

SAFETY DATA SHEET

PoliDent

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



POLITRAY POWDER

Creation date 21st November 2019
Revision date 18th January 2023 Version 2.0

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

- 1.1. Product identifier** POLITRAY 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 individual impression trays.
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 acrylic copolymer, polymethylmethacrylate, limestone, pigment 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 | 0,1-<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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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. Keep person under observation. If person becomes uncomfortable remove to hospital and bring these instructions.

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

Unsuitable extinguishing media

Water - full jet.

Avoid extinguishing methods which may generate dust clouds. Water stream can disperse dust into air producing a fire hazard and possible explosion hazard if exposed to ignition source.

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.

IMPORTANT: Polymer dust is combustible. The explosive limits of the polymer particles suspended in air are approximately those of coal dust.

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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. 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. After removal of the product, wash the contaminated site with plenty of water. Avoiding dust formation.

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.

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.

Incompatible materials: Strong oxidising agents

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 |
|---|--------------|------------------------|---|
| 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. |
| | KTV (15 min) | 20 mg/m ³ | |

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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 | characteristic |
| Melting point/freezing point | data not available |
| Boiling point or initial boiling point and boiling range | data not available |
| Flammability | data not available |
| Lower and upper explosion limit | data not available |
| Flash point | >93 °C |
| Auto-ignition temperature | data not available |
| Decomposition temperature | data not available |
| pH | data not available |
| Kinematic viscosity | data not available |
| Solubility in water | insoluble |
| Partition coefficient n-octanol/water (log value) | data not available |
| Vapour pressure | data not available |
| Density and/or relative density | data not available |
| Relative vapour density | data not available |

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Particle characteristics data not available

9.2. Other information

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 the formation of dust clouds which could cause an explosion hazard.
Depolymerization begins at 250 °C.

10.2. Chemical stability

Stable under normal temperature conditions and when used as directed.

10.3. Possibility of hazardous reactions

The product is stable under normal conditions.

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.

10.5. Incompatible materials

Strong oxidising agents.

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

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 | |

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.

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.

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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

Not available.

12.4. Mobility in soil

The substance is not water soluble.

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

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.

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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 I 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

| | |
|------|---|
| 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. |
|--------|--|

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 |

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| | |
|------------------|---|
| 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 |

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:

- 2.3 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.(www.chem-consulting.si)

Statement

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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.