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Safety Data Sheet according to WHS Regulations

Version number 4 Revision: 30.01.2024 Printing date 30.01.2024

Hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

- · Product identifier
 - · Trade name: Palavit 55 VS liquid
 - · 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
- · Details of the supplier of the safety data sheet
 - Manufacturer/Supplier: Kulzer Australia Pty Ltd

Unit 20. 53 Lorraine St PEAKHURST NSW 2210

Australia

Tel: +61 (02) 9153 0311

- · Informing department: see above
- Emergency telephone number:

Poison Information Number: Australia 13 11 26 & New Zealand 0800 764 766

2 Hazard(s) Identification

Classification of the substance or mixture

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.

- · Label elements
 - GHS label elements

The product is classified and labelled according to the Globally Harmonised System (GHS).

· Hazard pictograms





GHS02 GHS07

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

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/sparks/open flames/hot surfaces. No smoking.

Avoid breathing mist/vapours/spray.

Wear protective gloves / eye protection.

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

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

3 Composition and Information on Ingredients

- · Chemical characterisation: Mixtures
 - · **Description:** Product based on methacrylates

· Dangerous components:		
80-62-6	methyl methacrylate	>90%
	Flam. Liq. 2, H225 Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	
2082-81-7	1,4-butandioldimethacrylate	<i>≥</i> 1- <i>≤</i> 5%
	Skin Sens. 1B, H317	

[·] Additional information For the wording of the listed hazard phrases refer to section 16.

4 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.

If skin irritation continues, consult a doctor.

· 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.

Product based on methacrylates

- 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

- · 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.

- · Protective equipment: No special measures required.
- Additional information -

ΔΙΙ



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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 material from reaching sewage system, holes 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 materials are released.

See Section 8 for information on personal protection equipment.

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7 Handling and Storage

- · Handling
 - · 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.

- 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.
- Specific end use(s) No further relevant information available.

8 Exposure controls and personal protection

- · Additional information about design of technical systems: No further data; see section 7.
- · Components with critical values that require monitoring at the workplace:

80-62-6 methyl methacrylate

WES Short-term value: 416 mg/m³, 100 ppm Long-term value: 208 mg/m³, 50 ppm Sen

· DNELs

80-62-6 methyl methacrylate

general population, long term, systemic 8.2 mg/Kg (not defined) Oral Dermal worker industrial, long term, systemic 13.67 mg/Kg/d (not defined) general population, long term, systemic 8.2 mg/Kg/d (not defined) Inhalative worker industrial, acute, local 416 mg/m3 (not defined) worker industrial, long term, systemic 348.4 mg/m3 (not defined) worker industrial, long term, local 208 mg/m3 (not defined) general population, acute, local 208 mg/m3 (not defined)

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	general population, long	term systemic	74.3 mg/m3 (not defined)	(Contd. of pa
2082-81-7	' 1,4-butandioldimethacı		175 mg/m5 (not defined)	
Oral	general population, long		2.5 mg/Kg (not defined)	
Dermal worker industrial, long ter		•	4.2 mg/Kg/d (not defined)	
general population, long to		. •	2.5 mg/Kg/d (not defined)	
Inhalative		•	,	
IIIIIaiative	general population, long	-	4.3 mg/m3 (not defined)	
131-57-7	Oxybenzone	terrii, systerriic	4.5 mg/m5 (not defined)	
Oral	general population, long	term systemic	2 mg/Kg (not defined)	
Dermal	worker industrial, long te		39 mg/Kg/d (not defined)	
Dominar	general population, long	-	20 mg/Kg/d (not defined)	
Inhalative	worker industrial, long te		27.7 mg/m3 (not defined)	
	general population, long		6.8 mg/m3 (not defined)	
63393-96-		•	tri-C8-10-alkylmethyl, chlorides	
			0.42 mg/m3 (not defined)	
· PNI	, ,	, torrin, by bloring	o. 12 mg/me (net demied)	
	ethyl methacrylate			
freshwater	<u> </u>	0.94 mg/l (not c	dofinad)	
marine wa		0.94 mg/l (not 0.094 mg/l (not	•	
	eatment plant	10 mg/l (not de	•	
		- '		
sediment, dry weight, freshwater		10.2 mg/Kg (no		
sediment, dry weight, marine water soil, dry weight		1.48 mg/Kg (no	•	
•	ั 1,4-butandioldimethac ı		it delined)	
freshwater		0.043 mg/l (not	defined)	
marine wa		0.004 mg/l (not	· · · · · · · · · · · · · · · · · · ·	
	eatment plant	2 mg/l (not defii	,	
-	dry weight, freshwater	3.12 mg/Kg (no	•	
	dry weight, marine water	0.312 mg/Kg (n		
soil, dry w		0.573 mg/Kg (n		
	Oxybenzone	o.oro mg/ng (n	or domina)	
freshwater	-	0.00067 mg/l (r	not defined)	
marine wa		0.000007 mg/l (· · · · · · · · · · · · · · · · · · ·	
sewage treatment plant		10 mg/l (not de	· · · · · · · · · · · · · · · · · · ·	
•		0.066 mg/Kg (n	,	
sediment, dry weight, marine water 0.007 i		. .	•	
		0.013 mg/Kg (n	•	
			tri-C8-10-alkylmethyl, chlorides	
freshwater		0.00015 mg/l (r		
marine water 0.00000002 mg/l (not defined)				
(Contd. on page				



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sewage treatment plant
sediment, dry weight, freshwater
sediment, dry weight, marine water
soil, dry weight

0.44 mg/l (not defined)
0.00063 mg/Kg (not defined)
0.00000006 mg/Kg (not defined)
0.00000004 mg/Kg (not defined)

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

· 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).

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 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: Safety glasses
- · Body protection: Light weight protective clothing

9 Physical and Chemical Properties

- · General Information
 - · Appearance:
 - Form:
 Colour:
 - · Smell:

Odour threshold: pH-value:

Fluid Colourless Characteristic Not determined.

Mixture is non-soluble (in water).

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· Change in condition

Melting point/freezing point: -48 °C Initial boiling point and boiling range: 100 °C

10 °C · Flash point:

Inflammability (solid, gaseous) Not applicable. 430.0°C Auto-ignition temperature:

Decomposition temperature: Not determined.

Palavit 55 VS liquid > 60 °C

· Self-inflammability: Product is not selfigniting.

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

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 0.940 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/water: Not determined.

· Viscosity:

· dynamic at 20 °C: 1 mPas

· kinematic: Not determined. Solvent content:

Water: 0.2 %

· Other information No further relevant information available.

10 Stability and Reactivity

Reactivity No further relevant information available.

Conditions to be avoided: No decomposition if used and stored according to specifications.

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:

If stored longer than recommended and/or above recommended temperature, product may polymerize generating heat.

11 Toxicological Information

· Information on toxicological effects

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

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· LD/LC50 values that are relevant for classification:			
80-62-6 methyl methacrylate			
LD50	~7,900 mg/kg (rat)		
LD50	>5,000 mg/kg (guinea pig) (OECD 402)		
LC50/4 h	29.8 mg/l (rat)		
2082-81-7 1,4-butandioldimethacrylate			
LD50	10,066 mg/kg (rat) (OECD 401)		
131-57-7 Oxybenzone			
LD50	>12,800 mg/kg (rat) (OECD 401)		
LD50	>16,000 mg/kg (rabbit) (OECD 402)		
63393-96-4 Quaternary ammonium compounds, tri-C8-10-alkylmethyl, chlorides			
LD50	200 mg/kg (ATE)		
	>200-<2,000 mg/kg (rat) (OECD 401)		
	LD50 LD50 LC50/4 h 7 1,4-butan LD50 Oxybenzo LD50 LD50 4 Quatern		

- · 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.

12 Ecological Information

· Toxicity			
<u> </u>	· Aquatic toxicity:		
80-62-6 meth	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)		
LC50/ 35d	33.7 mg/L (fish) (OECD 210)		
2082-81-7 1,4	2082-81-7 1,4-butandioldimethacrylate		
EC50/21d	14.1 mg/L (daphnia) (OECD 211)		
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	EC50/48h	32.5 mg/l (fish)	
		5.09 mg/l (daphnia) (OECD 211)	
		9.79 mg/l (algae) (OECD 201)	
		2.11 mg/l (algae) (OECD 201)	
	NOEC / 48h	25 mg/l (fish)	
	ErC10/72h		
	131-57-7 Oxy	/benzone	
	EC50/48h	1.87 mg/l (daphnia) (OECD 202)	
	LC50/96h	3.8 mg/l (fish) (OECD 203)	
	ErC50 / 72 h	0.67 mg/l (algae) (OECD 201)	
	NOEC / 72h	0.18 mg/l (algae) (OECD 201)	
	NOEC / 96h	0.72 mg/l (fish) (OECD 203)	
		1.15 mg/l (daphnia) (OECD 202)	
		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)	
		and degradability	
		nyl methacrylate	
		on 94 % /14d (not defined) (OECD 301C)	
		4-butandioldimethacrylate	
		on 84 % /28d (not defined) (OECD 310)	
	131-57-7 Oxy		
	Biodegradation 60-70 % /28d (not defined)		
	63393-96-4 Quaternary ammonium compounds, tri-C8-10-alkylmethyl, chlorides		
		on 10-<20 % /60d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)	
•	Behaviour in	n 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 bodies or sewage system. Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage

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

Results of PBT and vPvB assessment

- - PBT: Not applicable.
 - vPvB: Not applicable.

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· Other adverse effects No further relevant information available.

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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.

4 Transport information	
· UN-Number · ADG, IMDG, IATA	UN1247
· UN proper shipping name · ADG	1247 METHYL METHACRYLATE MONOME STABILIZED solution
· IMDG, IATA	METHYL METHACRYLATE MONOMER, STABILIZE solution
· Transport hazard class(es)	
ADG	
· Class · Label	3 (F1) Flammable liquids. 3
· IMDG, IATA	
· Class · Label	3 Flammable liquids. 3
Packing group ADG, IMDG, IATA	II
Environmental hazards: Marine pollutant:	No
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Special precautions for user Kemler Number: EMS Number: Stowage Category Stowage Code	Warning: Flammable liquids. 339 F-E,S-D B SW2 Clear of living quarters.
Transport in bulk according to Annex Marpol and the IBC Code	II of Not applicable.
Transport/Additional information:	-
· ADG · Limited quantities (LQ) · Excepted quantities (EQ)	1L Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· Transport category · Tunnel restriction code	2 D/E
· IMDG · Limited quantities (LQ) · Excepted quantities (EQ)	1L 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

	· Australian Inventory of Industrial Chemicals		
	methyl methacrylate		
	1,4-butandioldimethacrylate		
	5137-55-3 methyltrioctylammonium chloride		
131-57-7	Oxybenzone		
	N,N-bis(2-hydroxyethyl)-p-toluidine		
13395-16-9	copper(II) 4-oxopent-2-en-2-olate		
150-76-5 mequinol			
7732-18-5	water, distilled, conductivity or of similar purity		
· Aust	· Australia: Priority Existing Chemicals		

Australia: Priority Existing Chemicals

None of the ingredients is listed.

- · 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

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• Qualifying quantity (tonnes) for the application of upper-tier requirements 50,000 t

National regulations

The product is subject to classification in accordance with the prevailing version of the regulations on hazardous materials.

Other regulations, limitations and prohibitive regulations

- Australian Inventory of Chemical Substances
methyl methacrylate
1,4-butandioldimethacrylate
Oxybenzone
Quaternary ammonium compounds, tri-C8-10-alkylmethyl, chlorides
2,2'-[(4-methylphenyl)imino]bisethanol
water, distilled, conductivity or of similar purity
maleic acid
copper(II) 4-oxopent-2-en-2-olate
1-Octanol
1-Decanol
Amines, tri-C8-10-alkyl
mequinol

[·] 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.

Abbreviations and acronyms:

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

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 Skin Irrit. 2: Skin corrosion/irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1 Skin Sens. 1B: Skin sensitisation – Category 1B

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

* Data compared to the previous version altered.