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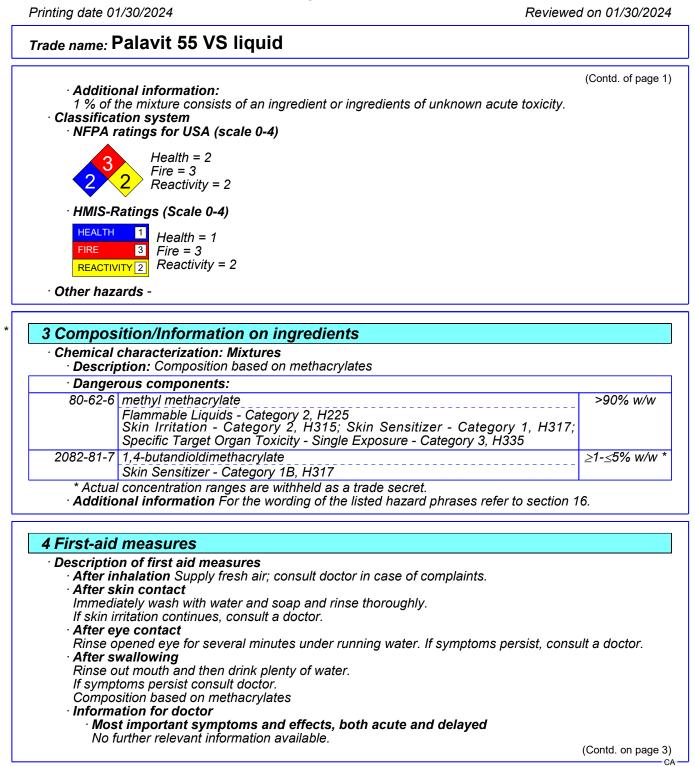
Safety Data Sheet according to HPR, Schedule 1

Reviewed on 01/30/2024 Printing date 01/30/2024 1 Identification · Product identifier Trade name: Palavit 55 VS 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. Specific Target Organ Toxicity - Single Exposure -H335 May cause respiratory irritation. Category 3 · Label elements GHS label elements The product is classified and labeled according to the Globally Harmonized System (GHS). · Hazard pictograms GHS02 GHS07 · Signal word Danger · Hazard-determining components of labeling: methyl methacrylate 1,4-butandioldimethacrylate · Hazard statements Highly flammable liquid and vapour. Causes skin irritation. May cause an allergic skin reaction. May cause respiratory irritation. · Precautionary statements Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Avoid breathing mist/vapours/spray. Wear protective gloves / eye protection. If skin irritation or rash occurs: Get medical advice/attention. (Contd. on page 2)



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• 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. Avoid contact with eyes and skin.
- 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.

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8 Exp	osure controls/ Personal protection	
· Add	itional information about design of technical systems: No further data; see section 7.	
· Con	trol parameters	
·C	omponents with limit values that require monitoring at the workplace:	
80-6	2-6 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.	
	osure controls ersonal 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 bro protective mask (filter A). • Protection of hands:	eathi
	The glove material has to be impermeable and resistant to the product/ the substan	ce/ t
	preparation. Selection of the glove material on consideration of the penetration times, rates of diffusion degradation	and t
	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 marks of quality and varies from manufacturer to manufacturer. As the product is a prep of several substances, the resistance of the glove material can not be calculated in a and has therefore to be checked prior to the application.	barati
	Penetration time of glove material The exact break through time has to be found out by the manufacturer of the protective	e glov
	and has to be observed. • For the permanent contact of a maximum of 15 minutes gloves made of the fol materials are suitable:	llowir
	Butyl rubber, BR	
	Nitrile rubber, NBR	
	• Eye protection: Safety glasses	

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· Body protection: Light weight protective clothing

Information on basic physical and che General Information	emical properties
· Appearance:	
· Form: · Color:	Fluid Colorless
Odor:	Characteristic
Odor threshold:	Not determined.
· pH-value:	Mixture is non-soluble (in water).
• Change in condition	
Melting point/Melting range:	-48 °C (-54,4 °F)
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 explosiv 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):	0,940 g/cm³ (7,8443 lbs/gal)
Relative density	Not determined.
Vapor density Evaporation rate	Not determined. Not determined.
· Solubility in / Miscibility with	
· Water at 20 °C (68 °F):	1,6 g/l
· Partition coefficient (n-octanol/wate	er): Not determined.
· Viscosity:	
dynamic at 20 °C (68 °F):	1 mPas
· kinematic:	Not determined.
· Solvent content:	0.0.0/
· Water:	0,2 %

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· 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.

11 Toxicological information

· Information on toxicological effects

· Acute toxicity:

· LD/LC50 values that are relevant for classification:

· LD/	LC50 valu	les that are relevant for classification:
80-62-6 m	nethyl met	hacrylate
Oral	LD50	~7.900 mg/kg (rat)
		weight of evidence
Dermal	LD50	>5.000 mg/kg (guinea pig) (OECD 402)
		29,8 mg/l (rat)
2082-81-7	' 1,4-butar	ndioldimethacrylate
Oral	LD50	10.066 mg/kg (rat) (OECD 401)
131-57-7	Öxybenzo	ne
Oral	LD50	>12.800 mg/kg (rat) (OECD 401)
Dermal	LD50	>16.000 mg/kg (rabbit) (OECD 402)
63393-96	4 Quatern	ary ammonium compounds, tri-C8-10-alkylmethyl, chlorides
Oral	LD50	200 mg/kg (ATE)
		>200-<2.000 mg/kg (rat) (OECD 401)
	mary irrita on the ski	nt effect: n: Irritant to skin and mucous membranes.
		No irritating effect.
· Ser	nsitization	: Sensitization possible through skin contact.
· Additi	onal toxic	ological information:
The pr	oduct sho	ws the following dangers according to the calculation method of the General EU
		idelines for Preparations as issued in the latest version:
Irritant		
· Car	rcinogenic	categories
-	IARC (Inte	rnational Agency for Research on Cancer)
80-62-6 r	nethyl metl	hacrylate 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.

Toxicity						
Aquatic toxicity:						
80-62-6 meth	nyl 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)					
LC50/ 35d	33,7 mg/L (fish) (OECD 210)					
	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)					
	2,11 mg/l (algae) (OECD 201)					
	25 mg/l (fish)					
ErC10/72h	4,35 mg/L (algae) (OECD 201)					
131-57-7 Oxy						
	1,87 mg/l (daphnia) (OECD 202)					
LC50/96h						
	0,67 mg/l (algae) (OECD 201)					
	0,18 mg/l (algae) (OECD 201)					
	0,72 mg/l (fish) (OECD 203)					
	1,15 mg/l (daphnia) (OECD 202)					
	Quaternary ammonium compounds, tri-C8-10-alkylmethyl, chlorides					
	0,16 mg/l (daphnia) (OECD 202)					
LC50/96h	0,15 mg/l (fish) (OECD 203)					
	0,29 mg/l (algae) (OECD 201)					
ErC10/72h	0,138 mg/L (algae) (OECD 201)					
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• 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)

131-57-7 Oxybenzone

biodegradability 60-70 % /28d (not defined)

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

131-57-7 Oxybenzone

Bloconcentration factor (BCF) >33-<160 (fish) (OECD 305)

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.

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.

14 Transport information

UN-Number · DOT/TDG, ADR, IMDG, IATA

UN1247

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 DOT/TDG, ADR, IMDG, IATA \parallel · Environmental hazards: • Marine pollutant: No · Special precautions for user Warning: Flammable liquids Hazard identification number (Kemler code): 339 · EMS Number: F-E,S-D · Stowage Category В · 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: -(Contd. on page 10) CA



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ADR Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 m Maximum net quantity per outer packaging: 500 ml
 IMDG Limited quantities (LQ) Excepted quantities (EQ) 	1L Code: E2 Maximum net quantity per inner packaging: 30 m 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.

H315 Causes skin irritation.

- H317 May cause an allergic skin reaction.
- H335 May cause respiratory irritation.
- Date of the latest revision of the safety data sheet 01/30/2024

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 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
- * Data compared to the previous version altered.