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Revision: 17.11.2022

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

Printing date 17.11.2022

Version number 4 (replaces version 3)

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

- · 1.1 Product identifier
  - Trade name: PALA cre-active white, polar, pink, red, maroon, black
- · 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.

- · 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



- · Signal word Warning
- · Hazard-determining components of labelling:

triethylen glycol dimethacrylate

diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

Hazard statements

H317 May cause an allergic skin reaction.

Precautionary statements

P280 Wear protective gloves / eye protection.

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

- · 3.1 Substances
  - · Identification number(s): -
- 3.2 Mixtures
  - · **Description:** Product based on methacrylates

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Dangerous components:		
CAS: 109-16-0 EINECS: 203-652-6 Reg.nr.: 01-2119969287-21-xxx	triethylen glycol dimethacrylate Skin Sens. 1B, H317 (	≥25-≤50%
CAS: 75980-60-8 EINECS: 278-355-8 Reg.nr.: 01-2119972295-29-xxx	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide Repr. 2, H361f Aquatic Chronic 2, H411 Skin Sens. 1B, H317	≥0.25-<1%
CAS: 79-41-4 EINECS: 201-204-4	methacrylic acid Acute Tox. 3, H311 Skin Corr. 1A, H314; Eye Dam. 1, H318 Acute Tox. 4, H302; Acute Tox. 4, H332; STOT SE 3, H335 ATE: LD50 oral: 1,320 mg/kg LD50 dermal: 500 mg/kg LC50/4 h inhalative: 11 mg/l Specific concentration limit: STOT SE 3; H335: C ≥ 1%	≥0-<1%
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%

### 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.

In case of persistent symptoms consult doctor.

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. Use fire fighting measures that suit the environment.

5.2 Special hazards arising from the substance or mixture

No further relevant information available.

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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:

Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues). Dispose of the material collected according to regulations.

· 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.

### SECTION 7: Handling and storage

- · 7.1 Precautions for safe handling No special measures required.
  - Information about protection against explosions and fires: No special measures required.
- · 7.2 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).
- · 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:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

Not required.

· DNI	ELs		
109-16-0	riethylen glycol dimethacrylate		
Oral	general population, long term, systemic	8.33 mg/Kg (not defined)	
Dermal	worker industrial, long term, systemic	13.9 mg/Kg/d (not defined)	
	general population, long term, systemic	8.33 mg/Kg/d (not defined)	
Inhalative	worker industrial, long term, systemic	48.5 mg/m3 (not defined)	
	general population, long term, systemic	14.5 mg/m3 (not defined)	
75980-60-	8 diphenyl(2,4,6-trimethylbenzoyl)phos	sphine oxide	
Oral	general population, long term, systemic	0.0833 mg/Kg (not defined)	
Dermal	worker industrial, long term, systemic	0.233 mg/Kg/d (not defined)	
	general population, long term, systemic	0.0833 mg/Kg/d (not defined)	
	•		(Contd. on page



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lada al-45			0.000	(Contd. of pa
Inhalative worker industrial, long ter		-	0.822 mg/m3 (not defined)	
	general population, long	term, systemic	0.145 mg/m3 (not defined)	
	ethacrylic acid			
Dermal	1		4.25 mg/Kg/d (not defined)	
	general population, long	•	2.55 mg/Kg/d (not defined)	
Inhalative	worker industrial, long te		88 mg/m3 (not defined)	
		•	29.6 mg/m3 (not defined)	
	general population, long	-	6.3 mg/m3 (not defined)	
	general population, long	term, local	6.55 mg/m3 (not defined)	
	ethyl methacrylate			
Oral	general population, long	-	8.2 mg/Kg (not defined)	
Dermal	worker industrial, long te	-	13.67 mg/Kg/d (not defined)	
	general population, long	-	8.2 mg/Kg/d (not defined)	
Inhalative	worker industrial, acute,		416 mg/m3 (not defined)	
	worker industrial, long te	•	348.4 mg/m3 (not defined)	
	worker industrial, long te		208 mg/m3 (not defined)	
	general population, acute		208 mg/m3 (not defined)	
	general population, long	term, systemic	74.3 mg/m3 (not defined)	
· PNE	Cs			
109-16-0 t	riethylen glycol dimetha	acrylate		
freshwater	•	0.016 mg/l (not	defined)	
marine wa	ter	0.002 mg/l (not defined)		
sewage tre	eatment plant	1.7 mg/l (not de	efined)	
sediment,	dry weight, freshwater	0.185 mg/Kg (n	ot defined)	
sediment,	dry weight, marine water	0.018 mg/Kg (n	ot defined)	
soil, dry w	eight	0.027 mg/Kg (n	ot defined)	
75980-60-	8 diphenyl(2,4,6-trimeth	ylbenzoyl)phos	sphine oxide	
freshwater	•	0.0014 mg/l (no	ot defined)	
marine wa	ter	0.00014 mg/l (n	not defined)	
sediment,	dry weight, freshwater	0.115 mg/Kg (not defined)		
sediment,	dry weight, marine water	,		
soil, dry w	eight	0.0222 mg/Kg (	(not defined)	
79-41-4 m	ethacrylic acid			
freshwater	•	0.82 mg/l (not d	lefined)	
marine wa	ter	0.82 mg/l (not d	lefined)	
sewage tre	eatment plant	10 mg/l (not defined)		
soil, dry w	eight	1.2 mg/Kg (not	defined)	
80-62-6 m	ethyl methacrylate			
freshwater	•	0.94 mg/l (not d	lefined)	
marine wa	ter	0.094 mg/l (not	defined)	
sewage tre	eatment plant	10 mg/l (not de	fined)	
sediment,	dry weight, freshwater	10.2 mg/Kg (no	t defined)	
	dry weight, marine water	0.102 mg/Kg (n	ot defined)	



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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

Wash hands during breaks and at the end of the work.

- · Breathing equipment: Not necessary if room is well-ventilated.
- Hand protection

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

- Eve/face protection 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 Fluid Colour: Brown White

Pink

· Smell: Weak, characteristic Odour threshold: Not determined. Not determined

· Melting point/freezing point: · Boiling point or initial boiling point and

boiling range Not determined · Flammability Not applicable.

· Lower and upper explosion limit

Lower: Not determined. · Upper: Not determined.

· Flash point: >150 °C

· Decomposition temperature: Not determined.

SADT

pН Not determined.

Viscosity:

Kinematic viscosity Not determined. dynamic: Not determined.

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•	Sol	u	bil	ity

· Water: Not miscible or difficult to mix

· Partition coefficient n-octanol/water (log

value)Not determined.Steam pressure:Not determined.

Density and/or relative density

Density
 Relative density
 Vapour density
 Not determined.
 Not determined.
 Not determined.

#### 9.2 Other information

No further relevant information available.

· Appearance:

Form: Viscous

Important information on protection of health and environment, and on safety.

• Self-inflammability: Product is not selfigniting. Explosive properties: Product is not explosive.

· Change in condition

· Evaporation rate Not determined.

### · 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
· 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

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#### · Additional information:

If stored longer than recommended and/or above recommended temperature, product may polymerize generating heat.

### **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.

Acute	Acute toxicity based on available data, the classification chiefla are not met.				
· LD/	· LD/LC50 values that are relevant for classification:				
1565-94-2	1565-94-2 (1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate				
Oral	Oral LD50 >5,000 mg/kg (rat)				
109-16-0 1	triethylen	glycol dimethacrylate			
Oral	LD50	8,300 mg/kg (rat)			
Dermal	LD50	>2,000 mg/kg (mouse)			
112945-52	2-5 Amorp	hous silica			
Oral	LD50	>10,000 mg/kg (rat)			
Dermal	LD50	>5,000 mg/kg (rabbit)			
68187-15-	5 Zirconia	Praseodymium Yellow Zircon			
Oral	LD50	>2,200 mg/kg (rat) (OECD 401)			
75980-60-	8 dipheny	rl(2,4,6-trimethylbenzoyl)phosphine oxide			
Oral	LD50	>5,000 mg/kg (rat) (OECD 401)			
Dermal	LD50	>2,000 mg/kg (rat) (OECD 402)			
79-41-4 m	79-41-4 methacrylic acid				
Oral	LD50	1,320 mg/kg (rat) (OECD 401)			
Dermal	LD50	500-1,000 mg/kg (rabbit)			
Inhalative	LC50/4 h	7.1 mg/l (rat) (OECD 403)			
80-62-6 m	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)			
Ckin	Skin correction/irritation Passed on available data, the classification criteria are not met				

- · 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.



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SECTION 12: Ecological information		
12.1 Toxicity		
· Aquatic t	<u> </u>	
	-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl) smethacrylate	
LC50/96h	>100 mg/l (fish) (OECD 203)	
109-16-0 trie	thylen glycol dimethacrylate	
EC50/21d	51.9 mg/L (daphnia) (OECD 211)	
LC50/96h	16.4 mg/l (fish) (OECD 203)	
NOEC / 21d	32 mg/l (daphnia) (OECD 211)	
ErC50 / 72 h	>100 mg/l (algae) (OECD 201)	
NOEC / 72h	18.6 mg/l (algae) (OECD 201)	
EbC50 / 72h	72.8 mg/l (algae) (OECD 201)	
112945-52-5	Amorphous silica	
LC50/96h	>10,000 mg/l (fish)	
75980-60-8 d	liphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	
EC50/48h	10,100 mg/l (algae)	
	3.53 mg/l (daphnia) (OECD 202)	
LC50/96h	1.4 mg/l (fish) (OECD 203)	
ErC50 / 72 h	>2.01 mg/l (algae) (OECD 201)	
ErC10/72h	1.56 mg/L (algae) (OECD 201)	
79-41-4 meth	nacrylic acid	
EC50/48h	>130 mg/l (daphnia) (EPA OTS 797.1300)	
LC50/96h	85 mg/l (fish) (EPA OTS 797.1400)	
NOEC / 21d	53 mg/l (daphnia)	
ErC50 / 72 h	45 mg/l (algae) (OECD 201)	
NOEC / 72h	8.2 mg/l (algae) (OECD 201)	
NOEC / 96h	12 mg/l (fish) (EPA OTS 797.1400)	
NOEC / 48h	130 mg/l (daphnia) (EPA OTS 797.1300)	
NOEC/ 35d	10 mg/L (fish) (OECD 210)	
LC50/ 35d	42 mg/L (fish) (OECD 210)	
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)	
	>110 mg/l (algae) (OECD 201)	
NOEC/35d	9.4 mg/L (fish) (OECD 210)	
LC50/ 35d	33.7 mg/L (fish) (OECD 210)	
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#### 12.2 Persistence and degradability

### 1565-94-2 (1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate

Biodegradation 21 % /28d (not defined) (OECD 301F; ISO 9408/EEC 92/69/V, C.4-D)

109-16-0 triethylen glycol dimethacrylate

Biodegradation 85 % /28d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)

75980-60-8 diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

Biodegradation 0-10 % /28d (not defined) (OECD 301F; ISO 9408/ EEC 92/69/V, C.4-D)

79-41-4 methacrylic acid

Biodegradation 86 % /28d (not defined) (OECD 301D)

80-62-6 methyl methacrylate

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

#### · 12.3 Bioaccumulative potential

#### 75980-60-8 diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

Bloconcentration factor (BCF) 47-55 (not defined)

- · 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

For information on endocrine disrupting properties see section 11.

- · 12.7 Other adverse effects
  - · Additional ecological information:
    - · General notes:

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

### 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.

Non contaminated packagings can be used for recycling.

### SECTION 14: Transport information

•	14.1	UN	nump	er or IL	) numbei	r
		$\mathbf{n}$	ADM		IATA	

· **ADR, ADN, IMDG, IATA** Void

· 14.2 UN proper shipping name

· ADR, ADN, IMDG, IATA Void

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· 14.3 Transport hazard class(es)		
· ADR, ADN, IMDG, IATA · Class	Void	
· 14.4 Packing group · ADR, IMDG, IATA	Void	
· 14.5 Environmental hazards: · Marine pollutant:	No	
· 14.6 Special precautions for user	Not applicable.	
· 14.7 Maritime transport in bulk accordin IMO instruments	<b>g to</b> Not applicable.	
· Transport/Additional information:	-	
· UN "Model Regulation":	Void	

### SECTION 15: Regulatory information

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

No further relevant information available.

· 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.

H302 Harmful if swallowed.

H311 Toxic in contact with skin.

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation. H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H332 Harmful if inhaled.

H335 May cause respiratory irritation.

H361f Suspected of damaging fertility. H411 Toxic to aquatic life with long lasting effects.

Abbreviations and acronyms:

SADT: Self Accelerating Decomposition Temperature
ADR: 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 (ÚK REACH)

LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent

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PBT: Persistent, Bioaccumulative and Toxic PBT: Persistent, Bioaccumulative and Toxic VPVB: very Persistent and very Bioaccumulative Flam. Liq. 2: Flammable liquids – Category 2 Acute Tox. 4: Acute toxicity – Category 4 Acute Tox. 3: Acute toxicity – Category 3 Skin Corr. 1A: Skin corrosion/irritation – Category 1A Skin Irrit. 2: Skin corrosion/irritation – Category 2 Eye Dam. 1: Serious eye damage/eye irritation – Category 1 Skin Sens. 1: Skin sensitisation – Category 1B Skin Sens. 1B: Skin sensitisation – Category 1B Repr 2: Reproductive toxicity – Category 2

Repr. 2: Reproductive toxicity – Category 2 STOT SE 3: Specific target organ toxicity (single exposure) – Category 3 Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2

\* Data compared to the previous version altered.