, consult a doctor.
- **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.
- **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.
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.
- **Additional information** Cool endangered receptacles with water spray.

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6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Ensure adequate ventilation.
- **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.
Ensure good ventilation/exhaustion at the workplace.
For use in dentistry only.
- **Information about fire - and explosion protection:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
- **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 oxidizing agents.
- **Further information about storage conditions:**
Keep container tightly sealed.
Store receptacle in a well ventilated area.
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:	
80-62-6 methyl methacrylate	
WEL ()	Short-term value: 416 mg/m ³ , 100 ppm Long-term value: 208 mg/m ³ , 50 ppm
8002-74-2 Paraffin waxes and Hydrocarbon waxes	
WEL ()	Short-term value: 6 mg/m ³ Long-term value: 2 mg/m ³

- **Additional information:** The lists valid during the making were used as basis.

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- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Usual hygienic measures for dental practice.
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
Do not inhale gases / fumes / aerosols.
- **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 AX
- **Protection of hands:**



Protective gloves

After use of gloves apply skin-cleaning agents and skin cosmetics.

- **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

9 Physical and chemical properties

• Information on basic physical and chemical properties

• General Information

• Appearance:

Form:	Fluid
Colour:	Colourless
Odour:	Pungent
Odour threshold:	Not determined.

• pH-value:	Not determined.
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• Change in condition

Melting point/Melting range:	-48°C
Boiling point/Boiling range:	101°C

• Flash point:	10°C
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• Ignition temperature:	430°C
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· Self-igniting:	Product is not selfigniting.
· Danger of explosion:	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
· Explosion limits:	
Lower:	2.1 Vol %
Upper:	12.5 Vol %
· Vapour pressure at 20°C:	47 hPa
· Density at 20°C:	0.943 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with water at 20°C:	1.6 g/l
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
· Other information	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**
Forms explosive gas mixture with air.
Reacts with strong oxidizing agents.
Exothermic polymerization.
- **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:**

· LD/LC50 values relevant for classification:
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80-62-6 methyl methacrylate

Oral	LD50	7872 mg/kg (rat)
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- **Primary irritant effect:**
- **on the skin:** Irritant to skin and mucous membranes.
- **on the eye:** No irritating effect.
- **Sensitization:** Sensitization possible through skin contact.

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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**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
 - **European waste catalogue**
- | | |
|-----------|--|
| 18 01 06* | chemicals consisting of or containing dangerous substances |
|-----------|--|
- **Uncleaned packaging:**
 - **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|--------------------------|------|
| · UN-Number | |
| · ADR, IMDG, IATA | 1247 |
- | | |
|----------------------------------|--|
| · UN proper shipping name | |
| · ADR | 1247 METHYL METHACRYLATE MONOMER, STABILIZED |
| · IMDG, IATA | METHYL METHACRYLATE MONOMER, STABILIZED |
- **Transport hazard class(es)**
 - **ADR**
- 

- **Class**
- 3 (F1) Flammable liquids.

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· Label	3
· IMDG, IATA	
	
· Class	3 Flammable liquids.
· Label	3
· Packing group	
· ADR, IMDG, IATA	II
· Environmental hazards:	
· Marine pollutant:	No
· Special precautions for user	Warning: Flammable liquids.
· Danger code (Kemler):	33
· EMS Number:	F-E,S-E
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
· Transport/Additional information:	
· ADR	
· Limited quantities (LQ)	LQ4
· Transport category	2
· Tunnel restriction code	D/E
· UN "Model Regulation":	UN1247, METHYL METHACRYLATE MONOMER, STABILIZED, 3, II

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.

- **Relevant phrases**
H225 Highly flammable liquid and vapour.
H315 Causes skin irritation.
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 Harmonized System of Classification and Labelling of Chemicals

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LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

** Data compared to the previous version altered.*

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

- **Product identifier**
- **Trade name:** **SR Ivolen Polymer**
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the preparation** Custom tray 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 Regulation (EC) No 1272/2008**
Skin Sens. 1 H317 May cause an allergic skin reaction.
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
Xi; Sensitising
R43: May cause sensitisation by skin contact.
- **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 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.

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- **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:**

CAS: 94-36-0	dibenzoyl peroxide	≤ 2.5%
EINECS: 202-327-6	Xi R36; Xi R43; E R2	
	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.

4 First aid measures

- **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.
- **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 to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:** Pick up mechanically.

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- **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.

- **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:**

94-36-0 dibenzoyl peroxide

WEL ()	Long-term value: 5 mg/m ³
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- **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.

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Trade name: **SR Ivolen Polymer**

· Eye protection: Safety glasses

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9 Physical and chemical properties

· 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.

· Other information: 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.

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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:** Sensitization possible through skin contact.
- **Additional toxicological information:**
The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
Irritant

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.
- **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 |

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· 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 of MARPOL73/78 and the IBC Code	Not applicable.
· UN "Model Regulation":	-

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.

· **Relevant phrases**

H241 Heating may cause a fire or explosion.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

R2 Risk of explosion by shock, friction, fire or other sources of ignition.

R36 Irritating to eyes.

R43 May cause sensitisation by skin contact.

· **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 Harmonized System of Classification and Labelling of Chemicals

- *** Data compared to the previous version altered.**