

# SAFETY DATA SHEET

PoliDent

according to Commission Regulation (EU) 2020/878 as amended



## POLIREPAR S POWDER

Creation date 21st November 2019  
Revision date 15th February 2023 Version 2.0

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

- 1.1. Product identifier** POLIREPAR S POWDER  
Substance / mixture mixture
- 1.2. Relevant identified uses of the substance or mixture and uses advised against**  
**Mixture's intended use**  
Material for the fabrication of dental prosthesis repairs.  
**Mixture uses advised against**  
The product should not be used in ways other than those referred in Section 1.
- 1.3. Details of the supplier of the safety data sheet**  
**Supplier**  
Name or trade name Polident d.o.o., Dental Products Industry  
Address Volčja Draga 42, Volčja Draga, 5293  
Slovenia  
VAT Reg No SI31319297  
Phone 00386 5 3304840, Fax: 00386 5 3304870  
E-mail polident@polident.si
- Competent person responsible for the safety data sheet**  
Name Polident d.o.o., Dental Products  
Industry Industry  
E-mail polident@polident.si
- 1.4. Emergency telephone number**  
00386 5 3304840 - Polident d.o.o. - Available from Mon to Fri 7 a.m. to 3 p.m.  
112 - Information center - available 0-24

### SECTION 2: Hazards identification

- 2.1. Classification of the substance or mixture**  
**Classification of the mixture in accordance with Regulation (EC) No 1272/2008**  
The mixture is not classified as dangerous according to Regulation (EC) No 1272/2008.  
Full text of all classifications and hazard statements is given in the section 16.
- 2.2. Label elements**  
**Supplemental information**  
EUH208 Contains Dibenzoyl peroxide, Methyl methacrylate. May produce an allergic reaction.
- 2.3. Other hazards**  
The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605. Mixture does not contain any substance meet the criteria for PBT or vPvB in accordance with Annex XIII of Regulation (EC) No. 1907/2006 (REACH) as amended. Dust may form explosive mixture with air.

### SECTION 3: Composition/information on ingredients

- 3.2. Mixtures**  
**Chemical characterization**  
Product contents polymethylmethacrylate, pigments and dibenzoyl peroxide.  
**Mixture contains these hazardous substances and substances with the highest permissible concentration in the working environment**

Identification numbers	Substance name	Content in % weight	Classification according to Regulation (EC) No 1272/2008	Note
Index: 617-008-00-0 CAS: 94-36-0 EC: 202-327-6 Registration number: 01-2119511472-50	Dibenzoyl peroxide	<1	Org. Perox. B, H241 Skin Sens. 1, H317 Eye Irrit. 2, H319 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410 (M=10)	1, 2

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Identification numbers	Substance name	Content in % weight	Classification according to Regulation (EC) No 1272/2008	Note
Index: 607-035-00-6 CAS: 80-62-6 EC: 201-297-1 Registration number: 01-2119452498-28	Methyl methacrylate	<1	Flam. Liq. 2, H225 Skin Irrit. 2, H315 Skin Sens. 1B, H317 STOT SE 3, H335 Specific concentration limit: STOT SE 3, H335: C ≥ 10 %	1, 2

### Notes

- Note D: Certain substances which are susceptible to spontaneous polymerisation or decomposition are generally placed on the market in a stabilised form. It is in this form that they are listed in Part 3 of Annex VI to Regulation (EC) No 1272/2008. However, such substances are sometimes placed on the market in a non-stabilised form. In this case, the supplier who places such a substance on the market must state on the label the name of the substance followed by the words "non-stabilised".
- A substance for which exposure limits are set.

Full text of all classifications and hazard statements is given in the section 16.

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

Take care of your own safety. If any health problems are manifested or if in doubt, inform a doctor and show him information from this safety data sheet.

#### If inhaled

There are not any particular first aid measures required. Remove person to fresh air and keep comfortable for breathing. If the affected person is not breathing, breathing is irregular or in respiratory arrest provide artificial respiration or oxygen. Provide medical treatment if irritation, dyspnoea or other symptoms persist.

#### If on skin

Remove contaminated clothes. Rinse contaminated areas with a flow of water, lukewarm at best, for 10-30 minutes; do not use any brush, soap or neutralizers. Provide medical treatment if skin irritation persists.

#### If in eyes

Rinse eyes immediately with a flow of running water, open the eyelids (also using force if needed); remove contact lenses immediately if worn by the affected person. Depending on the situation, call medical rescue service or ensure medical treatment.

#### If swallowed

Rinse out the mouth with clean water. In the event of issues, find medical help.

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

#### If inhaled

Not expected. May cause respiratory irritation. Cough, headache.

#### If on skin

Not expected. May cause an allergic skin reaction. Irritation, itching, redness.

#### If in eyes

Not expected. It can cause irritation and restorable damage. Irritation, lacrimation, pain.

#### If swallowed

Not expected.

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

Symptomatic treatment.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

#### Suitable extinguishing media

Carbon dioxide, water spray jet, water mist. Accommodate extinguishing components to the location of fire.

#### Unsuitable extinguishing media

Water - full jet. Avoid extinguishing methods that may create dust clouds. The water jet can disperse dust into the air, creating a fire hazard and possible explosion hazard if exposed to an ignition source.

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### 5.2. Special hazards arising from the substance or mixture

In the event of fire, carbon monoxide, carbon dioxide and other toxic gases may arise. Inhalation of hazardous degradation (pyrolysis) products may cause serious health damage.

Polymer powder is flammable. Burning or thermal decomposition produces toxic, irritating and flammable fumes.

### 5.3. Advice for firefighters

Self-Contained Breathing Apparatus (SCBA) with a chemical protection suit only where personal (close) contact is likely. Use a self-contained breathing apparatus and full-body protective clothing. Closed containers with the product near the fire should be cooled with water. Do not allow run-off of contaminated fire extinguishing material to enter drains or surface and ground water.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

Follow the instructions in the Sections 7 and 8. Prevent contact with skin and eyes. Do not inhale dust. Spillage presents a slip hazard - sweep up carefully, avoiding dust formation.

### 6.2. Environmental precautions

Prevent contamination of the soil and entering surface or ground water.

### 6.3. Methods and material for containment and cleaning up

Clean up mechanically. Dispose of the collected material according to the instructions in the section 13. Small amount of the product can be wiped out with dry cloth. Clean up mechanically. After removal of the product, wash the contaminated site with plenty of water.

### 6.4. Reference to other sections

See the Section 7, 8 and 13.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Only adequate trained persons may deal with product. For use in dentistry only.

Use personal protective equipment as per Section 8. Observe valid legal regulations on safety and health protection. Protect from moisture. Do not inhale dust. Ensure empty containers have been cleaned of any residue before reuse. Before transferring product, ensure that there are no traces of incompatible material residues in the containers.

Do not eat, drink or smoke when using this product. Contaminated clothing must be changed before entering the dining room.

### 7.2. Conditions for safe storage, including any incompatibilities

Keep the powder only in the original vessel in cool and dry place.

Do not store together with food, drink and animal feed. Store in a well-ventilated place. See section 10.

### 7.3. Specific end use(s)

Expiry date: Considering the instructions for safety storage and handling the expiry date of the powder is five years.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

The mixture contains substances for which occupational exposure limits are set.

#### European Union

#### Commission Directive 2009/161/EU

Substance name (component)	Type	Value	Note
Methyl methacrylate (CAS: 80-62-6)	OEL 8 hours	50 ppm	
	OEL 15 minutes	100 ppm	

#### Slovenia

#### Uradni list RS, Št. 38

Substance name (component)	Type	Value	Note
Dibenzoyl peroxide dust - alveolar fraction (CAS: 94-36-0)	8 hours	1,25 mg/m <sup>3</sup>	Alveolar fraction - respirable fraction which can penetrate the sac alveolar.

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**Slovenia**

**Uradni list RS, Št. 38**

Substance name (component)	Type	Value	Note
Dibenzoyl peroxide dust - alveolar fraction (CAS: 94-36-0)	KTV (15 min)	2,5 mg/m <sup>3</sup>	Alveolar fraction - respirable fraction which can penetrate the sac alveolar.
Dibenzoyl peroxide dust - inhalable fraction (CAS: 94-36-0)	8 hours	10 mg/m <sup>3</sup>	Inhalable fraction - the part of the total suspended substance inhaled by the worker.
	KTV (15 min)	20 mg/m <sup>3</sup>	

**Slovenia**

**Uradni list RS, Št. 72/2021**

Substance name (component)	Type	Value	Note
Dibenzoyl peroxide (CAS: 94-36-0)	8 hours	5 mg/m <sup>3</sup>	Inhalable fraction - the part of the total suspended substance inhaled by the worker.
	KTV (15 min)	5 mg/m <sup>3</sup>	
Methyl methacrylate (CAS: 80-62-6)	8 hours	210 mg/m <sup>3</sup>	Substances representing no risk to the foetus with reference to the limit values.
	8 hours	50 ppm	
	KTV (15 min)	420 mg/m <sup>3</sup>	
	KTV (15 min)	100 ppm	

**United Kingdom**

**EH40/2005 Workplace exposure limits (Fourth Edition 2020)**

Substance name (component)	Type	Value	Note
Dibenzoyl peroxide (CAS: 94-36-0)	WEL 8h	5 mg/m <sup>3</sup>	
Methyl methacrylate (CAS: 80-62-6)	WEL 8h	208 mg/m <sup>3</sup>	
	WEL 8h	50 ppm	
	WEL 15min	416 mg/m <sup>3</sup>	
	WEL 15min	100 ppm	

**DNEL**

Methyl methacrylate

Workers / consumers	Route of exposure	Value	Effect	Value determination	Source
Workers	Inhalation	348.4 mg/m <sup>3</sup>	Chronic effects systemic		ECHA REACH
Workers	Inhalation	208 mg/m <sup>3</sup>	Chronic effects local		ECHA REACH
Workers	Inhalation	416 mg/m <sup>3</sup>	Acute effects local		ECHA REACH
Workers	Dermal	13.67 mg/kg bw/day	Chronic effects systemic		ECHA REACH
Workers	Dermal	1.5 mg/cm <sup>2</sup>	Chronic effects local		ECHA REACH
Workers	Dermal	1.5 mg/cm <sup>2</sup>	Acute effects local		ECHA REACH

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Methyl methacrylate

Workers / consumers	Route of exposure	Value	Effect	Value determination	Source
Consumers	Inhalation	74.3 mg/m <sup>3</sup>	Chronic effects systemic		ECHA REACH
Consumers	Inhalation	104 mg/m <sup>3</sup>	Chronic effects local		ECHA REACH
Consumers	Inhalation	208 mg/m <sup>3</sup>	Acute effects local		ECHA REACH
Consumers	Dermal	8.2 mg/kg bw/day	Chronic effects systemic		ECHA REACH
Consumers	Dermal	1.5 mg/cm <sup>2</sup>	Chronic effects local		ECHA REACH
Consumers	Dermal	1.5 mg/cm <sup>2</sup>	Acute effects local		ECHA REACH
Consumers	Oral	8.2 mg/kg bw/day	Chronic effects systemic		ECHA REACH

### PNEC

Methyl methacrylate

Route of exposure	Value	Value determination	Source
Freshwater environment	0.94 mg/l		ECHA REACH
Marine water	0.094 mg/l		ECHA REACH
Microorganisms in sewage treatment	10 mg/l		ECHA REACH
Freshwater sediment	10.2 mg/kg of food		ECHA REACH
Sea sediments	1.02 mg/kg of food		ECHA REACH
Soil (agricultural)	1.48 mg/kg of dry substance of soil		ECHA REACH

### 8.2. Exposure controls

Do not eat, drink and smoke during work. Wash your hands thoroughly with water and soap after work and before breaks for a meal and rest. Follow the usual measures intended for health protection at work and especially for good ventilation. This can be achieved only by local suction or efficient general ventilation. If exposure limits cannot be observed in this mode, suitable protection of airways must be used.

#### Eye/face protection

If there is a risk of dust, use safety glasses with side protection (EN 166:2007).

#### Skin protection

Hand protection: Protective gloves resistant to the product. EN ISO 374-1. When choosing appropriate thickness, material and permeability of the gloves, observe recommendations of their particular manufacturer. On the whole, for permanent contact in work areas, natural latex (NR) gloves are suitable.

#### Respiratory protection

Under regular circumstances it is not necessary. Use a mask with anti-dust filter when the exposition limits of the substances are exceeded or at the place with insufficient ventilation.

Half mask with dust filter P3 or FFP3 - EN 405:2002+A1:2010, EN 136:1998/AC:2000, EN 14387:2021. For concentrations of dust/gases/vapours above the usable limit of the filters, for oxygen concentrations below 17% or in unclear conditions, use self-contained breathing apparatus with a closed circuit according to EN 145:1998, EN 138:1996.

#### Thermal hazard

Not available.

#### Environmental exposure controls

Observe usual measures for protection of the environment, see Section 6.2.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	solid
Colour	pink shades
Odour	without fragrance
Melting point/freezing point	110 °C (softening point)
Boiling point or initial boiling point and boiling range	data not available
Flammability	data not available

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Lower and upper explosion limit	data not available
Flash point	>250 °C
Auto-ignition temperature	>400 °C
Decomposition temperature	data not available
pH	data not available
Kinematic viscosity	data not available
Solubility in water	insoluble
Solubility esters, ketones and chlorinated hydrocarbons	soluble
Partition coefficient n-octanol/water (log value)	data not available
Vapour pressure	data not available
Density and/or relative density	
Density	1,2 g/cm <sup>3</sup> at 20 °C
Relative vapour density	data not available
Particle characteristics	data not available

### 9.2. Other information

not available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

When used in the standard way, there is not any dangerous reaction with other substances.  
Avoid the formation of dust clouds which could cause an explosion hazard.  
Depolymerization begins at 250 °C.

### 10.2. Chemical stability

The product is stable under normal conditions.

### 10.3. Possibility of hazardous reactions

The product is stable under normal conditions. According to the instructions for use, there are no known dangerous reactions.

### 10.4. Conditions to avoid

The product is stable and no degradation occurs under normal use. Protect against flames, sparks, overheating and against frost.  
Avoid heating above 240 °C. Avoid dust formation / dusting.

### 10.5. Incompatible materials

The polymer contains a deposit of benzoyl peroxide. It can react with oxidants, reductants, acids, bases and amines, leading to decomposition.

### 10.6. Hazardous decomposition products

Not developed under normal uses. Dangerous outcomes such as carbon monoxide and carbon dioxide are formed at high temperature and in fire. Methacrylate monomer.

## SECTION 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Inhalation of solvent vapors above values exceeding exposure limits for working environment may result in acute inhalation poisoning, depending on the level of concentration and exposure time. No toxicological data is available for the mixture.

#### Acute toxicity

Based on available data the classification criteria are not met.

Dibenzoyl peroxide

Route of exposure	Parameter	Value	Exposure time	Species	Sex
	LD <sub>50</sub>	7710 mg/kg		Rat	
	LC <sub>50</sub>	24.3 mg/l	4 hours	Rat	

Methyl methacrylate

Route of exposure	Parameter	Value	Exposure time	Species	Sex
Oral	LD <sub>50</sub>	>5000 mg/kg		Rat	
Inhalation	LC <sub>50</sub>	29.8 mg/l	4 hours	Rat	

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Methyl methacrylate

Route of exposure	Parameter	Value	Exposure time	Species	Sex
Dermal	LD <sub>50</sub>	>5000 mg/kg		Rabbit	M

### 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.

Methyl methacrylate

Route of exposure	Result	Exposure time	Species
Eye	No effect		Rabbit

### Respiratory or skin sensitisation

Based on available data the classification criteria are not met.

May cause an allergic skin reaction.

Dibenzoyl peroxide

Route of exposure	Result	Method	Exposure time	Species	Sex	Source
Dermal	Sensitizing					

Methyl methacrylate

Route of exposure	Result	Method	Exposure time	Species	Sex	Source
Dermal	Sensitizing	OECD 429		Mouse		LLNA

### 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.

### Toxicity for specific target organ - single exposure

Based on available data the classification criteria are not met.

Methyl methacrylate

Route of exposure	Parameter	Value	Specific target organ	Result	Species	Sex
Inhalation			Lungs	Irritating		

### Toxicity for specific target organ - repeated exposure

Based on available data the classification criteria are not met.

Methyl methacrylate

Route of exposure	Parameter	Value	Result	Species	Sex
Inhalation	NOAEL	25 ppm		Rat	
Oral	NOAEL	2000 ppm		Rat	

### Aspiration hazard

Based on available data the classification criteria are not met.

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### 11.2. Information on other hazards

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

The product has not been tested toxicologically. The polymers have a high molecular weight and are not soluble in water, for which reason they cannot penetrate biological membranes and elicit systemic effects. For this reason, it must be assumed that it presents no hazard to humans or the environment. The product contains small amounts of sensitising substances (see chapter 2). After intensive contact with skin, especially with the dissolved product, these substances may produce an allergic reaction to persons already sensitised. The fine particles contained in the product may cause mechanical irritations of the skin, eyes and mucous membranes. Avoid skin and eye contact and inhalation of product dust/aerosols. In its marketed form the product does not represent any hazard to health, as long as the hazardous component(s) is/are enclosed in the polymer. These substances are not biologically available in the product as such. It can be released when the product dissolves.

## SECTION 12: Ecological information

### 12.1. Toxicity

#### Acute toxicity

The product has not been tested ecotoxicologically. The polymers have a high molecular weight and are not soluble in water, for which reason they cannot penetrate biological membranes and elicit systemic effects. For this reason, it must be assumed that it presents no hazard to humans or the environment. Studies on products with similar composition confirm this assumption. Prevent substance from entering soil, natural bodies of water and sewer systems. In its marketed form, the product does not present an environmental hazard as long as the component(s) requiring a label mention is(are) integrated in the polymer.

Dibenzoyl peroxide

Parameter	Method	Value	Exposure time	Species	Environment
LC <sub>50</sub>	OECD 203	0.0602 mg/l	96 hours	Fish (Oncorhynchus mykiss)	
EC <sub>50</sub>	OECD 202	0.11 mg/l	48 hours	Daphnia (Daphnia magna)	
EC <sub>50</sub>	OECD 201	0.0711 mg/l	72 hours	Algae (Pseudokirchneriella subcapitata)	
EC <sub>50</sub>	OECD 209	35 mg/l	0,5 hours	Bacteria	

Methyl methacrylate

Parameter	Method	Value	Exposure time	Species	Environment
LC <sub>50</sub>		>79 mg/l	96 hours	Fish (Oncorhynchus mykiss)	
EC <sub>50</sub>		69 mg/l	48 hours	Daphnia (Daphnia magna)	
EC <sub>50</sub>	OECD 201	>110 mg/l	72 hours	Algae (Senastrum capricornutum)	
NOEC		48 mg/l	48 hours	Daphnia (Daphnia magna)	
NOEC	OECD 201	110 mg/l	72 hours	Algae (Senastrum capricornutum)	
NOEC	OECD 201	49 mg/l	72 hours	Algae (Senastrum capricornutum)	

#### Chronic toxicity

Dibenzoyl peroxide

Parameter	Method	Value	Exposure time	Species	Environment
EC <sub>10</sub>		0.001 mg/l	21 days	Daphnia (Daphnia magna)	



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Methyl methacrylate

Parameter	Method	Value	Exposure time	Species	Environment
NOEC	OECD 210	9.4 mg/l	35 days	Fish (Danio rerio)	
LC <sub>50</sub>	OECD 210	33.7 mg/l	35 days	Fish (Danio rerio)	
NOEC	OECD 211	37 mg/l	21 days	Daphnia (Daphnia magna)	
EC <sub>50</sub>	OECD 211	49 mg/l	21 days	Daphnia (Daphnia magna)	

### 12.2. Persistence and degradability

#### Biodegradability

Methyl methacrylate

Parameter	Method	Value	Exposure time	Environment	Result
					Easily biodegradable
	OECD 301C	94 %	14 days		

The product is not biodegradable in soil. There is no evidence of degradation in soil and water.

### 12.3. Bioaccumulative potential

Methyl methacrylate

Parameter	Value	Exposure time	Species	Environment	Temperature [°C]
Log Kow	1.38				

The product has a low potential for bioaccumulation.

### 12.4. Mobility in soil

The product is assumed to be poorly mobile in the soil.

### 12.5. Results of PBT and vPvB assessment

Product does not contain any substance meeting the criteria for PBT or vPvB in accordance with the Annex XIII of Regulation (EC) No 1907/2006 (REACH) as amended.

### 12.6. Endocrine disrupting properties

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

### 12.7. Other adverse effects

Not available.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Dispose of the waste in accordance with the local and/or national regulations. Proceed in accordance with valid regulations on waste disposal. Any unused product and contaminated packaging should be put in labelled containers for waste collection and submitted for disposal to a person authorised for waste removal (a specialized company) that is entitled for such activity. Do not empty unused product in drainage systems. The product must not be disposed of with municipal waste. Empty containers may be used at waste incinerators to produce energy or deposited in a dump with appropriate classification. Perfectly cleaned containers can be submitted for recycling.

#### Waste management legislation

Producer Responsibility Obligations (Packaging Waste) Regulations 2007 (S.I. No. 871 of 2007).  
Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste, as amended.  
Decision 2000/532/EC establishing a list of wastes, as amended.

## SECTION 14: Transport information

### 14.1. UN number or ID number

not subject to transport regulations

### 14.2. UN proper shipping name

not relevant

### 14.3. Transport hazard class(es)

not relevant

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#### 14.4. Packing group

not relevant

#### 14.5. Environmental hazards

not relevant

#### 14.6. Special precautions for user

Reference in the Sections 4 to 8.

#### 14.7. Maritime transport in bulk according to IMO instruments

not relevant

### SECTION 15: Regulatory information

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

Clean Air Act 1993 as amended.

The Chemicals (Hazard Information and Packaging for Supply) Regulations 2009 as amended.

Public health act 1961.

Environmental Protection Act 1990 as amended.

Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18th December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, as amended.

REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL as amended.

Product is a medical device class IIa according to the Medical Device Regulation MDR 2017/745.

#### 15.2. Chemical safety assessment

A chemical safety assessment has not been carried out.

### SECTION 16: Other information

#### A list of standard risk phrases used in the safety data sheet

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.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

#### A list of additional standard phrases used in the safety data sheet

EUH208	Contains Dibenzoyl peroxide, Methyl methacrylate. May produce an allergic reaction.
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#### Other important information about human health protection

The product must not be - unless specifically approved by the manufacturer/importer - used for purposes other than as per the Section 1. The user is responsible for adherence to all related health protection regulations.

#### Key to abbreviations and acronyms used in the safety data sheet

ADR	European agreement concerning the international carriage of dangerous goods by road
BCF	Bioconcentration Factor
CAS	Chemical Abstracts Service
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substance and mixtures
EC	Identification code for each substance listed in EINECS
EC <sub>10</sub>	Concentration of a substance when it is affected 10% of the population
EC <sub>50</sub>	Concentration of a substance when it is affected 50% of the population
EINECS	European Inventory of Existing Commercial Chemical Substances
EmS	Emergency plan
EU	European Union

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EuPCS	European Product Categorisation System
IATA	International Air Transport Association
IBC	International Code For The Construction And Equipment of Ships Carrying Dangerous Chemicals
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods
IMO	International Maritime Organization
INCI	International Nomenclature of Cosmetic Ingredients
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
LC <sub>50</sub>	Lethal concentration of a substance in which it can be expected death of 50% of the population
LD <sub>50</sub>	Lethal dose of a substance in which it can be expected death of 50% of the population
log Kow	Octanol-water partition coefficient
NOAEL	No observed adverse effect level
NOEC	No observed effect concentration
OEL	Occupational Exposure Limits
PBT	Persistent, Bioaccumulative and Toxic
ppm	Parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Agreement on the transport of dangerous goods by rail
UN	Four-figure identification number of the substance or article taken from the UN Model Regulations
UVCB	Substances of unknown or variable composition, complex reaction products or biological materials
VOC	Volatile organic compounds
vPvB	Very Persistent and very Bioaccumulative
Aquatic Acute	Hazardous to the aquatic environment
Aquatic Chronic	Hazardous to the aquatic environment (chronic)
Eye Irrit.	Eye irritation
Flam. Liq.	Flammable liquid
Org. Perox.	Organic peroxide
Skin Irrit.	Skin irritation
Skin Sens.	Skin sensitization
STOT SE	Specific target organ toxicity - single exposure

### Training guidelines

Inform the personnel about the recommended ways of use, mandatory protective equipment, first aid and prohibited ways of handling the product.

### Recommended restrictions of use

not available

### Information about data sources used to compile the Safety Data Sheet

REGULATION (EC) No. 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (REACH) as amended. REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL as amended. Data from the manufacturer of the substance / mixture, if available - information from registration dossiers.

### The changes (which information has been added, deleted or modified)

The version 2.0 replaces the SDS from 21.11.2019.

Changes were made in sections:

- 2.2. Label elements,
- 2.3 Other hazards,
- 11.2 Information on other hazards,
- 12.6 Endocrine disrupting properties and
- 16 Other information.

### More information

Classification procedure - calculation method.

Safety Data Sheet created by CHEM CONSULTING s.p. (info@chem-consulting.si).

# SAFETY DATA SHEET

PoliDent

according to Commission Regulation (EU) 2020/878 as amended



## POLIREPAR S POWDER

Creation date	21st November 2019		
Revision date	15th February 2023	Version	2.0

### Statement

The safety data sheet provides information aimed at ensuring safety and health protection at work and environmental protection. The provided information corresponds to the current status of knowledge and experience and complies with valid legal regulations. The information should not be understood as guaranteeing the suitability and usability of the product for a particular application.