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

Printing date 06.08.2020 Version number 4 Revision: 06.08.2020

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

- · 1.1 Product identifier
  - · Trade name: Palabond
- · 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 Auxiliary for manufacture of dental prothesis
- · 1.3 Details of the supplier of the safety data sheet
  - Manufacturer/Supplier:

Kulzer GmbH

Leipziger Straße 2, 63450 Hanau (Germany)

Tel.: +49 (0)800 4372522

- · Informing department: E-Mail: msds@kulzer-dental.com
- · 1.4 Emergency telephone number: Emergency CONTACT (24-Hour-Number): +49 (0)6132-84463

#### 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 Corr. 1A H314 Causes severe skin burns and eye damage.

Eye Dam. 1 H318 Causes serious eye damage.

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







GHS02 GHS05

- · Signal word Danger
- · Hazard-determining components of labelling:

methyl methacrylate

methacrylic acid

tetramethylene dimethacrylate

maleic acid

meguinol

· Hazard statements

H225 Highly flammable liquid and vapour.

H314 Causes severe skin burns and eye damage.

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.

P260 Do not breathe mist/vapours/spray.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

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

P337+P313 If eye irritation persists: Get medical advice/attention.

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#### · Additional information:

1 % of the mixture consists of component(s) of unknown toxicity.

Contains 1 % of components with unknown hazards to the aquatic environment.

· 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**: Product based on methacrylates

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	<i>≥</i> 75- <i>≤</i> 90%
CAS: 79-41-4 EINECS: 201-204-4 Reg.nr.: 01-2119463884-26-XXXX	methacrylic acid Acute Tox. 3, H311 Skin Corr. 1A, H314; Eye Dam. 1, H318 Acute Tox. 4, H302; Acute Tox. 4, H332; STOT SE 3, H335 Specific concentration limit: STOT SE 3; H335: C ≥ 1 %	5%
CAS: 2082-81-7 EINECS: 218-218-1 Reg.nr.: 02-2119849716-25	tetramethylene dimethacrylate Skin Sens. 1B, H317	≥1-≤5%
CAS: 110-16-7 EINECS: 203-742-5 Reg.nr.: 01-2119488705-25-XXXX	maleic acid Eye Dam. 1, H318 Acute Tox. 4, H302; Acute Tox. 4, H312; Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	≥0.1-<1%
CAS: 131-57-7 EINECS: 205-031-5	2-Hydroxy-4-methoxy benzophenone Aquatic Acute 1, H400; Aquatic Chronic 2, H411	≥0-<0.25%
CAS: 150-76-5 EINECS: 205-769-8 Reg.nr.: 01-2119541813-40-XXXX	meguinol Acute Tox. 4, H302; Eye Irrit. 2, H319; Skin Sens. 1, H317 Aquatic Chronic 3, H412	≥0.1-<1%
CAS: 63393-96-4	Quaternary ammonium compounds, tri-C8-10- alkylmethyl, chlorides Acute Tox. 3, H301 Repr. 2, H361 Skin Corr. 1C, H314; Eye Dam. 1, H318 Aquatic Acute 1, H400 (M=10); Aquatic Chronic 1, H410 (M=1)	<i>≥</i> 0.025-<0.25%

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

· After inhalation Supply fresh air; consult doctor in case of symptoms.

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· After skin contact

Instantly wash with water and soap and rinse thoroughly.

If skin irritation continues, consult a doctor.

· After eye contact

Rinse opened eye for several minutes under running water. If symptoms persist, consult doctor.

After swallowing

Rinse out mouth and then drink plenty of water.

In case of persistent symptoms consult doctor.

Product based on methacrylates

· 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, sand, extinguishing powder. Do not use water.
  - · For safety reasons unsuitable extinguishing agents Water.
- · 5.2 Special hazards arising from the substance or mixture

Can form explosive gas-air mixtures.

Formation of toxic gases is possible during heating or in case of fire.

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

#### SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

Avoid contact with eyes and skin.

- **6.2 Environmental precautions:** Prevent material from reaching sewage system, holes and cellars.
- · 6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).

Do not flush with water or aqueous cleansing agents

Send for recovery or disposal in suitable containers.

6.4 Reference to other sections

See Section 13 for information on disposal.

See Section 8 for information on personal protection equipment.

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## SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

Keep containers tightly sealed.

Keep away from heat and direct sunlight.

Information about protection against explosions and fires:

Keep ignition sources away - Do not smoke.

Protect from heat.

Protect against electrostatic charges.

· 7.2 Conditions for safe storage, including any incompatibilities

Storage

· Requirements to be met by storerooms and containers: Store in cool location.

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- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions:

Store cool (not above 25 °C).

Store in cool, dry conditions in well sealed containers.

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 systems: No further data; see item 7.

· 8.1 Control <sub> </sub>	· 8.1 Control parameters			
· Compone	ents witl	h critical values t	that require monitoring at the workplace:	
80-62-6 metl	hyl meth	nacrylate		
		alue: 416 mg/m³, 1		
		lue: 208 mg/m³, 5	ьи ppm	
79-41-4 metl				
OES () Shor	t-term va -term va	alue: 143 mg/m³, 4 nlue: 72 mg/m³, 20	40 ppm	
		. 72 mg/m , 20	, ррш	
	DNELs			
	80-62-6 methyl methacrylate			
		lustr., l.te., syst.	74.3 mg/Kg/d (human)	
	worker industr., l.te., syst. 210 mg/m3 (human)			
110-16-7 ma	110-16-7 maleic acid			
Dermal wo	mal worker industr., acute, syst. 58 mg/Kg/d (nd)			
W	worker industr., I.te., syst. 3.3 mg/Kg/d (nd)			
·PN	· PNECs			
80-62-6 metl	80-62-6 methyl methacrylate			
freshwater	·			
110-16-7 ma	110-16-7 maleic acid			
freshwater	freshwater 0.074			
STP	TP 3.33 mg/l (nd)			
63393-96-4	63393-96-4 Quaternary ammonium compounds, tri-C8-10-alkylmethyl, chlorides			
marine water	marine water 0.02 mg/l (nd)			
STP		5.5 mg/l (nd)		
sedim., dw, fi	re.wat.	2.1 mg/Kg (nd)		
sedim., dw, n	edim., dw, mar.wat. 0.21 mg/Kg (nd)			

<sup>·</sup> Additional information: The lists that were valid during the compilation were used as basis.

#### · 8.2 Exposure controls

Personal protective equipment

General protective and hygienic measures
Keep away from foodstuffs, beverages and food.

Instantly remove any soiled and impregnated garments.

Wash hands during breaks and at the end of the work.

Avoid contact with the eyes and skin.

Breathing equipment:

Not neccessary with efficient local exhaust. If exposition to vapours is possible, use breathing protective mask (filter A).

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· Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

If skin contact cannot be avoided, protective gloves are recommended to avoid possible sensitization.

Solvent resistant gloves

Check protective gloves prior to each use for their proper condition.

recommended

Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· Penetration time of glove material

The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:

Butyl rubber, BR Nitrile rubber, NBR

Eye protection: Tightly sealed safety glasses.

Body protection: Light weight protective clothing

## SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties General Information Appearance:			
Form:	Fluid		
Colour:	Colourless		
· Smell:	Characteristic		
· Odour threshold:	Not determined.		
· pH-value:	Not determined.		
· Change in condition · Melting point/freezing point: · Initial boiling point and boiling ra	Not determined ange: 100 °C		
· Flash point:	10 °C		
· Inflammability (solid, gaseous)	Not applicable.		
· Ignition temperature:	370.0 °C		
· Decomposition temperature:	Not determined.		
· Self-inflammability:	Product is not selfigniting.		
Explosive properties:	Product is not explosive. However, formation of explosive air/vapour mixtures is possible.		
· Critical values for explosion:			
	0.434.404		
· Lower:	2.1 Vol %		

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· Steam pressure at 20 °C:	47 hPa	
· Density at 20 °C	0.940 g/cm³	
· Relative density	Not determined.	
· Vapour density	Not determined.	
Evaporation rate	Not determined.	
· Solubility in / Miscibility with		
· Water:	Not miscible or difficult to mix	
· Partition coefficient: n-octanol/	water: Not determined.	
· Viscosity:		
· dynamic at 20 °C:	1 mPas	
· kinematic:	Not determined.	
· Solvent content:		
· VOC EU	841.2 g/l	
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
  - Conditions to be avoided: No decomposition if used and stored 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
  - Additional information:

If stored longer than recommended and/or above recommended temperature, product may polymerize generating heat.

## SECTION 11: Toxicological information

- 11.1 Information on toxicological effects
  - · Acute toxicity Based on available data, the classification criteria are not met.

· LD/	· LD/LC50 values that are relevant for classification:		
80-62-6 m	80-62-6 methyl methacrylate		
Oral	LD50	~7,900 mg/kg (rat)	
Dermal	LD50	>5,000 mg/kg (rab) (OECD 402)	
Inhalative	LC50/4 h	/4 h   29.8 mg/l (rat)	
79-41-4 m	79-41-4 methacrylic acid		
Oral	LD50	1,320 mg/kg (rat) (OECD 401)	
Dermal	LD50	500-1,000 mg/kg (rab)	
Inhalative	LC50/4 h	7.1 mg/l (rat) (OECD 403)	
2082-81-7	2082-81-7 tetramethylene dimethacrylate		
Oral	LD50	10,066 mg/kg (rat) (OECD 401)	
110-16-7	110-16-7 maleic acid		
Oral	LD50	708 mg/kg (rat)	
Dermal	LD50	1,560 mg/kg (rabbit)	
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131-57-7	131-57-7 2-Hydroxy-4-methoxy benzophenone		
Oral	LD50	>12,800 mg/kg (rat) (OECD 401)	
Dermal	LD50	>16,000 mg/kg (rabbit) (OECD 402)	
150-76-5	150-76-5 mequinol		
Oral	LD50	1,630 mg/kg (rat)	
Dermal	LD50	>2,000 mg/kg (rat)	
63393-96-	63393-96-4 Quaternary ammonium compounds, tri-C8-10-alkylmethyl, chlorides		
Oral	LD50	>200-<2,000 mg/kg (rat) (OECD 401)	

- · Primary irritant effect:
  - Skin corrosion/irritation

Causes severe skin burns and eye damage.

- · Serious eye damage/irritation Causes serious eye damage.
- · Respiratory or skin sensitisation

May cause an allergic skin reaction.

- CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
  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.

12.1 Toxicity	/	
· Aquatic t	oxicity:	
80-62-6 metl	hyl methacrylate	
EC50/48h	69 mg/l (daphnia)	
LC50/96h	191 mg/l (fish)	
79-41-4 metl	hacrylic acid	
EC50/72h	45 mg/l (algae)	
EC50/48h	>130 mg/l (daphnia)	
LC50/96h	85 mg/l (fish)	
NOEC / 21d	53 mg/l (daphnia)	
NOEC / 72h	8.2 mg/l (algae)	
110-16-7 ma	leic acid	
EC50/72h	74.35 mg/l (algae)	
EC50/48h	42.81 mg/l (daphnia)	
LC50/96h	5 mg/l (fish)	
150-76-5 me	quinol	
EC50/48h	3 mg/l (daphnia)	
LC50/96h	28.5 mg/l (fish)	
NOEC / 21d	0.68 mg/l (daphnia)	
IC 50/ 72h	171.4 mg/l (bacteria)	
ErC50 / 72 h	54.7 mg/l (algae)	



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#### NOEC / 72h | 2.96 mg/l (algae)

- 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:

Do not allow undiluted product or large quantities of it to reach ground water, water bodies 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 of together with household garbage. Do not allow product to reach sewage

Disposal must be made according to official regulations.

European waste catalogue

18 01 06\* chemicals consisting of or containing hazardous substances

- · Uncleaned packagings:
  - Recommendation:

Disposal must be made according to official regulations.

Non contaminated packagings can be used for recycling.

SECTION 14: Transport information	
· 14.1 UN-Number · ADR, IMDG, IATA	2924
· 14.2 UN proper shipping name · ADR · IMDG, IATA	2924 FLAMMABLE LIQUID, CORROSIVE, N.O.S. (METHYL METHACRYLATE MONOMER, STABILIZED, METHACRYLIC ACID, STABILIZED) FLAMMABLE LIQUID, CORROSIVE, N.O.S. (METHYL METHACRYLATE MONOMER, STABILIZED, METHACRYLIC ACID, STABILIZED)

- · 14.3 Transport hazard class(es)
  - · ADR





3 (FC) Flammable liquids. · Class

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(Contd. of page 8) 3+8 · Label · IMDG, IATA 3 Flammable liquids. · Class · Label 14.4 Packing group ADR, IMDG, IATA · 14.5 Environmental hazards: Marine pollutant: No · 14.6 Special precautions for user Warning: Flammable liquids. · Kemler Number: 338 · EMS Number: F-E,S-C 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code Not applicable. · Transport/Additional information: · UN "Model Regulation": UN2924, FLAMMABLE LIQUID, CORROSIVE, N.O.S. (METHYL METHACRYLATE MONOMER, STABILIZED, METHACRYLIC ACID, STABILIZED), 3 (8), II

#### SECTION 15: Regulatory information

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
  - · Directive 2012/18/EU
    - 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 to REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3
- · 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

#### SECTION 16: Other information

These data are based on our present knowledge. However, they 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.

H301 Toxic if swallowed.

H302 Harmful if swallowed.

H311 Toxic in contact with skin.

H312 Harmful in contact with skin.

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

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H332 Harmful if inhaled.

H335 May cause respiratory irritation.

H361 Suspected of damaging fertility or the unborn child.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

H411 Toxic to aquatic life with long lasting effects.

H412 Harmful to aquatic life with long lasting effects.

#### 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)

VOCV: Lenkungsabgabe auf flüchtigen organischen Verbindungen, Schweiz (Swiss Ordinance on volatile organic

DNEL: Derived No-Effect Level (REACH)
PNEC: Predicted No-Effect Concentration (REACH)
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 - oral - Category 4
Acute Tox. 3: Acute toxicity - oral - Category 3
Skin Corr. 1A: Skin corrosion/irritation - Category 1A
Skin Corr. 1C: Skin corrosion/irritation - Category 1C
Skin Irrit. 2: Skin corrosion/irritation - Category 2
Eye Dam. 1: Serious eye damage/eye irritation - Category 1
Eye Irrit. 2: Serious eye damage/eye irritation - Category 1
Eye Irrit. 2: Serious eye damage/eye irritation - Category 2
Skin Sens. 1: Skin constitication. Category 1

Skin Sens. 1: Skin sensitisation - Category 1

Skin Sens. 1B: Skin sensitisation - Category 1B

Repr. 2: Reproductive toxicity – Category 2 STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard - Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard — Category 1 Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard — Category 2 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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