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

1.1 Product identifier

Trade name: **IPS e.max ZirCAD Colouring Liquid Diluter**

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: Manufacture of dental prosthesis

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

Further information obtainable from:
Regulatory Affairs
sds@ivoclarvivadent.com

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.

- **Nitric acid**
  - CAS: 7697-37-2
  - EINECS: 231-714-2
  - Ox. Liq. 2, H272; Skin Corr. 1A, H314
  - <0.1%

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

General information: No special measures required.

After inhalation:
Supply fresh air or oxygen; call for doctor.
In case of unconsciousness place patient stably in side position for transportation.

(Contd. on page 2)
 SECTION 5: Firefighting measures

- 5.1 Extinguishing media
  - Suitable extinguishing agents:
    - The product is not flammable.
    - Use fire extinguishing methods suitable to surrounding conditions.

- 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
  - Wear protective clothing.

- 6.2 Environmental precautions:
  - Dilute with plenty of 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: 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 and dental laboratories.
    Keep away from foodstuffs, beverages and feed.
    Wash hands before breaks and at the end of work.
  - Respiratory protection: Not required.
  - Protection of hands:
    Impervious gloves
    After use of gloves apply skin-cleaning agents and skin cosmetics.

- Material of gloves
  Natural rubber, NR
  Chloroprene rubber, CR
  Nitrile rubber, NBR
  Butyl rubber, BR
  Fluorocarbon rubber (Viton)

- 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:
    Odourless
  - Odour threshold: Not determined.
  - pH-value at 20 °C: 2.1
  - Change in condition
    - Melting point/freezing point: Undetermined.
    - Initial boiling point and boiling range: 100 °C
  - Flash point: Not applicable.
  - Flammability (solid, gas): Not applicable.
  - Auto-ignition temperature: Product is not selfigniting.
  - Explosive properties: Product does not present an explosion hazard.
  - 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.
  - Solubility in / Miscibility with water: Fully miscible.
  - Partition coefficient: n-octanol/water: Not determined.
  - Viscosity:
    Dynamic: Not determined.
Trade name: IPS e.max ZirCAD Colouring Liquid Diluter

**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.
- **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** 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.
  - **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:** 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** Disposal must be made according to official regulations.
- **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

- 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

- 14.4 Packing group
  - ADR/RID/ADN, IMDG, IATA Void

- 14.5 Environmental hazards:
  - Not applicable.

- 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.

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

- 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.

- 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
  - H272 May intensify fire; oxidiser.
  - H314 Causes severe skin burns and eye damage.

- 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
  - Ox. Liq. 2: Oxidizing liquids – Category 2
  - Skin Corr. 1A: Skin corrosion/irritation – Category 1A