

**Safety Data Sheet according to Regulation (EC) No.
1907/2006 (REACH)**

Version: 2
Replaces version: 1

Revision date: 30.04.2019
from: 26.10.2015

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

1.1. Product identifier

Thermeo Powder (PL-2)

CAS No.:
EC No.:
INDEX No.:
REACH No.:

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

Relevant identified uses: Manufacture.
Uses advised against: Do not use for private purposes (household).

1.3. Details of the supplier of the safety data sheet

Manufacturer

pro3dure medical GmbH

Am Burgberg 13
D 58642 Iserlohn

Telephone +49 (0)2374 920050-10
Telefax: +49 (0)2374 920050-50

Supplier

pro3dure medical GmbH

Am Burgberg 13
D 58642 Iserlohn

Telephone +49 (0)2374 920050-10
Telefax: +49 (0)2374 920050-50

Information contact

pro3dure medical GmbH

Information telephone +49 (0)2374 920050-10
Information telefax +49 (0)2374 920050-50
E-mail (competent person) info@pro3dure.com
Website www.pro3dure.com

1.4. Emergency telephone number

this number is only available during office time

Telephone +49 (0)2374 920050-10

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008:
Skin Sens. 1/1A/1B, H317; Aquatic Chronic 3, H412

2.2. Label elements

Classification according to Regulation (EC) No 1272/2008 [CLP]

Hazard pictograms



Signal word: GHS07
Warning

Hazard statements:

H317 May cause an allergic skin reaction.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements:

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P302+352 IF ON SKIN: Wash with plenty of water/?.
P321 Specific treatment (see ? on this label).
P333+313 If skin irritation or rash occurs: Get medical advice/attention.
P362+364 Take off contaminated clothing and wash it before reuse.
P501 Dispose of contents/container to ?.

Hazardous component(s) for labelling:

xxx (Dibenzoylperoxid)

Special labelling of particular preparations:

Safety data sheet available for professional user on request.

2.3. Other hazards

See attached safety data sheets and/or usage instructions.

SECTION 3: Composition / information on ingredients

3.1. Substances

not applicable

3.2. Mixtures

Mixture related information

Composition/information on ingredients

Substance:	EC-no.:	CAS-No.:	INDEX no.:	REACH-no.:	Concentration:	Classification: EC 1272/2008 (CLP):
Polymethylmethacrylat, homopolymer		9011-14-7			99	-
Dibenzoylperoxide	202-327-6	94-36-0	617-008-00-0		1	-

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

SECTION 4: First aid measures

4.1. Description of first aid measures

General information: In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible). Take off immediately all contaminated clothing.

In case of inhalation: Move victim to fresh air. Put victim at rest and keep warm. In case of irregular breathing or respiratory arrest provide artificial respiration. Call a physician immediately.

Following skin contact: Wash immediately with: Water and soap

After eye contact: In case of contact with eyes, rinse immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Subsequently consult an ophthalmologist.

After ingestion: If accidentally swallowed rinse the mouth with plenty of water (only if the person is conscious) and obtain immediate medical attention. Do NOT induce vomiting.

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

-

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

-

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media Water fog. High power water jet. Carbon dioxide (CO₂). Foam. dry extinguishing powder.
Unsuitable extinguishing media -

5.2. Special hazards arising from the substance or mixture

In case of fire may be liberated: Pyrolysis products, toxic.

5.3. Advice for firefighters

General information

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

Special protective equipment for fire-fighters:

-

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Wear breathing apparatus if exposed to vapours/dusts/aerosols.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

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

Advices on safe handling

-

Precautions against fire and explosion:

Only use the material in places where open light, fire and other flammable sources can be kept away. Always close containers tightly after the removal of product. Use only in well-ventilated areas.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed in a cool, well-ventilated place. Ensure adequate ventilation of the storage area. Keep in a cool, well-ventilated place. Keep away from sources of ignition - No smoking. Keep/Store only in original container. Keep container tightly closed. Protect against: heat. Air. moisture. Provide earthing of containers, equipment, pumps and ventilation facilities.

Hints on joint storage

-

7.3. Specific end use(s)

Observe instructions for use.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

occupational exposure limit value

Substance:	CAS-No.:	Source:	Occupational exposure limit value:[ppm]	Occupational exposure limit value:[mg/m ³]	Limitation of exposure peaks:	Remark:

Substance with a common (EC) occupational exposure limit value.

Substance:	CAS-No.:	Source:	Occupational exposure limit value:[ppm]	Occupational exposure limit value:[mg/m ³]	Limitation of exposure peaks:	Remark:

DNEL-/PNEC-values

DNEL value

Substance:	CAS-No.:	DNEL/DMEL

PNEC Value

Substance:	CAS-No.:	PNEC

Additional information

-

8.2. Exposure controls

Occupational exposure controls:

-

General protection and hygiene measures:

When using do not eat, drink, smoke, sniff. Wash hands before breaks and after work. Apply skin care products after work. Wash contaminated clothing prior to re-use.

Personal protection equipment

Only wear fitting, comfortable and clean protective clothing.

Respiratory protection

With correct and proper use, and under normal conditions, breathing protection is not required. Respiratory protection necessary at: insufficient ventilation Suitable respiratory protection apparatus: Self-contained respirator (breathing apparatus) (DIN EN 133)

Hand protection

Tested protective gloves are to be worn: DIN-/EN-Norms: DIN EN 374

Eye/face protection

Tightly sealed safety glasses.

Body protection:

For the protection against direct skin contact, body protective clothing is essential (in addition to the usual working clothes). Only wear fitting, comfortable and clean protective clothing. Barrier creams are not substitutes for body protection.

Environmental exposure controls

-

Consumer exposure controls

-

Exposure Scenario:

-

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state: Powder
Colour: white
Odour: -
Odour threshold: -

Safety relevant basis data

	parameter	Value	unit	Remark
pH:				No data available
Melting point/freezing point:				No data available
Initial boiling point and boiling range:				No data available
Flash point:				No data available
Evaporation rate:				No data available
Flammability (solid, gas):				No data available
Explosivity:				No data available
Upper flammability or explosive limits:				No data available
lower flammability or explosive limits:				No data available
Vapour pressure:				No data available
Vapour density:				No data available
Relative density:				No data available
Density:	at °C:	1,1	g/cm ³	
Soluble (g/L) in:				No data available
Water solubility (g/L):				No data available
Fat solubility (g/L):				No data available
Partition coefficient: n-octanol/water:				No data available
Ignition temperature:				No data available
Decomposition temperature:				No data available
Viscosity:				No data available
Oxidizing properties:				No data available

9.2. Other information

none

SECTION 10: Stability and reactivity

10.1. Reactivity

-

10.2. Chemical stability

-

10.3. Possibility of hazardous reactions

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10.4. Conditions to avoid

Oxidizing agent

10.5. Incompatible materials

metal. Oxidizing agents. Acid. Base. Reducing agent. metal.

10.6. Hazardous decomposition products

-

SECTION 11: Toxicological information

11.1. Information on toxicological effects

There are no data available on the preparation/mixture itself.

M-factor: -

Acute toxicity (dermal): -

Acute toxicity (oral): -

Acute toxicity (inhalative): -

Acute toxicity

Substance:	CAS-No.:	Toxicological information
Dibenzoylperoxide	94-36-0	
Polymethylmethacrylat, homopolymer	9011-14-7	

Skin corrosion/irritation:

No information available.

Serious eye damage/irritation:

No information available.

Respiratory or skin sensitisation:

No information available.

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

Carcinogenicity:

-

Germ cell mutagenicity:

-

Reproductive toxicity:

-

STOT-single exposure:

-

STOT-repeated exposure:

-

Aspiration hazard:

No information available.

SECTION 12: Ecological information

12.1. Toxicity

There are no data available on the preparation/mixture itself.

Ecotoxicity

Substance:	CAS-No.:	Ecotoxicity
Dibenzoylperoxide	94-36-0	
Polymethylmethacrylat, homopolymer	9011-14-7	

12.2. Persistence and degradability

There are no data available on the preparation/mixture itself.

12.3. Bioaccumulative potential

There are no data available on the mixture itself.

12.4. Mobility in soil

There are no data available on the mixture itself.

12.5. Results of PBT and vPvB assessment

There are no data available on the mixture itself.

12.6. Other adverse effects

There are no data available on the mixture itself.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Appropriate disposal/Product:

-

Appropriate disposal / Package

Can be incinerated together with household waste in compliance with applicable technical regulations following consultation with approved waste disposal management companies and authorities in charge.

List of proposed waste codes / waste designations according to EWC / AVV

-

Waste key product: -

Waste key packaging: -

SECTION 14: Transport information

14.1. UN number

UN No.: -

14.2. UN proper shipping name

Land transport (ADR/RID)

-

-

Sea transport (IMDG), Air transport (ICAO-TI / IATA-DGR)

-
-

14.3. Transport hazard class(es)

Hazard label(s) / Label: - Classification code: / Classification Code: -

14.4. Packing group

Packing group/ Packing Group: -

14.5. Environmental hazards

ADR/RID / IMDG / ICAO-TI / IATA-DGR:
Marine pollutant:

Yes

No

14.6. Special precautions for user

Land transport (ADR/RID)

transport category: - tunnel restriction code: -
Special provisions: - Limited quantity (LQ): -

Sea transport (IMDG)

EmS-No: -
Special provisions: - Limited quantity (LQ): -

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Remark -

SECTION 15: Regulatory information

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

EU legislation

Information on Regulation (EC) No 166/2006 establishing a European Pollutant Release and Transfer Register:
-

Regulation (EC) No. 1005/2009 on substances that lead to the depletion of the ozone layer:
-

Regulation (EC) No. 648/2004 (Detergents regulation)
-

Regulation (EC) No 850/2004 [POP-Regulation]:
-

Regulation (EU) No 649/2012 on the export and import of dangerous chemicals:
-

Use restriction according to REACH annex XVII, no.::
-

National regulations

Observe in addition any national regulations!

Restrictions of occupation

-

Other regulations, restrictions and prohibition regulations

none

15.2. Chemical Safety Assessment

For this preparation a chemical safety assessment has been carried out.

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SECTION 16: Other information

Relevant H- and EUH-phrases (Number and full text):

Hazard statements

H317 May cause an allergic skin reaction.

H412 Harmful to aquatic life with long lasting effects.

Training advice

-

Recommended restrictions of use:

-

Further remarks:

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

Documentation of changes:

-

Key literature references and sources for data

-

Abbreviations and acronyms

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