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

· 1.1 Product identifier
  Trade name: Ivostar, Gnathostar

· 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
  Manufacture of dental prothesis

· 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
  Avoid breathing sanding dust /swarf.
  Results of PBT and vPvB assessment
  PBT: Not applicable.
  vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

· 3.2 Chemical characterisation: Mixtures
  Description: Resin teeth based on polymethylmethacrylate
  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.
  After skin contact: 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: Seek medical treatment.
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
  - Not required.
- 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
  - No dangerous substances are released.
  - 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: No special requirements.
    - 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:
    - 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.
    - Respiratory protection: Use respiratory protective device against the effects of dust.
Protection of hands:
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

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 cannot 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:
Always wear safety goggles during mechanical processing (grinding, sawing/cutting, drilling, milling).

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties
General Information
Appearance:
Form: Solid
Colour: According to product specification
Odour: Odourless
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:
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.
Trade name: Ivostar, Gnathostar

**Kinematic:** Not applicable.

- **Solvent content:**
  - Solids content: 100.0 %
  - 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 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: No sensitising effects known.

### 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, 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 MARPOL 73/78 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:**
  - 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)

- **Data compared to the previous version altered.**