

**Safety Data Sheet**

according to UK REACH Regulation

**PremEco Line Gießkunststoff, Polymer**

Revision date: 25.01.2024

Product code: D258\_rosa

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

PremEco Line Gießkunststoff, Polymer

**Further trade names**

PremEco Line Gießkunststoff, Polymer: all colors

**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  
e-mail: info@merz-dental.de  
Contact person: Dipl. Chem Dr. Thomas Panther  
e-mail: Thomas.Panther@merz-dental.de  
Internet: www.merz-dental.de  
Responsible Department: Qualitaetssicherung (Quality Assurance)

Telefax: +49-(0)4381-403-100

Telephone: +49-(0)4381-403-448

**1.4. Emergency telephone**

+49-(0)551-19240 (Giftinformationszentrum-Nord)

**number:****SECTION 2: Hazards identification****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****3.1. Substances****Chemical characterization**

polymethyl methacrylate

**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 | 01-2119452498-28-0028 |             |
|         | 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.

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#### 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 (CO<sub>2</sub>), Water spray jet, Foam.

#### Unsuitable extinguishing media

Full water jet

### 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 (CO<sub>2</sub>), 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.

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**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****Exposure limits (EH40)**

| CAS No  | Substance           | ppm | mg/m <sup>3</sup> | 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    |

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#### DNEL/DMEL values

| CAS No                   | Substance                            | Exposure route | Effect   | Value                   |
|--------------------------|--------------------------------------|----------------|----------|-------------------------|
| 94-36-0                  | dibenzoyl peroxide; benzoyl peroxide |                |          |                         |
| Consumer DNEL, long-term |                                      | inhalation     | systemic | 2,9 mg/m <sup>3</sup>   |
| 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/m <sup>3</sup> |
| 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/m <sup>3</sup>   |
| Worker DNEL, long-term   |                                      | dermal         | systemic | 13,67 mg/kg bw/day      |

#### PNEC values

| CAS No   | Substance                            | Value         |
|--|--------------------------------------|---------------|
| 94-36-0  | dibenzoyl peroxide; benzoyl peroxide |               |
| Freshwater                                       |                                      | 0,000602 mg/l |
| Marine water                                     |                                      | 0,000602 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 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.

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**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:                                | various |                            |
| 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 <sup>3</sup> |
| 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

**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.

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| CAS No  | Chemical name                        |               |           |        |                      |
|---------|--------------------------------------|---------------|-----------|--------|----------------------|
|         | Exposure route                       | Dose          | Species   | Source | Method               |
| 94-36-0 | dibenzoyl peroxide; benzoyl peroxide |               |           |        |                      |
|         | oral                                 | LD50<br>mg/kg | > 2000    | Mouse  | Nier, Korea 2001     |
|         | inhalation dust/mist                 | LC50<br>mg/l  | > 24300   | Rat    |                      |
| 80-62-6 | methyl methacrylate                  |               |           |        |                      |
|         | oral                                 | LD50<br>mg/kg | 7872      | Rat    | RTECS                |
|         | dermal                               | LD50<br>mg/kg | > 5000    | Rabbit | REACH Dossier        |
|         | 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.

Similar to related material, not skin sensitizing. Contains: dibenzoyl peroxide, methyl methacrylate. There is no danger as long as the substances are immobilized within the polymer matrix. Only through the Destruction of the polymer matrix, e.g. by suitable solvents, can cause the sensitizing components be mobilized again. In people who have already been sensitized, the remobilized components can lead to allergic reactions. Similar to related material, not skin sensitizing. Contains: dibenzoyl peroxide, methyl methacrylate. There is no danger as long as the substances are immobilized within the polymer matrix. Only through the Destruction of the polymer matrix, e.g. by suitable solvents, can cause the sensitizing components be mobilized again. In people who have already been sensitized, the remobilized 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**

This substance does not meet the PBT/vPvB criteria of UK REACH.

The product has not been tested.

**12.6. Endocrine disrupting properties**

This substance does not have endocrine disrupting properties with respect to non-target organisms.

**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

**14.6. Special precautions for user**



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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  
(SEVESO III):

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

##### **National regulatory information**

Water hazard class (D):

2 - obviously hazardous to water

Skin resorption/Sensitization:

Causes allergic hypersensitivity reactions.

### **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

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

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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.