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

Printing date 26.04.2024

Version number 10 (replaces version 9)

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 for characterization of denture base materials
- · 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

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 GB CLP regulation.

· Hazard pictograms





GHS02

GHS07

· 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

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No

smoking.

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

P262 Do not get in eyes, on skin, or on clothing.

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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 or 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 Mixtures
- · **Description:** Mixture of substances listed below with nonhazardous additions.

· Dangerous components:		
CAS: 80-62-6 EINECS: 201-297-1 Reg.nr.: 01-2119452498-28-XXXX	methyl methacrylate Flam. Liq. 2, H225; Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	50-100%
CAS: 2082-81-7 EINECS: 218-218-1 Reg.nr.: 01-2119967415-30-XXXX	1,4-butanediol dimethacrylate Skin Sens. 1, H317	2.5-10%
CAS: 3077-12-1 EINECS: 221-359-1 Reg.nr.: 01-2120791684-40-xxxx	2,2'-[(4-methylphenyl)imino]bisethanol Eye Dam. 1, H318; Acute Tox. 4, H302; Skin Sens. 1, H317; Aquatic Chronic 3, H412	0.1-<1%

[·] 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.

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- 5.3 Advice for firefighters
- · Protective equipment: No special measures required.
- · 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

- · 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

- Regulatory information WEL: EH40/2020
- · 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.

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- · 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.

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

· Hand protection



Protective gloves (EN 374)

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/face protection



Tightly sealed goggles (EN 166)

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

General Information

· Colour: Colourless · Odour: Pungent Not determined. · Odour threshold:

-48 °C · Melting point/freezing point:

· Boiling point or initial boiling point and boiling

101 °C range

· Lower and upper explosion limit

· Lower: 2.1 Vol % · Upper: 12.5 Vol % · Flash point: 10 °C · Auto-ignition temperature: 430 °C $\cdot pH$ Not determined.

· Viscosity:

· Kinematic viscosity Not determined.

· Dynamic: Not determined.

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Solubility

• water at 20 °C: 1.6 g/l

· Partition coefficient n-octanol/water (log value) Not determined.

· Vapour pressure at 20 °C: 47 hPa

· Density and/or relative density

Density at 20 °C: 0.943 g/cm³
 Relative density Not determined.
 Vapour density Not determined.

• 9.2 Other information No further relevant information available.

· Appearance:

· Form:

· Important information on protection of health and

environment, and on safety.

• Ignition temperature: Product is not selfigniting.

• Explosive properties: Product is not explosive. However, formation of

explosive air/vapour mixtures are possible.

· Change in condition

· Evaporation rate Not determined.

· Information with regard to physical hazard classes

Explosives Void
Flammable gases Void
Aerosols Void
Oxidising gases Void
Gases under pressure Void

• Flammable liquids Highly flammable liquid and vapour.

· Flammable solids Void · Self-reactive substances and mixtures Void · Pyrophoric liquids Void · Pyrophoric solids Void Void · Self-heating substances and mixtures · Substances and mixtures, which emit flammable Void gases in contact with water Void · Oxidising liquids Void · Oxidising solids

Organic peroxides
 Corrosive to metals
 Desensitised explosives

Void

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.

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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.
- · LD/LC50 values relevant for classification:

Oral LD50 7872 mg/kg (rat)

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.

- · 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.
- · 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 For information on endocrine disrupting properties see section 11.
- · 12.7 Other adverse effects 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.

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.

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

14.1 UN number or ID number ADR/RID/ADN, IMDG, IATA	UNI 247
14.2 UN proper shipping name ADR/RID/ADN	1247 METHYL METHACRYLATE MONOMER, STABILIZED
IMDG, IATA	METHYL METHACRYLATE MONOMER, STABILIZ
14.3 Transport hazard class(es)	
ADR/RID/ADN	
Class Label	3 (F1) Flammable liquids.
IMDG, IATA	
Class Label	3 Flammable liquids.
	3
14.4 Packing group ADR/RID/ADN, IMDG, IATA	II
14.5 Environmental hazards: Marine pollutant:	No
14.6 Special precautions for user	Warning: Flammable liquids.
Hazard identification number (Kemler code):	339 E E C D
EMS Number: Stowage Category	F-E,S-D B
Stowage Code	SW2 Clear of living quarters.
14.7 Maritime transport in bulk according to IM	
instruments	Not applicable.
Transport/Additional information:	
ADR/RID/ADN	11
Limited quantities (LQ)	1L Code: E2
Excepted quantities (EQ)	Coae: 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

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· IMDG · Limited quantities (LQ) · Excepted quantities (EQ)	1L Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· UN "Model Regulation":	UNI 247, 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 5000 t
- Qualifying quantity (tonnes) for the application of upper-tier requirements 50000 t
- · National regulations:
- · Other regulations, limitations and prohibitive regulations

The product is a medical device according to Regulation 2017/745 on Medical Devices (MDR).

· 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

H225 Highly flammable liquid and vapour.

H302 Harmful if swallowed.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H335 May cause respiratory irritation.

H412 Harmful to aquatic life with long lasting effects.

Classification according to Regulation (EC) No 1272/2008

The classification of the mixture is generally based on the calculation method using substance data according to Regulation (EC) No 1272/2008.

Abbreviations and acronyms:

IMO: International Maritime Organization

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

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 – Category 2

Acute Tox. 4: Acute toxicity - Category 4

Skin Irrit. 2: Skin corrosion/irritation - Category 2

Eye Dam. 1: Serious eye damage/eye irritation - Category 1

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Skin Sens. 1: Skin sensitisation – Category 1 STOT SE 3: Specific target organ toxicity (single exposure) – Category 3 Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

*Data compared to the previous version altered.

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