

Version number 9

Revision: 03.06.2016

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

· 1.1 Product identifier

• Trade name: AESTHETIC BLUE Monomer

• 1.2 Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.

 \cdot 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

 \cdot Classification according to Regulation (EC) No 1272/2008

Flam. Liq. 2 H225 Highly flammable liquid and vapour.

Skin Irrit. 2 H315 Causes skin irritation.

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

STOT SE 3 H335 May cause respiratory irritation.

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 Danger

· Hazard-determining components of labelling: methyl methacrylate 1,4-butanediol dimethacrylate · Hazard statements H225 Highly flammable liquid and vapour. H315 Causes skin irritation. H317 May cause an allergic skin reaction. H335 May cause respiratory irritation. · Precautionary statements Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No P210 smoking. Avoid breathing dust/fume/gas/mist/vapours/spray. P261 Do not get in eyes, on skin, or on clothing. P262

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P280 Wear protective gloves/protective clothing/eye protection/face protection. P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. P501 Dispose of contents/container in accordance with local/regional/national/international regulations. · 2.3 Other hazards

· Results of PBT and vPvB assessment

· **PBT:** Not applicable.

· vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

· 3.2 Chemical characterisation: Mixtures

• Description: Mixture of substances listed below with nonhazardous additions.

• Dangerous compone	ents:	
CAS: 80-62-6	methyl methacrylate	50-100%
EINECS: 201-297-1	Flam. Liq. 2, H225; Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	
		2.5-<10%
EINECS: 218-218-1	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	
Additional information	Eastha wording of the listed har and physical vefor to section 16	

• 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: Immediately remove any clothing soiled by the product.

· After inhalation:

Supply fresh air; consult doctor in case of complaints.

In case of unconsciousness place patient stably in side position for transportation.

• After skin contact:

Immediately rinse with water.

If skin irritation continues, consult a doctor.

- 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.

Do not induce vomiting; call for medical help immediately.

- 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.

· For safety reasons unsuitable extinguishing agents: Water with full jet

• 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.

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· Additional information Cool endangered receptacles with water spray.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures Wear protective equipment. Keep unprotected persons away.
6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.
6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Ensure adequate ventilation.

- Do not flush with water or aqueous cleansing agents
- 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. Ensure good ventilation/exhaustion at the workplace. For use in dentistry only.
- Information about fire and explosion protection: Keep ignition sources away - Do not smoke. Protect against electrostatic charges.
- · 7.2 Conditions for safe storage, including any incompatibilities
- Storage:
- Requirements to be met by storerooms and receptacles:
- Store in a cool location. Store only in the original receptacle.
- Information about storage in one common storage facility: Store away from oxidising agents.
- Further information about storage conditions:
- Keep container tightly sealed. Store receptacle in a well ventilated area.
- 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: 80-62-6 methyl methacrylate

- WEL Short-term value: 416 mg/m³, 100 ppm Long-term value: 208 mg/m³, 50 ppm
 - Long-term value. 208 mg/m , 50 ppm
- 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.

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(Contd. of page 3) Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing Wash hands before breaks and at the end of work. Avoid contact with the eyes and skin. Do not inhale gases / fumes / aerosols. • **Respiratory protection:** Use suitable respiratory protective device in case of insufficient ventilation. • Recommended filter device for short term use: Filter A1 Filter A2 Filter A3 Protection of hands: Protective gloves After use of gloves apply skin-cleaning agents and skin cosmetics. · Material of gloves Butyl rubber, BR 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. • Not suitable are gloves made of the following materials: Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates. • Eye protection: Tightly sealed goggles **SECTION 9: Physical and chemical properties** •9.1 Information on basic physical and chemical properties · General Information

Appearance: Form:	Fluid
Colour:	Colourless
Odour:	Pungent
Odour threshold:	Not determined.
pH-value:	Not determined.
Change in condition	
Melting point/Melting range:	-48 °C
Boiling point/Boiling range:	101 °C
Flash point:	10 °C
Ignition temperature:	430 °C
Self-igniting:	Product is not selfigniting.
Danger of explosion:	Product is not explosive. However, formation of explosive air/ vapour mixtures are possible.

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· Explosion limits:		
Lower:	2.1 Vol %	
Upper:	12.5 Vol %	
· Vapour pressure at 20 °C:	47 hPa	
• Density at 20 •C:	0.943 g/cm^3	
· Relative density	Not determined.	
· Vapour density	Not determined.	
· Evaporation rate	Not determined.	
· Solubility in / Miscibility with		
water at 20 °C:	1.6 g/l	
· Partition coefficient (n-octanol/wo	ater): Not determined.	
· Viscosity:		
Dynamic:	Not determined.	
Kinematic:	Not determined.	
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

Forms explosive gas mixture with air.

Reacts with strong oxidising agents.

Exothermic polymerisation.

• 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.

· LD/LC50 values relevant for classification:

CAS: 80-62-6 methyl methacrylate

Oral LD50 7872 mg/kg (rat)

Skin corrosion/irritation

Causes skin irritation.

· 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

May cause respiratory irritation.

• 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 product 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

Must not be disposed together with household garbage. Do not allow product to reach sewage system. Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

European waste catalogue

18 01 06* chemicals consisting of or containing dangerous substances

· Uncleaned packaging:

• Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information · 14.1 UN-Number · ADR,RID,ADN, IMDG, IATA UN1247 · 14.2 UN proper shipping name · ADR/RID/ADN 1247 METHYL METHACRYLATE MONOMER, **STABILIZED** METHYL METHACRYLATE MONOMER, STABILIZED · IMDG, IATA · 14.3 Transport hazard class(es) · ADR/RID/ADN Class 3 (F1) Flammable liquids. (Contd. on page 7) GB

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Trade name: AESTHETIC BLUE Monomer (Contd. of page 6) · Label 3 · IMDG, IATA · Class 3 Flammable liquids. · Label 3 · 14.4 Packing group · ADR,RID,ADN, IMDG, IATA Π · 14.5 Environmental hazards: · Marine pollutant: No Warning: Flammable liquids. · 14.6 Special precautions for user · Danger code (Kemler): 339 • EMS Number: F-E,S-D· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code Not applicable. • Transport/Additional information: · ADR/RID/ADN \cdot Limited quantities (LQ) lL• Excepted quantities (EQ) Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml · Transport category 2 • Tunnel restriction code D/E·IMDG · Limited quantities (LQ) lL• Excepted quantities (EQ) Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml · UN ''Model Regulation'': UN1247, METHYL METHACRYLATE MONOMER, STABILIZED, 3, II

SECTION 15: Regulatory information

· 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

· Directive 2012/18/EU

· Named dangerous substances - ANNEX I None of the ingredients is listed.

• Qualifying quantity (tonnes) for the application of lower-tier requirements 5,000 t

• Qualifying quantity (tonnes) for the application of upper-tier requirements 50,000 t

· 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.

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This i	TION 16: Other information information is based on our present knowledge. However, this shall not constitute a guarantee for any fic product features and shall not establish a legally valid contractual relationship.
	vant phrases
	<i>Highly flammable liquid and vapour.</i>
	Causes skin irritation
	⁷ May cause an allergic skin reaction.
	Causes serious eye irritation.
	May cause respiratory irritation.
	eviations and acronyms: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International
	record europeen sur re transport des marchandises dungereuses par Roue (European Agreement concerning the international ige of Dangerous Goods by Road)
	International Maritime Code for Dangerous Goods
	International Air Transport Association
GHS:	Globally Harmonised System of Classification and Labelling of Chemicals
EINEC	CS: European Inventory of Existing Commercial Chemical Substances
ELINC	CS: European List of Notified Chemical Substances
CAS: C	Chemical Abstracts Service (division of the American Chemical Society)
LC50:	Lethal concentration, 50 percent
	Lethal dose, 50 percent
	Persistent, Bioaccumulative and Toxic
vPvB:	very Persistent and very Bioaccumulative
Flam	Liq. 2: Flammable liquids, Hazard Category 2
Skin Ir	rit. 2: Skin corrosion/irritation, Hazard Category 2
Eye Iri	rit. 2: Serious eye damage/eye irritation, Hazard Category 2
Skin Se	ens. 1: Sensitisation - Skin, Hazard Category 1
STOT	SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3