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

- **1.1 Product identifier**
  - Trade name: **Telio Lab Opaquer Powder**

- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
  - **Application of the substance / the mixture**: Auxiliary for manufacture of dental prothesis
  - **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

- **1.4 Emergency telephone number:**
  - +423 / 235 33 33 (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.

- **2.3 Other hazards**
  - **Dust generation**
    - Particular danger of slipping on leaked/spilled product.

- **Signal word** Warning

- **Hazard-determining components of labelling:**
  - dibenzoyl peroxide

- **Hazard statements**
  - **H317** May cause an allergic skin reaction.

- **Precautionary statements**
  - **P280** Wear protective gloves/protective clothing/eye protection/face protection.
  - **P333+P313** If skin irritation or rash occurs: Get medical advice/attention.

- **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.

(Contd. on page 2)
**SECTION 3: Composition/information on ingredients**

**3.2 Chemical characterisation: Mixtures**

**Description:** Mixture of substances listed below with nonhazardous additions.

**Dangerous components:**

- **CAS: 7727-43-7** EINECS: 231-784-4
  - barium sulphate, natural substance with a Community workplace exposure limit 25-50%

- **CAS: 1344-28-1** EINECS: 215-691-6
  - aluminium oxide substance with a Community workplace exposure limit 25-50%

- **CAS: 94-36-0** EINECS: 202-327-6
  - dibenzoyl peroxide 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.

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**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.

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**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.

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**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.
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: None.
- 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:
    - 7727-43-7 barium sulphate, natural
      WEL Long-term value: 10* 4** mg/m³
      *inhalable dust **respirable dust
    - 1344-28-1 aluminium oxide
      WEL Long-term value: 10* 4** mg/m³
      *inhalable dust **respirable dust
    - 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
  - 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.
      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.
Trade name: Telio Lab Opaquer Powder

- **Eye protection**: Safety glasses

### SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
  - **General Information**
  - **Appearance**: Powder
  - **Form**: Powder
  - **Colour**: According to product specification
  - **Odour**: Characteristic
  - **Odour threshold**: Not determined.
  - **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 determined.

- **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**: 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.

- **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: Toxicalogical information

11.1 Information on toxicalogical 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 toxicalogical 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.
- 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: 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:
  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.