



**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/undertaking

· **1.1 Product identifier**

· Trade name: **Palapress vario 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.

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

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

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

· **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.

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· **vPvB:** Not applicable.

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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	<i>methyl methacrylate</i> 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	<i>tetramethylene dimethacrylate</i> Skin Sens. 1B, H317	≥1-≤5%
CAS: 99-85-4 EINECS: 202-794-6	<i>p-Mentha-1,4-diene</i> Flam. Liq. 3, H226 Repr. 2, H361 Aquatic Chronic 2, H411	<0.25%
CAS: 63393-96-4	<i>Quaternary ammonium compounds, tri-C8-10-alkylmethyl, chlorides</i> 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%
CAS: 110-16-7 EINECS: 203-742-5 Reg.nr.: 01-2119488705-25-XXXX	<i>maleic acid</i> 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: 10125-13-0	<i>Kupfer-II-chlorid-2-hydrat</i> Eye Dam. 1, H318 Aquatic Acute 1, H400 (M=10); Aquatic Chronic 2, H411 Acute Tox. 4, H302; Acute Tox. 4, H312; Skin Irrit. 2, H315	≥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** Instantly wash with water and soap and rinse thoroughly.

· **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.

· **4.2 Most important symptoms and effects, both acute and delayed**

No further relevant information available.

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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 8 for information on personal protection equipment.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** Keep containers tightly sealed.
 - **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.

8.1 Control parameters

- **Components with critical values that require monitoring at the workplace:**

80-62-6 methyl methacrylate

OES ()	Short-term value: 416 mg/m ³ , 100 ppm Long-term value: 208 mg/m ³ , 50 ppm
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· DNELs		
80-62-6 methyl methacrylate		
Dermal	worker industr., l.te., syst.	74.3 mg/Kg/d (human)
Inhalative	worker industr., l.te., syst.	210 mg/m3 (human)
110-16-7 maleic acid		
Dermal	worker industr., acute, syst.	58 mg/Kg/d (nd)
	worker industr., l.te., syst.	3.3 mg/Kg/d (nd)
· PNECs		
80-62-6 methyl methacrylate		
freshwater	0.94 mg/l (aqua)	
63393-96-4 Quaternary ammonium compounds, tri-C8-10-alkylmethyl, chlorides		
marine water	0.02 mg/l (nd)	
STP	5.5 mg/l (nd)	
sedim., dw, fre.wat.	2.1 mg/Kg (nd)	
sedim., dw, mar.wat.	0.21 mg/Kg (nd)	
110-16-7 maleic acid		
freshwater	0.074 mg/l (nd)	
STP	3.33 mg/l (nd)	

· **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 necessary 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 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 through 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

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Nitrile rubber, NBR

- **Eye protection:** 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:** Not determined
- **Initial boiling point and boiling range:** 100 °C

· **Flash point:** 10 °C

· **Inflammability (solid, gaseous)** Not applicable.

· **Ignition temperature:** 430.0 °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:**

- **Lower:** 2.1 Vol %
- **Upper:** 12.5 Vol %

· **Steam pressure at 20 °C:** 47 hPa

· **Density at 20 °C** 0.950 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:**

· **Water:** 0.1 %

· **Solids content:** 0.3 %

· **9.2 Other information** No further relevant information available.

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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/LC50 values that are relevant for classification:**

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	29.8 mg/l (rat)

2082-81-7 tetramethylene dimethacrylate

Oral	LD50	10,066 mg/kg (rat) (OECD 401)
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99-85-4 p-Mentha-1,4-diene

Oral	LD50	>2,000 mg/kg (rat) (OECD 423)
Dermal	LD50	>2,000 mg/kg (rat) (OECD 402)

63393-96-4 Quaternary ammonium compounds, tri-C8-10-alkylmethyl, chlorides

Oral	LD50	>200-<2,000 mg/kg (rat) (OECD 401)
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110-16-7 maleic acid

Oral	LD50	708 mg/kg (rat)
Dermal	LD50	1,560 mg/kg (rabbit)

10125-13-0 Kupfer-II-chlorid-2-hydrat

Oral	LD50	584 mg/kg (rat)
Dermal	LD50	1,224 mg/kg (rat) (OECD 402)

- **Primary irritant effect:**
 - **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.
- **CMR effects (carcinogenicity, 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.

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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:**

80-62-6 methyl methacrylate

EC50/48h | 69 mg/l (daphnia)

LC50/96h | 191 mg/l (fish)

110-16-7 maleic acid

EC50/72h | 74.35 mg/l (algae)

EC50/48h | 42.81 mg/l (daphnia)

LC50/96h | 5 mg/l (fish)

· **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 system.

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**

1247

· **14.2 UN proper shipping name**

· **ADR**

1247 METHYL METHACRYLATE
MONOMER, STABILIZED, solution

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· IMDG, IATA	METHYL METHACRYLATE MONOMER, STABILIZED, solution
· 14.3 Transport hazard class(es)	
· ADR	
	
· Class	3 (F1) Flammable liquids.
· Label	3
· IMDG, IATA	
	
· Class	3 Flammable liquids.
· Label	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:	339
· EMS Number:	F-E,S-D
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	-
· UN "Model Regulation":	UN1247, 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**
 - **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.

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H226 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.
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.

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. Liq. 3: Flammable liquids – Category 3
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
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

*** Data compared to the previous version altered.**