



**Safety Data Sheet
according to WHS Regulations**

Printing date 30.01.2024

Version number 4

Revision: 30.01.2024

Hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

· **Product identifier**

· Trade name: **Palavit 55 VS powder**

· **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 prosthesis

· **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**

Skin Sens. 1 H317 May cause an allergic skin reaction.

· **Label elements**

· **GHS label elements**

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

· **Hazard pictograms**



GHS07

· **Signal word** Warning

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

dibenzoyl peroxide
methyl methacrylate

· **Hazard statements**

May cause an allergic skin reaction.

· **Precautionary statements**

Avoid release to the environment.
Wear protective gloves / eye protection.
If skin irritation or rash occurs: Get medical advice/attention.

· **Other hazards -**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.
· **vPvB:** Not applicable.

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3 Composition and Information on Ingredients

· **Chemical characterisation: Mixtures**

· **Description:** Product based on methacrylate copolymers

· **Dangerous components:**

94-36-0	dibenzoyl peroxide Self-react. B, H241; Org. Perox. B, H241 Serious eye damage/irritation – Category 2A, H319; Skin Sens. 1, H317	≥1-≤5%
80-62-6	methyl methacrylate Flam. Liq. 2, H225 Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	≥1-≤5%
1953-33-9	5-butyl-1H,3H,5H-pyrimidine-2,4,6-trione Skin Irrit. 2, H315; Serious eye damage/irritation – Category 2A, H319	≥0-≤5%

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

4 First Aid Measures

· **General information** No special measures required.

· **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. Then consult doctor.

· **After swallowing**

Rinse out mouth and then drink plenty of water.

In case of persistent symptoms consult doctor.

· **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, extinguishing powder or water jet. Fight larger fires with water jet or alcohol-resistant foam.

· **Special hazards arising from the substance or mixture** No further relevant information available.

· **Protective equipment:** No special measures required.

· **Additional information** -

6 Accidental Release Measures

· **Personal precautions, protective equipment and emergency procedures** Not required.

· **Environmental precautions:** No special measures required.

· **Methods and material for containment and cleaning up:** Collect mechanically.

· **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** No special measures required.
 - **Information about protection against explosions and fires:** No special measures required.
- **Storage**
 - **Requirements to be met by storerooms and containers:** No special requirements.
 - **Information about storage in one common storage facility:** Not required.
 - **Further information about storage conditions:** Store cool (not above 25 °C).
- **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:**

94-36-0 dibenzoyl peroxide

WES	Long-term value: 5 mg/m ³ Sen
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80-62-6 methyl methacrylate

WES	Short-term value: 416 mg/m ³ , 100 ppm Long-term value: 208 mg/m ³ , 50 ppm Sen
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- **DNELs**

94-36-0 dibenzoyl peroxide

Oral	general population, long term, systemic	2 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	13.3 mg/Kg/d (not defined)
Inhalative	worker industrial, long term, systemic	39 mg/m ³ (not defined)

80-62-6 methyl methacrylate

Oral	general population, long term, systemic	8.2 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	13.67 mg/Kg/d (not defined)
Inhalative	general population, long term, systemic	8.2 mg/Kg/d (not defined)
	worker industrial, acute, local	416 mg/m ³ (not defined)
	worker industrial, long term, systemic	348.4 mg/m ³ (not defined)
	worker industrial, long term, local	208 mg/m ³ (not defined)
	general population, acute, local	208 mg/m ³ (not defined)
	general population, long term, systemic	74.3 mg/m ³ (not defined)

- **PNECs**

94-36-0 dibenzoyl peroxide

freshwater	0.00002 mg/l (not defined)
marine water	0.000002 mg/l (not defined)

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sewage treatment plant	0.35 mg/l (not defined)
sediment, dry weight, freshwater	0.013 mg/Kg (not defined)
sediment, dry weight, marine water	0.001 mg/Kg (not defined)
soil, dry weight	0.003 mg/Kg (not defined)
80-62-6 methyl methacrylate	
freshwater	0.94 mg/l (not defined)
marine water	0.094 mg/l (not defined)
sewage treatment plant	10 mg/l (not defined)
sediment, dry weight, freshwater	10.2 mg/Kg (not defined)
sediment, dry weight, marine water	0.102 mg/Kg (not defined)
soil, dry weight	1.48 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** Wash hands during breaks and at the end of the work.
 - **Breathing equipment:** Not necessary if room is well-ventilated.
 - **Protection of hands:**
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:	Powder
· Colour:	Colourless Pink
· Smell:	Odourless
· Odour threshold:	Not determined.
· pH-value:	Mixture is non-soluble (in water).
· Change in condition	
· Melting point/freezing point:	Not determined

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- **Initial boiling point and boiling range:** Not determined
- **Flash point:** Not applicable
- **Inflammability (solid, gaseous):** Not determined.
- **Auto-ignition temperature:** 400.0 °C
- **Decomposition temperature:** Not determined.
- **Self-inflammability:** Product is not selfigniting.
- **Explosive properties:** Product is not explosive. However, formation of explosive powder/air mixtures is possible.
- **Critical values for explosion:**
 - **Lower:** Not determined.
 - **Upper:** Not determined.
- **Steam pressure:** Not applicable.
- **Density:** Not determined
 - **Relative density:** Not determined.
 - **Vapour density:** Not applicable.
 - **Evaporation rate:** Not applicable.
- **Solubility in / Miscibility with:**
 - **Water:** Insoluble
- **Partition coefficient: n-octanol/water:** Not determined.
- **Viscosity:**
 - **dynamic:** Not applicable.
 - **kinematic:** Not applicable.
- **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

11 Toxicological Information

- **Information on toxicological effects**
 - **Acute toxicity:** Based on available data, the classification criteria are not met.

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

94-36-0 dibenzoyl peroxide

Oral	LD0	>2,000 mg/kg (mouse) (OECD 401)
Inhalative	LC0/4h	24.3 ppm (rat) (OECD 403)

80-62-6 methyl methacrylate

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)

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- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **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** Based on available data, the classification criteria are not met.
- **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**

· **Aquatic toxicity:**

94-36-0 dibenzoyl peroxide

EC50/72h	0.042 mg/l (algae) (OECD 201)
EC50/48h	0.11 mg/l (daphnia) (OECD 202)
LC50/96h	0.06 mg/l (fish) (OECD 203)
ErC50 / 72 h	0.071 mg/l (algae) (OECD 201)
NOEC / 72h	0.02 mg/l (algae) (OECD 201)
NOEC / 96h	0.032 mg/l (fish) (OECD 203)
NOEC / 48h	0.076 mg/l (daphnia) (OECD 202)
ErC10	0.001 mg/L /21d (daphnia) (OECD 211)

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)

· **Persistence and degradability**

94-36-0 dibenzoyl peroxide

Biodegradation 71 % /28d (not defined) (OECD 301D)

80-62-6 methyl methacrylate

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

· **Behaviour in environmental systems:**

- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.

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· **Additional ecological information:**

· **General notes:**

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

· **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**

· **ADG, IMDG, IATA**

UN3077

· **UN proper shipping name**

· **ADG**

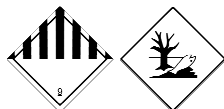
3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (dibenzoyl peroxide)

· **IMDG, IATA**

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (dibenzoyl peroxide)

· **Transport hazard class(es)**

· **ADG**



· **Class**

9 (M7) Miscellaneous dangerous substances and articles.

· **Label**

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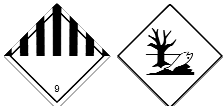
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<ul style="list-style-type: none"> · IMDG  <ul style="list-style-type: none"> · Class · Label 	<p>9 Miscellaneous dangerous substances and articles. 9</p>
<ul style="list-style-type: none"> · IATA  <ul style="list-style-type: none"> · Class · Label 	<p>9 Miscellaneous dangerous substances and articles. 9</p>
<ul style="list-style-type: none"> · Packing group · ADG, IMDG, IATA 	<p>III</p>
<ul style="list-style-type: none"> · Environmental hazards: · Marine pollutant: · Special marking (ADG): · Special marking (IATA): 	<p>No Symbol (fish and tree) Symbol (fish and tree)</p>
<ul style="list-style-type: none"> · Special precautions for user · Kemler Number: · EMS Number: · Stowage Category · Stowage Code 	<p>Warning: Miscellaneous dangerous substances and articles. 90 F-A,S-F A SW23 When transported in BK3 bulk container, see 7.6.2.12 and 7.7.3.9.</p>
<ul style="list-style-type: none"> · Transport in bulk according to Annex II of Marpol and the IBC Code 	<p>Not applicable.</p>
<ul style="list-style-type: none"> · Transport/Additional information: 	<p>-</p>
<ul style="list-style-type: none"> · ADG · Limited quantities (LQ) · Excepted quantities (EQ) · Transport category · Tunnel restriction code 	<p>5 kg Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g 3 (-)</p>
<ul style="list-style-type: none"> · IMDG · Limited quantities (LQ) 	<p>5 kg</p>

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· Excepted quantities (EQ)	Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g
· UN "Model Regulation":	UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (DIBENZOYL PEROXIDE), 9, III

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**

· Australian Inventory of Industrial Chemicals	
94-36-0	dibenzoyl peroxide
80-62-6	methyl methacrylate
	Chrome Antimony Titanate
13463-67-7	Titanium dioxide
68186-88-9	Zinc iron chromite brown spinel
4948-15-6	C.I. Pigment Red 149
68186-91-4	Kupfer-, Chrom-, Eisenoxid-Spinell
	Diethyl-(2,5-dihydroxyterephthalat)
· 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 E1** Hazardous to the Aquatic Environment
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 100 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 200 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**

· AICS - Australian Inventory of Chemical Substances	
94-36-0	dibenzoyl peroxide
80-62-6	methyl methacrylate
	Chrome Antimony Titanate
13463-67-7	Titanium dioxide
68186-88-9	Zinc iron chromite brown spinel
4948-15-6	C.I. Pigment Red 149
68186-91-4	Kupfer-, Chrom-, Eisenoxid-Spinell
	Diethyl-(2,5-dihydroxyterephthalat)

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

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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.
- H241 Heating may cause a fire or explosion.
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.
- H335 May cause respiratory irritation.

· **Abbreviations and acronyms:**

- 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
- Self-react. B: Self-reactive substances and mixtures – Type B
- Org. Perox. B: Organic peroxides – Type B
- Skin Irrit. 2: Skin corrosion/irritation – Category 2
- Serious eye damage/irritation – Category 2A: Serious eye damage/eye irritation – Category 2A
- Skin Sens. 1: Skin sensitisation – Category 1
- STOT SE 3: Specific target organ toxicity (single exposure) – Category 3