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

· 1.1 Product identifier

• Trade name: SR Spectra Opaquer Liquid

• 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 Crowns- and bridges material

 1.3 Details of the supplier of the safety data sheet
 Manufacturer/Supplier: Ivoclar Vivadent AG Bendererstrasse 2

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.
Eye Irrit. 2 H319 Causes serious eye irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.
STOT SE 3 H335 May cause respiratory irritation.

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

· 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



· Signal word Danger

 Hazard-determining components of labelling: methyl methacrylate urethane dimethacrylate
 Hazard statements

Hazara statements H225 Highly flammable liquid and vapour. H315 Causes skin irritation. H319 Causes serious eye irritation. H317 May cause an allergic skin reaction.

H335 May cause respiratory irritation.

H412 Harmful to aquatic life with long lasting effects.

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- · 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.
- P280 Wear protective gloves/protective clothing/eye protection/face protection.

P363 Wash contaminated clothing before reuse.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P337+P313 If eye irritation persists: Get medical advice/attention.

· 2.3 Other hazards

· Results of PBT and vPvB assessment

- **PBT:** Not applicable.
- · 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: 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: 72869-86-4	urethane dimethacrylate	25-50%	
EINECS: 276-957-5	Eye Irrit. 2, H319; Skin Sens. 1, H317; Aquatic Chronic 3, H412		
CAS: 10373-78-1	camphorquinone	1-<2.5%	
	Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335		
Additional information: For the wording of the listed risk phrases refer to section 16			

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.
- 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:
- 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
- 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.

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• Additional information Cool endangered receptacles with water spray.

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.
- \cdot 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.
- · 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/m³, 100 ppm Long-term value: 208 mg/m³, 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. Immediately remove all soiled and contaminated clothing

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(Contd. of page 3) Wash hands before breaks and at the end of work. Do not inhale gases / fumes / aerosols. Avoid contact with the eyes and skin. · Respiratory protection: Use suitable respiratory protective device in case of insufficient ventilation. Filter A · 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 The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application. · 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. · For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable: Butyl rubber, BR • 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: Undetermined. 101 °C Boiling point/Boiling range: 10 °C · Flash point: 430 °C · Ignition temperature: (Contd. on page 5) GB

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Self-igniting:	Product is not selfigniting.
Danger of explosion:	<i>Product is not explosive. However, formation of explosive air/ vapour mixtures are possible.</i>
• Explosion limits:	
Lower:	2.1 Vol %
Upper:	12.5 Vol %
• Vapour pressure at 20 •C:	47 hPa
Density:	Not determined.
Relative density	Not determined.
Vapour density	Not determined.
Evaporation rate	Not determined.
Solubility in / Miscibility with	
water:	Not miscible or difficult to mix.
Partition coefficient (n-octanol/wo	ater): Not determined.
· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
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 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: 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 2 (German Regulation) (Self-assessment): hazardous for water Do not allow product 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	1247
· 14.2 UN proper shipping name	1217
· 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
· IMDG, IATA	
*	
· Class	3 Flammable liquids.
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· Label	3
· 14.4 Packing group · ADR, IMDG, IATA	11
· 14.5 Environmental hazards: · Marine pollutant:	No
· 14.6 Special precautions for user · Danger code (Kemler): · EMS Number:	Warning: Flammable liquids. 33 F-E,S-E
· 14.7 Transport in bulk according to Anne MARPOL73/78 and the IBC Code	ex II of Not applicable.
· Transport/Additional information:	
· ADR · Limited quantities (LQ) · Transport category · Tunnel restriction code	LQ4 2 D/E
· 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.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H412 Harmful to aquatic life with long lasting effects.

• 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

Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2

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

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STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3 Aquatic Chronic 3: Hazardous to the aquatic environment - Chronic Hazard, Category 3

 \cdot * Data compared to the previous version altered.

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