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

- 1.1 Product identifier
  - Trade name: ProBase Hot Polymer

- 1.2 Relevant identified uses of the substance or mixture and uses advised against
  - Application of the substance / the mixture Denture base material

- 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

- 1.4 Emergency telephone number: +423 / 235 33 13 (Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein)

SECTION 2: Hazards identification

- 2.1 Classification of the substance or mixture
  - Classification according to Regulation (EC) No 1272/2008
    Skin Sens. 1 H317 May cause an allergic skin reaction.

- 2.2 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: > 95% polymethylmethacrylate

Dangerous components:

<table>
<thead>
<tr>
<th>CAS:</th>
<th>EINECS:</th>
<th>Ingredient</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>94-36-0</td>
<td>202-327-6</td>
<td>dibenzoyl peroxide</td>
<td>1-&lt;2.5%</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

General information: No special measures required.

After inhalation: Supply fresh air; consult doctor in case of complaints.

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:
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.

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

8.1 Control parameters
Ingredients with limit values that require monitoring at the workplace:
- 94-36-0 dibenzoyl peroxide
  WEL Long-term value: 5 mg/m³

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 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:** Powder
  - **Colour:** According to product specification
  - **Odour:** Characteristic
  - **Odour threshold:** Not determined.
  - **pH-value:** Not applicable.
- **Change in condition**
  - **Melting point/Melting range:** 150 °C
  - **Boiling point/Boiling range:** Undetermined.
- **Flash point:** 250 °C
- **Flammability (solid, gaseous):** Not determined.
- **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 applicable.
- **Density at 20 °C:** 1.2 g/cm³
- **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.

10.3 Possibility of hazardous reactions

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

Trade name: ProBase Hot Polymer

(Contd. of page 4)

SECTION 11: Toxicological information

11.1 Information on toxicological effects
Acute toxicity:
Primary irritant effect:
on the skin: No irritant effect.
on the eye: No irritating effect.
Sensitisation: Sensitisation possible through skin contact.
Additional toxicological information: No further relevant information available.

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

SECTION 14: Transport information

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

14.2 UN proper shipping name
ADR, ADN, IMDG, IATA Void

14.3 Transport hazard class(es)
ADR, ADN, IMDG, IATA Void
Class

14.4 Packing group
ADR, IMDG, IATA Void

14.5 Environmental hazards:
Marine pollutant: No
**Trade name: ProBase Hot Polymer**

- **14.6 Special precautions for use**
  Not applicable.

- **14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**
  Not applicable.

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

- **UN "Model Regulation":**
  -

**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)
  - Org. Perox. B: Organic Peroxides, Type B
  - 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.