Revision: 18.07.2023



Safety data sheet according to 1907/2006/EC, Article 31

Printing date 07.08.2023

Version number 9 (replaces version 8)

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

- · 1.1 Product identifier
- · Trade name: AESTHETIC BLUE Polymer
- \cdot 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 Self-curing denture base material
- · 1.3 Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

CANDULOR AG
Boulevard Lilienthal 8
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, 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 GB 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.

P280 Wear protective gloves.

P302+P352 IF ON SKIN: Wash with plenty of water.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P321 Specific treatment (see on this label).

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.

(Contd. on page 2)

Printing date 07.08.2023

Version number 9 (replaces version 8)

Trade name: AESTHETIC BLUE Polymer

(Contd. of page 1)

Revision: 18.07.2023

· vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

- · 3 2 Mixtures
- **Description:** > 95% polymethylmethacrylate
- · Dangerous components:

CAS: 94-36-0 dibenzoyl peroxide 1-<2.5% EINECS: 202-327-6 Org. Perox. B, H241; Eye Irrit. 2, H319; Skin Sens. 1, H317 Reg.nr.: 01-2119511472-50-XXXX

· 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 and to be sure call for a doctor.
- · 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.

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.

(Contd. on page 3)

Printing date 07.08.2023

Version number 9 (replaces version 8)

Trade name: AESTHETIC BLUE Polymer

(Contd. of page 2)

Revision: 18.07.2023

- · 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.

SECTION 8: Exposure controls/personal protection

- · 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
- · Appropriate engineering controls No further data; see section 7.
- · Individual protection measures, such as 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.
- · Hand protection



Protective gloves (EN 374)

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/face protection Safety glasses

SECTION 9: Physical and chemical properties

- · 9.1 Information on basic physical and chemical properties
- · General Information

· Colour: According to product specification

· Odour: Characteristic

· *Odour threshold:* Not determined.

(Contd. on page 4)

Printing date 07.08.2023 Version number 9 (replaces version 8) Revision: 18.07.2023

Trade name: AESTHETIC BLUE Polymer

(Contd. of page 3)

Melting point/freezing point:	150 °C
Boiling point or initial boiling point and boiling	
range	Undetermined.
Flammability	Not determined.
Lower and upper explosion limit	
Lower:	Not determined.
Upper:	Not determined.
Flash point:	250 °C
pH 1	Not applicable.
Viscosity:	**
Kinematic viscosity	Not applicable.
Dynamic:	Not applicable.
Solubility	11
water:	Nearly insoluble.
Partition coefficient n-octanol/water (log value)	Not determined.
Vapour pressure:	Not applicable.
Density and/or relative density	11
Density at 20 °C:	1.2 g/cm^3
Relative density	Not determined.
Vapour density	Not applicable.
Appearance: Form: Important information on protection of health an	Powder n d
environment, and on safety.	•••
Ignition temperature:	Product is not selfigniting.
Explosive properties:	Product does not present an explosion hazard.
Change in condition	T
Evaporation rate	Not applicable.
<u> </u>	
Information with regard to physical hazard class	
Explosives	Void Void
Flammable gases Aerosols	Void Void
	voia Void
Oxidising gases	voia Void
Gases under pressure	voia Void
Flammable liquids Flammable solids	voia Void
Self-reactive substances and mixtures Pyrophoric liquids	Void Void
	voia Void
Pyrophoric solids	v ota

Void

Void

Void

Void

Void

Void

Void

SECTION 10: Stability and reactivity

· Self-heating substances and mixtures

gases in contact with water

· Oxidising liquids

· Organic peroxides

· Corrosive to metals

· Desensitised explosives

· Oxidising solids

· Substances and mixtures, which emit flammable

- · 10.1 Reactivity No further relevant information available.
- · 10.2 Chemical stability Stable under normal handling and storage conditions.

(Contd. on page 5)

Printing date 07.08.2023

Version number 9 (replaces version 8)

Trade name: AESTHETIC BLUE Polymer

(Contd. of page 4)

Revision: 18.07.2023

- 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 hazard classes as defined in Regulation (EC) No 1272/2008
- · 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.

- · 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.
- · Aspiration hazard Based on available data, the classification criteria are not met.
- · Additional toxicological information: No further relevant information available.
- · 11.2 Information on other hazards
- Endocrine disrupting properties

None of the ingredients is listed.

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.
- · 12.5 Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.
- · 12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

- · 12.7 Other adverse effects
- · 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.

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.

(Contd. on page 6)

- GB

Printing date 07.08.2023

Version number 9 (replaces version 8)

Trade name: AESTHETIC BLUE Polymer

(Contd. of page 5)

Revision: 18.07.2023

- · Uncleaned packaging:
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport informatio	n
14.1 UN number or ID 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 Maritime transport in bulk according t instruments	t o IMO 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 relatif au transport international 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)

(Contd. on page 7)

Printing date 07.08.2023

Version number 9 (replaces version 8)

Revision: 18.07.2023

Trade name: AESTHETIC BLUE Polymer

(Contd. of page 6)

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.