



**Safety Data Sheet
according to HPR, Schedule 1**

Printing date 07/31/2023

Reviewed on 07/31/2023

1 Identification

· **Product identifier**

· **Trade name: Palapress vario liquid**

· -

· **Application of the substance / the mixture** Manufacture of dental prothesis

· **Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**

Kulzer GmbH

Leipziger Straße 2, 63450 Hanau (Germany)

Tel.: +49 (0)800 4372522

· **Information department:**

Tel. +1 (800) 431-1785 Fax: +1 (800) 522-1545

e-mail: customer.servicehkna@kulzer-dental.com

· **Emergency telephone number:**

Emergency CONTACT (24-Hour-Number)

ID 105860: (domestic) 1 800 535 5053 or international (001) 352 323 3500

2 Hazard identification

· **Classification of the substance or mixture**

Flammable Liquids - Category 2

H225 Highly flammable liquid and vapour.

Skin Irritation - Category 2

H315 Causes skin irritation.

Skin Sensitizer - Category 1

H317 May cause an allergic skin reaction.

Reproductive Toxicity - Category 2

H361 Suspected of damaging fertility or the unborn child.

Specific Target Organ Toxicity - Single Exposure - Category 3

H335 May cause respiratory irritation.

· **Label elements**

· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**



GHS02 GHS07 GHS08

· **Signal word** Danger

· **Hazard-determining components of labeling:**

methyl methacrylate

1,4-butandiol dimethacrylate

· **Hazard statements**

Highly flammable liquid and vapour.

Causes skin irritation.

May cause an allergic skin reaction.

Suspected of damaging fertility or the unborn child.

May cause respiratory irritation.

· **Precautionary statements**

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

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

Wear protective gloves / eye protection.

Wear protective clothing.

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

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- **Additional information:**
1 % of the mixture consists of an ingredient or ingredients of unknown acute toxicity.
- **Classification system**
- **NFPA ratings for USA (scale 0-4)**



Health = 2
Fire = 3
Reactivity = 2

- **HMIS-Ratings (Scale 0-4)**



Health = 1
Fire = 3
Reactivity = 2

- **Other hazards -**

3 Composition/Information on ingredients

- **Chemical characterization: Mixtures**
- **Description:** Composition based on methacrylates

- **Dangerous components:**

80-62-6	<i>methyl methacrylate</i> Flammable Liquids - Category 2, H225 Skin Irritation - Category 2, H315; Skin Sensitizer - Category 1, H317; Specific Target Organ Toxicity - Single Exposure - Category 3, H335	>90% w/w
2082-81-7	<i>1,4-butandiol dimethacrylate</i> Skin Sensitizer - Category 1B, H317	≥1-≤5% w/w *
99-85-4	<i>p-Mentha-1,4-diene</i> Flammable Liquids - Category 3, H226 Reproductive Toxicity - Category 2, H361	≥0,1- <0,5% w/w *
63393-96-4	<i>Quaternary ammonium compounds, tri-C8-10-alkylmethyl, chlorides</i> Acute Toxicity (Oral) - Category 3, H301 Reproductive Toxicity - Category 2, H361 Skin Corrosion - Category 1C, H314; Serious Eye Damage - Category 1, H318 Flammable Liquids - Category 4, H227	≥0,1- <0,2% w/w *

* Actual concentration ranges are withheld as a trade secret.

- **Additional information** For the wording of the listed hazard phrases refer to section 16.

4 First-aid measures

- **Description of first aid measures**

- **After inhalation** Supply fresh air; consult doctor in case of complaints.
- **After skin contact** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing**
Rinse out mouth and then drink plenty of water.
If symptoms persist consult doctor.

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- **Information for doctor**
 - **Most important symptoms and effects, both acute and delayed**
No further relevant information available.
 - **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire-fighting measures

- **Extinguishing media**
 - **Suitable extinguishing agents** CO₂, sand, extinguishing powder. Do not use water.
 - **For safety reasons unsuitable extinguishing agents** Water.
- **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.
- **Advice for firefighters**
 - **Protective equipment:** No special measures required.
- **Additional information** -

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
- **Environmental precautions:** Prevent seepage into sewage system, workpits and cellars.
- **Methods and material for containment and cleaning up:**
Absorb with liquid binding material (diatomite, universal binders, for small amounts tissues).
- **Reference to other sections**
No dangerous substances are released.
See Section 8 for information on personal protection equipment.
-

7 Handling and storage

- **Handling**
 - **Precautions for safe handling** Keep receptacles tightly sealed.
 - **Information about protection against explosions and fires:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
- **Conditions for safe storage, including any incompatibilities**
 - **Storage**
 - **Requirements to be met by storerooms and receptacles:** Store in a cool location.
 - **Information about storage in one common storage facility:** Not required.
 - **Further information about storage conditions:**
Keep cool, if possible (not above 25 °C).
Store in cool, dry conditions in well sealed receptacles.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/ Personal protection

- **Additional information about design of technical systems:** No further data; see section 7.

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· **Control parameters**

· **Components with limit values that require monitoring at the workplace:**

80-62-6 methyl methacrylate

EL	STEL: 100 ppm TWA: 50 ppm S(D)
EV	STEL: 100 ppm TWA: 50 ppm

· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**

· **Personal protective equipment**

· **General protective and hygienic measures**

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.

· **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

Nitrile rubber, NBR

· **Eye protection:** Safety glasses

· **Body protection:** Light weight protective clothing

9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

· **Form:** Fluid
· **Color:** Colorless

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· Odor:	Characteristic
· Odor threshold:	Not determined.
· pH-value:	Mixture is non-soluble (in water).
· Change in condition	
· Melting point/Melting range:	undetermined
· Boiling point/Boiling range:	100 °C (212 °F)
· Flash point:	10 °C (50 °F)
· Flammability (solid, gaseous)	Not applicable.
· Auto igniting:	430,0 °C (806 °F)
· Decomposition temperature:	Not determined.
· Ignition temperature:	Product is not selfigniting.
· Danger of explosion:	Product is not explosive. However, formation of explosive air/vapor mixtures are possible.
· Explosion limits:	
· Lower:	2,1 Vol %
· Upper:	12,5 Vol %
· Vapor pressure at 20 °C (68 °F):	47 hPa (35,3 mm Hg)
· Density at 20 °C (68 °F):	0,950 g/cm ³ (7,92775 lbs/gal)
· Relative density	Not determined.
· Vapor 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 (68 °F):	1 mPas
· kinematic:	Not determined.
· Solvent content:	
· Water:	0,1 %
· Solids content:	0,3 %
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Possibility of hazardous reactions** No dangerous reactions known
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** none
- **Additional information:**
Product might polymerize after considerable exceeding of recommended storage time or temperature.

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11 Toxicological information

· **Information on toxicological effects**

· **Acute toxicity:**

· **LD/LC50 values that are relevant for classification:**

80-62-6 methyl methacrylate

Oral	LD50	~7.900 mg/kg (rat) weight of evidence
Dermal	LD50	>5.000 mg/kg (guinea pig) (OECD 402)
Inhalative	LC50/4 h	29,8 mg/l (rat)

2082-81-7 1,4-butandioldimethacrylate

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 mg/kg (ATE) >200-<2.000 mg/kg (rat) (OECD 401)
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· **Primary irritant effect:**

- **on the skin:** Irritant to skin and mucous membranes.
- **on the eye:** No irritating effect.

· **Sensitization:** Sensitization possible through skin contact.

· **Additional toxicological information:**

The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
Irritant

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

80-62-6	methyl methacrylate	3
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· **NTP (National Toxicology Program)**

None of the ingredients is listed.

· **Reproductive toxicity** Based on available data, the classification criteria are not met.

12 Ecological information

· **Toxicity**

· **Aquatic toxicity:**

80-62-6 methyl methacrylate

EC50/21d	49 mg/L (daphnia) (OECD 211)
EC50/48h	69 mg/l (daphnia) (EPA OTS 797.1300)
NOEC / 21d	37 mg/l (daphnia) (OECD 211)
ErC50 / 72 h	>110 mg/l (algae) (OECD 201)
NOEC / 72h	110 mg/l (algae) (OECD 201)
NOEC / 48h	48 mg/l (daphnia) (EPA OTS 797.1300)
EbC50 / 72h	>110 mg/l (algae) (OECD 201)
NOEC/ 35d	9,4 mg/L (fish) (OECD 210)

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LC50/ 35d	33,7 mg/L (fish) (OECD 210)
2082-81-7 1,4-butandioldimethacrylate	
EC50/21d	14,1 mg/L (daphnia) (OECD 211)
EC50/48h	32,5 mg/l (fish)
NOEC / 21d	5,09 mg/l (daphnia) (OECD 211)
ErC50 / 72 h	9,79 mg/l (algae) (OECD 201)
NOEC / 72h	2,11 mg/l (algae) (OECD 201)
NOEC / 48h	25 mg/l (fish)
ErC10/72h	4,35 mg/L (algae) (OECD 201)
99-85-4 p-Mentha-1,4-diene	
EC50/72h	>10,82 mg/l (algae) (OECD 201)
EC50/48h	10,189 mg/l (daphnia) (OECD 202)
LC50/96h	2,792 mg/l (fish) (OECD 203)
63393-96-4 Quaternary ammonium compounds, tri-C8-10-alkylmethyl, chlorides	
EC50/48h	0,16 mg/l (daphnia) (OECD 202)
LC50/96h	0,15 mg/l (fish) (OECD 203)
ErC50 / 72 h	0,29 mg/l (algae) (OECD 201)
ErC10/72h	0,138 mg/L (algae) (OECD 201)

Persistence and degradability

80-62-6 methyl methacrylate

biodegradability 94 % /14d (not defined) (OECD 301C)

2082-81-7 1,4-butandioldimethacrylate

biodegradability 84 % /28d (not defined) (OECD 310)

99-85-4 p-Mentha-1,4-diene

biodegradability 27 % /28d (not defined) (OECD 301F; ISO 9408/ EEC 92/69/V, C.4-D)

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

biodegradability 10-<20 % /60d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)

Behavior in environmental systems:

· **Bioaccumulative potential** No further relevant information available.

· **Mobility in soil** No further relevant information available.

Additional ecological information:

· **General notes:**

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

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

Danger to drinking water if even small quantities leak into the ground.

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **Other adverse effects** No further relevant information available.

13 Disposal considerations

· **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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· Uncleaned packagings:

· Recommendation:

Disposal must be made according to official regulations.
Non contaminated packagings can be used for recycling.

14 Transport information

· UN-Number

· DOT/TDG, ADR, IMDG, IATA UN1247

· UN proper shipping name

· DOT/TDG Methyl methacrylate monomer, stabilized solution
1247 Methyl methacrylate monomer, stabilized solution
· ADR METHYL METHACRYLATE MONOMER, STABILIZED solution
· IMDG, IATA

· Transport hazard class(es)

· DOT/TDG (Transport dangerous goods):



· Class 3 Flammable liquids
· Label 3

· ADR



· Class 3 (F1) Flammable liquids
· Label 3

· IMDG, IATA



· Class 3 Flammable liquids
· Label 3

· Packing group

· DOT/TDG, ADR, IMDG, IATA II

· Environmental hazards:

· Marine pollutant: No

· Special precautions for user

Warning: Flammable liquids

· Hazard identification number (Kemler code): 339
· EMS Number: F-E, S-D

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· Stowage Category	B
· Stowage Code	SW2 Clear of living quarters.
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
· Transport/Additional information:	-
· ADR	
· Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· IMDG	
· Limited quantities (LQ)	1L
· Excepted quantities (EQ)	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

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**
No further relevant information available.

· **Sara**

· **SARA Section 355 (extremely hazardous substances)**

None of the ingredients is listed.

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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.

H226 Flammable liquid and vapour.

H227 Combustible liquid.

H301 Toxic if swallowed.

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.

· **Date of the latest revision of the safety data sheet** 07/31/2023

· **Abbreviations and acronyms:**

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial Chemical Substances

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*ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)
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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*** Data compared to the previous version altered.**

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