Safety Data Sheet
acc. to OSHA HCS

Printing date 07/07/2022 Reviewed on 07/04/2022

1 Identification

· **Product identifier**

· **Trade name:** **Paladon 65 powder**

· **-**

· **Application of the substance / the mixture** Manufacture of dental prothesis

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

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

· **Information department:**
Tel. +1 (800) 431-1785 Fax: +1 (800) 522-1545
e-mail: customer.servicehkna@kulzer-dental.com

· **Emergency telephone number:**
Emergency CONTACT (24-Hour-Number)
ID 105860: (domestic) 1 800 535 5053 or international (001) 352 323 3500

2 Hazard(s) identification

· **Classification of the substance or mixture**
Sensitization - Skin 1 H317 May cause an allergic skin reaction.

· **Label elements**

· **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**

GHS07

· **Signal word** Warning

· **Hazard-determining components of labeling:**
methyl methacrylate
dibenzoyl peroxide

· **Hazard statements**
May cause an allergic skin reaction.

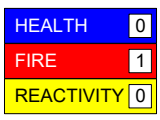
· **Precautionary statements**
Avoid release to the environment.
Wear protective gloves / eye protection.
If on skin: Wash with plenty of soap and water.

· **Classification system**

· **NFPA ratings for USA (scale 0-4)**

Health = 1
Fire = 1
Reactivity = 0

· **HMIS-Ratings (Scale 0-4)**



Health = 0
Fire = 1
Reactivity = 0

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· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**
· **Description:** Product based on methacrylate copolymerisates

· **Dangerous components:**

80-62-6	methyl methacrylate Flammable Liquids 2, H225 Skin Irritation 2, H315; Sensitization - Skin 1, H317; Specific Target Organ Toxicity - Single Exposure 3, H335	≥1-≤5%
94-36-0	dibenzoyl peroxide Self-reactive substances and mixtures - Type B, H241; Organic Peroxides - Type B, H241 Eye Irritation 2A, H319; Sensitization - Skin 1, H317	≥0.1-<1%

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 complaints.
· **After skin contact**
Immediately 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.
· **After swallowing**
Rinse out mouth and then drink plenty of water.
If symptoms persist 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**
CO_2, extinguishing powder or water spray. Fight larger fires with water spray 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**
Avoid contact with eyes and skin.
· **Environmental precautions:** Prevent seepage into sewage system, workpits and cellars.

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· **Methods and material for containment and cleaning up:** Pick up mechanically.
· **Reference to other sections**
No dangerous substances 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.

· **Conditions for safe storage, including any incompatibilities**
· **Storage**
· **Requirements to be met by storerooms and receptacles:** No special requirements.
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:** Keep cool, if possible (not above 25 °C).
· **Specific end use(s)** No further relevant information available.

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8 Exposure controls/personal protection

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

· **Control parameters**

· **Components with limit values that require monitoring at the workplace:**	
80-62-6 methyl methacrylate	
PEL	Long-term value: 410 mg/m³, 100 ppm
REL	Long-term value: 410 mg/m³, 100 ppm
TLV	Short-term value: 100 ppm Long-term value: 50 ppm DSEN, A4
94-36-0 dibenzoyl peroxide	
PEL	Long-term value: 5 mg/m³
REL	Long-term value: 5 mg/m³
TLV	Long-term value: 5 mg/m³ A4

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

· **Exposure controls**
· **Personal protective equipment**
· **General protective and hygienic measures**
Wash hands before breaks and at the end of 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.
· **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

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calculated in advance and has therefore to be checked prior to the application.
· **Penetration time of glove material**
The exact break through 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

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9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
· **Form:**	Powder
· **Color:**	Colorless Pink
· **Odor:**	Odorless
· **Odor threshold:**	Not determined.
· **pH-value:**	Mixture is non-soluble (in water).
· **Change in condition**	
· **Melting point/Melting range:**	undetermined
· **Boiling point/Boiling range:**	undetermined
· **Flash point:**	Not applicable
· **Flammability (solid, gaseous)**	Not determined.
· **Ignition temperature:**	400.0 °C (752 °F)
· **Decomposition temperature:**	Not determined.
· **Auto igniting:**	Product is not selfigniting.
· **Danger of explosion:**	Product is not explosive. However, formation of explosive powder/air mixture mis possible.
· **Explosion limits:**	
· **Lower:**	Not determined.
· **Upper:**	Not determined.
· **Vapor pressure:**	Not applicable.
· **Density at 20 °C (68 °F):**	0 g/cm³
· **Relative density**	Not determined.
· **Vapor 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.

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· **Solvent content:**	
· **Solids content:**	100.0 %
· **Other information**	No further relevant information available.

10 Stability and reactivity

· **Reactivity** No further relevant information available.
· **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:**

· **LD/LC50 values that are relevant for classification:**		
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)
94-36-0 dibenzoyl peroxide		
Oral	LD0	>2,000 mg/kg (mouse) (OECD 401)
Inhalative	LC0/4h	24.3 ppm (rat) (OECD 403)

· **Primary irritant effect:**
· **on the skin:** No irritant effect.
· **on the eye:** No irritating effect.
· **Sensitization:** No sensitizing effects known.
· **Additional toxicological information:**
The product is not subject to classification according to the calculation method of the General EU 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.

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**		
94-36-0	dibenzoyl peroxide	3

· **NTP (National Toxicology Program)**
None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**
None of the ingredients is listed.

· **Reproductive toxicity** Based on available data, the classification criteria are not met.

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12 Ecological information

· **Toxicity**

· **Aquatic toxicity:**	
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)
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)

· **Persistence and degradability**	
80-62-6 methyl methacrylate	
biodegradability	94 % /14d (not defined) (OECD 301C)
94-36-0 dibenzoyl peroxide	
biodegradability	71 % /28d (not defined) (OECD 301D)

· **Behavior 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 undiluted product or large quantities of it to reach ground water, water course 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.

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

14 Transport information

· **UN-Number**
· **DOT** Void
· **ADR, IMDG, IATA** UN3077

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

· **Transport hazard class(es)**
· **DOT**
· **Class** Void

· **ADR**

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

· **IMDG, IATA**

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

· **Packing group**
· **DOT** Void
· **ADR, IMDG, IATA** III

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

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· **Special precautions for user**	Warning: Miscellaneous dangerous substances and articles
· **Hazard identification number (Kemler code):**	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.
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.
· **Transport/Additional information:**	-
· **ADR**	
· **Excepted quantities (EQ)**	Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g
· **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

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**
No further relevant information available.

· **Sara**

· **SARA Section 355 (extremely hazardous substances)**

None of the ingredients is listed.

· **SARA Section 313 (specific toxic chemical listings)**

94-36-0	dibenzoyl peroxide

· **Proposition 65**

· **Prop 65 - Chemicals known to cause cancer**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

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· **Cancerogenity categories**

· **EPA (Environmental Protection Agency)**		
None of the ingredients is listed.		

· **TLV (Threshold Limit Value)**		
94-36-0	dibenzoyl peroxide	A4

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**		
None of the ingredients is listed.		

· **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 vapor.
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.

· **Date of preparation / last revision** 07/07/2022 / 3

· **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
DOT: US Department of Transportation
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)
NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
NIOSH: National Institute for Occupational Safety
OSHA: Occupational Safety & Health
TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit
Flammable Liquids 2: Flammable liquids – Category 2
Self-reactive substances and mixtures - Type B: Self-reactive substances and mixtures – Type B
Organic Peroxides - Type B: Organic peroxides – Type B
Skin Irritation 2: Skin corrosion/irritation – Category 2
Eye Irritation 2A: Serious eye damage/eye irritation – Category 2A
Sensitization - Skin 1: Skin sensitisation – Category 1
Specific Target Organ Toxicity - Single Exposure 3: Specific target organ toxicity (single exposure) – Category 3

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