

Printing date 29.04.2015 Version number 6 Revision: 17.04.2015

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

· 1.1 Product identifier

· Trade name: SR Composiv

· 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 Auxiliary for dental technology
- · 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

Eye Irrit. 2 H319 Causes serious eye irritation.

Skin Sens. 1 H317 May cause an allergic skin reaction.

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 Warning
- · Hazard-determining components of labelling:

urethane dimethacrylate

1,10-decandiol dimethacrylate

· Hazard statements

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

H412 Harmful to aquatic life with long lasting effects.

· Precautionary statements

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.

P302+P352 IF ON SKIN: Wash with plenty of water.

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- · 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:		
	urethane dimethacrylate	50-100%
EINECS: 276-957-5	Eye Irrit. 2, H319; Skin Sens. 1, H317; Aquatic Chronic 3, H412	
CAS: 6701-13-9	1,10-decandiol dimethacrylate	10-<25%
EINECS: 229-745-1	Eye Irrit. 2, H319; Skin Sens. 1, H317	
	2,6-di-tert-butyl-p-cresol	0.3-<1%
EINECS: 204-881-4	Aquatic Chronic 2, H411; Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319	

[·] 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: 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.

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:

CO2, 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 Not required.
- 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.

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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.

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 exposure to the light.

Protect from heat and direct sunlight.

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:

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.
- · 8.2 Exposure controls
- · Personal protective equipment:
- · General protective and hygienic measures:

Usual hygienic measures for dental practice.

Wash hands before breaks and at the end of work.

Keep away from foodstuffs, beverages and feed.

Avoid contact with the eyes and skin.

- · Respiratory protection: Not required.
- · 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.

· Not suitable are gloves made of the following materials:

Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates.

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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:

· pH-value:

Form: Pasty
Colour: Whitish
Odour: Characteristic
Odour threshold: Not determined.

· Change in condition

Melting point/Melting range: Undetermined.
Boiling point/Boiling range: Undetermined.

Flash point: Not applicable.

· Flammability (solid, gaseous): Not applicable.

· Self-igniting: Product is not selfigniting.

• Danger of explosion: Product does not present an explosion hazard.

Not applicable.

· Explosion limits:

Lower:Not determined.Upper:Not determined.

· Vapour pressure: Not determined.

Density at 20 °C:
 Relative density
 Vapour density
 Evaporation rate
 1.1 - 1.3 g/cm³
 Not determined.
 Not determined.
 Not determined.

· Solubility in / Miscibility with

water: Nearly insoluble.

· Partition coefficient (n-octanol/water): 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.

Photoreactive (Danger of polymerization).

- · 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

Protect from exposure to the light.

Keep away from heat and direct sunlight.

· 10.5 Incompatible materials: No further relevant information available.

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• 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:
- · Primary irritant effect:
- · on the skin: No irritant effect.
- · on the eye: 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 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

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.

· 14.1 UN-Number		
· ADR, ADN, IMDG, IATA	Void	
· 14.2 UN proper shipping name		
· ADR, ADN, IMDG, IATA	Void	
· 14.3 Transport hazard class(es)		
· ADR, ADN, IMDG, IATA		
· Class	Void	

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· 14.4 Packing group · ADR, IMDG, IATA	Void
· 14.5 Environmental hazards: · Marine pollutant:	No
· 14.6 Special precautions for user	Not applicable.
· 14.7 Transport in bulk according to Anno MARPOL73/78 and the IBC Code	e x II of Not applicable.
· Transport/Additional information:	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
· UN "Model Regulation":	-

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

H302 Harmful if swallowed.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H411 Toxic to aquatic life with long lasting effects.

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)

Acute Tox. 4: Acute toxicity, Hazard Category 4

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

Aquatic Chronic 2: Hazardous to the aquatic environment - Chronic Hazard, Category 2

Aquatic Chronic 3: Hazardous to the aquatic environment - Chronic Hazard, Category 3

* Pata compared to the previous version altered.

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