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

1.1 Product identifier
   Trade name: IPS e.max Ceram Build-Up Liquid soft / IPS Build-Up Liquid soft

1.2 Relevant identified uses of the substance or mixture and uses advised against
   No further relevant information available.

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
   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.
   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 inhalation: Supply fresh air; consult doctor in case of complaints.
   After skin contact:
   Rinse with water.
   Generally the product does not irritate the skin.

(Contd. on page 2)
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: The product is not flammable.

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:
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

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: 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.
    Wash hands before breaks and at the end of work.
    Keep away from foodstuffs, beverages and feed.
  - Respiratory protection: Not required.
  - 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.
  - 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

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- General Information
  - Appearance:
    Form: Fluid
    Colour: Colourless
  - Odour:
    Nearly odourless
  - Odour threshold:
    Not determined.
  - pH-value:
    Not determined.
  - Change in condition
    Melting point/Melting range: Undetermined.
    Boiling point/Boiling range: 100 °C
  - 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 at 20 °C:
    23 hPa
  - Density at 20 °C: 1 g/cm³
  - Relative density
    Not determined.
  - Vapour density
    Not determined.
  - Evaporation rate
    Not determined.
Trade name: IPS e.max Ceram Build-Up Liquid soft / IPS Build-Up Liquid soft

- Solubility in / Miscibility with water: Fully miscible.
- Partition coefficient (n-octanol/water): Not determined.
- Viscosity:
  - Dynamic: Not determined.
  - Kinematic: Not determined.
- 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
  - 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.

(Contd. on page 5)
\textbf{SECTION 13: Disposal considerations}

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

\textbullet\  European waste catalogue
18 01 07 chemicals other than those mentioned in 18 01 06

\textbullet\  Uncleaned packaging:
\textbullet\  Recommendation: Disposal must be made according to official regulations.
\textbullet\  Recommended cleansing agents: Water, if necessary together with cleansing agents.

\textbf{SECTION 14: Transport information}

\textbullet\  14.1 UN-Number
\textbullet\  ADR, RID, ADN, ADN, IMDG, IATA Void

\textbullet\  14.2 UN proper shipping name
\textbullet\  ADR, RID, ADN, ADN, IMDG, IATA Void

\textbullet\  14.3 Transport hazard class(es)
\textbullet\  ADR, RID, ADN, ADN, IMDG, IATA Void

\textbullet\  14.4 Packing group
\textbullet\  ADR, RID, ADN, IMDG, IATA Void

\textbullet\  14.5 Environmental hazards:
\textbullet\  Marine pollutant: No

\textbullet\  14.6 Special precautions for user Not applicable.

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

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

\textbullet\  UN "Model Regulation": Void

\textbf{SECTION 15: Regulatory information}

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

\textbf{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.

(Contd. on page 6)
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

* Data compared to the previous version altered.