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

1.1 Product identifier

Trade name: SR Ivocron Opaquer

1.2 Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

Application of the substance / the mixture Crowns- and bridges material

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:
Ivoclar Vivadent AG
Bendererstrasse 2
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, 9494 Schaan, Liechtenstein)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008
Skin Sens. 1 H317 May cause an allergic skin reaction.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008
The product is classified and labelled according to the CLP regulation.

Hazard pictograms

GHS07

Signal word Warning

Hazard-determining components of labelling:
dibenzoyl peroxide
Hazard statements
H317 May cause an allergic skin reaction.

Precautionary statements
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P262 Do not get in eyes, on skin, or on clothing.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

2.3 Other hazards

Dust generation
Particular danger of slipping on leaked/spilled product.

Results of PBT and vPvB assessment
PBT: Not applicable.

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

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

- **Dangerous components:**
  - CAS: 7727-43-7  
  - EINECS: 231-784-4  
  - *barium sulphate, natural*  
  - *substance with a Community workplace exposure limit 25-50%*

  - CAS: 1344-28-1  
  - EINECS: 215-691-6  
  - *aluminium oxide*  
  - *substance with a Community workplace exposure limit 25-50%*

  - CAS: 94-36-0  
  - EINECS: 202-327-6  
  - *dibenzoyl peroxide*  
  - *Org. Perox. B, H241; Eye Irrit. 2, H319; Skin Sens. 1, H317*  
  - *1-<2.5%*

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

**SECTION 4: First aid measures**

- **4.1 Description of first aid measures**
  - **After inhalation:**  
    Supply fresh air; consult doctor in case of complaints.  
    In case of unconsciousness place patient stably in side position for transportation.
  - **After skin contact:**  
    Rinse with water.  
    If skin irritation continues, consult a doctor.
  - **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:**
  - No special measures required.  
  - Do not allow to enter sewers/surface or ground water.

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

<table>
<thead>
<tr>
<th>CAS</th>
<th>Substance</th>
<th>WEL Long-term value:</th>
</tr>
</thead>
<tbody>
<tr>
<td>7727-43-7</td>
<td>barium sulphate, natural</td>
<td>10* 4** mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>*inhalable dust **respirable dust</td>
</tr>
<tr>
<td>1344-28-1</td>
<td>aluminium oxide</td>
<td>10* 4** mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>*inhalable dust **respirable dust</td>
</tr>
<tr>
<td>94-36-0</td>
<td>dibenzoyl peroxide</td>
<td>5 mg/m³</td>
</tr>
</tbody>
</table>

Additional information: The lists valid during the making were used as basis.

8.2 Exposure controls

Personal protective equipment:

General protective and hygienic measures:
Usual hygienic measures for dental practice and dental laboratories.
Immediately remove all soiled and contaminated clothing
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
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

(Contd. of page 4)
Safety data sheet
according to 1907/2006/EC, Article 31

Trade name: SR Ivocron Opaquer

- Penetration time of glove material
  The exact breakthrough 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: According to product specification
    - Odour: Odourless
    - Odour threshold: Not determined.
  - pH-value: Not applicable.
- Change in condition
  - Melting point/freezing point: Undetermined.
  - Initial boiling point and boiling range: Undetermined.
- Flash point: Not applicable.
- Flammability (solid, gas): Not determined.
- Auto-ignition temperature: Product is not selfigniting.
  - Explosion limits: Product does not present an explosion hazard.
    - Lower: Not determined.
    - Upper: Not determined.
- Vapour pressure: Not applicable.
  - Density:
    - Relative density: Not determined.
    - Vapour density: Not applicable.
    - Evaporation rate: Not applicable.
  - Solubility in / Miscibility with water: Nearly insoluble.
  - Partition coefficient: n-octanol/water: Not determined.
- Viscosity
  - Dynamic: Not applicable.
  - Kinematic: Not applicable.
- 9.2 Other information
  No further relevant information available.

SECTION 10: Stability and reactivity

- 10.1 Reactivity
  No further relevant information available.
- 10.2 Chemical stability
  Stable under normal handling and storage conditions.
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- 10.3 Possibility of hazardous reactions
  No dangerous reactions known.
- 10.4 Conditions to avoid
  No further relevant information available.
- 10.5 Incompatible materials
  No further relevant information available.
SECTION 11: Toxicological information

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

SECTION 12: Ecological information

12.1 Toxicity
- Aquatic toxicity: No further relevant information available.
- 12.2 Persistence and degradability: No further relevant information available.
- 12.3 Bioaccumulative potential: No further relevant information available.
- 12.4 Mobility in soil: No further relevant information available.
- Additional ecological information:
  - General notes: Water hazard class 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 03 99: Municipal wastes not otherwise specified
- 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
**SECTION 15: Regulatory information**

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

**SECTION 16: Other information**

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

- **Relevant phrases**
  - H241 Heating may cause a fire or explosion.
  - 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. B: Organic peroxides – Type B
  - Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
  - Skin Sens. 1: Skin sensitisation – Category 1

* Data compared to the previous version altered.