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

· **1.1 Product identifier**

· **Trade name: Paladur 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** 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.
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 GB CLP regulation.
· **Hazard pictograms**

GHS07 GHS09

· **Signal word** Warning

· **Hazard-determining components of labelling:**
dibenzoyl peroxide
methyl methacrylate
· **Hazard statements**
H317 May cause an allergic skin reaction.
H411 Toxic to aquatic life with long lasting effects.
· **Precautionary statements**
P273 Avoid release to the environment.
P280 Wear protective gloves / eye protection.
P280 Wear protective clothing.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
· **2.3 Other hazards** -
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

· **3.2 Mixtures**
· **Description:** -

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· **Dangerous components:**		
CAS: 94-36-0 EINECS: 202-327-6	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: 1953-33-9 EINECS: 217-781-0	5-butyl-1H,3H,5H-pyrimidine-2,4,6-trione Skin Irrit. 2, H315; Eye Irrit. 2, H319	≥0-≤5%
CAS: 80-62-6 EINECS: 201-297-1	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.

SECTION 4: First aid measures

· **4.1 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.
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.
· **4.2 Most important symptoms and effects, both acute and delayed** Allergic reactions
· **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**
CO_2, extinguishing powder or water jet. Fight larger fires with water jet or alcohol-resistant foam.
Use fire fighting measures that suit the environment.
· **5.2 Special hazards arising from the substance or mixture**
Formation of toxic gases is possible during heating or in case of fire.
· **5.3 Advice for firefighters**
· **Protective equipment:** No special measures required.
· **Additional information** -

SECTION 6: Accidental release measures

· **6.1 Personal precautions, protective equipment and emergency procedures**
Avoid contact with eyes and skin.
· **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 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for information on disposal.

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SECTION 7: Handling and storage

· **7.1 Precautions for safe handling**
No special measures required.
Please observe the additional instructions in the product's instructions for use.
Ensure good ventilation/exhaustion at the workplace.
· **Information about protection against explosions and fires:** No special measures required.

· **7.2 Conditions for safe storage, including any incompatibilities**
· **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:** None.

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

SECTION 8: Exposure controls/personal protection

· **8.1 Control parameters**

· **Components with critical values that require monitoring at the workplace:**	
94-36-0 dibenzoyl peroxide	
WEL (Great Britain)	Long-term value: 5 mg/m³
80-62-6 methyl methacrylate	
WEL (Great Britain)	Short-term value: 416 mg/m³, 100 ppm Long-term value: 208 mg/m³, 50 ppm
IOELV (European Union)	Short-term value: 100 ppm Long-term value: 50 ppm

· **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		
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 mg/m3 (not defined)

· **PNECs**	
94-36-0 dibenzoyl peroxide	
freshwater	0.00002 mg/l (not defined)
marine water	0.000002 mg/l (not defined)
sewage treatment plant	0.35 mg/l (not defined)

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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.

· **8.2 Exposure controls**
· **Individual protection measures, such as personal protective equipment**
· **General protective and hygienic measures**
Instantly remove any soiled and impregnated garments.
Wash hands during breaks and at the end of the work.
· **Breathing equipment:** Not necessary if room is well-ventilated.
· **Hand protection**
If skin contact cannot be avoided, protective gloves are recommended to avoid possible sensitization.
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/face 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**

· **Physical state**	Solid.
· **Colour:**	Colourless Pink
· **Smell:**	Odourless
· **Odour threshold:**	Not determined.
· **Melting point/freezing point:**	Not determined
· **Boiling point or initial boiling point and boiling range**	Not determined
· **Flammability**	Not determined.

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· **Lower and upper explosion limit**	
· **Lower:**	Not determined.
· **Upper:**	Not determined.
· **Flash point:**	251 °C
· **Ignition temperature:**	>400 °C
· **Decomposition temperature:**	Not determined.
· **SADT**	
· **pH**	Mixture is non-soluble (in water).
· **Viscosity:**	
· **Kinematic viscosity**	Not applicable.
· **dynamic:**	Not applicable.
· **Solubility**	
· **Water:**	Insoluble
· **Partition coefficient n-octanol/water (log value)**	Not determined.
· **Steam pressure:**	Not applicable.
· **Density and/or relative density**	
· **Density**	Not determined
· **Relative density**	Not determined.
· **Vapour density**	Not applicable.

· **9.2 Other information**	No further relevant information available.
· **Appearance:**	
· **Form:**	Powder
· **Important information on protection of health and environment, and on safety.**	
· **Self-inflammability:**	Product is not selfigniting.
· **Explosive properties:**	Product is not explosive. Not determined.
· **Solvent content:**	
· **Water:**	0.2-0.3 %
· **Solids content:**	99.8 %
· **Change in condition**	
· **Evaporation rate**	Not applicable.

· **Information with regard to physical hazard classes**	
· **Explosives**	Void
· **Flammable gases**	Void
· **Aerosols**	Void
· **Oxidising gases**	Void
· **Gases under pressure**	Void
· **Flammable liquids**	Void
· **Flammable solids**	Void
· **Self-reactive substances and mixtures**	Void
· **Pyrophoric liquids**	Void
· **Pyrophoric solids**	Void
· **Self-heating substances and mixtures**	Void
· **Substances and mixtures, which emit flammable gases in contact with water**	Void
· **Oxidising liquids**	Void
· **Oxidising solids**	Void
· **Organic peroxides**	Void
· **Corrosive to metals**	Void

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· **Desensitised explosives**	Void

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 hazard classes as defined in Regulation (EC) No 1272/2008**
· **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)

· **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.
· **11.2 Information on other hazards**

· **Endocrine disrupting properties**
None of the ingredients is listed.

SECTION 12: Ecological information

· **12.1 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)

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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)

· **12.2 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)

· **12.3 Bioaccumulative potential** No further relevant information available.
· **12.4 Mobility in soil** No further relevant information available.
· **12.5 Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **12.6 Endocrine disrupting properties**
The product does not contain substances with endocrine disrupting properties.
· **12.7 Other adverse effects**
· **Remark:** Harmful to fish
· **Additional ecological information:**
· **General notes:**
Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.
Harmful to aquatic organisms
Do not allow product to reach ground water, water bodies or sewage system.
Danger to drinking water if even small quantities leak into soil.

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.

· **Uncleaned packagings:**
· **Recommendation:**
Disposal must be made according to official regulations.

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Non contaminated packagings can be used for recycling.

SECTION 14: Transport information

· **14.1 UN number or ID number**
· **ADR, IMDG, IATA** UN3077

· **14.2 UN proper shipping name**
· **ADR** 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (dibenzoyl peroxide)
· **IMDG, IATA** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (dibenzoyl peroxide)

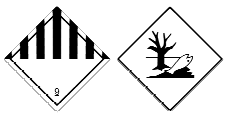
· **14.3 Transport hazard class(es)**
· **ADR**

· **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:**
· **Special marking (ADR):** Symbol (fish and tree)
· **Special marking (IATA):** Symbol (fish and tree)

· **14.6 Special precautions for user** Warning: Miscellaneous dangerous substances and articles.
· **Kemler Number:** 90

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· **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 Maritime transport in bulk according to IMO instruments**	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":**	UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (DIBENZOYL PEROXIDE), 9, III

SECTION 15: Regulatory information

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

· **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

· **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.
H335 May cause respiratory irritation.
H400 Very toxic to aquatic life.

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H410 Very toxic to aquatic life with long lasting effects.

· ***Abbreviations and acronyms:***
SADT: Self Accelerating Decomposition 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
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 (UK REACH)
PNEC: Predicted No-Effect Concentration (UK 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
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
Skin Sens. 1: Skin sensitisation – Category 1
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