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Safety Data Sheet according to WHS Regulations

Printing date 07.07.2022 Version number 4 Revision: 07.07.2022

Hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

- · Product identifier
 - · Trade name: Palapress vario 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 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 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.

3 Composition and Information on Ingredients

- · Chemical characterisation: Mixtures
 - · Description: Product based on methacrylate copolymers

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	(00	a. o. pago 1)
· Dangero	ous components:	
94-36-0	dibenzoyl peroxide	<i>≥1-≤</i> 5%
	Self-react. B, H241; Org. Perox. B, H241 Eye Irritation 2A, H319; Skin Sens. 1, H317	
80-62-6	methyl methacrylate	<i>≥1-≤</i> 5%
	Flam. Liq. 2, H225 Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	
72846-00-5	1-benzyl-5-phenylbarbituric acid	<i>≥</i> 0- <i>≤</i> 5%
	Acute Tox. 4, H302; Eye Irritation 2A, H319	
A -1-1'4'	al information For the consuling of the listed because above as a section 10	

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

4 First Aid Measures

- · 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.
 - · 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

- · 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 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.

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- · Conditions for safe storage, including any incompatibilities
 - · 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 item 7.

Conti	oi parameters
· Co	omponents with critical values that require monitoring at the workplace:
94-36	-0 dibenzoyl peroxide
	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

D	N	F	Ls

94-36-0	dibenzoyl	peroxide
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	<u> </u>	
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

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)
	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 ma/m3 (not defined)

· PNECs

94-36-0 dibenzoyl peroxide

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

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sediment, dry weight, freshwater sediment, dry weight, marine water soil, dry weight 1.48 mg/Kg (not defined) 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: Not necessary if room is well-ventilated.
- 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: 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:	Colourless	
	. Pink	
Smell:	Nearly odourless	
· Odour threshold:	Not determined.	
· pH-value:	Mixture is non-soluble (in water).	
Change in condition Melting point/freezing point: Initial boiling point and boiling I	Not determined range: Not determined	
· Flash point:	Not applicable	
· Inflammability (solid, gaseous)	Not determined.	
· Ignition temperature:	400.0 °C	
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· Decomposition temperature:	Not determined.
· Self-inflammability:	Product is not selfigniting.
Explosive properties:	Product is not explosive. However, formation explosive powder/air mixtures is possible.
Critical values for explosion: Lower: Upper:	Not determined. Not determined.
Steam pressure:	Not applicable.
Density at 20 °C Relative density Vapour density Evaporation rate	0 g/cm³ Not determined. Not applicable. Not applicable.
Solubility in / Miscibility with Water:	Insoluble
· Partition coefficient: n-octanol/w	ater: Not determined.
Viscosity: dynamic: kinematic:	Not applicable. Not applicable.
· Solvent content:	
· Solids content:	100.0 %
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	toxicity	
· LD/LC50 values that are relevant for classification:		
94-36-0 d	ibenzoyl p	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)
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Inhalative	LC50/4 h	29.8 mg/l (rat)
72846-00)-5 1-benzy	l-5-phenylbarbituric acid
Oral	LD50	500 mg/kg (ATE)
		500 mg/kg (rat) (OECD 423)

- · Primary irritant effect:
 - · Skin corrosion/irritation No irritant effect.
 - · Serious eve 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 0.042 mg/l (algae) (OECD 201) EC50/72h 0.11 mg/l (daphnia) (OECD 202) EC50/48h 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 49 mg/L (daphnia) (OECD 211) EC50/21d 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) 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) 72846-00-5 1-benzyl-5-phenylbarbituric acid EC50/48h >50 mg/l (daphnia) (OECD 202) ErC50 / 72 h | >50 mg/l (algae) (OECD 201) · Persistence and degradability 94-36-0 dibenzoyl peroxide Biodegradation 71 % /28d (not defined) (OECD 301D)

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80-62-6 methyl methacrylate

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

72846-00-5 1-benzyl-5-phenylbarbituric acid

Biodegradation 29.1 % /29d (not defined) (OECD 301D)

· Behaviour in environmental systems:

- Bioaccumulative potential No further relevant information available.
- 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 system.

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

- · 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

Disposal must be made according to official regulations.

- · Uncleaned packagings:
 - Recommendation:

Packaging can be reused or recycled after cleaning.

Non contaminated packagings can be used for recycling.

UN-Number	
ADG, IMDG, IATA	UN3077
UN proper shipping name	
ÁDĠ	3077 ENVIRONMENTALLY HAZARDOU
	SUBSTANCE, SOLID, N.O.S. (dibenzoyl peroxide ENVIRONMENTALLY HAZARDOÚ
· IMDG	ENVIRONMENTALLY` HAZARDOÚ
	SUBSTANCE, SOLID, N.O.S. (dibenzoyl peroxide
	MARINE POLLUTANT
·IATA	ENVIRONMENTALLY HAZARDOU
	SUBSTANCE, SOLID, N.O.S. (dibenzoyl peroxide,



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· Transport hazard class(es)	
· ADG	
1	
Class	9 (M7) Miscellaneous dangerous substance and articles.
Label	9
· IMDG, IATA	
· Class	9 Miscellaneous dangerous substances an articles.
· Label	9
· Packing group · ADG, IMDG, IATA	III
· Environmental hazards: · Marine pollutant:	No Symbol (fish and tree)
· Special marking (ADG): · Special marking (IATA):	Symbol (fish and tree) Symbol (fish and tree)
· Special precautions for user	Warning: Miscellaneous dangerous substances an articles.
· Kemler Number:	90
EMS Number:	F-A,S-F
· Stowage Category · Stowage Code	SW23 When transported in BK3 bulk containe see 7.6.2.12 and 7.7.3.9.
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)	5 kg Code: E1 Maximum net quantity per inner packaging: 30 g
	Maximum net quantity per outer packaging 1000 g
· Transport category · Tunnel restriction code	3 (-)
IMDG Limited quantities (LQ)	5 kg
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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

Safety, fleatiff and environmental regulations/legislation specific for the substance of mixture		
· Australian Inventory of Industrial Chemicals		
25086-15-1	2-Propenoic acid, 2-methyl-, polymer with methyl 2-methyl-2-propenoate	
94-36-0	dibenzoyl peroxide	
68186-87-8	Cobalt zinc aluminate blue spinel	

- · Directive 2012/18/EU
 - Qualifying quantity (tonnes) for the application of lower-tier requirements 200 t
- Qualifying quantity (tonnes) for the application of upper-tier requirements 500 t 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.

H302 Harmful if swallowed.

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 Acute Tox. 4: Acute toxicity – Category 4 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.