

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

Printing date 04.05.2012



Version number 1


Revision: 04.05.2012

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

- **Product identifier**
- **Trade name:** SR Nexco Stains
- **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; Irritant
- **R36:** Irritating to eyes.
-  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.

- **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:**
36 Irritating to eyes.
43 May cause sensitisation by skin contact.
- **Safety phrases:**
24 Avoid contact with skin.

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- 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- 27 Take off immediately all contaminated clothing.
- 37/39 Wear suitable gloves and eye/face protection.
- 60 This material and its container must be disposed of as hazardous waste.

- **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	10-25%
CAS: 43048-08-4 EINECS: 256-062-6	tricyclodocane dimethanol dimethacrylate	☒ Xi R38-41	2.5-10%
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:**
CO₂, 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.

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- **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.
- **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 eyes and skin.
- **Respiratory protection:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
- **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

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Trade name: **SR Nexco Stains**

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- **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:**



Tightly sealed goggles

9 Physical and chemical properties

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

- **General Information**

- **Appearance:**

Form:	Viscous
Colour:	According to product specification
· Odour:	Characteristic
· Odour threshold:	Not determined.

- **pH-value:** 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.

- **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.

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

- **Viscosity:**

Dynamic:	Not determined.
Kinematic:	Not determined.

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· **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.
- **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:** 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 3 (German Regulation) (Self-assessment): extremely hazardous for water
Do not allow product to reach ground water, water course or sewage system, even in small quantities.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

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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

- | | |
|----------------------------------------------------------------------------------------|-----------------|
| · UN-Number
· ADR, ADN, IMDG, IATA | Void |
| · UN proper shipping name
· ADR, ADN, IMDG, IATA | Void |
| · Transport hazard class(es)
· ADR, ADN, IMDG, IATA
· Class | Void |
| · Packing group
· ADR, IMDG, IATA | Void |
| · Environmental hazards:
· Marine pollutant: | No |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | 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 Pontic Fill***
- **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.
-
- **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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- **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:**
CO₂, 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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Trade name: SR Nexco Pontic Fill

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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Trade name: **SR Nexco Pontic Fill**

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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:**
 - **Form:** Pasty
 - **Colour:** According to product specification
- **Odour:** Characteristic
- **Odour threshold:** Not determined.
- **pH-value:** 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.
- **Explosion limits:**
 - **Lower:** Not determined.
 - **Upper:** Not determined.
- **Vapour pressure:** Not determined.
- **Density at 20°C:** 1.56 g/cm³
- **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.

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Trade name: SR Nexco Pontic Fill

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

- **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:**
CO₂, 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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**Trade name: SR Nexco Paste (Margin, Dentin, Incisal, Effect, Gingiva, Intensiv
Gingiva, Basic Gingiva)**

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

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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:**

Form:	Pasty
Colour:	According to product specification
Odour:	Characteristic
Odour threshold:	Not determined.

- **pH-value:** 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.

- **Explosion limits:**

Lower:	Not determined.
Upper:	Not determined.

- **Vapour pressure:** Not determined.

Density at 20°C:	1.56 g/cm ³
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.

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

Printing date 09.05.2012

Version number 1

Revision: 27.04.2012

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

(Contd. of page 4)

- **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.

GB

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

Printing date 09.05.2012

Version number 1

Revision: 27.04.2012

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

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14 Transport information

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

GB

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

Printing date 04.05.2012


Version number 1


Revision: 04.05.2012

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.

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

Printing date 04.05.2012

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Trade name: SR Nexco Opaquer / Gingiva Opaquer

· **vPvB:** Not applicable.

(Contd. of page 1)

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:**
CO₂, 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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Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 04.05.2012

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Trade name: SR Nexco Opaquer / Gingiva Opaquer

(Contd. of page 2)

- **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

GB

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Safety data sheet
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Trade name: SR Nexco Opaquer / Gingiva Opaquer

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9 Physical and chemical properties

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

· **General Information**

· **Appearance:**

· Form:	Viscous
· Colour:	According to product specification
· Odour:	Characteristic
· Odour threshold:	Not determined.

· **pH-value:** 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.

· **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.

· **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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Safety data sheet
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Trade name: SR Nexco Opaquer / Gingiva Opaquer

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- **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.

14 Transport information

- | | |
|----------------------------------|------|
| · UN-Number | |
| · ADR, ADN, IMDG, IATA | Void |
| · UN proper shipping name | |
| · ADR, ADN, IMDG, IATA | Void |

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Trade name: SR Nexco Opaquer / Gingiva Opaquer

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

GB

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

Printing date 04.05.2012



Version number 1


Revision: 04.05.2012

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

- **Product identifier**
- **Trade name:** SR Nexco Liner
- **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; Irritant
R36: Irritating to eyes.
-  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.

- **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:**
36 Irritating to eyes.
43 May cause sensitisation by skin contact.
- **Safety phrases:**
24 Avoid contact with skin.

(Contd. on page 2)

Safety data sheet

according to 1907/2006/EC, Article 31

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Trade name: **SR Nexco Liner**

(Contd. of page 1)

26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

37/39 Wear suitable gloves and eye/face protection.

60 This material and its container must be disposed of as hazardous waste.

- **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	10-25%
CAS: 43048-08-4 EINECS: 256-062-6	tricyclodocane dimethanol dimethacrylate	☒ Xi R38-41	2.5-10%
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:**
CO₂, 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.

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Safety data sheet
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Trade name: **SR Nexco Liner**

(Contd. of page 2)

- **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.
- **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 eyes and skin.
- **Respiratory protection:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
- **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

(Contd. on page 4)

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Safety data sheet
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Revision: 04.05.2012

Trade name: **SR Nexco Liner**

(Contd. of page 3)

- **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:**



Tightly sealed goggles

9 Physical and chemical properties

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

- **General Information**

- **Appearance:**

Form:	Viscous
Colour:	According to product specification
· Odour:	Characteristic
· Odour threshold:	Not determined.

- **pH-value:** 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.

- **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.

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

- **Viscosity:**

Dynamic:	Not determined.
Kinematic:	Not determined.

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Safety data sheet
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Trade name: **SR Nexco Liner**

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· **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**
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:** *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 3 (German Regulation) (Self-assessment): extremely hazardous for water
Do not allow product to reach ground water, water course or sewage system, even in small quantities.
- **Results of PBT and vPvB assessment**
- **PBT:** *Not applicable.*
- **vPvB:** *Not applicable.*
- **Other adverse effects** *No further relevant information available.*

GB

(Contd. on page 6)

Safety data sheet
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Trade name: **SR Nexco Liner**

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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

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

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

Printing date 04.05.2012



Version number 1


Revision: 04.05.2012

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

- **Product identifier**
- **Trade name:** **SR Modelling Liquid**
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the preparation** Auxiliary for manufacture of dental prosthesis
- **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; Irritant
R36/37: Irritating to eyes and respiratory system.
-  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.

- **Label elements**
- **Labelling according to EU guidelines:**
- **Code letter and hazard designation of product:**
-  Xi Irritant
- **Hazard-determining components of labelling:**
decamethylene dimethacrylate
ethylene dimethacrylate
- **Risk phrases:**
36/37 Irritating to eyes and respiratory system.
43 May cause sensitisation by skin contact.
- **Safety phrases:**
23 Do not breathe fumes/aerosol.

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- 24 Avoid contact with skin.
- 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- 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.
- **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	50-100%
CAS: 97-90-5 EINECS: 202-617-2	ethylene dimethacrylate	☒ Xi R37; ☒ Xi R43	2.5-10%

- **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:** Immediately rinse with water.
- **After eye contact:**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing:**
Rinse out mouth and then drink plenty of water.
Do not induce vomiting; call for medical help immediately.
- **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:**
CO₂, 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:**
No special measures required.

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Trade name: SR Modelling Liquid

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- Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Ensure adequate ventilation.
- **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.
Ensure good ventilation/exhaustion at the workplace.
- **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.
Store receptacle in a well ventilated area.
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.
Keep away from foodstuffs, beverages and feed.
Wash hands before breaks and at the end of work.
Immediately remove all soiled and contaminated clothing
Avoid contact with the eyes and skin.
- **Respiratory protection:** Use suitable respiratory protective device in case of insufficient ventilation.
- **Protection of hands:**



Protective gloves

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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:**



Tightly sealed goggles

9 Physical and chemical properties

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

· **General Information**

· **Appearance:**

· Form:	Fluid
· Colour:	Colourless
· Odour:	Characteristic
· Odour threshold:	Not determined.

· **pH-value:** 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.

· **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:** Not miscible or difficult to mix.

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Trade name: SR Modelling Liquid

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

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Trade name: SR Modelling Liquid

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

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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

- | | |
|----------------------------------------------------------------------------------|-----------------|
| · UN-Number | |
| · ADR, ADN, IMDG, IATA | Void |
| · UN proper shipping name | |
| · ADR, ADN, IMDG, IATA | Void |
| · Transport hazard class(es) | |
| · ADR, ADN, IMDG, IATA | |
| · Class | Void |
| · Packing group | |
| · ADR, IMDG, IATA | Void |
| · Environmental hazards: | |
| · Marine pollutant: | No |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | 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.
R37 Irritating to respiratory system.
R43 May cause sensitisation by skin contact.

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

- **Product identifier**
- **Trade name:** **SR Link**
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the preparation** Bonding agent
- **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**
-  **Xn; Harmful**
R20: Harmful by inhalation.
-  **Xi; Irritant**
R36/37: Irritating to eyes and respiratory system.
-  **Xi; Sensitising**
R43: May cause sensitisation by skin contact.
-  **F; Highly flammable**
R11: Highly flammable.
- **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.
-
- **Label elements**
- **Labelling according to EU guidelines:**
The product has been classified and marked in accordance with EU Directives / Ordinance on Hazardous Materials.
- **Code letter and hazard designation of product:**
-   **Xn Harmful**
F Highly flammable
- **Hazard-determining components of labelling:**
dibenzoyl peroxide
2-methylpropan-2-ol

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Trade name: SR Link

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4-methylpentan-2-one

· Risk phrases:

- 11 Highly flammable.
- 20 Harmful by inhalation.
- 36/37 Irritating to eyes and respiratory system.
- 43 May cause sensitisation by skin contact.

· Safety phrases:

- 9 Keep container in a well-ventilated place.
- 16 Keep away from sources of ignition - No smoking.
- 23 Do not breathe fumes/aerosol.
- 24 Avoid contact with skin.
- 37 Wear suitable gloves.
- 60 This material and its container must be disposed of as hazardous waste.
- 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

· 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: 75-65-0 EINECS: 200-889-7	2-methylpropan-2-ol ☒ Xn R20; ☒ Xi R36/37; 🔥 F R11	50-100%
CAS: 108-10-1 EINECS: 203-550-1	4-methylpentan-2-one ☒ Xn R20; ☒ Xi R36/37; 🔥 F R11 R66	10-25%
CAS: 94-36-0 EINECS: 202-327-6	dibenzoyl peroxide ☒ Xi R36; ☒ Xi R43; ☠ E R3; 🔥 O R7	≤ 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:** Immediately wash with water and soap and rinse thoroughly.

· After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

· **After swallowing:** Do not induce vomiting; call for medical help immediately.

· 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:**

CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

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Trade name: **SR Link**

(Contd. of page 2)

- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** Mouth respiratory protective device.
- **Additional information** Cool endangered receptacles with water spray.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Dispose contaminated material as waste according to item 13.
Ensure adequate ventilation.
Do not flush with water or aqueous cleansing agents
- **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.
Ensure good ventilation/exhaustion at the workplace.
- **Information about fire - and explosion protection:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store in a cool location.
- **Information about storage in one common storage facility:**
Store away from oxidizing agents.
Store away from reducing agents.
- **Further information about storage conditions:**
Keep container tightly sealed.
Store in cool, dry conditions in well sealed receptacles.
Protect from heat and direct sunlight.
- **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:**

75-65-0 2-methylpropan-2-ol

WEL	Short-term value: 462 mg/m ³ , 150 ppm
	Long-term value: 308 mg/m ³ , 100 ppm

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Trade name: SR Link

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108-10-1 4-methylpentan-2-one

WEL	Short-term value: 416 mg/m ³ , 100 ppm
	Long-term value: 208 mg/m ³ , 50 ppm
	Sk

· **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.

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

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:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

· **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:**



Tightly sealed goggles

9 Physical and chemical properties

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

· **General Information**

· **Appearance:**

Form: Fluid

Colour: Colourless

· **Odour:** Ether-like

· **Odour threshold:** Not determined.

· **pH-value:** Not determined.

· **Change in condition**

Melting point/Melting range: Undetermined.

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Boiling point/Boiling range:	Undetermined.
· Flash point:	11°C
· Ignition temperature:	460°C
· Self-igniting:	Product is not selfigniting.
· Danger of explosion:	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
· Explosion limits:	
Lower:	1.7 Vol %
Upper:	9.0 Vol %
· Vapour pressure at 20°C:	40 hPa
· Density:	Not determined.
· Relative density at 20°C	0.9 g/cm ³
· Vapour density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with water:	Not miscible or difficult to mix.
· 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** 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** No further relevant information available.
- **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:**

- **LD/LC50 values relevant for classification:**

75-65-0 2-methylpropan-2-ol

Oral	LD50	3500 mg/kg (rat)
------	------	------------------

108-10-1 4-methylpentan-2-one

Oral	LD50	2080 mg/kg (rat)
Dermal	LD50	16000 mg/kg (rab)
Inhalative	LC50/4 h	8.3-16.6 mg/l (rat)

- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** Irritating effect.
- **Sensitization:** Sensitization possible through skin contact.

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Trade name: SR Link

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· 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:

Harmful

Irritant

· **Sensitisation** May cause sensitisation by skin contact.

12 Ecological information**· Toxicity**

· **Acquatic 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 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 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**

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.

14 Transport information**· Land transport ADR/RID (cross-border)**

· **ADR/RID class:** 3 (F1) Flammable liquids.

· **Danger code (Kemler):** 33

· **UN-Number:** 1993

· **Packaging group:** II

· **Hazard label:** 3

· **UN proper shipping name:** 1993 FLAMMABLE LIQUID, N.O.S. (BUTANOLS, METHYL ISOBUTYL KETONE)

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Trade name: SR Link

(Contd. of page 6)

· **Tunnel restriction code** D/E· **Maritime transport IMDG:**

- **IMDG Class:** 3
- **UN Number:** 1993
- **Label** 3
- **Packaging group:** II
- **EMS Number:** F-E,S-E
- **Marine pollutant:** No
- **Proper shipping name:** FLAMMABLE LIQUID, N.O.S. (BUTANOLS, METHYL ISOBUTYL KETONE)

· **Air transport ICAO-TI and IATA-DGR:**

- **ICAO/IATA Class:** 3
- **UN/ID Number:** 1993
- **Label** 3
- **Packaging group:** II
- **Proper shipping name:** FLAMMABLE LIQUID, N.O.S. (BUTANOLS, METHYL ISOBUTYL KETONE)

- **Special precautions for user** Warning: Flammable liquids.
- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** 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**

- R11 Highly flammable.
- R20 Harmful by inhalation.
- R3 Extreme risk of explosion by shock, friction, fire or other sources of ignition.
- R36 Irritating to eyes.
- R36/37 Irritating to eyes and respiratory system.
- R43 May cause sensitisation by skin contact.
- R66 Repeated exposure may cause skin dryness or cracking.
- R7 May cause fire.

EU-Sicherheitsdatenblatt

SR Gel



Ausgabedatum / Referenz

03.12.2004 hot

Ersetzt Fassung vom

Druckdatum

20.09.2005 **Blatt Nr. 1580**

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Firma

Ivoclar Vivadent AG, Bendererstrasse 2, FL - 9494 Schaan
Fürstentum Liechtenstein

1 Handelsname und Lieferant

- 1.1 Handelsname / Warenkennzeichnung **SR Gel**
- 1.2 Anwendung / Einsatz Kronen- und Brückenmaterial - System
- 1.3 Hersteller Ivoclar Vivadent AG, Bendererstrasse 2, FL - 9494 Schaan
Fürstentum Liechtenstein
- 1.4 Lieferant
- 1.5 TOX NOTRUF Notfall-No: +423 / 235 35 35 oder 373 40 40
Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein

2 Zusammensetzung

- 2.1 Chemische Charakterisierung Mischung aus > 90 % Glycerin (CAS Nr. 56-81-5), Siliziumdioxid und Aluminiumoxid
- 2.2 Gefährliche Bestandteile Keine.
- 2.3 Weitere Angaben Keine.

3 Mögliche Gefahren

Keine.

4 Erste Hilfe

- 4.1 Augenkontakt Sofort die Augen mit viel Wasser spülen (10-15 Min.). Bei anhaltender Reizung Arzt konsultieren.
- 4.2 Hautkontakt Gründlich mit Wasser und Seife waschen.
- 4.3 Verschlucken Grosse Mengen Wasser zu trinken geben.
- 4.4 Einatmen Zufuhr von Frischluft.
- 4.5 Weitere Angaben Bei Unwohlsein ärztlichen Rat einholen (dieses Sicherheitsdatenblatt vorzeigen).

5 Brandbekämpfung

- 5.1 Geeignete Löschmittel Wassernebel, Kohlendioxid, Schaum, Trockenlöschmittel.
- 5.2 Ungeeignete Löschmittel Keine bekannt
Keine.
- 5.3 Weitere Angaben Keine.

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6 Massnahmen bei unbeabsichtigter Freisetzung Mechanisch aufnehmen.
Unter Beachtung der massgeblichen Vorschriften und Regelungen entsorgen.

7 Handhabung und Lagerung

- 7.1 Handhabung Handhabung dieses Produkts nur durch ausreichend geschultes Personal.
Darf nicht in die Hände von Kindern gelangen.
- 7.2 Arbeitshygiene Berufstätige Hygienemassnahmen einhalten.
Bei der Arbeit nicht essen, trinken oder rauchen.
- 7.3 Lagerung Lagerung bei 2-28 °C
- 7.4 Lagerplatz Vor Lichteinwirkung schützen.
- 7.5 Brand- und Ex-Schutz Nicht erforderlich.

8 Expositionsbegrenzung und Schutzausrüstung

- 8.1 Technische Massnahmen Gute allgemeine Belüftung ist ausreichend.
- 8.2 Grenzwertüberwachung ACGIH (USA) Threshold Limit Value (TLV): 10 mg/m³ (8 h-Schichtmittelwert).
- 8.3 Persönliche Schutzausrüstung
 - 8.3.1 Atemschutz Nicht erforderlich.
 - 8.3.2 Handschutz Schutzhandschuhe.
 - 8.3.3 Augenschutz Schutzbrille.
 - 8.3.4 Andere Keine.

9 Physikalische und chemische Eigenschaften

- 9.1 Erscheinungsform Gel
- 9.2 Farbe weisslich
- 9.3 Geruch praktisch geruchlos
- 9.4 Zustandsänderung Geprüft nach:

- 9.5 Dichte nicht anwendbar
- 9.6 Dampfdruck nicht anwendbar
- 9.7 Viskosität nicht bestimmt

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9.8 Löslichkeit

Wasser

löslich

9.9 pH-Wert

nicht bestimmt

9.10 Flammpunkt

> 150 °C

9.11 Zündtemperatur

> 400 °C

9.12 Explosionsgrenzen

Untere:

Obere:

nicht bestimmt

9.13 Weitere Angaben

10 Stabilität und Reaktivität**10.1 Thermische Zersetzung**

Keine bei bestimmungsgemässer Verwendung.

10.2 Gefährliche Zersetzungsprodukte

Keine unter normalen Lager- und Handhabungsbedingungen.

10.3 Gefährliche Reaktionen

Keine.

10.4 Weitere AngabenKeine.

11 Angaben zur Toxikologie**11.1 Akute Toxizität**

Orale LD50 / Ratte: > 10'000 mg/kg

11.2 Subakute / Chronische Toxizität

Längerer oder wiederholter Hautkontakt kann Austrocknung oder Reizung der Haut verursachen.

Verschlucken, längerer Haut- und Augenkontakt sowie Einatmen jeglicher entstehender Dämpfe vermeiden.

11.3 Weitere AngabenVersehentliches Verschlucken kleinster Mengen dürfte keine gesundheitliche Schädigung hervorrufen.

12 Angaben zur ÖkologieBei sachgemässer Handhabung und Verwendung sind keine ökologischen Probleme zu erwarten.

13 Entsorgung

Unter Beachtung der örtlichen, behördlichen Vorschriften einer Verbrennungsanlage zuführen.

13.1 EU waste key

16 05 09

13.2 Swiss waste code

13.3 OriginDentallabor

14 Transport

EU-Sicherheitsdatenblatt

SR Gel



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14.1	Landtransport	ADR Klassifizierungscode GGVS UN Nummer Verpackungsgr. Korrekte Versandbezeichn.	RID GGVE Kemler Zahl
14.2	Schiffstransport	ADNR GGVSee UN Nummer EMS Verpackungsgr. Korrekte Versandbezeichn.	IMDG MFAG
14.3	Lufttransport	ICAO / IATA-DGR UN Nummer Korrekte Versandbezeichn. Subsidiary Risk Labels Verpackungsgr. Packing Instructions	
	Passagierflugzeug		
	Frachtflugzeug	Max. Packing Instructions	
		Max.	
14.4	Weitere Angaben	Kein Gefahrgut im Sinne der Transportvorschriften.	

15 Vorschriften

Das Produkt fällt unter die EG-Richtlinie 93/42 für Medizinprodukte.

15.1 UN-Nummer

15.2 Nationale Vorschriften

15.3 EU Nummer

15.4 Gefahrensymbole

15.5 Gefahrenbezeichnung

15.6 R-Sätze (Gefahrenhinweise)

15.7 S-Sätze (Sicherheitsratschläge)

15.8 MAK-Wert

15.9 BVD-Klassierung (CH)

15.10 VbF (D)

15.11 Weitere Angaben

Keine.

EU-Sicherheitsdatenblatt

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16 Weitere Hinweise

Version: 1

Alle vorstehenden Angaben entsprechen dem heutigen Stand unserer Kenntnisse und Erfahrungen. Das Sicherheitsdatenblatt dient der Beschreibung der Produkte im Hinblick auf Sicherheitserfordernisse. Die Angaben haben nicht die Bedeutung von Eigenschaftszusicherungen.

Dieses Datenblatt wurde mit der Datenbank 'ChemManager' erstellt.
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91/155/EWG

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

Printing date 04.05.2012






Version number 1

Revision: 04.05.2012

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

- **Product identifier**
- **Trade name:** **SR Connect**
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the preparation** Auxiliary for manufacture of dental prosthesis
- **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; Irritant**
R37/38: Irritating to respiratory system and skin.
 -  **Xi; Sensitising**
R43: May cause sensitisation by skin contact.
 -  **F; Highly flammable**
R11: Highly flammable.
 - **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.
-
- **Label elements**
 - **Labelling according to EU guidelines:**
 - **Code letter and hazard designation of product:**
 -   **Xi Irritant**
F Highly flammable
 - **Hazard-determining components of labelling:**
methyl methacrylate
 - **Risk phrases:**
11 Highly flammable.
37/38 Irritating to respiratory system and skin.

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43 May cause sensitisation by skin contact.

- **Safety phrases:**

9 Keep container in a well-ventilated place.

16 Keep away from sources of ignition - No smoking.

23 Do not breathe fumes/aerosol.

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.

- **vPvB:** Not applicable.

3 Composition/information on ingredients

- **Chemical characterization: Mixtures**

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

- **Dangerous components:**

CAS: 80-62-6	methyl methacrylate	50-100%
EINECS: 201-297-1	☒ Xi R37/38; ☒ Xi R43; ☒ F R11	
CAS: 75980-60-8	diphenyl-trimethylbenzoyl-phosphinoxide	2.5-10%
EINECS: 278-355-8	☒ Xn R62 R52/53	

- **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:** Immediately rinse with water.

- **After eye contact:**

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

- **After swallowing:**

Rinse out mouth and then drink plenty of water.

Do not induce vomiting; call for medical help immediately.

- **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:**

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

- **Special hazards arising from the substance or mixture** No further relevant information available.

- **Advice for firefighters**

- **Protective equipment:** No special measures required.

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· **Additional information** Cool endangered receptacles with water spray.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **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
- **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.
Ensure good ventilation/exhaustion at the workplace.
- **Information about fire - and explosion protection:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**
Store in a cool location.
Store only in the original receptacle.
- **Information about storage in one common storage facility:** Store away from oxidizing agents.
- **Further information about storage conditions:**
Protect from heat and direct sunlight.
Store receptacle in a well ventilated area.
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:**

80-62-6 methyl methacrylate

WEL ()	Short-term value: 416 mg/m ³ , 100 ppm Long-term value: 208 mg/m ³ , 50 ppm
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· **Additional information:** The lists valid during the making were used as basis.

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- **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
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
Do not inhale gases / fumes / aerosols.
- **Respiratory protection:**
Use suitable respiratory protective device in case of insufficient ventilation.
Filter AX
- **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:** Safety glasses

9 Physical and chemical properties

- **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.
Boiling point/Boiling range:	101°C

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· Flash point:	10°C
· Flammability (solid, gaseous):	Not applicable.
· Ignition temperature:	430°C
· Self-igniting:	Product is not selfigniting.
· Danger of explosion:	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
· Explosion limits:	
Lower:	2.1 Vol %
Upper:	12.5 Vol %
· Vapour pressure at 20°C:	47 hPa
· Density at 20°C:	1 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with water:	Not miscible or difficult to mix.
· 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** Stable under normal handling and storage conditions.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions**
 - Forms explosive gas mixture with air.
 - Reacts with strong oxidizing agents.
 - Exothermic polymerization.
- **Conditions to avoid** No further relevant information available.
- **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:

· LD/LC50 values relevant for classification:

80-62-6 methyl methacrylate

Oral	LD50	7872 mg/kg (rat)
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· Primary irritant effect:

- **on the skin:** Irritant to skin and mucous membranes.
- **on the eye:** No irritating effect.

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- **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 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 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

- | | |
|-------------------------------------------------------------------------------------|-------------------------------------------------------|
| · UN-Number | |
| · ADR, IMDG, IATA | UN1247 |
| · UN proper shipping name | |
| · ADR | 1247 METHYL METHACRYLATE MONOMER, STABILIZED, mixture |
| · IMDG, IATA | METHYL METHACRYLATE MONOMER, STABILIZED, mixture |
| · Transport hazard class(es) | |
| · ADR | |
|  | |
| · Class | 3 (F1) Flammable liquids. |

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· Label	3
· IMDG, IATA	
	
· Class	3 Flammable liquids.
· Label	3
· Packing group	
· ADR, IMDG, IATA	II
· Environmental hazards:	
· Marine pollutant:	No
· Special precautions for user	Warning: Flammable liquids.
· Danger code (Kemler):	339
· EMS Number:	F-E,S-D
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
· Transport/Additional information:	
· ADR	
· Tunnel restriction code	D/E

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**
 - R11 Highly flammable.
 - R37/38 Irritating to respiratory system and skin.
 - R43 May cause sensitisation by skin contact.
 - R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
 - R62 Possible risk of impaired fertility.