

SAFETY DATA SHEET

PoliDent

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



ORTOPOLI POWDER

Creation date 16th June 2021
Revision date 16th January 2023 Version 3.0

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

- 1.1. Product identifier** ORTOPOLI 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 orthodontic appliances.
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
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. 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.

SECTION 3: Composition/information on ingredients

- 3.2. Mixtures**
Chemical characterization
Product contents polyethylmethacrylate.
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
CAS: 9003-42-3 EC: 618-365-5	Poly(ethyl methacrylate)	>98	not classified as dangerous	2

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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	0,5-0,8	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

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.

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 water and provide 2-5 dL of water. DO NOT INDUCE VOMITING! 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

Water mist, extinguishing powder, carbon dioxide. Accommodate extinguishing components to the location of fire.

Unsuitable extinguishing media

Water - full jet.

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.

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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.

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.

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.

7.2. Conditions for safe storage, including any incompatibilities

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

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.

Slovenia

Uradni list RS, Št. 38

Substance name (component)	Type	Value	Note
Poly(ethyl methacrylate) dust - alveolar fraction (CAS: 9003-42-3)	8 hours	1,25 mg/m ³	Alveolar fraction - respirable fraction which can penetrate the sac alveolar.
	KTV (15 min)	2,5 mg/m ³	
Poly(ethyl methacrylate) dust - inhalable fraction (CAS: 9003-42-3)	8 hours	10 mg/m ³	Inhalable fraction - the part of the total suspended substance inhaled by the worker.
	KTV (15 min)	20 mg/m ³	
Dibenzoyl peroxide dust - alveolar fraction (CAS: 94-36-0)	8 hours	1,25 mg/m ³	Alveolar fraction - respirable fraction which can penetrate the sac alveolar.
	KTV (15 min)	2,5 mg/m ³	
Dibenzoyl peroxide dust - inhalable fraction (CAS: 94-36-0)	8 hours	10 mg/m ³	Inhalable fraction - the part of the total suspended substance inhaled by the worker.

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Slovenia

Uradni list RS, Št. 38

Substance name (component)	Type	Value	Note
Dibenzoyl peroxide dust - inhalable fraction (CAS: 94-36-0)	KTV (15 min)	20 mg/m ³	Inhalable fraction - the part of the total suspended substance inhaled by the worker.

Slovenia

Uradni list RS, Št. 72/2021

Substance name (component)	Type	Value	Note
Dibenzoyl peroxide (CAS: 94-36-0)	8 hours	5 mg/m ³	Inhalable fraction - the part of the total suspended substance inhaled by the worker.
	KTV (15 min)	5 mg/m ³	

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 ³	

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

When handling in long-term or repeatedly, use protective gloves. 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 P2 - 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	according to product specification
Odour	without fragrance
Melting point/freezing point	data not available
Boiling point or initial boiling point and boiling range	data not available
Flammability	>400 °C
Lower and upper explosion limit	data not available
Flash point	data not available
Auto-ignition temperature	data not available
Decomposition temperature	data not available

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pH	data not available
Kinematic viscosity	data not available
Solubility in water	insoluble
Solubility organic solvents	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 ³ at 20 °C
Relative vapour density	data not available
Particle characteristics	data not available

9.2. Other information

Explosive properties 20 g /m³ (Lower Explosion Limit)
The product is not self-igniting or explosive, however formation of explosive powder/air mixtures is possible.

SECTION 10: Stability and reactivity

10.1. Reactivity

When used in the standard way, there is not any dangerous reaction with other substances. Avoid contact with other chemicals.

10.2. Chemical stability

Stable under normal temperature conditions and when used as directed. Decomposition can occur at elevated temperatures (>250°C), releasing potentially irritating vapours (ethyl methacrylate).

10.3. Possibility of hazardous reactions

The product is stable under normal conditions. No hazardous reactions known when used as directed.

10.4. Conditions to avoid

The product is stable and no degradation occurs under normal use. Protect against flames, sparks, overheating and against frost. Protect from humidity.

10.5. Incompatible materials

None known.

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. Organic products of decomposition.

SECTION 11: Toxicological information

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

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 ₅₀	7710 mg/kg		Rat	
	LC ₅₀	24.3 mg/l	4 hours	Rat	

Poly(ethyl methacrylate)

Route of exposure	Parameter	Value	Exposure time	Species	Sex
	LD ₅₀	>10000 mg/kg		Rat	

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.

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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	Exposure time	Species	Sex
Dermal	Sensitizing			

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.

Toxicity for specific target organ - 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

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.

SECTION 12: Ecological information

12.1. Toxicity

Acute toxicity

Toxicity to the aquatic environment is not expected. The product is insoluble in water - an inert polymer.

Dibenzoyl peroxide

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

Chronic toxicity

Dibenzoyl peroxide

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

12.2. Persistence and degradability

Product is solid, chemically inert and non-biodegradable.

12.3. Bioaccumulative potential

No evidence for hazardous properties.

12.4. Mobility in soil

The substance is not water soluble. No evidence for hazardous properties.

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

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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

Hazard of environmental contamination; 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.

Waste type code

07 00 00	WASTES FROM ORGANIC CHEMICAL PROCESSES
07 02 00	wastes from the MFSU of plastics, synthetic rubber and man-made fibres
07 02 13	waste plastic

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

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

The Chemicals (Hazard Information and Packaging for Supply) Regulations 2009 as amended. Environmental Protection Act 1990 as amended. Clean Air Act 1993 as amended. Public health act 1961. 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

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

H241	Heating may cause a fire or explosion.
H317	May cause an allergic skin reaction.
H319	Causes serious eye 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. 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 ₁₀	Concentration of a substance when it is affected 10% of the population
EC ₅₀	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
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 ₅₀	Lethal concentration of a substance in which it can be expected death of 50% of the population
LD ₅₀	Lethal dose of a substance in which it can be expected death of 50% of the population
log Kow	Octanol-water partition coefficient
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
Org. Perox.	Organic peroxide
Skin Sens.	Skin sensitization

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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 3.0 replaces the SDS version 2.0. and first version from 16.06.2021.

Changes were made in sections:

- 2.2. Label elements,
- 2.3 Other hazards,
- 3.2 Mixtures - content in % weight,
- 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.(www.chem-consulting.si)

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.