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

- 1.1 Product identifier
  - Trade name: Vivaglass Liner (Powder)

- 1.2 Relevant identified uses of the substance or mixture and uses advised against
  - Application of the substance / the mixture: Light-curing glass ionomer cement

- 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 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
  - Additional information:
    Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

- 2.3 Other hazards
  - Results of PBT and vPvB assessment
    - PBT: Not applicable.
    - vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

- 3.2 Chemical characterisation: Mixtures
  - Description: Mixture of substances listed below with nonhazardous additions.
  - 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
  - General information: No special measures required.


**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** 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.
  - 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.
  - 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.
40.1.5 - 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.
- 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. Do not inhale dust / smoke / mist.
  - Respiratory protection: Use respiratory protective device against the effects of dust.
  - 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. 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: Safety glasses

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties
- General Information
  - Appearance: Powder
  - Colour: White
  - 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: Undetermined.

- Flammability (solid, gaseous): Not applicable.

- Self-igniting: Product is not selfigniting.

- Danger of explosion: Product does not present an explosion hazard.

- Explosion limits:
  - Lower: Not determined.
Upper:
- Not determined.
- Vapour pressure: Not determined.
- Density: Not determined.
- Relative density: Not determined.
- Vapour density: Not determined.
- Evaporation rate: Not determined.
- Solubility in / Miscibility with water: Insoluble.
- Partition coefficient (n-octanol/water): Not determined.
- Viscosity:
  - Dynamic: Not determined.
  - Kinematic: Not determined.
- 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.
- 10.3 Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- 10.4 Conditions to avoid: No dangerous reactions known.
- 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: No irritating effect.
- Sensitisation: No sensitising effects known.
- Additional toxicological information:
The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.

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.

(Contd. on page 5)
Safety data sheet
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- 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, 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).
- 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)
Trade name: Vivaglass Liner (Powder)

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)