

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

Printing date 09.05.2012


Version number 1

Revision: 27.04.2012


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

- **Product identifier**
- **Trade name:** **SR Nexco Paste (Margin, Dentin, Incisal, Effect, Gingiva, Intensiv Gingiva, Basic Gingiva)**
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the preparation** Light-curing labside composite
- **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

## 2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**  
 Xi; Sensitising  
R43: May cause sensitisation by skin contact.
- **Information concerning particular hazards for human and environment:**  
The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.
- **Classification system:**  
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

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- **Label elements**
- **Labelling according to EU guidelines:**
- **Code letter and hazard designation of product:**  
 Xi Irritant
- **Hazard-determining components of labelling:**  
decamethylene dimethacrylate  
urethane dimethacrylate
- **Risk phrases:**  
43 May cause sensitisation by skin contact.
- **Safety phrases:**  
24 Avoid contact with skin.  
37 Wear suitable gloves.  
60 This material and its container must be disposed of as hazardous waste.

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**Trade name: SR Nexco Paste (Margin, Dentin, Incisal, Effect, Gingiva, Intensiv Gingiva, Basic Gingiva)**

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- **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: 6701-13-9	decamethylene dimethacrylate	☒ Xi R36; ☒ Xi R43	2.5-10%
CAS: 43048-08-4 EINECS: 256-062-6	tricyclodocane dimethanol dimethacrylate	☒ Xi R38-41	≤ 2.5%
CAS: 72869-86-4 EINECS: 276-957-5	urethane dimethacrylate	☒ Xi R36; ☒ Xi R43 R52/53	≤ 2.5%

- **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.  
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.
- **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:**  
CO<sub>2</sub>, 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** Not required.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **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.

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## 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 exposure to the light.  
Protect from heat and direct sunlight.  
Keep container tightly sealed.
- **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:**  
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.
- **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.  
Avoid contact with the skin.  
Keep away from foodstuffs, beverages and feed.
- **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.

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- **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

## 9 Physical and chemical properties

### · Information on basic physical and chemical properties

#### · General Information

#### · Appearance:

· <b>Form:</b>	Pasty
· <b>Colour:</b>	According to product specification
· <b>Odour:</b>	Characteristic
· <b>Odour threshold:</b>	Not determined.

· **pH-value:** Not determined.

#### · Change in condition

· <b>Melting point/Melting range:</b>	Undetermined.
· <b>Boiling point/Boiling range:</b>	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:

· <b>Lower:</b>	Not determined.
· <b>Upper:</b>	Not determined.

· **Vapour pressure:** Not determined.

· <b>Density at 20°C:</b>	1.56 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.

· **Solubility in / Miscibility with water:** Nearly insoluble.

· **Segregation coefficient (n-octanol/water):** Not determined.

#### · Viscosity:

· <b>Dynamic:</b>	Not determined.
· <b>Kinematic:</b>	Not determined.

· **Other information** No further relevant information available.

## 10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**  
Photoreactive (Danger of polymerization).  
Stable under normal handling and storage conditions.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.

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**Trade name: SR Nexco Paste (Margin, Dentin, Incisal, Effect, Gingiva, Intensiv Gingiva, Basic Gingiva)**

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- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid**  
Protect from exposure to the light.  
Keep away from heat and direct sunlight.
- **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:**
- **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 2 (German Regulation) (Self-assessment): hazardous for water  
Do not allow product 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.

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Gingiva, Basic Gingiva)**

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### 14 Transport information

- |  |                 |
|--|-----------------|
| · <b>UN-Number</b><br>· <b>ADR, ADN, IMDG, IATA</b>                                    | Void            |
| · <b>UN proper shipping name</b><br>· <b>ADR, ADN, IMDG, IATA</b>                      | Void            |
| · <b>Transport hazard class(es)</b><br>· <b>ADR, ADN, IMDG, IATA</b><br>· <b>Class</b> | Void            |
| · <b>Packing group</b><br>· <b>ADR, IMDG, IATA</b>                                     | Void            |
| · <b>Environmental hazards:</b><br>· <b>Marine pollutant:</b>                          | No              |
| · <b>Special precautions for user</b>  | Not applicable. |
| · <b>Transport in bulk according to Annex II of<br/>MARPOL73/78 and the IBC Code</b>   | Not applicable. |

### 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**  
R36 Irritating to eyes.  
R38 Irritating to skin.  
R41 Risk of serious damage to eyes.  
R43 May cause sensitisation by skin contact.  
R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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

- **Product identifier**
- **Trade name:** **SR Nexco Opaquer / Gingiva Opaquer**
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the preparation** Light-curing labside composite
- **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

**2 Hazards identification**

- **Classification of the substance or mixture**
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**  
 **Xi; Sensitising**  
R43: May cause sensitisation by skin contact.
- **Information concerning particular hazards for human and environment:**  
The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.
- **Classification system:**  
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

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- **Label elements**
- **Labelling according to EU guidelines:**
- **Code letter and hazard designation of product:**  
 **Xi Irritant**
- **Hazard-determining components of labelling:**  
decamethylene dimethacrylate
- **Risk phrases:**  
43 May cause sensitisation by skin contact.
- **Safety phrases:**  
24 Avoid contact with skin.  
37 Wear suitable gloves.  
60 This material and its container must be disposed of as hazardous waste.
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.

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· **vPvB:** Not applicable.

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### 3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

6701-13-9	decamethylene dimethacrylate	☒ Xi R36; ☒ Xi R43	2.5-10%
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- **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.  
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.
- **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:**  
CO<sub>2</sub>, 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** Not required.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **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.

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**Trade name: SR Nexco Opaquer / Gingiva Opaquer**

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- **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 exposure to the light.
  - Protect from heat and direct sunlight.
  - Keep container tightly sealed.
- **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:**
  - 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.
- **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 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

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### 9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

· <b>Form:</b>	Viscous
· <b>Colour:</b>	According to product specification
· <b>Odour:</b>	Characteristic
· <b>Odour threshold:</b>	Not determined.

· **pH-value:** Not determined.

· **Change in condition**

· <b>Melting point/Melting range:</b>	Undetermined.
· <b>Boiling point/Boiling range:</b>	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:**

· <b>Lower:</b>	Not determined.
· <b>Upper:</b>	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.

· **Segregation 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**

Photoreactive (Danger of polymerization).

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**

Keep away from heat and direct sunlight.

Protect from exposure to the light.

· **Incompatible materials:** No further relevant information available.

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· **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 2 (German Regulation) (Self-assessment): hazardous for water  
Do not allow product 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

- |                                  |      |
|----------------------------------|------|
| · <b>UN-Number</b>               |      |
| · <b>ADR, ADN, IMDG, IATA</b>    | Void |
| · <b>UN proper shipping name</b> |      |
| · <b>ADR, ADN, IMDG, IATA</b>    | Void |

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- |  |                 |
|--|-----------------|
| · <b>Transport hazard class(es)</b>  |                 |
| · <b>ADR, ADN, IMDG, IATA</b>  |                 |
| · <b>Class</b>   | Void            |
| · <b>Packing group</b>   |                 |
| · <b>ADR, IMDG, IATA</b>   | Void            |
| · <b>Environmental hazards:</b>  |                 |
| · <b>Marine pollutant:</b>   | No              |
| · <b>Special precautions for user</b>  | Not applicable. |
| · <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b> | Not applicable. |

### 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**  
R36 Irritating to eyes.  
R43 May cause sensitisation by skin contact.

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