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

1.1 Product identifier

Trade name: **IPS e.max CAD**

CAS Number: 66402-68-4

EC number: 266-340-9

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

Manufacture of dental prothesis

Lithium disilicate glass-ceramic ingot for the CAD/CAM technology

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

Avoid breathing sanding dust /swarf.

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

66402-68-4 ceramic materials

Identification number(s) ---

EC number: 266-340-9

Description: Lithium disilicate glass-ceramic ingot

(Contd. on page 2)
SECTION 4: First aid measures

4.1 Description of first aid measures
- General information: No special measures required.
- After inhalation: Grinding dust: Supply fresh air; consult doctor in case of complaints.
- After skin contact: Generally the product does not irritate the skin.
- After eye contact: Grinding dust: Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- Mechanical effects only.
- After swallowing: Grinding dust: 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: The product is not flammable.

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: No special measures required.

6.3 Methods and material for containment and cleaning up: Pick up mechanically.

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: None.

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: Not required.
  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.
  Respiratory protection: Use respiratory protective device against the effects of dust.
  Protection of hands: Not required.
  Material of gloves:
  Penetration time of glove material:
  Eye protection:
  Always wear safety goggles during mechanical processing (grinding, sawing/cutting, drilling, milling).

SECTION 9: Physical and chemical properties

- 9.1 Information on basic physical and chemical properties
  General Information
  Appearance:
    Form: Solid
    Colour: According to product specification
    Odour: Odourless
    Odour threshold: Not determined.
  pH-value: Not applicable.
  Change in condition
    Melting point/Melting range: Undetermined.
    Boiling point/Boiling range: Undetermined.
  Flash point: Not applicable.
  Flammability (solid, gaseous): Product is not flammable.
  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 applicable.
  Density: Not determined.
  Relative density: Not determined.
  Vapour density: Not applicable.
  Evaporation rate: Not applicable.
  Solubility in / Miscibility with water: Insoluble.
  Partition coefficient (n-octanol/water): 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** Based on available data, the classification criteria are not met.
  - **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:** 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:** Generally not hazardous for water
    - **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.
SECTION 14: Transport information

- **14.1 UN-Number**
  - ADR, RID, ADN, ADN, IMDG, IATA: Void

- **14.2 UN proper shipping name**
  - ADR, RID, ADN, ADN, IMDG, IATA: Void

- **14.3 Transport hazard class(es)**
  - ADR, RID, ADN, ADN, IMDG, IATA: 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.

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

* Data compared to the previous version altered.