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

1.1 Product identifier

Trade name: SR Nexco Opaquer / Gingiva Opaquer

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
Light-curing labside composite

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

The product is classified and labelled according to the CLP regulation.

Hazard pictograms

GHS07

Signal word Warning

Hazard-determining components of labelling:
Aromatic aliphatic urethane dimethacrylate
1,10-decandiol dimethacrylate

Hazard statements
H317 May cause an allergic skin reaction.

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.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

(Contd. on page 2)
SECTION 3: Composition/information on ingredients

3.2 Chemical characterisation: Mixtures

Description: Mixture of substances listed below with nonhazardous additions.

Dangerous components:

- CAS: 6701-13-9
- EINECS: 229-745-1
- 1,10-decandiol dimethacrylate

Eye Irrit. 2, H319; Skin Sens. 1, H317
3-<10%

Additional information: For the wording of the listed hazard 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. If symptoms persist, consult a doctor.

After swallowing:
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.
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 and dental laboratories.
Wash hands before breaks and at the end of work.
Keep away from foodstuffs, beverages and food.
Avoid contact with the skin.
Respiratory protection: Not required.
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.
Eye protection: Safety glasses
## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Information</td>
<td></td>
</tr>
<tr>
<td>Appearance:</td>
<td>Viscous</td>
</tr>
<tr>
<td>Form: Viscous</td>
<td></td>
</tr>
<tr>
<td>Colour: According to product specification</td>
<td></td>
</tr>
<tr>
<td>Odour: Characteristic</td>
<td></td>
</tr>
<tr>
<td>Odour threshold:</td>
<td>Not determined.</td>
</tr>
<tr>
<td>pH-value:</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Change in condition</td>
<td></td>
</tr>
<tr>
<td>Melting point/Melting range:</td>
<td>Undetermined.</td>
</tr>
<tr>
<td>Boiling point/Boiling range:</td>
<td>Undetermined.</td>
</tr>
<tr>
<td>Flash point:</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Flammability (solid, gaseous):</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Self-igniting:</td>
<td>Product is not selfigniting.</td>
</tr>
<tr>
<td>Danger of explosion:</td>
<td>Product does not present an explosion hazard.</td>
</tr>
<tr>
<td>Explosion limits:</td>
<td></td>
</tr>
<tr>
<td>Lower: Not determined.</td>
<td></td>
</tr>
<tr>
<td>Upper: Not determined.</td>
<td></td>
</tr>
<tr>
<td>Vapour pressure:</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Density: Not determined.</td>
<td></td>
</tr>
<tr>
<td>Relative density:</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Vapour density:</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Evaporation rate:</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Solubility in / Miscibility with water:</td>
<td>Nearly insoluble.</td>
</tr>
<tr>
<td>Partition coefficient (n-octanol/water):</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Viscosity:</td>
<td></td>
</tr>
<tr>
<td>Dynamic: Not determined.</td>
<td></td>
</tr>
<tr>
<td>Kinematic: Not determined.</td>
<td></td>
</tr>
<tr>
<td>9.2 Other information</td>
<td>No further relevant information available.</td>
</tr>
</tbody>
</table>

## SECTION 10: Stability and reactivity

### 10.1 Reactivity
No further relevant information available.

### 10.2 Chemical stability
- Photoreactive (Danger of polymerization).
- Stable under normal handling and storage conditions.

### 10.3 Possibility of hazardous reactions
No dangerous reactions known.

### 10.4 Conditions to avoid
- Keep away from heat and direct sunlight.
- Protect from exposure to the light.

### 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: Based on available data, the classification criteria are not met.
- Skin corrosion/irritation: Based on available data, the classification criteria are not met.
- Serious eye damage/irritation: Based on available data, the classification criteria are not met.
- Respiratory or skin sensitisation: May cause an allergic skin reaction.
- Additional toxicological information: No further relevant information available.
- Germ cell mutagenicity: Based on available data, the classification criteria are not met.
- Carcinogenicity: Based on available data, the classification criteria are not met.
- Reproductive toxicity: Based on available data, the classification criteria are not met.
- STOT-single exposure: Based on available data, the classification criteria are not met.
- STOT-repeated exposure: Based on available data, the classification criteria are not met.
- Aspiration hazard: Based on available data, the classification criteria are not met.

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.
- Uncleaned packaging:
  Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information

14.1 UN-Number
- ADR, RID, ADN, ADN, IMDG, IATA: Void

14.2 UN proper shipping name
- ADR, RID, ADN, ADN, IMDG, IATA: Void

14.3 Transport hazard class(es)
- ADR, RID, ADN, ADN, IMDG, IATA: Void
### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
  - REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

- **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**
  - 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)
  - PBT: Persistent, Bioaccumulative and Toxic
  - vPvB: very Persistent and very Bioaccumulative
  - Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
  - Skin Sens. 1: Skin sensitisation – Category 1

- * Data compared to the previous version altered.