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

- 1.1 Product identifier
  · Trade name: IPS InLine - Dentin, Deep Dentin, Occlusal Dentin, Incisal, Transpa Incisal, Cervical Incisal, Transpa, Gingiva, Intensiv Gingiva, Mamelon, Add-On Margin, Add-On
  · CAS Number: 66402-68-4
  · EC number: 266-340-9

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

(Contd. on page 2)
Trade name: IPS InLine - Dentin, Deep Dentin, Occlusal Dentin, Incisal, Transpa Incisal, Cervical Incisal, Transpa, Gingiva, Intensiv Gingiva, Mamelon, Add-On Margin, Add-On

- Identification number(s)
- EC number: 266-340-9

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.
    - Further information about storage conditions:
      Keep container tightly sealed.
      Store in dry conditions.

- 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.
        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.
      - 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.
**SECTION 10: Stability and reactivity**

- **10.1 Reactivity**
  No further relevant information available.

- **10.2 Chemical stability**
  Stable under normal handling and storage conditions.

- **10.3 Thermal decomposition / conditions to be avoided**
  No decomposition if used according to specifications.

- **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:**
  - **Primary irritant effect:**
    - **on the skin:** No irritant effect.
    - **on the eye:** Mechanical effects only.

- **Sensitisation:**
  No sensitising effects known.
**Trade name:** IPS InLine - Dentin, Deep Dentin, Occlusal Dentin, Incisal, Transpa Incisal, Cervical Incisal, Transpa, Gingiva, Intensiv Gingiva, Mamelon, Add-On Margin, Add-On

**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.
  - **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, ADN, IMDG, IATA Void
- **14.2 UN proper shipping name**
  - ADR, ADN, IMDG, IATA Void
- **14.3 Transport hazard class(es)**
  - ADR, ADN, IMDG, IATA Void
  - Class Void
- **14.4 Packing group**
  - ADR, IMDG, IATA Void
- **14.5 Environmental hazards:**
  - Marine pollutant: No
- **14.6 Special precautions for user** Not applicable.
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- 14.7 Transport in bulk according to Annex II of MARPOL73/78 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": -

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)
- * Data compared to the previous version altered.