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

1.1 Product identifier

Trade name: IPS Empress Universal Glaze and Stain Liquid

CAS Number: 107-88-0
EC number: 203-529-7

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: Auxiliar 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

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 substance 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

3.1 Chemical characterisation: Substances

CAS No. Description
107-88-0 butane-1,3-diol

Identification number(s)
EC number: 203-529-7

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.
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.
  - 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:
    - This product is hygroscopic.
    - 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.
Trade name: **IPS Empress Universal Glaze and Stain Liquid**

- **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.
    - **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

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**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:** -50 °C
    - **Boiling point/Boiling range:** Undetermined.
  - **Flash point:** 109 °C
  - **Flammability (solid, gaseous):** Not applicable.
  - **Ignition temperature:** 375 °C
  - **Self-igniting:** Not determined.
  - **Danger of explosion:** Product does not present an explosion hazard.
  - **Explosion limits:**
    - **Lower:** Not determined.
    - **Upper:** Not determined.
  - **Vapour pressure:** 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.
- 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:
    - LD/LC50 values relevant for classification:
      - 107-88-0 butane-1,3-diol
      - Oral LD50 18610 mg/kg (rat)
    - Primary irritant effect:
      - on the skin: No irritant effect.
      - on the eye: No irritating effect.
    - Sensitisation: No sensitising effects known.
    - Additional toxicological information: No further relevant information available.

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.
**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 07 chemicals other than those mentioned in 18 01 06

- **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
    Void
  - 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.

- **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:
- 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
- CAS: Chemical Abstracts Service (division of the American Chemical Society)
- LC50: Lethal concentration, 50 percent
- LD50: Lethal dose, 50 percent

* Data compared to the previous version altered.