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

1.1 Product identifier
· Trade name: IPS Ivocolor Glaze Powder / FLUO
· 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
  Ceramic material for the staining and glazing of ceramic restorations

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

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
· 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
· Description: dental ceramic

(Contd. on page 2)
Trade name: IPS Ivocolor Glaze Powder / FLUO

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. Then 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.
Use fire extinguishing methods suitable to surrounding conditions.

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
Avoid formation of dust.

6.2 Environmental precautions:
Do not allow to enter sewers/surface or ground water.

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.
For use in dentistry only.
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of dust.
· **41.1.9 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.
    · **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.

· **8.2 Exposure controls**
  
  · **Personal protective equipment:**
    · **General protective and hygienic measures:** Usual hygienic measures for dental practice.
    - Keep away from foodstuffs, beverages and feed.
    - Wash hands before breaks and at the end of work.
    - Vacuum clean contaminated clothing. Do not blow or brush off contamination.
    - Do not inhale dust / smoke / mist.

  · **Respiratory protection:** Use respiratory protective device against the effects of dust.

  · **Recommended filter device for short term use:** FFP2

· **Protection of hands:** Not required.

· **Material of gloves -**

· **Penetration time of glove material -**

· **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:** Different according to colouring
      - **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.
Trade name: IPS Ivocolor Glaze Powder / FLUO

- Flammability (solid, gaseous): Not applicable.
- Self-igniting: Product is not self-igniting.
- 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.

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 Possibility of hazardous reactions 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
  - LD/LC50 values relevant for classification: 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.
  - 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:
    - 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.
  - **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.
  - **Uncleaned packaging:**
    - **Recommendation:** Disposal must be made according to official regulations.

### SECTION 14: Transport information

- **14.1 UN-Number**
  - ADR, RID, ADN, ADJ, IMDG, IATA: Void
- **14.2 UN proper shipping name**
  - ADR, RID, ADN, ADJ, IMDG, IATA: Void
- **14.3 Transport hazard class(es)**
  - ADR, RID, ADN, ADJ, 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:**
  - 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
  - Directive 2012/18/EU
  - Named dangerous substances - ANNEX I Substance is not listed.
  - 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)
  LC50: Lethal concentration, 50 percent
  LD50: Lethal dose, 50 percent
  PBT: Persistent, Bioaccumulative and Toxic
  vPvB: very Persistent and very Bioaccumulative