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

· 1.1 Product identifier
  · Trade name: IPS Empress Esthetic Veneer: Incisal Opal, Incisal, Chroma
  Modifier, Brightener, Transparent, Add-On 770 °C / 1418 °F

· 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 prosthesis

· 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)
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.
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.

SECTION 5: Firefighting measures

5.1 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: 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.
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.
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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.
  - 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

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 applicable.
Safety data sheet
according to 1907/2006/EC, Article 31

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Version number 4

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· 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.

· 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:
  Primary irritant effect:
  · on the skin: No irritant effect.
  · on the eye: Mechanical effects only.
  Sensitisation: No sensitising effects known.

· Additional toxicological information: No further relevant information available.
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: 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.
- 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).
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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.