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Safety Data Sheet according to WHS Regulations

Printing date 01.03.2023 Version number 6 Revision: 01.03.2023

Hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

- · Product identifier
 - · Trade name: Palavit G Powder
 - · Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
 - Application of the substance / the mixture Auxiliary for 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

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



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

dibenzoyl peroxide

· Hazard statements

May cause an allergic skin reaction.

· Precautionary statements

Wear protective gloves / eye protection.

Wear protective clothing.

If skin irritation 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 methacrylate copolymers

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· Dangerous components:			
	Self-react. B, H241; Org. Perox. B, H241 Eye Irritation 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	≥0.1-<1%	
Additional information For the wording of the listed hazard phrases refer to section 16.			

4 First Aid Measures

- · Description of first aid measures
 - General information No special measures required.
 - · 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. Then consult doctor.

After swallowing

Rinse out mouth and then drink plenty of water.

Do not induce vomiting; instantly call for medical help.

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, 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.
- 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 causing dust.
- **Environmental precautions:** Prevent material from reaching sewage system, holes and cellars.
- Methods and material for containment and cleaning up: Collect mechanically.
- · Reference to other sections

See Section 8 for information on personal protection equipment.

7 Handling and Storage

· Handling

• Precautions for safe handling Store in cool, dry place in tightly closed containers.

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- Information about protection against explosions and fires: Keep ignition sources away - Do not smoke.
- · Conditions for safe storage, including any incompatibilities Storage
 - Requirements to be met by storerooms and containers:
 - Store in cool, dry place in tightly closed containers.
 - Information about storage in one common storage facility:
 - Store away from flammable substances.
 - 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 item 7.
- · Control parameters

· Components with critical values that require monitoring at the workplace:
94-36-0 dibenzoyl peroxide

WES Long-term value: 5 mg/m3

Sen

80-62-6 methyl methacrylate WES Short-term value: 416 mg/m³, 100 ppm Long-term value: 208 mg/m³, 50 ppm

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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/m3 (not defined)

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) general population, long term, systemic 74.3 mg/m3 (not defined)

PNECs

94-36-0 dibenzoyl peroxide

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

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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.

· Exposure controls

Personal protective equipment

General protective and hygienic measures

Wash hands during breaks and at the end of the work.

- · Breathing equipment: Use a mask with particle filter in case of dust generation.
- 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

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: Tightly sealed safety glasses.
- · Body protection: Light weight protective clothing

9 Physical and Chemical Properties

· Information on basic physical and chemical properties

General Information

Appearance:

Form: Powder Colour: Red · Smell: Odourless · Odour threshold: Not determined.

· pH-value: Mixture is non-soluble (in water).

· Change in condition

Melting point/freezing point: Not determined · Initial boiling point and boiling range: Not determined

· Flash point: Not applicable

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· Inflammability (solid, gaseous)	Not determined.
· Ignition temperature:	400 °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 at 20 °C	0 g/cm³
· Relative density	Not determined.
Vapour density	Not applicable.
Evaporation rate	Not applicable.
· Solubility in / Miscibility with	
· Water:	Insoluble
· Partition coefficient: n-octanol/wa	ater: 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.
- · Chemical stability · 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: -

11 Toxicological Information

- · Information on toxicological effects
 - · Acute toxicity

Acuto	CONTERLY			
· LD/	· 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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- · Primary irritant effect:
 - Skin corrosion/irritation No irritant effect.
 - Serious eye damage/irritation No irritant effect.
- Respiratory or skin sensitisation No sensitizing effect known.
- Additional toxicological information:

The product is not subject to classification according to the calculation method of the General EC Classification Guidelines for Preparations as issued in the latest version.

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

- CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
 - Reproductive toxicity 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)		

Persistence and degradability

94-36-0 dibenzoyl peroxide

LC50/ 35d

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

33.7 mg/L (fish) (OECD 210)

80-62-6 methyl methacrylate

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

Behaviour in environmental systems:

NOEC/ 35d 9.4 mg/L (fish) (OECD 210)

- Bioaccumulative potential No further relevant information available.
- **Mobility in soil** No further relevant information available.
- · Additional ecological information:
 - General notes:

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

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- · 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.

UN-Number	
· ADG, IMDG, IATA	UN3077
UN proper shipping name	
ÀDĞ	3077 ENVIRONMENTALLY HAZARDOUS
· IMDG, IATA	SUBSTANCE, SOLID, N.O.S. (dibenzoyl peroxide) ENVIRONMENTALLY HAZARDOUS
INIDG, IATA	SUBSTANCE, SOLID, N.O.S. (dibenzoyl peroxide)
Transport hazard class(es)	
· ADG	
¥2>	
·Class	9 (M7) Miscellaneous dangerous substance and articles.
· Label	9
· IMDG	
₩	
· Class	9 Miscellaneous dangerous substances and articles.
· Label	9



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·IATA



· Class

9 Miscellaneous dangerous substances and

articles.

· Label

Packing group
ADG, IMDG, IATA

III

No

· Environmental hazards:

Marine pollutant: Special marking (ADG): Symbol (fish and tree) Symbol (fish and tree) Special marking (IATA):

· Special precautions for user Warning: Miscellaneous dangerous substances and

articles.

· Kemler Number: F-A,S-F · EMS Number:

· Stowage Category

· Stowage Code SW23 When transported in BK3 bulk container,

see 7.6.2.12 and 7.7.3.9.

· Transport in bulk according to Annex II of

Marpol and the IBC Code Not applicable.

· Transport/Additional information:

· ADG

· Limited quantities (LQ) 5 kg

Excepted quantities (EQ) Code: E1

Maximum net quantity per inner packaging: 30 g

Maximum net quantity per outer packaging:

1000 g

3 · Transport category · Tunnel restriction code (-)

·IMDG

Limited quantities (LQ) 5 kg Excepted quantities (ÉQ)

Code: E1

Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging:

1000 g

UN 3077 ENVIRONMENTALLY HAZARDOUS · UN "Model Regulation":

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

All ingredients are listed.

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· 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 E2 Hazardous to the Aquatic Environment
- Qualifying quantity (tonnes) for the application of lower-tier requirements 200 t
- Qualifying quantity (tonnes) for the application of upper-tier requirements 500 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

8002-74-2 Paraffin waxes and Hydrocarbon waxes

4948-15-6 C.I. Pigment Red 149

· 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.

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)
LCSO: Lethal concentration, 50 percent

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
Eye Irritation 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

* Data compared to the previous version altered.