

**Safety Data Sheet**

according to UK REACH Regulation

PremEco Line Gießkunststoff klar

Revision date: 19.01.2024

Product code: D258_klar

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SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

PremEco Line Gießkunststoff klar

Further trade names

PremEco Line Gießkunststoff, Polymer klar

1.2. Relevant identified uses of the substance or mixture and uses advised against**Use of the substance/mixture**

Material for the manufacture of dental medical devices.

1.3. Details of the supplier of the safety data sheet

Company name:	Merz Dental GmbH	
Street:	Kieferweg 1	
Place:	D-24321 Luetjenburg (GERMANY)	
Telephone:	+49-(0)4381-403-0	Telefax: +49-(0)4381-403-100
e-mail:	info@merz-dental.de	
Contact person:	Dipl. Chem Dr. Thomas Panther	Telephone: +49-(0)4381-403-448
e-mail:	Thomas.Panther@merz-dental.de	
Internet:	www.merz-dental.de	
Responsible Department:	Qualitaetssicherung (Quality Assurance)	

1.4. Emergency telephone number: +49-(0)551-19240 (Giftinformationszentrum-Nord)

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture****GB CLP Regulation**

This mixture is not classified as hazardous in accordance with GB CLP Regulation.

2.2. Label elements**GB CLP Regulation****Special labelling of certain mixtures**

EUH208	Contains dibenzoyl peroxide; benzoyl peroxide, methyl methacrylate. May produce an allergic reaction.
EUH210	Safety data sheet available on request.

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients**3.2. Mixtures****Chemical characterization**

polymethyl methacrylate

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Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (GB CLP Regulation)			
94-36-0	dibenzoyl peroxide; benzoyl peroxide			0.1 - < 1 %
	202-327-6	617-008-00-0		
	Org. Perox. B, Eye Irrit. 2, Skin Sens. 1; H241 H319 H317			
80-62-6	methyl methacrylate			0.1 - < 1 %
	201-297-1	607-035-00-6	01-2119452498-28	
	Flam. Liq. 2, Skin Irrit. 2, Skin Sens. 1, STOT SE 3; H225 H315 H317 H335			

Full text of H and EUH statements: see section 16.

Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
		Specific Conc. Limits, M-factors and ATE	
94-36-0	202-327-6	dibenzoyl peroxide; benzoyl peroxide	0.1 - < 1 %
		inhalation: LC50 = > 24300 mg/l (dusts or mists); oral: LD50 = > 2000 mg/kg	
80-62-6	201-297-1	methyl methacrylate	0.1 - < 1 %
		inhalation: LC50 = 29,8 mg/l (vapours); dermal: LD50 = > 5000 mg/kg; oral: LD50 = 7872 mg/kg	

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

Change contaminated clothing.

After inhalation

Provide fresh air. If breathing is irregular or stopped, administer artificial respiration. Medical treatment necessary. In all cases of doubt, or when symptoms persist, seek medical advice.

After contact with skin

After contact with skin, wash immediately with plenty of water and soap. Take off immediately all contaminated clothing and wash it before reuse. If skin irritation occurs: Get medical advice/attention.

After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water. Rinse immediately carefully and thoroughly with eye-bath or water. In case of eye irritation consult an ophthalmologist.

After ingestion

Rinse mouth immediately and drink 1 glass of water.

4.2. Most important symptoms and effects, both acute and delayed

No information available.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Co-ordinate fire-fighting measures to the fire surroundings. Extinguishing powder, Carbon dioxide (CO2), Water spray jet, Foam.

Unsuitable extinguishing media

Full water jet

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5.2. Special hazards arising from the substance or mixture

Non-flammable. This material is combustible, but will not ignite readily. In case of fire may be liberated: Carbon dioxide (CO₂), Carbon monoxide

5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus.

Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures****General advice**

Do not breathe dust. Wear breathing apparatus if exposed to vapours/dusts/aerosols. Wear personal protection equipment. Special danger of slipping by leaking/spilling product.

6.2. Environmental precautions

Do not allow to enter into surface water or drains. Clean contaminated articles and floor according to the environmental legislation.

6.3. Methods and material for containment and cleaning up**For cleaning up**

Take up mechanically. Treat the recovered material as prescribed in the section on waste disposal.

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

SECTION 7: Handling and storage**7.1. Precautions for safe handling****Advice on safe handling**

No special measures are necessary.

Advice on protection against fire and explosion

No special fire protection measures are necessary.

Advice on general occupational hygiene

Take off contaminated clothing. Wash hands before breaks and after work. When using do not eat, drink, smoke, sniff.

7.2. Conditions for safe storage, including any incompatibilities**Requirements for storage rooms and vessels**

Keep container tightly closed. Keep the packing dry and well sealed to prevent contamination and absorption of humidity.

Hints on joint storage

To follow: Storage class

7.3. Specific end use(s)

Material for the manufacture of dental medical devices.

SECTION 8: Exposure controls/personal protection**8.1. Control parameters**

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Exposure limits (EH40)

CAS No	Substance	ppm	mg/m ³	fibres/ml	Category	Origin
94-36-0	Dibenzoyl peroxide	-	5		TWA (8 h)	WEL
96-33-3	Methyl acrylate	5	18		TWA (8 h)	WEL
		10	36		STEL (15 min)	WEL
80-62-6	Methyl methacrylate	50	208		TWA (8 h)	WEL
		100	416		STEL (15 min)	WEL

DNEL/DMEL values

CAS No	Substance			
DNEL type		Exposure route	Effect	Value
94-36-0	dibenzoyl peroxide; benzoyl peroxide			
Consumer DNEL, long-term		inhalation	systemic	2,9 mg/m³
Worker DNEL, long-term		dermal	systemic	6,6 mg/kg bw/day
Consumer DNEL, long-term		oral	systemic	1,65 mg/kg bw/day
Worker DNEL, long-term		inhalation	systemic	11,75 mg/m³
Consumer DNEL, long-term		dermal	systemic	3,3 mg/kg bw/day
80-62-6	methyl methacrylate			
Worker DNEL, long-term		inhalation	local	210 mg/m³
Worker DNEL, long-term		dermal	systemic	13,67 mg/kg bw/day

PNEC values

CAS No	Substance	
Environmental compartment		Value
94-36-0	dibenzoyl peroxide; benzoyl peroxide	
Freshwater		0,000602 mg/l
Marine water		0,0000602 mg/l
Freshwater sediment		0,338 mg/kg
Micro-organisms in sewage treatment plants (STP)		0,35 mg/l
Soil		0,0758 mg/kg
80-62-6	methyl methacrylate	
Freshwater		< 0,94 mg/l
Marine water		< 0,94 mg/l
Soil		-----
Air		-----

8.2. Exposure controls



Appropriate engineering controls

Provide adequate ventilation as well as local exhaust at critical locations. Use an "other exhaust ventilation system" according to 2001/59/EC (Annex 7A).. If local exhaust ventilation is not possible or not sufficient, the

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entire working area should be ventilated by technical means.

Individual protection measures, such as personal protective equipment**Eye/face protection**

Wear eye/face protection.

Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

Skin protection

Use of protective clothing.

Respiratory protection

In case of inadequate ventilation wear respiratory protection.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state:	Powder
Colour:	white
Melting point/freezing point:	> 80 °C
Flash point:	> 250 °C
Water solubility:	poorly soluble
Solubility in other solvents	
not determined	
Partition coefficient n-octanol/water:	not determined
Density:	ca. 1,15 g/cm ³
Relative vapour density:	not determined

9.2. Other information**Information with regard to physical hazard classes****Explosive properties**

The product is not: Explosive.

Oxidizing properties

This material is combustible, but will not ignite readily.

Other safety characteristics

Evaporation rate:	not determined
Solvent separation test:	< 1%
Solid content:	not determined

SECTION 10: Stability and reactivity**10.1. Reactivity**

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

No known hazardous reactions.

10.4. Conditions to avoid

Decomposition takes place from temperatures above: 250 °C

10.5. Incompatible materials

Oxidising agent

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10.6. Hazardous decomposition products

Thermal decomposition can lead to the escape of irritating gases and vapours.

Hazardous decomposition products: SECTION 8: Exposure controls/personal protection

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in GB CLP Regulation

Acute toxicity

Based on available data, the classification criteria are not met.

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
94-36-0	dibenzoyl peroxide; benzoyl peroxide				
	oral	LD50 > 2000 mg/kg	Mouse	Nier, Korea 2001	OECD 401
	inhalation dust/mist	LC50 > 24300 mg/l	Rat		
80-62-6	methyl methacrylate				
	oral	LD50 7872 mg/kg	Rat	RTECS	
	dermal	LD50 > 5000 mg/kg	Rabbit	REACH Dossier	OECD 402
	inhalation (4 h) vapour	LC50 29,8 mg/l	Rat	REACH Dossier	standard acute metho

Irritation and corrosivity

Based on available data, the classification criteria are not met.

Sensitising effects

Based on available data, the classification criteria are not met.

Analogous to related material not skin sensitising. Contains: Dibenzoyl peroxide, methyl methacrylate There is no hazard as long as the substances are immobilised within the polymer matrix. Only when the polymer matrix is destroyed, e.g. by suitable solvents, can the sensitising components be mobilised again. In people who are already sensitised, the remobilised components can lead to allergic reactions.

Carcinogenic/mutagenic/toxic effects for reproduction

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

Further information

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

SECTION 12: Ecological information

12.1. Toxicity

The product is not: Ecotoxic.

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CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] [d]	Species	Source	Method
94-36-0	dibenzoyl peroxide; benzoyl peroxide					
	Acute fish toxicity	LC50 0,24 mg/l	96 h	Oryzias latipes (Ricefish)	Nier, Korea 2002c	OECD 203
	Acute algae toxicity	ErC50 0,44 mg/l	72 h	Selenastrum capricornutum	Nier, Korea 2002f	OECD 201
	Acute crustacea toxicity	EC50 0,07 mg/l	48 h	Daphnia pulex (water flea)	Nier, Korea 2002g	OECD 202
	Algae toxicity	NOEC 0,02 mg/l	3 d	Pseudokirchneriella subcapitata	REACH Dossier	EU Method C.3
	Crustacea toxicity	NOEC 0,001 mg/l	21 d	Daphnia pulex (water flea)	REACH Dossier	OECD 211
	Acute bacteria toxicity	0,30 g O2/g (EC50 0,35 mg/l)	0,5 h	activated sludge	REACH Dossier	OECD 209
80-62-6	methyl methacrylate					
	Acute fish toxicity	LC50 191 mg/l	96 h	Lepomis macrochirus (Bluegill)	Merck	
	Acute algae toxicity	ErC50 > 110 mg/l	72 h	Pseudokirchneriella subcapitata	REACH Dossier	OECD 201
	Acute crustacea toxicity	EC50 69 mg/l	48 h	Daphnia magna (Big water flea)	REACH Dossier	EPA OTS 797.1300

12.2. Persistence and degradability

The product has not been tested.

CAS No	Chemical name			
	Method	Value	d	Source
	Evaluation			
94-36-0	dibenzoyl peroxide; benzoyl peroxide			
	OECD 301D/ EEC 92/69/V, C.4-E	71 %	28	REACH Dossier
	Readily biodegradable (according to OECD criteria).			
80-62-6	methyl methacrylate			
	OECD 301C/ ISO 9408/ EEC 92/69/V, C.4-F	94 %	14	Publication
	Readily biodegradable (according to OECD criteria).			
	EPA, title 40 Code of Federal Regulations Part 160	> 99 %	2	40 CFR 160
	Readily biodegradable (according to OECD criteria).			

12.3. Bioaccumulative potential

The product has not been tested.

Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
94-36-0	dibenzoyl peroxide; benzoyl peroxide	3,2
80-62-6	methyl methacrylate	1,38

BCF

CAS No	Chemical name	BCF	Species	Source
94-36-0	dibenzoyl peroxide; benzoyl peroxide	47,4	n/h	EpiSuite QSAR tool
80-62-6	methyl methacrylate	2,97 - 3,5	Pisces	SDB HIT-ICE, B

12.4. Mobility in soil

The product has not been tested.

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12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to UK REACH.
The product has not been tested.

12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7. Other adverse effects

No information available.

Further information

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

SECTION 13: Disposal considerations**13.1. Waste treatment methods****Disposal recommendations**

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil. Dispose of waste according to applicable legislation.

List of Wastes Code - residues/unused products

070213 WASTES FROM ORGANIC CHEMICAL PROCESSES; wastes from the MFSU of plastics, synthetic rubber and man-made fibres; waste plastic

List of Wastes Code - used product

070213 WASTES FROM ORGANIC CHEMICAL PROCESSES; wastes from the MFSU of plastics, synthetic rubber and man-made fibres; waste plastic

Contaminated packaging

Non-contaminated packages may be recycled. Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information**Land transport (ADR/RID)**

14.1. UN number or ID number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

Inland waterways transport (ADN)

14.1. UN number or ID number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

Marine transport (IMDG)

14.1. UN number or ID number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number or ID number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

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14.6. Special precautions for user

No dangerous good in sense of this transport regulation.

14.7. Maritime transport in bulk according to IMO instruments

No dangerous good in sense of this transport regulation.

SECTION 15: Regulatory information

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

EU regulatory information

Restrictions on use (REACH, annex XVII):

Entry 75

Information according to 2012/18/EU

Not subject to 2012/18/EU (SEVESO III)

(SEVESO III):

National regulatory information

Water hazard class (D):

3 - highly hazardous to water

Skin resorption/Sensitization:

Causes allergic hypersensitivity reactions.

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

Changes

This data sheet contains changes from the previous version in section(s):

1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16.

Abbreviations and acronyms

CLP: Classification, labelling and Packaging

REACH: Registration, Evaluation and Authorization of Chemicals

GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals

UN: United Nations

CAS: Chemical Abstracts Service

DNEL: Derived No Effect Level

DMEL: Derived Minimal Effect Level

PNEC: Predicted No Effect Concentration

ATE: Acute toxicity estimate

LC50: Lethal concentration, 50%

LD50: Lethal dose, 50%

LL50: Lethal loading, 50%

EL50: Effect loading, 50%

EC50: Effective Concentration 50%

ErC50: Effective Concentration 50%, growth rate

NOEC: No Observed Effect Concentration

BCF: Bio-concentration factor

PBT: persistent, bioaccumulative, toxic

vPvB: very persistent, very bioaccumulative

ADR: Accord européen sur le transport des marchandises dangereuses par Route

(European Agreement concerning the International Carriage of Dangerous Goods by Road)

RID: Regulations concerning the international carriage of dangerous goods by rail

ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

(Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures)

IMDG: International Maritime Code for Dangerous Goods

EmS: Emergency Schedules

MFAG: Medical First Aid Guide

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IATA: International Air Transport Association

ICAO: International Civil Aviation Organization

MARPOL: International Convention for the Prevention of Marine Pollution from Ships

IBC: Intermediate Bulk Container

VOC: Volatile Organic Compounds

SVHC: Substance of Very High Concern

For abbreviations and acronyms, see: ECHA Guidance on information requirements and chemical safety assessment, chapter R.20 (Table of terms and abbreviations).

Key literature references and sources for data

(EU) 2020/878

OECD - SIDS

ECHA - REACH Dossier

Relevant H and EUH statements (number and full text)

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.

Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)