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

1.1 Product identifier

Trade name: IPS Style Ceram One, IPS Style Ceram Margin, Intensiv Margin, Dentin, Deep Dentin, Mamelon, Opal Effect, Transpa, Incisal, Special Incisal, InterIncisal, Incisal Edge, Occlusal Dentin, Gingiva, Intensive Gingiva, Basic Gingiva,

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
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

3.2 Chemical characterisation: Mixtures
Description: Leucite oxyapatite metal ceramic
Dangerous components: Void
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

4.1.1 General information: No special measures required.

4.1.2 After inhalation:
Supply fresh air; consult doctor in case of complaints.
In case of unconsciousness place patient stably in side position for transportation.

4.1.3 After skin contact:
Rinse with water.
Generally the product does not irritate the skin.

4.1.4 After eye contact:
Rinse opened eye for several minutes under running water. Then consult a doctor.
Mechanical effects only.

4.1.5 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.

(Contd. on page 3)
Prevent formation of dust.
· 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:
    · The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
· 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.
Safety data sheet
according to 1907/2006/EC, Article 31

Trade name: IPS Style Ceram One, IPS Style Ceram Margin, Intensiv Margin, Dentin, Deep Dentin, Mamelon, Opal Effect, Transpa, Incisal, Special Incisal, InterIncisal, Incisal Edge, Occlusal Dentin, Gingiva, Intensive Gingiva, Basic Gingiva,

- **pH-value:** Not applicable.
- **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.
  - 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.
- **9.2 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.
- **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
  - 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.
Safety data sheet
according to 1907/2006/EC, Article 31

Trade name: IPS Style Ceram One, IPS Style Ceram Margin, Intensiv Margin, Dentin, Deep Dentin, Mamelon, Opal Effect, Transpa, Incisal, Special Incisal, InterIncisal, Incisal Edge, Occlusal Dentin, Gingiva, Intensive Gingiva, Basic Gingiva,

- 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: 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.
  - 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
  - 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.
贸易名称: IPS Style Ceram One, IPS Style Ceram Margin, Intensiv Margin, Dentin, Deep Dentin, Mamelon, Opal Effect, Transpa, Incisal, Special Incisal, InterIncisal, Incisal Edge, Occlusal Dentin, Gingiva, Intensive Gingiva, Basic Gingiva,

(Contd. of page 5)

- 14.7 运输在散装应根据附录II的Marpol和IBC代码
  不适用。
- 运输/附加信息: 产品不被列为危险货物进行运输(ADR, IMDG, IATA)。
- UN "Model Regulation": Void

SECTION 15: Regulatory information

- 15.1 安全、健康和环境保护法规/立法适用于该物质或混合物
  - 指令2012/18/EU
  - 标注危险物质 - ANNEX I None of the ingredients is listed.
  - 国家法规:
    - 其他法规、限制和禁止性法规
      该产品是根据93/42/EEC指令的医疗设备。
- 15.2 化学安全评估: 未进行化学安全评估。

SECTION 16: Other information

此信息基于目前的知识。然而，这不构成对任何特定产品特性的保证，也不建立一个合法有效的合同关系。

- 缩写和缩略语:
  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)
  LC50: Lethal concentration, 50 percent
  LD50: Lethal dose, 50 percent
  PBT: Persistent, Bioaccumulative and Toxic
  vPvB: very Persistent and very Bioaccumulative