Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 08.10.2020 Version number 5 Revision: 08.10.2020

SECTION 1: Identification of the substance/mixture and of the company/undertaking

· **1.1 Product identifier**

· **Trade name:** **Palavit G Powder**

· **1.2 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

· **1.3 Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**
Kulzer GmbH
Leipziger Straße 2, 63450 Hanau (Germany) Tel.: +49 (0)800 4372522

· **Informing department:** E-Mail: msds@kulzer-dental.com

· **1.4 Emergency telephone number:** Emergency CONTACT (24-Hour-Number): +49 (0)6132-84463

SECTION 2: Hazards identification

· **2.1 Classification of the substance or mixture**

· **Classification according to Regulation (EC) No 1272/2008**

Skin Sens. 1	H317	May cause an allergic skin reaction.
Repr. 1B	H360D	May damage the unborn child.
Aquatic Chronic 2	H411	Toxic to aquatic life with long lasting effects.

· **2.2 Label elements**

· **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the CLP regulation.

· **Hazard pictograms**

GHS07 GHS08 GHS09

· **Signal word** Danger

· **Hazard-determining components of labelling:**
dicyclohexyl phthalate
dibenzoyl peroxide
methyl methacrylate

· **Hazard statements**
H317 May cause an allergic skin reaction.
H360D May damage the unborn child.
H411 Toxic to aquatic life with long lasting effects.

· **Precautionary statements**
P202 Do not handle until all safety precautions have been read and understood.
P261 Avoid breathing dust.
P273 Avoid release to the environment.
P280 Wear protective gloves / eye protection.
P308+P313 IF exposed or concerned: Get medical advice/attention.
P405 Store locked up.

· **Additional information:**
Restricted to professional users.

· **2.3 Other hazards** -

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

(Contd. on page 2)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 08.10.2020 Version number 5 Revision: 08.10.2020

Trade name: Palavit G Powder

(Contd. of page 1)

· **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

· **3.2 Chemical characterisation: Mixtures**
· **Description:** Product based on methacrylate copolymers

· **Dangerous components:**

CAS: 94-36-0 EINECS: 202-327-6 Reg.nr.: 01-2119511472-50	dibenzoyl peroxide Self-react. B, H241; Org. Perox. B, H241 Aquatic Acute 1, H400 (M=10); Aquatic Chronic 1, H410 (M=10) Eye Irrit. 2, H319; Skin Sens. 1, H317	≥1-<2.5%
CAS: 80-62-6 EINECS: 201-297-1 Reg.nr.: 01-2119452498-28-XXXX	methyl methacrylate Flam. Liq. 2, H225 Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	≥0.1-<1%
CAS: 84-61-7 EINECS: 201-545-9 Reg.nr.: 01-2119978223-34-XXXX	dicyclohexyl phthalate Repr. 1B, H360D Skin Sens. 1, H317 Aquatic Chronic 3, H412	≥0.3-<1%

· **SVHC**

84-61-7	dicyclohexyl phthalate

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

SECTION 4: First aid measures

· **4.1 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.
· **4.2 Most important symptoms and effects, both acute and delayed**
No further relevant information available.
· **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

· **5.1 Extinguishing media**
· **Suitable extinguishing agents**
CO2, extinguishing powder or water jet. Fight larger fires with water jet or alcohol-resistant foam.
· **5.2 Special hazards arising from the substance or mixture**
No further relevant information available.
· **5.3 Advice for firefighters**
· **Protective equipment:** No special measures required.

(Contd. on page 3)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 08.10.2020 *Version number 5* *Revision: 08.10.2020*

***Trade name:* Palavit G Powder**

(Contd. of page 2)

· ***Additional information*** -

SECTION 6: Accidental release measures

· ***6.1 Personal precautions, protective equipment and emergency procedures***
Wear protective equipment. Keep unprotected persons away.
Avoid causing dust.
· ***6.2 Environmental precautions:*** *Prevent material from reaching sewage system, holes and cellars.*
· ***6.3 Methods and material for containment and cleaning up:*** *Collect mechanically.*
· ***6.4 Reference to other sections***
See Section 8 for information on personal protection equipment.
-

SECTION 7: Handling and storage

· ***7.1 Precautions for safe handling*** *Store in cool, dry place in tightly closed containers.*
· ***Information about protection against explosions and fires:***
Keep ignition sources away - Do not smoke.

· ***7.2 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).*
· ***7.3 Specific end use(s)*** *No further relevant information available.*

*

SECTION 8: Exposure controls/personal protection

· ***Additional information about design of technical systems:*** *No further data; see item 7.*

· ***8.1 Control parameters***
· ***Components with critical values that require monitoring at the workplace:***
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
Not required.

· **DNELs**		
94-36-0 dibenzoyl peroxide		
Oral	ge.pop., l.te, syst.	1.65 mg/Kg (nd)
Dermal	worker industr., l.te., syst.	6.6 mg/Kg/d (nd)
	ge.pop., l.te, syst.	3.3 mg/Kg/d (nd)
Inhalative	worker industr., l.te., syst.	11.75 mg/m3 (nd)
	ge.pop., l.te, syst.	2.9 mg/m3 (nd)
80-62-6 methyl methacrylate		
Dermal	worker industr., l.te., syst.	74.3 mg/Kg/d (human)
Inhalative	worker industr., l.te., syst.	210 mg/m3 (human)
84-61-7 dicyclohexyl phthalate		
Dermal	worker industr., l.te., syst.	6.6 mg/Kg/d (nd)
Inhalative	worker industr., l.te., syst.	11.75 mg/m3 (nd)

(Contd. on page 4)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 08.10.2020 *Version number 5* *Revision: 08.10.2020*

Trade name: Palavit G Powder

(Contd. of page 3)

· **PNECs**	
80-62-6 methyl methacrylate	
freshwater	0.94 mg/l (aqua)
84-61-7 dicyclohexyl phthalate	
freshwater	0.000602 mg/l (nd)
marine water	0.0000602 mg/l (nd)
STP	0.35 mg/l (nd)
sedim., dw, fre.wat.	0.388 mg/Kg (nd)

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

· **8.2 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

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**
· **General Information**
· **Appearance:**
· **Form:** Powder
· **Colour:** Red
· **Smell:** Odourless
· **Odour threshold:** Not determined.

· **pH-value:** Not applicable.

· **Change in condition**
· **Melting point/freezing point:** Not determined
· **Initial boiling point and boiling range:** Not determined

(Contd. on page 5)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 08.10.2020 Version number 5 Revision: 08.10.2020

Trade name: Palavit G Powder

(Contd. of page 4)

· **Flash point:**	Not applicable
· **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/water:**	Not determined.
· **Viscosity:**	
· **dynamic:**	Not applicable.
· **kinematic:**	Not applicable.
· **9.2 Other information**	No further relevant information available.

SECTION 10: Stability and reactivity

· **10.1 Reactivity** No further relevant information available.
· **10.2 Chemical stability**
· **Conditions to be avoided:** No decomposition if used and stored according to specifications.
· **10.3 Possibility of hazardous reactions** No dangerous reactions known
· **10.4 Conditions to avoid** No further relevant information available.
· **10.5 Incompatible materials:** No further relevant information available.
· **10.6 Hazardous decomposition products:** None
· **Additional information:** -

*

SECTION 11: Toxicological information

· **11.1 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 (rab) (OECD 402)

(Contd. on page 6)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 08.10.2020 Version number 5 Revision: 08.10.2020

Trade name: Palavit G Powder

(Contd. of page 5)

Inhalative	LC50/4 h	29.8 mg/l (rat)
84-61-7 dicyclohexyl phthalate		
Oral	LD50	>2,000 mg/kg (rat) (OECD 423)
Dermal	LD50	>2,000 mg/kg (rat) (OECD 402)

· **Primary irritant effect:**
· **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.
· **CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)**
Repr. 1B
· **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**
May damage the unborn child.
· **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.

*

SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**	
94-36-0 dibenzoyl peroxide	
EC50/72h	>2 mg/l (algae)
EC50/48h	>2 mg/l (daphnia)
LC50/96h	>2 mg/l (fish)
80-62-6 methyl methacrylate	
EC50/48h	69 mg/l (daphnia)
LC50/96h	191 mg/l (fish)

· **12.2 Persistence and degradability** No further relevant information available.
· **12.3 Bioaccumulative potential** No further relevant information available.
· **12.4 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.
· **12.5 Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

· **13.1 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.

(Contd. on page 7)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 08.10.2020 *Version number 5* *Revision: 08.10.2020*

Trade name: Palavit G Powder

(Contd. of page 6)

· **European waste catalogue**	
18 01 06*	chemicals consisting of or containing hazardous substances

· **Uncleaned packagings:**
· **Recommendation:**
Disposal must be made according to official regulations.
Non contaminated packagings can be used for recycling.

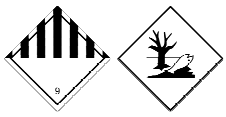
SECTION 14: Transport information

· **14.1 UN-Number**
· **ADR, IMDG, IATA** UN3077

· **14.2 UN proper shipping name**
· **IMDG, IATA** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (dibenzoyl peroxide)

· **14.3 Transport hazard class(es)**

· **ADR**



· **Class** 9 (M7) Miscellaneous dangerous substances and articles.
· **Label** 9

· **IMDG**

· **Class** 9 Miscellaneous dangerous substances and articles.
· **Label** 9

· **IATA**

· **Class** 9 Miscellaneous dangerous substances and articles.
· **Label** 9

· **14.4 Packing group**
· **ADR, IMDG, IATA** III

· **14.5 Environmental hazards:**
· **Marine pollutant:** No
· **Special marking (ADR):** Symbol (fish and tree)

(Contd. on page 8)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 08.10.2020 Version number 5 Revision: 08.10.2020

Trade name: Palavit G Powder

(Contd. of page 7)

· **Special marking (IATA):**	Symbol (fish and tree)
· **14.6 Special precautions for user**	Warning: Miscellaneous dangerous substances and articles.
· **Kemler Number:**	90
· **EMS Number:**	F-A,S-F
· **Stowage Category**	A
· **Stowage Code**	SW23 When transported in BK3 bulk container, see 7.6.2.12 and 7.7.3.9.
· **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**	Not applicable.
· **Transport/Additional information:**	-
· **ADR**	
· **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
· **Transport category**	3
· **Tunnel restriction code**	-
· **IMDG**	
· **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
· **UN "Model Regulation":**	Void

SECTION 15: Regulatory information

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

· **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
· **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 30

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

SECTION 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.

(Contd. on page 9)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 08.10.2020 *Version number 5* *Revision: 08.10.2020*

***Trade name:* Palavit G Powder**

(Contd. of page 8)

H335 May cause respiratory irritation.
H360D May damage the unborn child.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.
H412 Harmful to aquatic life with long lasting effects.

· ***Abbreviations and acronyms:***
ADR: Accord européen sur le transport 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
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
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
SVHC: Substances of Very High Concern
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 Irrit. 2: Serious eye damage/eye irritation – Category 2
Skin Sens. 1: Skin sensitisation – Category 1
Repr. 1B: Reproductive toxicity – Category 1B
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1
Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

· **** Data compared to the previous version altered.***