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

- **Product identifier**
  - **Trade name:** IPS d.SIGN Opaquer F

- **Relevant identified uses of the substance or mixture and uses advised against**
  - No further relevant information available.

- **Application of the substance / the preparation**
  - Auxiliary for manufacture of dental prothesis

- **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
    mds@ivoclarvivadent.com
  - **Emergency telephone number:** +423 / 235 33 13 (Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein)

2 Hazards identification

- **Classification of the substance or mixture**
  - **Classification according to Directive 67/548/EEC or Directive 1999/45/EC** Not applicable.

- **Classification system:**
  - The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

- **Label elements**
  - **Labelling according to EU guidelines:**
    The product is not subject to identification regulations under EU Directives and the Ordinance on Hazardous Materials (German GefStoffV).
  - **Special labelling of certain preparations:**
    Safety data sheet available for professional user on request.

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

3 Composition/information on ingredients

- **Chemical characterization:** Mixtures
  - **Description:** dental ceramic

- **Dangerous components:**
  - **CAS:** 56-81-5  glycerol  substance with a Community workplace exposure limit 2.5-10%
  - **EINECS:** 200-289-5

- **Additional information:** For the wording of the listed risk phrases refer to section 16.
Safety data sheet
according to 1907/2006/EC, Article 31

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Trade name: IPS d.SIGN Opaquer F

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.
  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. If symptoms persist, consult a doctor.
  Mechanical effects only.
  - After swallowing:
  Rinse out mouth and then drink plenty of water.
  If symptoms persist consult doctor.
  - 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:
  CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
  - 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: Do not allow to enter sewers/surface or ground water.
- Methods and material for containment and cleaning up: Pick up mechanically.
- 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.

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.
**Trade name:** IPS d.SIGN Opaquer F

- **Further information about storage conditions:**
  - This product is hygroscopic.
  - Keep container tightly sealed.
  - Store in dry conditions.
- **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:**
  - 56-81-5 glycerol
    - WEL: Long-term value: 10 mg/m³
- **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.
    - Keep away from foodstuffs, beverages and feed.
    - Wash hands before breaks and at the end of work.
  - **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:**
    - 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**
    - Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
    - 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. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
  - **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

## 9 Physical and chemical properties

- **Information on basic physical and chemical properties**
  - **General Information**
  - **Appearance:**
    - **Form:** Pasty
    - **Colour:** According to product specification
  - **Odour:** Characteristic
  - **Odour threshold:** Not determined.
  - **pH-value:** Not determined.
### Safety data sheet

**Trade name:** IPS d.SIGN Opaquer F

#### 36. Change in condition
- **Melting point/Melting range:** Undetermined.
- **Boiling point/Boiling range:** Undetermined.

#### 37. Flash point:
Undetermined.

#### 38. Self-igniting:
Product is not self-igniting.

#### 39. Danger of explosion:
Product does not present an explosion hazard.

#### 40. Explosion limits:
- **Lower:** Not determined.
- **Upper:** Not determined.

#### 41. Vapour pressure:
Not determined.

#### 42. Density:
Not determined.

#### 43. Relative density
Not determined.

#### 44. Vapour density
Not determined.

#### 45. Evaporation rate
Not determined.

#### 46. Solubility in / Miscibility with water:
Partly soluble.

#### 47. Partition coefficient (n-octanol/water):
Not determined.

#### 48. Viscosity:
- **Dynamic:** Not determined.
- **Kinematic:** Not determined.

#### 49. 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.
- **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:**
- **Primary irritant effect:**
  - **on the skin:** No irritant effect.
  - **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**
The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.
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.

13 Disposal considerations

- Waste treatment methods
- Recommendation
  Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
- European waste catalogue
  08 02 99 wastes not otherwise specified
- Uncleaned packaging:
  - Recommendation: Disposal must be made according to official regulations.

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: Void
  - 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.
Trade name: **IPS d.SIGN Opaquer F**

**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.