2)



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

Version number 9

Revision: 18.02.2016

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

· 1.1 Product identifier

Trade name: AESTHETIC BLUE LT Modelling Monomer

• 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

 $\cdot$  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-dete	rmining components of labelling:
methyl metho	acrylate
1,4-butanedi	ol dimethacrylate
· Hazard state	ments
H225 Highly	flammable liquid and vapour.
0,	s skin irritation.
H317 May c	ause an allergic skin reaction.
	ause respiratory irritation.
· Precautiona	
P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P262	Do not get in eyes, on skin, or on clothing.
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P280Wear 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<br/>water/shower.P501Dispose of contents/container in accordance with local/regional/national/international<br/>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	For the wording of the listed har and physical refer 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/m<sup>3</sup>, 100 ppm Long-term value: 208 mg/m<sup>3</sup>, 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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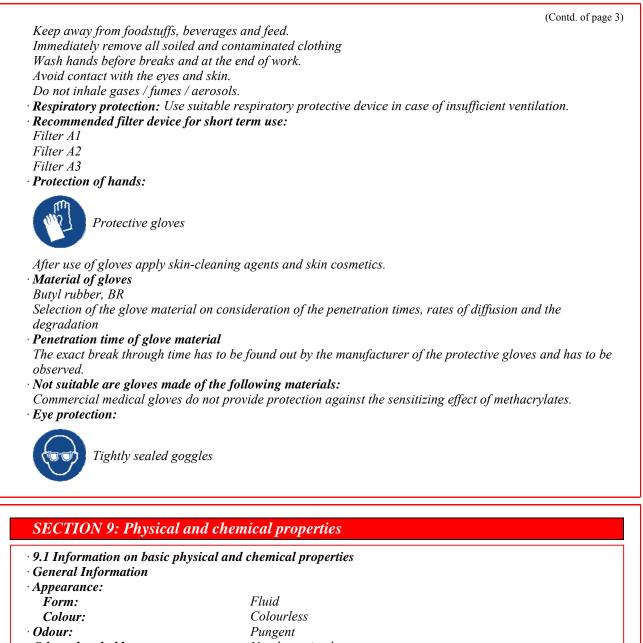
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· Odour threshold:	Not determined.		
· pH-value:	Not determined.		
• Change in condition Melting point/Melting range: Boiling point/Boiling range:	-48 °C 101 °C		
· Flash point:	10 °C		
· Ignition temperature:	430 °C		
· Self-igniting:	Product is not selfigniting.		
Danger of explosion:	<i>Product is not explosive. However, formation of explosive air/ vapour mixtures are possible.</i>		
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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:	$0.943 \text{ g/cm}^3$	
· 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	/ <b>water):</b> 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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Label	3
IMDG, IATA	
Class	3 Flammable liquids.
Label	3
14.4 Packing group	
ADR,RID,ADN, IMDG, IATA	11
14.5 Environmental hazards:	
Marine pollutant:	No
14.6 Special precautions for user	Warning: Flammable liquids.
Danger code (Kemler):	339
EMS Number:	F-E,S-D
14.7 Transport in bulk according to An	
Marpol and the IBC Code	Not applicable.
Transport/Additional information:	
ADR/RID/ADN	
Limited quantities (LQ)	1L
Excepted quantities $(EQ)$	Code: E2
	Maximum net quantity per inner packaging: 30 ml
Transport officer	Maximum net quantity per outer packaging: 500 ml
Transport category Tunnel restriction code	2 D/E
IMDG Limited quantities (LQ)	
Excepted quantities (EQ)	Code: E2
Excepted quantities (EQ)	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per unter 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.

· 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.

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(Contd. of page 7) · Relevant phrases H225 Highly flammable liquid and vapour. H315 Causes skin irritation. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. H335 May cause respiratory 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) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative Flam. Liq. 2: Flammable liquids, Hazard Category 2 Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2 Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2 Skin Sens. 1: Sensitisation - Skin, Hazard Category 1 STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3 \* \* Data compared to the previous version altered.