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

1.1 Product identifier

Trade name: IPS Paste Opaquer 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: Auxiliary for manufacture of dental prosthesis

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:
Ivoclar Vivadent AG
Bendererstrasse 2
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, 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.
Trade name: IPS Paste Opaquer Liquid

- **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:**
  Rinse with water.
  Generally the product does not irritate the skin.
- **After eye contact:**
  Rinse opened eye for several minutes under running water. Then 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.
- **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.
  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.

- 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: Use respiratory protective device against the effects of fumes/dust/aerosol.
  - Recommended filter device for short term use: Combination filter A-P2
  - 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
    Butyl rubber, BR
    Fluorocarbon rubber (Viton)
    PVC gloves
  - 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.
      Not applicable.

  - Change in condition
    Melting point/freezing point: -57 °C
    Initial boiling point and boiling range: 207 °C

  - Flash point: 121 °C

  - Flammability (solid, gas): Not applicable.

  - Ignition temperature: 375 °C

  - Auto-ignition temperature: Not determined.

  - Explosive properties: Product does not present an explosion hazard.
**Trade name: IPS Paste Opaquer Liquid**

- **Explosion limits:**
  - Lower: Not determined.
  - Upper: Not determined.
- **Vapour pressure:** Not determined.
- **Density at 20 °C:**
  - Relative density: Not determined.
  - Vapour density: Not determined.
  - Evaporation rate: Not determined.
- **Solubility in / Miscibility with water:**
  - Fully miscible.
  - Not miscible or difficult to mix.
- **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.
- **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.
  - **LD/LC50 values relevant for classification:**
    - CAS: 107-88-0 1,3-Butanediol
      - Oral LD50: 18610 mg/kg (rat)
      - Dermal LD50: > 20000 mg/kg (rabbit)
  - **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:
    - CAS: 107-88-0 1,3-Butanediol
    - LC50/48 h > 2000 mg/l (fish)

- 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 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/RID/ADN, ADN, IMDG, IATA Void

- 14.2 UN proper shipping name
  - ADR/RID/ADN Void
  - 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.
Trade name: IPS Paste Opaquer Liquid

- **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 Substance is not 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.

- **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
  - PBT: Persistent, Bioaccumulative and Toxic
  - vPvB: very Persistent and very Bioaccumulative