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# Safety data sheet according to Regulation (EC) No 1907/2006, Article 31

Printing date 03.10.2024

Version number 10 (replaces version 9)

Revision: 03.10.2024

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

· 1.1 Product identifier

· Trade name: BASEPLAST 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 Heat-curing denture base material
- $\cdot$  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



· Signal word Danger

· Hazard-determining components of labelling: methyl methacrylate ethylene glycol 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. P261 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	l vPvB assessment

· **PBT:** Not applicable.

• **vPvB:** Not applicable.

## **SECTION 3: Composition/information on ingredients**

#### · 3.2 Mixtures

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

· Dangerous components:

Dungerous components.		
CAS: 80-62-6 EINECS: 201-297-1	methyl methacrylate Flam. Liq. 2, H225; Skin Irrit. 2, H315; Skin Sens. 1, H317;	50-100%
Reg.nr.: 01-2119452498-28-xxxx		
CAS: 97-90-5	ethylene glycol dimethacrylate	2.5-10%
EINECS: 202-617-2	Skin Sens. 1, H317; STOT SE 3, H335, EUH208	
Reg.nr.: 01-2119965172-38-xxxx	Specific concentration limit: STOT SE 3; H335: $C \ge 10 \%$	
· Additional information · For the	wording of the listed hazard phrases 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.

*Induce vomiting and call for medical help.* 

• 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**

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· 8.1 Control parameters
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· 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
- 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.
- · Individual protection measures, such as personal protective equipment
- · General protective and hygienic measures:

Usual hygienic measures for dental practice and dental laboratories.

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• 9.1 Information on basic physical and chemical properties • General Information		
· Colour:	Colourless	
· Odour:	Characteristic	
· Odour threshold:	Not determined	
• Melting point/freezing point:	-48 °C	
Boiling point or initial boiling point and boiling		
range	; 101 °C	
Lower and upper explosion limit	101 0	
Lower:	2.1 Vol %	
· Upper:	12.5 Vol %	
· Flash point:	12.5 VOI 70 10 °C	
• Auto-ignition temperature:	430 °C	
· pH	Not determined	
· Viscosity:	nor acterminea	
· Kinematic viscosity	Not determined	
· Dynamic:	Not determined	
· Solubility	1.01 0000000000000000000000000000000000	
• water at 20 °C:	1.6 g/l	
• Partition coefficient n-octanol/water (log value)	•	
· Vapour pressure at 20 °C:	47 hPa	

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Density and/or relative density	
Density at 20 °C:	0.943 g/cm <sup>3</sup>
Relative density	Not determined.
Vapour density	Not determined.
9.2 Other information	No further relevant information available.
Appearance:	
Form:	Fluid
Important information on protection of heal environment, and on safety.	'th and
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 of	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
Self-heating substances and mixtures	Void
Substances and mixtures, which emit flamm	able
gases in contact with water	Void
Oxidising liquids	Void
Oxidising solids	Void
Organic peroxides	Void
Corrosive to metals	Void
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.

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- $\cdot$  **10.4 Conditions to avoid** No further relevant information available.
- $\cdot \ \textit{10.5 Incompatible materials:} No further relevant information available.$
- 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.

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· 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.
- · 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.
- $\cdot$  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 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.

## **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.

• Uncleaned packaging:

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

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# Trade name: BASEPLAST Monomer

· 14.1 UN number or ID number · ADR/RID/ADN, IMDG, IATA	UN1247
· 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	3 (F1) Flammable liquids.
· Label · IMDG, IATA	3
· Class	3 Flammable liquids. 3
·Label	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.
<ul> <li>Hazard identification number (Kemler code):</li> <li>EMS Number:</li> </ul>	33 F-E,S-D
· Stowage Category	С
· Stowage Code	SW1 Protected from sources of heat. SW2 Clear of living quarters.
· 14.7 Maritime transport in bulk according to IM	
instruments	Not applicable.
· Transport/Additional information:	
· ADR/RID/ADN	
$\cdot$ Limited quantities (LQ)	
$\cdot$ 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
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$\cdot$ Limited quantities (LQ)	1L

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• Excepted quantities (EQ)

· UN "Model Regulation":

Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml

UN 1247 METHYL METHACRYLATE MONOMER, STABILIZED, 3, II

## SECTION 15: Regulatory information

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

· Regulated explosives precursors

None of the ingredients is listed.

#### · Regulated poisons

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None of the ingredients is listed.

· Reportable explosives precursors

None of the ingredients is listed.

· Reportable poisons

None of the ingredients is listed.

- · Directive 2012/18/EU
- $\cdot$  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.
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H335 May cause respiratory irritation.

EUH208 Contains . May produce an allergic reaction.

#### • 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* 

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Flam. Liq. 2: Flammable liquids – Category 2 Skin Irrit. 2: Skin corrosion/irritation – Category 2 Skin Sens. 1: Skin sensitisation – Category 1

STOT SE 3: Specific target organ toxicity (single exposure) - Category 3

 $\cdot$  \* Data compared to the previous version altered.

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