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

1.1 Product identifier

Trade name: IPS Classic Glaze and Stain Liquid

- CAS Number: 107-21-1
- EC number: 203-473-3
- Index number: 603-027-00-1

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: Auxiliary for 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
  Acute Tox. 4 H302 Harmful if swallowed.

- Classification according to Directive 67/548/EEC or Directive 1999/45/EC
  Xn; Harmful
  R22: Harmful if swallowed.

- Information concerning particular hazards for human and environment: Not applicable.

2.2 Label elements

- Labelling according to Regulation (EC) No 1272/2008
  The substance is classified and labelled according to the CLP regulation.

- Hazard pictograms

GHS07

- Signal word Warning

- Hazard-determining components of labelling: ethanediol

- Hazard statements
  H302 Harmful if swallowed.
  P264 Wash thoroughly after handling.

(Contd. on page 2)
Trade name: IPS Classic Glaze and Stain Liquid

40.1.5 P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P330 Rinse mouth.

2.3 Other hazards
- Results of PBT and vPvB assessment
  - PBT: Not applicable.
  - vPvB: Not applicable.

SECTION 3: Composition/information on ingredients
- 3.1 Chemical characterisation: Substances
  - CAS No. Description
    107-21-1 ethanediol
  - Identification number(s)
    - EC number: 203-473-3
    - Index number: 603-027-00-1

SECTION 4: First aid measures
- 4.1 Description of first aid measures
  - After inhalation:
    Supply fresh air; consult doctor in case of complaints.
    In case of unconsciousness place patient stably in side position for transportation.
  - After skin contact:
    Immediately wash with water and soap and rinse thoroughly.
  - 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.
    Induce vomiting and call for medical help.
- 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.
Trade name: **IPS Classic Glaze and Stain Liquid**

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:**
    Keep container tightly sealed.
    This product is hygroscopic.
- **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:**
    - 107-21-1 ethanediol
      - WEL Short-term value: 104** mg/m³, 40** ppm
      - Long-term value: 10* 52** mg/m³, 20** ppm
      - Sk *particulate **vapour
      - **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.
      Keep away from foodstuffs, beverages and feed.
      Wash hands before breaks and at the end of work.
      Avoid contact with the eyes and skin.
    - **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:**
      - **Protective gloves**
      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**
        Butyl rubber, BR
        Fluorocarbon rubber (Viton)
Nitrile rubber, NBR
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.
· **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:** Not determined.

  · **Change in condition**
    · Melting point/Melting range: -12.4 °C
    · Boiling point/Boiling range: 197 °C
  · **Flash point:** 111 °C
  · **Flammability (solid, gaseous):** Not applicable.
  · **Ignition temperature:** 410 °C
  · **Self-igniting:** Not determined.
  · **Danger of explosion:** Product does not present an explosion hazard.
  · **Explosion limits:**
    · Lower: 3.2 Vol %
    · Upper: 53 Vol %
  · **Vapour pressure at 20 °C:** 0.08 hPa
  · **Density at 20 °C:** 1.11 g/cm³
  · **Relative density** Not determined.
  · **Vapour density** Not determined.
  · **Evaporation rate** Not determined.

  · **Solubility in / Miscibility with water at 20 °C:** 1 g/l
  · **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.
SECTION 11: Toxicological information

- 11.1 Information on toxicological effects
  - Acute toxicity:
    - LD/LC50 values relevant for classification:
      | 107-21-1 ethanediol |
      | Oral   | LD50 5840 mg/kg (rat) |
      | Dermal | LD50 9530 mg/kg (rabbit) |
  - Primary irritant effect:
    - on the skin: No irritant effect.
    - on the eye: 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:
    Water hazard class 1 (German Regulation) (Assessment by list): 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.
- European waste catalogue
  - 18 01 06* chemicals consisting of or containing dangerous substances
- Uncleaned packaging:
  - Recommendation: Disposal must be made according to official regulations.

(Contd. on page 6)
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: 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.

- 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.

- 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
  - CAS: Chemical Abstracts Service (division of the American Chemical Society)
  - LC50: Lethal concentration, 50 percent
  - LD50: Lethal dose, 50 percent
  - Acute Tox. 4: Acute toxicity, Hazard Category 4

- * Data compared to the previous version altered.