



**Safety Data Sheet
acc. to OSHA HCS**

Printing date 07/07/2022

Reviewed on 07/07/2022

1 Identification

· **Product identifier**

· **Trade name: Palapress vario 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:**

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.

· **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

(Contd. on page 2)

US



Safety Data Sheet
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Trade name: Palapress vario powder

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

(Contd. of page 1)

3 Composition/information on ingredients

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

- **Dangerous components:**

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	≥1-≤5%
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%
72846-00-5	1-benzyl-5-phenylbarbituric acid Acute Toxicity - Oral 4, H302; Eye Irritation 2A, H319	≥0-≤5%

- **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 complaints.
 - **After skin contact** Immediately 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.
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**
CO₂, 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** Not required.
- **Environmental precautions:** No special measures required.

(Contd. on page 3)



**Safety Data Sheet
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Trade name: Palapress vario powder

(Contd. of page 2)

- **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.

· **Protective Action Criteria for Chemicals**

· PAC-1:		
94-36-0	dibenzoyl peroxide	15 mg/m ³
80-62-6	methyl methacrylate	17 ppm
13463-67-7	Titanium dioxide	30 mg/m ³
· PAC-2:		
94-36-0	dibenzoyl peroxide	1,200 mg/m ³
80-62-6	methyl methacrylate	120 ppm
13463-67-7	Titanium dioxide	330 mg/m ³
· PAC-3:		
94-36-0	dibenzoyl peroxide	7,000 mg/m ³
80-62-6	methyl methacrylate	570 ppm
13463-67-7	Titanium dioxide	2,000 mg/m ³

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.

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:**
The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit.
At this time, the remaining constituent has no known exposure limits.

94-36-0 dibenzoyl peroxide	
PEL	Long-term value: 5 mg/m ³
REL	Long-term value: 5 mg/m ³
TLV	Long-term value: 5 mg/m ³
	A4
80-62-6 methyl methacrylate	
PEL	Long-term value: 410 mg/m ³ , 100 ppm

(Contd. on page 4)



Safety Data Sheet
acc. to OSHA HCS

Printing date 07/07/2022

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Trade name: Palapress vario powder

(Contd. of page 3)

REL Long-term value: 410 mg/m³, 100 ppm
TLV Short-term value: 100 ppm
Long-term value: 50 ppm
DSEN, 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.
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 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

9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

· **Form:**

Powder

· **Color:**

Colorless

Pink

· **Odor:**

Nearly 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)

(Contd. on page 5)



Safety Data Sheet
acc. to OSHA HCS

Printing date 07/07/2022

Reviewed on 07/07/2022

Trade name: Palapress vario powder

(Contd. of page 4)

· 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/cm ³
· 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.
· 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:		
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)

(Contd. on page 6)



Safety Data Sheet
acc. to OSHA HCS

Printing date 07/07/2022

Reviewed on 07/07/2022

Trade name: Palapress vario powder

(Contd. of page 5)

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

Oral	LD50	500 mg/kg (ATE) 500 mg/kg (rat) (OECD 423)
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- **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
80-62-6	methyl methacrylate	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.

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)
NOEC/ 35d	9.4 mg/L (fish) (OECD 210)
LC50/ 35d	33.7 mg/L (fish) (OECD 210)

(Contd. on page 7)



Safety Data Sheet
acc. to OSHA HCS

Printing date 07/07/2022

Reviewed on 07/07/2022

Trade name: Palapress vario powder

(Contd. of page 6)

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

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

80-62-6 methyl methacrylate

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

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

biodegradability 29.1 % /29d (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 product to reach ground water, water course or sewage system.

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

Danger to drinking water if even small quantities leak into the ground.

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:**

Packaging can be reused or recycled after cleaning.

Non contaminated packagings can be used for recycling.

14 Transport information

UN-Number

· DOT

· ADR, IMDG, IATA

Void

UN3077

UN proper shipping name

· DOT

· ADR

· IMDG

Void

3077 ENVIRONMENTALLY HAZARDOUS
SUBSTANCE, SOLID, N.O.S. (dibenzoyl peroxide)
ENVIRONMENTALLY HAZARDOUS
SUBSTANCE, SOLID, N.O.S. (dibenzoyl peroxide),
MARINE POLLUTANT

(Contd. on page 8)







Safety Data Sheet
acc. to OSHA HCS

Printing date 07/07/2022

Reviewed on 07/07/2022

Trade name: Palapress vario powder

(Contd. of page 7)

· 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)
· 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

(Contd. on page 9)



Safety Data Sheet
acc. to OSHA HCS

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Trade name: Palapress vario powder

(Contd. of page 8)

<ul style="list-style-type: none"> · IMDG · Limited quantities (LQ) · Excepted quantities (EQ) 	<p>5 kg Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g</p>
<ul style="list-style-type: none"> · UN "Model Regulation": 	<p>UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (DIBENZOYL PEROXIDE), 9, III</p>

15 Regulatory information

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

· **Sara**

<ul style="list-style-type: none"> · SARA Section 355 (extremely hazardous substances) 	<p>None of the ingredients is listed.</p>
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<ul style="list-style-type: none"> · SARA Section 313 (specific toxic chemical listings) 	<table border="1"> <tr> <td>94-36-0</td> <td>dibenzoyl peroxide</td> </tr> <tr> <td>80-62-6</td> <td>methyl methacrylate</td> </tr> <tr> <td>1345-16-0</td> <td>Cobalt zinc aluminate blue spinel</td> </tr> </table>	94-36-0	dibenzoyl peroxide	80-62-6	methyl methacrylate	1345-16-0	Cobalt zinc aluminate blue spinel
94-36-0	dibenzoyl peroxide						
80-62-6	methyl methacrylate						
1345-16-0	Cobalt zinc aluminate blue spinel						

<ul style="list-style-type: none"> · Hazardous Air Pollutants 	<table border="1"> <tr> <td>80-62-6</td> <td>methyl methacrylate</td> </tr> <tr> <td>1345-16-0</td> <td>Cobalt zinc aluminate blue spinel</td> </tr> </table>	80-62-6	methyl methacrylate	1345-16-0	Cobalt zinc aluminate blue spinel
80-62-6	methyl methacrylate				
1345-16-0	Cobalt zinc aluminate blue spinel				

· **Proposition 65**

<ul style="list-style-type: none"> · Prop 65 - Chemicals known to cause cancer 	<table border="1"> <tr> <td>13463-67-7</td> <td>Titanium dioxide</td> </tr> </table>	13463-67-7	Titanium dioxide
13463-67-7	Titanium dioxide		

<ul style="list-style-type: none"> · Chemicals known to cause reproductive toxicity for females: 	<p>None of the ingredients is listed.</p>
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<ul style="list-style-type: none"> · Chemicals known to cause reproductive toxicity for males: 	<p>None of the ingredients is listed.</p>
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<ul style="list-style-type: none"> · Chemicals known to cause developmental toxicity: 	<p>None of the ingredients is listed.</p>
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· **Carcinogen categories**

<ul style="list-style-type: none"> · EPA (Environmental Protection Agency) 	<table border="1"> <tr> <td>80-62-6</td> <td>methyl methacrylate</td> <td>E, NL</td> </tr> </table>	80-62-6	methyl methacrylate	E, NL
80-62-6	methyl methacrylate	E, NL		

<ul style="list-style-type: none"> · TLV (Threshold Limit Value) 	<table border="1"> <tr> <td>94-36-0</td> <td>dibenzoyl peroxide</td> <td>A4</td> </tr> <tr> <td>80-62-6</td> <td>methyl methacrylate</td> <td>A4</td> </tr> </table>	94-36-0	dibenzoyl peroxide	A4	80-62-6	methyl methacrylate	A4
94-36-0	dibenzoyl peroxide	A4					
80-62-6	methyl methacrylate	A4					

<ul style="list-style-type: none"> · NIOSH-Ca (National Institute for Occupational Safety and Health) 	<table border="1"> <tr> <td>13463-67-7</td> <td>Titanium dioxide</td> </tr> </table>	13463-67-7	Titanium dioxide
13463-67-7	Titanium dioxide		

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



**Safety Data Sheet
acc. to OSHA HCS**

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Trade name: Palapress vario powder

(Contd. of page 9)

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.
- 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.

· **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
- Acute Toxicity - Oral 4: Acute toxicity – Category 4
- 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.**

US