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

- · 1.1 Product identifier
- · Trade name: SR Chromasit Color, Intensive
- $\cdot$  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

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 Irrit. 2 H315 Causes skin irritation.

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

1,4-butanediol dimethacrylate

dibenzoyl peroxide

· Hazard statements

H315 Causes skin irritation.

H319 Causes serious eve 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.

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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.

#### 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                 |         |
|                         | 1,4-butanediol dimethacrylate                                                   | 10-<25% |
|                         | Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3,<br>H335 |         |
|                         | dibenzoyl peroxide                                                              | 0.3-<1% |
| EINECS: 202-327-6       | Org. Perox. B, H241; Eye Irrit. 2, H319; Skin Sens. 1, H317                     |         |

<sup>·</sup> 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.

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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.

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.

Keep container tightly sealed.

 $\cdot$  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

#### SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Appearance:

Form: Pasty

Colour: According to product specification

Odour: OdourlessOdour 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 applicable.

· 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 determined.

Density: Not determined.
 Relative density Not determined.
 Vapour density Not determined.
 Evaporation rate 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.
- $\cdot$  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 Keep away from heat and direct sunlight.
- · 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: 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.

## 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

- · 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.

| · 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 |  |
| · 14.4 Packing group              |      |  |
| ADR, IMDG, IATA                   | Void |  |
| 14.5 Environmental hazards:       |      |  |
| Marine pollutant:                 | No   |  |

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|----------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| · 14.6 Special precautions for user                                        | Not applicable.                                                                |
| · 14.7 Transport in bulk according to Anne<br>MARPOL73/78 and the IBC Code | ex II of<br>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

H241 Heating may cause a fire or explosion.

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)

Org. Perox. B: Organic Peroxides, Type B

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

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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