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

1.1 Product identifier

Trade name: IPS e.max Ceram ZirLiner / Intensiv / Gingiva

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

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

Dust generation
Particular danger of slipping on leaked/spilled product.

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

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

- **4.1 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.
- **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**
  Particular danger of slipping on leaked/spilled product.
- **6.2 Environmental precautions:** No special measures required.
- **6.3 Methods and material for containment and cleaning up:**
  Pick up mechanically.
  Ensure adequate ventilation.
- **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.
  Prevent formation of dust.
  Ensure good ventilation/exhaustion at the workplace.
  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.
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.
        - Wash hands before breaks and at the end of work.
        - Keep away from foodstuffs, beverages and feed.
        - Vacuum clean contaminated clothing. Do not blow or brush off contamination.
        - Do not inhale dust / smoke / mist.
      - 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.
      - Recommended filter device for short term use: Filter P2
      - Protection of hands: Not required.
      - 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: Safety glasses

SECTION 9: Physical and chemical properties

- 9.1 Information on basic physical and chemical properties
  - General Information
    - Appearance:
      - Form: Powder
      - Colour: According to product specification
      - Odour: Odourless
      - Odour threshold: Not determined.
    - pH-value: Not applicable.
  - Change in condition
    - Melting point/freezing point: Undetermined.
    - Initial boiling point and boiling range: Undetermined.
  - Flash point: Not applicable.
  - Flammability (solid, gas): Product is not flammable.
  - Auto-ignition temperature: 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: Mechanical effects only.
  - 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.
Trade name: IPS e.max Ceram ZirLiner / Intensiv / Gingiva

- 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.
  - European waste catalogue
    - 08 02 99 wastes not otherwise specified
  - 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, 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.


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**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.