

Printing date 31.01.2020 Version number 4 Revision: 31.01.2020

Hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

- · Product identifier
- Trade name: IvoBase Hybrid Polymer / IvoBase High Impact Polymer
- · 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
- Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

Ivoclar Vivadent AG Bendererstrasse 2 9494 Schaan

PRINCIPALITY OF LIECHTENSTEIN
Tel: +423 235 35 35 / Fax: +423 235 33 60

Importer:

Ivoclar Vivadent Pty. Ltd. 1- 5 Overseas Drive Noble Park North VIC 3174

Tel: + 61 3 9795 9599 / Fax: + 61 3 9795 9645

· Further information obtainable from:

Regulatory Affairs sds@ivoclarvivadent.com

· Emergency telephone number: 131 126 (Poisons Information Centre - 24 hours / 7 days)

2 Hazard(s) Identification

· Classification of the substance or mixture

Skin Sens. 1 H317 May cause an allergic skin reaction.

- · Label elements
- · GHS label elements

The product is classified and labelled according to the Globally Harmonised System (GHS).

· Hazard pictograms



- · Signal word Warning
- · Hazard-determining components of labelling:

dibenzoyl peroxide

· Hazard statements

May cause an allergic skin reaction.

· Precautionary statements

Avoid breathing dust/fume/gas/mist/vapours/spray.

Do not get in eyes, on skin, or on clothing.

Wear protective gloves/protective clothing/eye protection/face protection.

Dispose of contents/container in accordance with local/regional/national/international regulations.

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· Other hazards

Dust generation

Particular danger of slipping on leaked/spilled product.

- · Results of PBT and vPvB assessment
- · **PBT**: Not applicable.
- · vPvB: Not applicable.

3 Composition and Information on Ingredients

- · Chemical characterisation: Mixtures
- **Description:** > 95% polymethylmethacrylate
- Dangerous components:

CAS: 94-36-0 | dibenzoyl peroxide | Org. Perox. B, H241; Eye Irrit. 2, H319; Skin Sens. 1, H317 | <2.5%

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

4 First Aid Measures

- 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.

- Information for doctor:
- · Most important symptoms and effects, both acute and delayed No further relevant information available.
- · Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Fire Fighting Measures

- · Extinguishing media
- · Suitable extinguishing agents: Use fire extinguishing methods suitable to surrounding conditions.
- · Special hazards arising from the substance or mixture No further relevant information available.
- · Advice for firefighters
- · Protective equipment: No special measures required.

6 Accidental Release Measures

- · Personal precautions, protective equipment and emergency procedures Not required.
- Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- · Methods and material for containment and cleaning up: Pick up mechanically.
- · 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.

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7 Handling and Storage

- · Handling:
- 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.
- · 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.
- · Specific end use(s) No further relevant information available.

8 Exposure controls and personal protection

- · Additional information about design of technical facilities: No further data; see item 7.
- · Control parameters
- · Ingredients with limit values that require monitoring at the workplace:

CAS: 94-36-0 dibenzoyl peroxide

NES | Long-term value: 5 mg/m³

Sen

WES Long-term value: 5 mg/m³

Sen

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

After use of gloves apply skin-cleaning agents and skin cosmetics.

· 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.

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· 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

9 Physical and Chemical Properties

- · Information on basic physical and chemical properties
- · General Information
- · Appearance:

Form: Powder

Colour: According to product specification

· Odour: Characteristic
· Odour threshold: Not determined.

· pH-value: Not applicable.

· Change in condition

Melting point/freezing point: 150 °C Initial boiling point and boiling range: Undetermined.

Flash point: Not applicable.
 Flammability (solid, gas): Not determined.

· Auto-ignition temperature: Product is not selfigniting.

• Explosive properties: Product does not present an explosion hazard.

· Explosion limits:

Lower:Not determined.Upper:Not determined.Vapour pressure:Not applicable.

Density at 20 °C:
 Relative density
 Vapour density
 Evaporation rate
 1.2 g/cm³
 Not determined.
 Not applicable.

· Solubility in / Miscibility with

water: Nearly insoluble.

· Partition coefficient: n-octanol/water: Not determined.

· Viscosity:

Dynamic: Not applicable. **Kinematic:** Not applicable.

• Other information No further relevant information available.

10 Stability and Reactivity

- · Reactivity No further relevant information available.
- · Chemical stability Stable under normal handling and storage conditions.
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available.

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· Hazardous decomposition products: None under normal conditions of storage and use.

11 Toxicological Information

- · Information on toxicological effects
- · Acute toxicity
- · Skin corrosion/irritation No irritant effect.
- · Serious eye damage/irritation No irritating effect.
- · Respiratory or skin sensitisation Sensitisation possible through skin contact.
- · Additional toxicological information: No further relevant information available.

12 Ecological Information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behaviour in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · **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.

- · Results of PBT and vPvB assessment
- · **PBT**: Not applicable.
- · vPvB: Not applicable.
- · Other adverse effects No further relevant information available.

13 Disposal considerations

- · 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.

| 14 Transport information | | |
|---|------|--|
| · UN-Number · ADG, ADN, IMDG, IATA | Void | |
| · UN proper shipping name · ADG, ADN, IMDG, IATA | Void | |
| · Transport hazard class(es) | | |
| · ADG, ADN, IMDG, IATA · Class | Void | |
| · Packing group · ADG, IMDG, IATA | Void | |

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|---|--|--|
| · Environmental hazards: · Marine pollutant: | No | |
| · Special precautions for user | Not applicable. | |
| · Transport in bulk according to Annex II of and the IBC Code | Marpol Not applicable. | |
| · Transport/Additional information: | Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). | |
| · UN "Model Regulation": | Void | |

15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Australian Inventory of Chemical Substances

CAS: 94-36-0 dibenzoyl peroxide

· Standard for the Uniform Scheduling of Medicines and Poisons

CAS: 94-36-0 dibenzoyl peroxide S2, S4, S5

· GHS label elements

The product is classified and labelled according to the Globally Harmonised System (GHS).

· Hazard pictograms



GHS07

- · Signal word Warning
- · Hazard-determining components of labelling:

 $dibenzoyl\ peroxide$

· Hazard statements

May cause an allergic skin reaction.

· Precautionary statements

Avoid breathing dust/fume/gas/mist/vapours/spray.

Do not get in eyes, on skin, or on clothing.

Wear protective gloves/protective clothing/eye protection/face protection.

Dispose of contents/container in accordance with local/regional/national/international regulations.

- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.
- · National regulations:
- · Other regulations, limitations and prohibitive regulations

The product is a medical device according to the Directive 93/42/EEC.

· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

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.

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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 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