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

Printing date 21.07.2020 Version number 4 Revision: 21.07.2020

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

- · 1.1 Product identifier
  - · Trade name: Palapress liquid
- · 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 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 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





GHS02 GHS07

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

methyl methacrylate

tetramethylene 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. P261

P280 Wear protective gloves / eye protection. P302+P352 IF ON SKIN: Wash with plenty of soap and water.

Call a doctor if you feel unwell.

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 -

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- · 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	>90%
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%
CAS: 131-57-7 EINECS: 205-031-5	2-Hydroxy-4-methoxy benzophenone Aquatic Acute 1, H400; Aquatic Chronic 2, H411	<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%
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)	≥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.
  - · After skin contact If skin irritation continues, consult a doctor.
  - · After eye contact

Rinse opened eye for several minutes under running water. Then consult doctor.

- · After swallowing
- Rinse out mouth and then drink plenty of water. In case of persistent symptoms consult doctor.
- · 4.2 Most important symptoms and effects, both acute and delayed Allergic reactions

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· 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.

- 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).

· 6.4 Reference to other sections

No dangerous materials are released.

See Section 7 for information on safe handling

See Section 8 for information on personal protection equipment.

See Section 13 for information on disposal.

# SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

Keep containers tightly sealed.

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

Ensure good interior ventilation, especially at floor level. (Fumes are heavier than air).

Information about protection against explosions and fires:

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 containers: Store in cool location.
    - · 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.

• 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.

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# · 8.1 Control parameters

· 8.1 Control parameters			
· Componen	nts with cri	tical values t	hat require monitoring at the workplace:
80-62-6 methy	/l methacry	/late	
			alue: 416 mg/m³, 100 ppm alue: 208 mg/m³, 50 ppm
IOELV (European Union) Short-term vo Long-term vo		Short-term va Long-term va	alue: 100 ppm alue: 50 ppm
· DNE	Ls		
80-62-6 methy	/l methacry	/late	
Dermal wor	worker industr., l.te., syst.		74.3 mg/Kg/d (human)
Inhalative worker industr., l.te., syst.		, l.te., syst.	210 mg/m3 (human)
110-16-7 male	ic acid		
Dermal wor	ker industr.	, acute, syst.	58 mg/Kg/d (nd)
wor	ker industr.	, l.te., syst.	3.3 mg/Kg/d (nd)
·PNE	Cs		
80-62-6 methy	/I methacry	/late	
freshwater	0.94	0.94 mg/l (aqua)	
110-16-7 male	ic acid		
freshwater	0.07	0.074 mg/l (nd)	
STP	3.33	3 mg/l (nd)	
63393-96-4 Qu	uaternary a	mmonium c	ompounds, tri-C8-10-alkylmethyl, chlorides

# · 8.2 Exposure controls

sedim., dw, fre.wat.

marine water

STP

### Personal protective equipment

sedim., dw, mar.wat. 0.21 mg/Kg (nd)

### General protective and hygienic measures

0.02 mg/l (nd) 5.5 mg/l (nd)

2.1 mg/Kg (nd)

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).

### 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 (Contd. on page 5)

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



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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 General Information Appearance:	chemical properties
Form:	Fluid
· Colour:	Colourless
· Smell:	Ester-like
· Odour threshold:	Not determined.
· pH-value:	Not determined.
· Change in condition · Melting point/freezing point: · Initial boiling point and boiling r	-48 °C range: 100 °C
· Flash point:	15 °C
· Inflammability (solid, gaseous)	Not applicable.
· Ignition temperature:	430 °C
· Decomposition temperature:	Not determined.
· Self-inflammability:	Product is not selfigniting.
· Explosive properties:	Product is not explosive. However, formation o explosive air/vapour mixtures is possible.
· Critical values for explosion: · Lower: · Upper:	2.1 Vol % 12.5 Vol %
· Steam pressure at 20 °C:	47 hPa
· Density at 20 °C	0.94559 g/cm³
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/wate	er: Not determined.
· Viscosity: · dynamic at 20 °C:	1 mPas

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· Solvent content:

· Water:

0.1 %

· Solids content:

0.0 %

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.

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# SECTION 11: Toxicological information

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

· LD/	LC50 valu	es that are relevant for classification:	
80-62-6 m	ethyl met	hacrylate	
Oral	LD50	~7,900 mg/kg (rat)	
Dermal	LD50	>5,000 mg/kg (rab) (OECD 402)	
Inhalative	LC50/4 h	29.8 mg/l (rat)	
2082-81-7	tetrametl	hylene dimethacrylate	
Oral	LD50	10,066 mg/kg (rat) (OECD 401)	
110-16-7	maleic aci	d	
Oral	LD50	708 mg/kg (rat)	
Dermal	LD50	1,560 mg/kg (rabbit)	
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	mequinol		
Oral	LD50	1,630 mg/kg (rat)	
Dermal	LD50	>2,000 mg/kg (rat)	
63393-96-	4 Quatern	nary ammonium compounds, tri-C8-10-alkylmethyl, chlorides	
Oral	LD50	>200-<2,000 mg/kg (rat) (OECD 401)	
. Drii	mary irrita	nt offoct:	

- · Primary irritant effect:
  - Skin corrosion/irritation

Causes skin irritation.

Serious eye damage/irritation

Based on available data, the classification criteria are not met.

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· 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.

# **SECTION 12: Ecological information**

#### · 12.1 Toxicity

· 12.1 loxicity	,
· Aquatic to	oxicity:
80-62-6 meth	nyl methacrylate
EC50/48h	69 mg/l (daphnia)
LC50/96h	191 mg/l (fish)
110-16-7 mai	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 med	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)
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.

Do not allow product to reach ground water, water bodies or sewage system.

Danger to drinking water if even small quantities leak into soil.

- · 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 system.

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Disposal must be made according to official regulations.

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· 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	on
14.1 UN-Number · ADR, IMDG, IATA	UN1247
14.2 UN proper shipping name · ADR	1247 METHYL METHACRYLA MONOMER, STABILIZED solution
· IMDG, IATA	METHYL METHACRYLATE MONOM STABILIZED solution
14.3 Transport hazard class(es)	
· ADR	
· Class · Label	3 (F1) Flammable liquids. 3
· IMDG, IATA	
· Class · Label	3 Flammable liquids. 3
14.4 Packing group · ADR, IMDG, IATA	II
14.5 Environmental hazards: · Marine pollutant:	No
14.6 Special precautions for user	Warning: Flammable liquids.
Kemler Number: EMS Number:	339 F-E,S-D
· Stowage Category	В
Stowage Code	SW2 Clear of living quarters.
14.7 Transport in bulk according to Anne Marpol and the IBC Code	ex II of Not applicable.

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· ADR

Limited quantities (LQ)

Excepted quantities (ÉQ)

Code: E2

Maximum net quantity per inner

packaging: 30 ml

Maximum net quantity per outer

packaging: 500 ml

· Transport category

Tunnel restriction code

D/E

· Limited quantities (LQ)

Excepted quantities (ÉQ)

Code: E2

Maximum net quantity per inner

packaging: 30 ml

Maximum net quantity per outer

packaging: 500 ml

UN "Model Regulation":

UN 1247 METHYL METHACRYLATE MONOMER, STABILIZED SOLUTION, 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.
    - · Seveso category P5c FLAMMABLE LIQUIDS
    - 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 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.

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.

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.

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· 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) 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

Flam. Ltq. 2: Flammable liquids — Category 2
Acute Tox. 3: Acute toxicity - oral — Category 3
Acute Tox. 4: Acute toxicity - oral — Category 4
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 2
Skin Sens. 1: Skin sensitisation — Category 1
Skin Sens. 1B: Skin sensitisation — Category 1B
Renr. 2: Reproductive toxicity — Category 2

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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