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

1.1 Product identifier
Trade name: IPS Classic V Powder Opaquer

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

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 product 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
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

3.2 Chemical characterisation: Mixtures
Description: dental ceramic

Dangerous components:
CAS: 1314-23-4 zirconium dioxide
EINECS: 215-227-2 substance with a Community workplace exposure limit 10-<25%

Additional information: For the wording of the listed risk phrases refer to section 16.

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.

(Contd. on page 2)
Safety data sheet
according to 1907/2006/EC, Article 31

Trade name: IPS Classic V Powder Opaquer

41.1.0
· 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: 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
Not required.

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.

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.

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: 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.
(Contd. on page 3)
8.1 Control parameters

- Ingredients with limit values that require monitoring at the workplace:
  - 1314-23-4 zirconium dioxide

<table>
<thead>
<tr>
<th>WEL</th>
<th>Short-term value: 10 mg/m³</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Long-term value: 5 mg/m³</td>
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</tbody>
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  |     | as Zr

- 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.
    - Keep away from foodstuffs, beverages and feed.
    - Wash hands before breaks and at the end of work.
  - 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:
    - The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
    - After use of gloves apply skin-cleaning agents and skin cosmetics.
  - 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. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
  - 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: Not required.

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 determined.
  - Change in condition
    - Melting point/Melting range: Undetermined.
    - Boiling point/Boiling range: Undetermined.
  - Flash point: Not applicable.
  - 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.
Trade name: IPS Classic V Powder Opaquer

**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:** Nearly insoluble.
- **Partition coefficient (n-octanol/water):** Not determined.
- **Viscosity:**
  - Dynamic: Not applicable.
  - Kinematic: Not applicable.

### 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**
  - **Primary irritant effect:**
    - **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.
SECTION 13: Disposal considerations

13.1 Waste treatment methods
Recommendation: Disposal must be made according to official regulations.

Uncleaned packaging:
Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information

14.1 UN-Number
ADR, RID, ADN, AD, 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, AD, IMDG, IATA: Void
Class: 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": -

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
- ELINCS: European List of Notified 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.