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

· 1.1 Product identifier
  · Trade name: IPS Ivocolor Essence Fluid

· 1.2 Relevant identified uses of the substance or mixture and uses advised against
  · Application of the substance / the mixture: Auxiliary for 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
  · 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>Dangerous components:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS: 56-81-5</td>
<td>glycerol</td>
</tr>
<tr>
<td>EINECS: 200-289-5</td>
<td>substance with a Community workplace exposure limit 0.1-&lt;2.5%</td>
</tr>
</tbody>
</table>

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.
    In case of unconsciousness place patient stably in side position for transportation.

(Contd. on page 2)
· After skin contact:
  Rinse with water.
  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.
· 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 Not required.
· 6.2 Environmental precautions: Do not allow to enter sewers/surface or ground water.
· 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.
· 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: Keep container tightly sealed.
· 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: 56-81-5 glycerol</th>
<th>WEL Long-term value: 10 mg/m³</th>
</tr>
</thead>
</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:**
Keep away from foodstuffs, beverages and feed.
Wash hands before breaks and at the end of work.
Usual hygienic measures for dental practice.

**Respiratory protection:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

**Protection of hands:**
The glove material has to be impermeable and resistant to the product/the substance/the preparation.
After use of gloves apply skin-cleaning agents and skin cosmetics.

**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: Liquid
Colour: Colourless
Odour: Characteristic
Odour threshold: Not determined.

**pH-value:** Not determined.

**Change in condition**
Melting point/Melting range: Undetermined.
Boiling point/Boiling range: Undetermined.

**Flash point:** 109 °C
Undetermined.

**Flammability (solid, gaseous):** Not applicable.

**Self-igniting:** Not determined.

**Danger of explosion:** Product does not present an explosion hazard.

**Explosion limits:**
Lower: Not determined.
Upper: Not determined.
Safety data sheet
according to 1907/2006/EC, Article 31

Trade name: IPS Ivocolor Essence Fluid

- Vapour pressure: Not determined.
- Density: Not determined.
- Relative density: Not determined.
- Vapour density: Not determined.
- Evaporation rate: Not determined.
- Solubility in / Miscibility with water: Fully miscible.
- Partition coefficient (n-octanol/water): Not determined.
- Viscosity:
  - Dynamic: Not determined.
  - Kinematic: Not determined.

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
- LD/LC50 values relevant for classification: 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: 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.

(Contd. on page 5)
Trade name: IPS Ivocolor Essence Fluid

- 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.
    - Recommended cleansing agents: Water, if necessary together with cleansing agents.

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
  - Class 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.
- UN "Model Regulation": Void

SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
  - Directive 2012/18/EU
  - Named dangerous substances - ANNEX I None of the ingredients is listed.
41.1.9

· 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:
  RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
  ICAO: International Civil Aviation Organisation
  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)
  LC50: Lethal concentration, 50 percent
  LD50: Lethal dose, 50 percent
  PBT: Persistent, Bioaccumulative and Toxic
  vPvB: very Persistent and very Bioaccumulative