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Revision: 31.07.2023

Tel.: +49 (0)800 4372522

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

Printing date 31.07.2023

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Version number 4 (replaces version 3)

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

· 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)

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 GB CLP regulation.

· Hazard pictograms





GHS02 GHS07

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

methyl methacrylate

1,4-butandioldimethacrylate

· 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 / eye protection.

P280 Wear protective clothing.

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 -

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- · Results of PBT and vPvB assessment
 - · **PBT:** Not applicable. · **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

· 3.2 Mixtures

· **Description:** Product based on methacrylates

· Dangerous components:		
CAS: 80-62-6 EINECS: 201-297-1	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	1,4-butandioldimethacrylate Skin Sens. 1B, H317	≥1-≤5%
CAS: 99-85-4 EINECS: 202-794-6	p-Mentha-1,4-diene Flam. Liq. 3, H226 Repr. 2, H361 Aquatic Chronic 2, H411	<0.25%
CAS: 63393-96-4 EINECS: 264-120-7	Quaternary ammonium compounds, tri-C8-10-alkylmethyl, chlorides Acute Tox. 3, H301 Repr. 2, H361 Skin Corr. 1C, H314; Eye Dam. 1, H318 Aquatic Chronic 1, H410 (M=1) ATE: LD50 oral: 200 mg/kg	≥0.025-<0.25%
CAS: 10125-13-0	copper(2+) chloride hydrate (1:2:2) 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.
- · 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.

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· 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

· 8.1 Control parameters

· Components with critical values that require monitoring at the workplace:		
80-62-6 methyl methacry	late	
	Short-term value: 416 mg/m³, 100 ppm	
	Long-term value: 208 mg/m³, 50 ppm	

IOELV (European Union) Short-term value: 100 ppm

Long-term value: 50 ppm

· DNELs

80-62-6 methyl methacrylate

	general population, long term, systemic	8.2 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	13.67 mg/Kg/d (not defined)
		8.2 mg/Kg/d (not defined)
Inhalativa	worker industrial couts local	116 ma/m2 (not defined)

Inhalative worker industrial, acute, local 416 mg/m3 (not defined)

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	worker industrial, long ter		348.4 mg/m3 (not defined)	
	worker industrial, long te	·	208 mg/m3 (not defined)	
	general population, acute		208 mg/m3 (not defined)	
	general population, long	•	74.3 mg/m3 (not defined)	
	1,4-butandioldimethacı	rylate		
Oral	general population, long	term, systemic	2.5 mg/Kg (not defined)	
	worker industrial, long te	-	4.2 mg/Kg/d (not defined)	
	general population, long		2.5 mg/Kg/d (not defined)	
Inhalative	worker professional, long	term, systemic	14.5 mg/m3 (not defined)	
	general population, long	•	4.3 mg/m3 (not defined)	
			tri-C8-10-alkylmethyl, chlorides	
Inhalative	worker professional, long	term, systemic	0.42 mg/m3 (not defined)	
· PNE	Cs			
80-62-6 m	ethyl methacrylate			
freshwater		0.94 mg/l (not d	lefined)	
marine wa	ter	0.094 mg/l (not	defined)	
sewage tre	eatment plant	10 mg/l (not def	fined)	
sediment,	dry weight, freshwater	10.2 mg/Kg (no	t defined)	
sediment,	dry weight, marine water	0.102 mg/Kg (n	ot defined)	
soil, dry we	eight	1.48 mg/Kg (no	t defined)	
2082-81-7	1,4-butandioldimethacı	ylate		
freshwater		0.043 mg/l (not	defined)	
marine wa	marine water		defined)	
sewage tre	eatment plant	2 mg/l (not defir	ned)	
sediment,	dry weight, freshwater	3.12 mg/Kg (no	t defined)	
sediment,	sediment, dry weight, marine water		ot defined)	
soil, dry we	soil, dry weight		ot defined)	
63393-96-	63393-96-4 Quaternary ammonium compounds, tri-C8-10-alkylmethyl, chlorides			
freshwater	freshwater		ot defined)	
marine water		0.00000002 mg	ı/l (not defined)	
sewage tre	sewage treatment plant		lefined)	
sediment,	sediment, dry weight, freshwater		(not defined)	
sediment, dry weight, marine water		_	/Kg (not defined)	
	soil, dry weight		ı/Kg (not defined)	

Additional information: The lists that were valid during the compilation were used as basis.

Appropriate engineering controls No further data; see section 7.

Individual protection measures, such as 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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· Hand protection

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.

Not determined

Not applicable.

100 °C

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

Butyl rubber, BR Nitrile rubber, NBR

Eve/face 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

· Physical state · Colour: Colourless · Smell: Characteristic Odour threshold: Not determined.

• Melting point/freezing point:

Boiling point or initial boiling point and boiling range

· Flammability

· Lower and upper explosion limit

Lower: 2.1 Vol % 12.5 Vol % · Upper:

10 °C (80-62-6 methyl methacrylate) 430.0 °C Flash point:

Auto-ignition temperature:

Decomposition temperature: Not determined.

Palapress vario liquid > 60 °C

·SADT

Mixture is non-soluble (in water).

Viscosity: Kinematic viscosity

Not determined. · Kinematic viscosity

· dynamic at 20 °C: 1 mPas

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· Solubility Water:

Not miscible or difficult to mix

Partition coefficient n-octanol/water (log

· Steam pressure at 20 °C:

Not determined.

47 hPa

Vapour pressure:

Density and/or relative density

· Density at 20 °C 0.950 g/cm3 Not determined. · Relative density · Vapour density Not determined.

· 9.2 Other information

No further relevant information available.

Appearance:

Fluid Form:

· Important information on protection of health and environment, and on safety.

· Self-inflammability: Product is not selfigniting.

Product is not explosive. However, formation of · Explosive properties:

explosive air/vapour mixtures is possible.

· Solvent content:

0.1 % · Water: · Solids content: 0.3 %

Change in condition

Not determined. · Evaporation rate

· Information with regard to physical hazard classes

 Explosives Void Flammable gases Void Void · Aerosols · 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 flammable gases in contact with water Void · Oxidising liquids Void Oxidising solids Void Void Organic peroxides Corrosive to metals Void

· Desensitised explosives Void

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.

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· 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 hazard classes as defined in Regulation (EC) No 1272/2008 Acute toxicity Based on available data, the classification criteria are not met.

7.00.0		accurate distance data, the classification children 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 (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)
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)

- 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.
- · 11.2 Information on other hazards
 - **Endocrine disrupting properties**

None of the ingredients is listed.

SECTION 12: Ecological information

· 12.1 Toxicity

Aquatic toxicity: 80-62-6 methyl methacrylate

EC50/21d 49 mg/L (daphnia) (OECD 211)

69 mg/l (daphnia) (EPA OTS 797.1300) EC50/48h

NOEC / 21d | 37 mg/l (daphnia) (OECD 211)

ErC50 / 72 h >110 mg/l (algae) (OECD 201)

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	110 mg/l (algae) (OECD 201)
	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)
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-M	entha-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)
· 12.2 Persist	ence and degradability
80-62-6 met	hyl methacrylate
Biodegradati	on 94 % /14d (not defined) (OECD 301C)
2082-81-7 1,	4-butandioldimethacrylate
Biodegradati	on 84 % /28d (not defined) (OECD 310)
99-85-4 p-M	entha-1,4-diene
Biodegradati	on 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
Biodegradati	on 10-<20 % /60d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)

- 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
 - · Additional ecological information:
 - General notes:

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

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

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



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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.

· Uncleaned packagings:

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

SECTION 14: Transport information	uon
14.1 UN number or ID number · ADR, IMDG, IATA	UN1247
14.2 UN proper shipping name · ADR	1247 METHYL METHACRYLATE MONOM 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:	339
· EMS Number: · Stowage Category	F-E,S-D B
Stowage Code	SW2 Clear of living quarters.

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UN 1247 METHYL METHACRYLATE MONOMER, STABILIZED SOLUTION, 3, II

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IMO instruments	Not applicable.
· Transport/Additional information:	-
· ADR	
· Limited quantities (LQ)	1L
Excepted quantities (ÉQ)	Code: E2
	Maximum net quantity per inner packagin 30 ml
	Maximum net quantity per outer packagin 500 ml
· Transport category	2
Tunnel restriction code	D/E
· IMDG	
Limited quantities (LQ)	1L
Excepted quantities (ÉQ)	Code: E2
Zaospica gaunanos (Za)	Maximum net quantity per inner packagin 30 ml
	Maximum net quantity per outer packagir 500 ml

SECTION 15: Regulatory information

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
 - Directive 2012/18/EU

· UN "Model Regulation":

- 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
- 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.

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.

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Abbreviations and acronyms:

SADT: Self Accelerating Decomposition Temperature SAPT: Self Accelerating Polymerisation Temperature

ADR: Accord relatif au transport international 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

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 (UK REACH)
PNEC: Predicted No-Effect Concentration (UK REACH)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPVB: very Persistent and very Bioaccumulative 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 – Category 3 Acute Tox. 4: Acute toxicity – 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: Sk

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.