

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

- **Product identifier**
- **Trade name:** **IPS d.SIGN Glaze and Stain Liquid**
- **CAS Number:**
107-88-0
- **EC number:**
203-529-7
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the preparation** Auxiliary for manufacture of dental prosthesis
- **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
msds@ivoclarvivadent.com
- **Emergency telephone number:** +423 / 235 33 13

2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
The substance is not classified according to the CLP regulation.
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC** Not applicable.
- **Information concerning particular hazards for human and environment:** Not applicable.
- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

- **Chemical characterization:** Substances
- **CAS No. Description**
107-88-0 butane-1,3-diol
- **Identification number(s)**
- **EC number:** 203-529-7

4 First aid measures

- **Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Rinse with water.

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- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** Rinse out mouth and then drink plenty of water.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:**
Dilute with plenty of water.
Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **Reference to other sections**
No dangerous substances are released.
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

- **Handling:**
- **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.
- **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.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** The lists valid during the making were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:** Usual hygienic measures for dental practice.

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- **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:** Goggles recommended during refilling

9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form:	Fluid
Colour:	Colourless
Odour:	Characteristic
Odour threshold:	Not determined.

· **pH-value:** Not determined.

· **Change in condition**

Melting point/Melting range:	-50°C
Boiling point/Boiling range:	207°C

· **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.

Density at 20°C:	1 g/cm ³
Relative density	Not determined.
Vapour density	Not determined.
Evaporation rate	Not determined.

· **Solubility in / Miscibility with water:** Fully miscible.

· **Segregation coefficient (n-octanol/water):** Not determined.

· **Viscosity:**

Dynamic:	Not determined.
Kinematic:	Not determined.

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· **Other information**

No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability** Stable under normal handling and storage conditions.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions**
No dangerous reactions known.
Reacts with oxidizing agents.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** None under normal conditions of storage and use.

11 Toxicological information

- **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)
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- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**
When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.
The substance is not subject to classification according to the latest version of the EU lists.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **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.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

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13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**
Smaller quantities can be disposed of with household waste.
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.

14 Transport information

- | | |
|--|-----------------|
| · UN-Number
· ADR, ADN, IMDG, IATA | Void |
| · UN proper shipping name
· ADR, ADN, IMDG, IATA | Void |
| · Transport hazard class(es)
· ADR, ADN, IMDG, IATA
· Class | Void |
| · Packing group
· ADR, IMDG, IATA | Void |
| · Environmental hazards:
· Marine pollutant: | No |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |
| · UN "Model Regulation": | - |

15 Regulatory information

- **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 EC-directive 93/42/EEC.
- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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)

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

ICAO: International Civil Aviation Organization

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

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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

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