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

- **Product identifier**
- **Trade name:** IPS Impulse: Mamelon, Incisal Edge, Incisal, Transparent, Okklusal Dentin, Molar Incisal

- **CAS Number:**
  66402-68-4

- **EC number:**
  266-340-9

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

- **Application of the substance / the preparation**
  Metal-ceramic

- **Details of the supplier of the safety data sheet**

  - **Manufacturer/Supplier:**
    Ivoclar Vivadent AG
    Bendererstrasse 2
    FL-9494 Schaan
    FÜRSTENTUM LIECHTENSTEIN
    Tel: +423 235 35 35
    Fax: +423 235 33 60

  - **Further information obtainable from:**
    Regulatory Affairs
    msds@ivoclarvivadent.com

  - **Emergency telephone number:** +423 / 235 33 13

2 Hazards identification

- **Classification of the substance or mixture**

  - **Classification according to Regulation (EC) No 1272/2008**
    The substance is not classified according to the CLP regulation.

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

- **Information concerning particular hazards for human and environment:**
  Not applicable.

- **Label elements**

  - **Labelling according to Regulation (EC) No 1272/2008**
    Void

  - **Hazard pictograms**
    Void

  - **Signal word**
    Void

  - **Hazard statements**
    Void

  - **Additional information:**
    Void

  - **Other hazards**
    Dust generation
    Particular danger of slipping on leaked/spilled product.

- **Results of PBT and vPvB assessment**

  - **PBT:** Not applicable.
  - **vPvB:** Not applicable.

3 Composition/information on ingredients

- **Chemical characterization:** Substances

  - **CAS No. Description**
    66402-68-4 ceramic materials

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Trade name: IPS Impulse: Mamelon, Incisal Edge, Incisal, Transparent, Okklusal Dentin, Molar Incisal

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

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: The product is not flammable.
  - 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
  - Environmental precautions: No special measures required.
  - Methods and material for containment and cleaning up:
    Pick up mechanically.
    Ensure adequate ventilation.
  - 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.
Prevent formation of dust.
Ensure good ventilation/exhaustion at the workplace.

- **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:**
  - 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:** Not required.
- **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.
  - 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

### 9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**
  - **Form:** Powder
  - **Colour:** According to product specification
  - **Odour:** Odourless
  - **Odour threshold:** Not determined.
36.0.5

- **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.
- **Viscosity:**
  - Dynamic: Not applicable.
  - Kinematic: Not applicable.
- **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:** Mechanical effects only.
  - **Sensitization:** No sensitizing effects known.
Safety data sheet
according to 1907/2006/EC, Article 31

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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: Generally not hazardous for water
- 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.

<table>
<thead>
<tr>
<th>European waste catalogue</th>
<th>08 02 99 wastes not otherwise specified</th>
</tr>
</thead>
</table>

- 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.

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Trade name: IPS Impulse: Mamelon, Incisal Edge, Incisal, Transparent, Okklusal Dentin, Molar Incisal

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.

- 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 Organization
  - 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 Harmonized 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)