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

· Product identifier
  · Trade name: IPS Classic Build-Up Liquid S

· Relevant identified uses of the substance or mixture and uses advised against
  · 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

2 Hazards identification

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

· Information concerning particular hazards for human and environment:
  The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

· 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).
  · Other hazards
    · Results of PBT and vPvB assessment
      · PBT: Not applicable.
      · vPvB: Not applicable.

3 Composition/information on ingredients

· Chemical characterization: Mixtures
  · Description: Mixture of substances listed below with nonhazardous additions.

· Dangerous components: Void
  · Additional information: For the wording of the listed risk phrases refer to section 16.

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.

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· 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.

· 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:
  Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

· 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.
    · Further information about storage conditions: None.

· 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.
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- **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.

- **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. 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: Fluid
  - Colour: Colourless
  - Odour: Nearly odourless
  - Odour threshold: Not determined.
- **pH-value:** Not determined.

- **Change in condition**
  - Melting point/Melting range: Undetermined.
  - Boiling point/Boiling range: 100°C
- **Flash point:** Not applicable.
- **Flammability (solid, gaseous):** Not applicable.
- **Self-igniting:** Product is not selfigniting.
- **Danger of explosion:** Product does not present an explosion hazard.
- **Explosion limits:**
  - Lower: Not determined.
  - Upper: Not determined.
### 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.
Safety data sheet
according to 1907/2006/EC, Article 31

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

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.