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

- **1.1 Product identifier**
  - Trade name: Telio Lab Powder (Dentin, Transpa Incisal, Neck, Intensive, Bleach, Gingiva)

- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
  - No further relevant information available.
  - Application of the substance / the mixture: Auxiliary for 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 
    - Skin Sens. 1 H317 May cause an allergic skin reaction.

- **2.2 Label elements**
  - Labelling according to Regulation (EC) No 1272/2008 
    - The product is classified and labelled according to the CLP regulation.
  - **Hazard pictograms**
    - GHS07

- **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:** Mixture of substances listed below with nonhazardous additions.
  - **Dangerous components:**
    - CAS: 94-36-0 dibenzoyl peroxide
      EINECS: 202-327-6
      Org. Perox. B, H241; Eye Irrit. 2, H319; Skin Sens. 1, H317
      1-<2.5%
  - **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**
  - **After inhalation:** Supply fresh air and to be sure call for a doctor.
    In case of unconsciousness place patient stably in side position for transportation.
  - **After skin contact:** Rinse with water.
    If skin irritation continues, consult a doctor.
  - **After eye contact:** Rinse opened eye for several minutes under running water.
    If symptoms persist, consult a doctor.
  - **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:** CO2, powder or water spray.
    Fight larger fires with water spray or alcohol resistant foam.
  - **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.
    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.
  - **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.

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: Protect from heat and direct sunlight.

7.3 Specific end use(s)
- No further relevant information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace:
- 94-36-0 dibenzoyl peroxide
  - WEL Long-term value: 5 mg/m³

Additional information:
The lists valid during the making were used as basis.

8.2 Exposure controls

- General protective and hygienic measures:
  - Keep away from foodstuffs, beverages and feed.
  - Wash hands before breaks and at the end of work.
  - Avoid contact with the skin.

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

- Protection of hands:
  - Protective gloves
    - After use of gloves apply skin-cleaning agents and skin cosmetics.
    - Material of gloves
      - Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
    - 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

(Contd. on page 4)
SECTION 9: Physical and chemical properties

- 9.1 Information on basic physical and chemical properties
  - General Information
    - Appearance: Powder
    - Colour: According to product specification
    - Odour: Characteristic
    - Odour threshold: Not determined.
  - pH-value: Not applicable.
  - Change in condition
    - Melting point/Melting range: 150 °C
    - Boiling point/Boiling range: Undetermined.
  - Flash point: 250 °C
  - Flammability (solid, gaseous): Not determined.
  - 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 applicable.
  - Density at 20 °C: 1.2 g/cm³
  - 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.

- 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 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: No irritating effect.
· Sensitisation: Sensitisation possible through skin contact.
· Additional toxicological information: No further relevant information available.

SECTION 12: Ecological information

12.1 Toxicity
· Aquatic toxicity: No further relevant information available.
· Persistence and degradability: No further relevant information available.
· Bioaccumulative potential: No further relevant information available.
· Mobility in soil: No further relevant information available.
· Additional ecological information:
  · General notes: Generally not hazardous for water
  · Results of PBT and vPvB assessment
    · PBT: Not applicable.
    · vPvB: Not applicable.
· 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
  20 01 39 plastics
· Uncleaned packaging:
  · Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information

14.1 UN-Number
· ADR, ADN, IMDG, IATA Void
· UN proper shipping name
  · ADR, ADN, IMDG, IATA Void
· Transport hazard class(es)
  · ADR, ADN, IMDG, IATA Class Void
· Packing group
  · ADR, IMDG, IATA Void
Trade name: Telio Lab Powder (Dentin, Transpa Incisal, Neck, Intensive, Bleach, Gingiva)

- 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.

- Relevant phrases
  - H241 Heating may cause a fire or explosion.
  - H317 May cause an allergic skin reaction.
  - H319 Causes serious eye irritation.

- Abbreviations and acronyms:
  - 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)
  - Org. Perox. B: Organic Peroxides, Type B
  - Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2
  - Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

* Data compared to the previous version altered.