

Version number 8

Revision: 16.06.2016

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

· 1.1 Product identifier

• Trade name: BASEPLAST 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: CANDULOR AG Boulevard Lilienthal 8 CH-8152 Glattpark (Opfikon) SWITZERLAND

Tel. +41 (0) 44 805 9000 *Fax* +41 (0) 44 805 9090

 Further information obtainable from: Regulatory Affairs info@candulor.ch
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



· 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.

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0.3-<1%

· vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

· 3.2 Chemical characterisation: Mixtures

• *Description:* > 95% polymethylmethacrylate

· Dangerous components:

CAS: 94-36-0 dibenzoyl peroxide

EINECS: 202-327-6 Org. Perox. B, H241; Eye Irrit. 2, H319; Skin Sens. 1, H317

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

• After inhalation: Supply fresh air; consult doctor in case of complaints.

· After skin contact: Rinse with water.

• 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.

• 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.

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- · 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

• 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

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) 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

| 9.1 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. | |

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| · 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/cm^3 | |
| Relative density | Not determined. | |
| · Vapour density | Not applicable. | |
| · Evaporation rate | Not applicable. | |
| · Solubility in / Miscibility with | | |
| water: | Nearly insoluble. | |
| · Partition coefficient (n-octanol/wat | t er): 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: Toxicological information

· 11.1 Information on toxicological effects

• Acute toxicity Based on available data, the classification criteria are not met.

· Skin corrosion/irritation Based on available data, the classification criteria are not met.

• Serious eye damage/irritation Based on available data, the classification criteria are not met.

· Respiratory or skin sensitisation

May cause an allergic skin reaction.

• Additional toxicological information: No further relevant information available.

• Germ cell mutagenicity Based on available data, the classification criteria are not met.

· Carcinogenicity Based on available data, the classification criteria are not met.

• *Reproductive toxicity Based on available data, the classification criteria are not met.*

• STOT-single exposure Based on available data, the classification criteria are not met.

· STOT-repeated exposure Based on available data, the classification criteria are not met.

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· Aspiration hazard 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 |
| · 14.5 Environmental hazards: · Marine pollutant: | No |
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Transport in bulk according to Anne Marpol and the IBC Code | e x II of Not applicable. |
| · Transport/Additional information: | Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). |
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· 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 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, Hazard Category 2 Skin Sens. 1: Sensitisation - Skin, Hazard Category 1 * Data compared to the previous version altered.