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

1.1 Product identifier

Trade name: IvoBase Hybrid Polymer / IvoBase High Impact Polymer

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 Denture base material

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

The product is classified and labelled according to the CLP regulation.

Hazard pictograms

GHS07

Signal word Warning

Hazard-determining components of labelling:
dibenzoyl peroxide

Hazard statements
H317 May cause an allergic skin reaction.

Precautionary statements
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P262 Do not get in eyes, on skin, or on clothing.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

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

Results of PBT and vPvB assessment
PBT: Not applicable.
SECTION 3: Composition/information on ingredients

- 3.2 Chemical characterisation: Mixtures
  - Description: > 95% polymethylmethacrylate

- Dangerous components:
  
<table>
<thead>
<tr>
<th>CAS/EINECS</th>
<th>Chemical Name</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>94-36-0</td>
<td>dibenzoyl peroxide</td>
<td>0.3-&lt;1%</td>
</tr>
</tbody>
</table>

- Additional information: For the wording of the listed hazard phrases refer to section 16.

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.
  - 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. Then 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
  - 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.

- 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:** Protect from heat and direct sunlight.

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

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**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:**
    - **CAS:** 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 and dental laboratories.
      - 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**
      - **Material of gloves**
        - Butyl rubber, BR
        - Chloroprene rubber, CR
        - Natural rubber, NR
        - Nitrile rubber, NBR
        - Fluorocarbon rubber (Viton)
      - 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

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(Contd. of page 2)
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: 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 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: Based on available data, the classification criteria are not met.
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:
  Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
  Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- 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, RID, ADN, ADN, IMDG, IATA Void

14.2 UN proper shipping name
ADR, RID, ADN, ADN, IMDG, IATA Void

14.3 Transport hazard class(es)
- ADR, RID, ADN, ADN, IMDG, IATA
  - Class Void

14.4 Packing group
ADR, RID, ADN, IMDG, IATA Void

(Contd. on page 6)
Trade name: IvoBase Hybrid Polymer / IvoBase High Impact Polymer

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 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": Void

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)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Org. Perox. B: Organic peroxides – Type B
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
Skin Sens. 1: Skin sensitisation – Category 1

* Data compared to the previous version altered.