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

- **1.1 Product identifier**
  - **Trade name:** SR Ivocap Elastomer Polymer

- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
  - No further relevant information available.
  - **Application of the substance / the mixture** Resin for us as poitioner, mouth guard, and elastic bite splint

- **1.3 Details of the supplier of the safety data sheet**
  - **Manufacturer/Supplier:** Ivoclar Vivadent AG
    Bendererstrasse 2
    FL-9494 Schaan
    PRINCIPALITY OF LIECHTENSTEIN
  - **Tel:** +423 235 35 35
  - **Fax:** +423 235 33 60
  - **Further information obtainable from:** Regulatory Affairs
    sds@ivoclarvivadent.com
  - **1.4 Emergency telephone number:** +423 / 235 33 13 (Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein)

**SECTION 2: Hazards identification**

- **2.1 Classification of the substance or mixture**
  - **Classification according to Regulation (EC) No 1272/2008**
    The product is not classified according to the CLP regulation.

- **2.2 Label elements**
  - **Labelling according to Regulation (EC) No 1272/2008** Void
  - **Hazard pictograms** Void
  - **Signal word** Void
  - **Hazard statements** Void
  - **2.3 Other hazards**
    Dust generation
    Particular danger of slipping on leaked/spilled product.

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

**SECTION 3: Composition/information on ingredients**

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

<table>
<thead>
<tr>
<th><strong>Dangerous components:</strong></th>
<th><strong>org. Perox. CD, H242</strong></th>
<th><strong>Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS: 105-74-8</td>
<td>dilauroyl peroxide</td>
<td>I-&lt;2.5%</td>
</tr>
<tr>
<td>EINECS: 203-326-3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CAS: 868-77-9</td>
<td>2-hydroxyethyl methacrylate</td>
<td>I-&lt;2.5%</td>
</tr>
<tr>
<td>EINECS: 212-782-2</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **Additional information:** For the wording of the listed risk phrases refer to section 16.
SECTION 4: First aid measures

4.1 Description of first aid measures

After inhalation:
Supply fresh air and to be sure call for a doctor.
In case of unconsciousness place patient stably in side position for transportation.

After skin contact: Rinse with water.

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

After swallowing:
Rinse out mouth and then drink plenty of water.
If symptoms persist consult doctor.

4.2 Most important symptoms and effects, both acute and delayed
No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed
No further relevant information available.

SECTION 5: Firefighting measures

5.1 Extinguishing media
Suitable extinguishing agents:
CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

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

5.3 Advice for firefighters
Protective equipment: No special measures required.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
Avoid formation of dust.
Particular danger of slipping on leaked/spilled product.

6.2 Environmental precautions:
Do not allow to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up:
Pick up mechanically.

6.4 Reference to other sections
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

7.1 Precautions for safe handling
Only adequately trained personnel should handle this product.
For use in dentistry only.

Information about fire - and explosion protection: No special measures required.

7.2 Conditions for safe storage, including any incompatibilities
Storage:
Requirements to be met by storerooms and receptacles: Store only in the original receptacle.
Information about storage in one common storage facility: Not required.
Further information about storage conditions: Protect from heat and direct sunlight.

7.3 Specific end use(s)
No further relevant information available.
**SECTION 8: Exposure controls/personal protection**

- Additional information about design of technical facilities: No further data; see item 7.
- **8.1 Control parameters**
  - Ingredients with limit values that require monitoring at the workplace:
    The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
  - Additional information: The lists valid during the making were used as basis.
- **8.2 Exposure controls**
  - Personal protective equipment:
  - General protective and hygienic measures:
    Usual hygienic measures for dental practice.
    Keep away from foodstuffs, beverages and feed.
    Wash hands before breaks and at the end of work.
    Avoid contact with the skin.
  - Respiratory protection: Use respiratory protective device against the effects of dust.
  - Protection of hands:

  ![Protective gloves]

  After use of gloves apply skin-cleaning agents and skin cosmetics.
  - **Material of gloves**
    Butyl rubber, BR
    Chloroprene rubber, CR
    Natural rubber, NR
    Nitrile rubber, NBR
    Fluorocarbon rubber (Viton)
    Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
  - **Penetration time of glove material**
    The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
  - **Eye protection**: Safety glasses

**SECTION 9: Physical and chemical properties**

- **9.1 Information on basic physical and chemical properties**
  - **General Information**
  - Appearance:
    - Form: Powder
    - Colour: White
  - Odour: Characteristic
  - Odour threshold: Not determined.
  - pH-value: Not applicable.
  - **Change in condition**
    - Melting point/Melting range: Undetermined.
    - Boiling point/Boiling range: Undetermined.
  - **Flash point**: Not applicable.
SECTION 10: Stability and reactivity

- 10.1 Reactivity No further relevant information available.
- 10.2 Chemical stability Stable under normal handling and storage conditions.
- 10.3 Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- 10.4 Conditions to avoid No further relevant information available.
- 10.5 Incompatible materials: No further relevant information available.
- 10.6 Hazardous decomposition products: None under normal conditions of storage and use.

SECTION 11: Toxicological information

- 11.1 Information on toxicological effects
  - Acute toxicity
  - Skin corrosion/irritation Based on available data, the classification criteria are not met.
  - Serious eye damage/irritation Based on available data, the classification criteria are not met.
  - Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
  - Additional toxicological information: No further relevant information available.
  - Germ cell mutagenicity Based on available data, the classification criteria are not met.
  - Carcinogenicity Based on available data, the classification criteria are not met.
  - Reproductive toxicity Based on available data, the classification criteria are not met.
  - STOT-single exposure Based on available data, the classification criteria are not met.
  - STOT-repeated exposure Based on available data, the classification criteria are not met.
  - Aspiration hazard Based on available data, the classification criteria are not met.
SECTION 12: Ecological information

- 12.1 Toxicity
  - Aquatic toxicity: No further relevant information available.

- 12.2 Persistence and degradability: No further relevant information available.

- 12.3 Bioaccumulative potential: No further relevant information available.

- 12.4 Mobility in soil: No further relevant information available.

- Additional ecological information:
  - General notes:
    Water hazard class 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.

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

- 12.6 Other adverse effects: No further relevant information available.

SECTION 13: Disposal considerations

- 13.1 Waste treatment methods
  - Recommendation
    Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

- European waste catalogue
  - 20 01 39 plastics

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

SECTION 14: Transport information

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

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

- 14.3 Transport hazard class(es)
  - ADR, RID, ADN, ADN, IMDG, IATA: Void

- 14.4 Packing group
  - ADR, RID, ADN, IMDG, IATA: Void

- 14.5 Environmental hazards:
  - Marine pollutant: No

- 14.6 Special precautions for user
  - Not applicable.

- 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
  - Not applicable.

- Transport/Additional information:
  - Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).

(Contd. on page 6)
Trade name: SR Ivocap Elastomer Polymer

SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
  - National regulations:
  - Other regulations, limitations and prohibitive regulations
    The product is a medical device according to the Directive 93/42/EEC.
  - 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- Relevant phrases
  H242 Heating may cause a fire.
  H315 Causes skin irritation.
  H317 May cause an allergic skin reaction.
  H319 Causes serious eye irritation.

- Abbreviations and acronyms:
  ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
  IMDG: International Maritime Code for Dangerous Goods
  IATA: International Air Transport Association
  GHS: Globally Harmonised System of Classification and Labelling of Chemicals
  EINECS: European Inventory of Existing Commercial Chemical Substances
  ELINCS: European List of Notified Chemical Substances
  CAS: Chemical Abstracts Service (division of the American Chemical Society)
  PBT: Persistent, Bioaccumulative and Toxic
  vPvB: very Persistent and very Bioaccumulative
  Org. Perox. CD: Organic Peroxides, Types C, D
  Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
  Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2
  Skin Sens. 1: Sensitisation - Skin, Hazard Category 1
  * Data compared to the previous version altered.