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

· 1.1 Product identifier
  · Trade name: SR Vivodent, SR Orthotyp

· 1.2 Relevant identified uses of the substance or mixture and uses advised against
  · Application of the substance / the mixture: Manufacture of dental prothesis

· 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
    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
  · Avoid breathing sanding dust/swarf.
  · Results of PBT and vPvB assessment
    · PBT: Not applicable.
    · vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

· 3.2 Chemical characterisation: Mixtures
  · Description: Resin teeth based on polymethylmethacrylate
  · Dangerous components: Void
  · 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 skin contact: Generally the product does not irritate the skin.
  · After eye contact:
    Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
    Mechanical effects only.
  · After swallowing: Seek medical treatment.
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
  Not required.

- 6.2 Environmental precautions
  No special measures required.

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

- 6.4 Reference to other sections
  No dangerous substances are released.
  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: No special requirements.
  Information about storage in one common storage facility: Not required.
  Further information about storage conditions: None.

- 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.
  Respiratory protection: Use respiratory protective device against the effects of dust.

(Contd. on page 3)
40.1.5 · Protection of hands:
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 of the glove material is not possible.

· 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 cannot 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:
Always wear safety goggles during mechanical processing (grinding, sawing /cutting, drilling, milling).

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties
· General Information
· Appearance:
  Form: Solid
  Colour: According to product specification
· Odour: Odourless
· 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.
· Flammability (solid, gaseous): Not determined.
· Self-igniting: Product is not self-igniting.
· Danger of explosion: Product does not present an explosion hazard.
· Explosion limits:
  Lower: Not determined.
  Upper: Not determined.
· Vapour pressure: Not applicable.
· Density: Not determined.
· Relative density: Not determined.
· Vapour density: Not applicable.
· Evaporation rate: Not applicable.
· Solubility in / Miscibility with water: Insoluble.
· Partition coefficient (n-octanol/water): Not determined.
· Viscosity:
  Dynamic: Not applicable.
Kinematic: Not applicable.

Solvent content:

- Solids content: 100.0%
- 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 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:
    - Primary irritant effect:
      - on the skin: No irritant effect.
      - on the eyes: No irritating effect.
      - Sensitisation: No sensitising effects known.

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: Generally not hazardous for water.
- 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.
- 13.2 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
- 14.4 Packing group
  - ADR, 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 73/78 and the IBC Code
  - Not applicable.
- UN "Model Regulation": Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).

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.

- 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)
- * Data compared to the previous version altered.