

SAFETY DATA SHEET

PoliDent

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



POLIHOT POWDER

| | | | |
|---------------|--------------------|---------|-----|
| Creation date | 21st November 2019 | Version | 2.0 |
| Revision date | 31st January 2023 | | |

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

- 1.1. Product identifier** POLIHOT 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 full and partial dentures.
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 Methyl methacrylate, 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. Dust may form explosive mixture with air.

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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 | 0,1-<1,0 | Org. Perox. B, H241 Skin Sens. 1, H317 Eye Irrit. 2, H319 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410 (M=10) | 2 |
| Index: 607-035-00-6 CAS: 80-62-6 EC: 201-297-1 | Methyl methacrylate | 0,1-<1,0 | Flam. Liq. 2, H225 Skin Irrit. 2, H315 Skin Sens. 1, H317 STOT SE 3, H335 | 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.

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SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Carbon dioxide, extinguishing powder, water mist.

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.

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. In the event of substantial pollution, contact respective authorities and wastewater treatment plants. Do not allow to enter drains.

6.3. Methods and material for containment and cleaning up

Place the product mechanically in an appropriate manner. 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.

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 ³ | 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 ³ | Alveolar fraction - respirable fraction which can penetrate the sac alveolar. |
| 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 | |

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 | |
| Methyl methacrylate (CAS: 80-62-6) | 8 hours | 210 mg/m ³ | Substances representing no risk to the foetus with reference to the limit values. |
| | 8 hours | 50 ppm | |
| | KTV (15 min) | 420 mg/m ³ | |
| | 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 ³ | |
| Methyl methacrylate (CAS: 80-62-6) | WEL 8h | 208 mg/m ³ | |
| | WEL 8h | 50 ppm | |
| | WEL 15min | 416 mg/m ³ | |
| | WEL 15min | 100 ppm | |

DNEL

Methyl methacrylate

| Workers / consumers | Route of exposure | Value | Effect | Value determination | Source |
|---------------------|-------------------|-------------------------|--------------------------|---------------------|------------|
| Workers | Inhalation | 348.4 mg/m ³ | Chronic effects systemic | | ECHA REACH |
| Workers | Inhalation | 208 mg/m ³ | Chronic effects local | | ECHA REACH |
| Workers | Inhalation | 416 mg/m ³ | Acute effects local | | ECHA REACH |
| Workers | Dermal | 13.67 mg/kg bw/day | Chronic effects systemic | | ECHA REACH |
| Workers | Dermal | 1.5 mg/cm ² | Chronic effects local | | ECHA REACH |
| Workers | Dermal | 1.5 mg/cm ² | 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 ³ | Chronic effects systemic | | ECHA REACH |
| Consumers | Inhalation | 104 mg/m ³ | Chronic effects local | | ECHA REACH |
| Consumers | Inhalation | 208 mg/m ³ | Acute effects local | | ECHA REACH |
| Consumers | Dermal | 8.2 mg/kg bw/day | Chronic effects systemic | | ECHA REACH |
| Consumers | Dermal | 1.5 mg/cm ² | Chronic effects local | | ECHA REACH |
| Consumers | Dermal | 1.5 mg/cm ² | 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

When handling in long-term or repeatedly, use protective gloves. EN ISO 374-1.

In practise, as the product is a preparation of several substances, resistance tests of glove materials cannot be conducted in advance and should be performed by the end user prior to application. A suitable glove type should be selected for each work environment. On the whole, for permanent contact in work areas, natural latex (NR) gloves are suitable.

Body protection - On handling larger quantities: light weight protective clothing.

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 | white |
| Odour | faint |
| Melting point/freezing point | 110 °C (Softening Temperature) |

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| | |
|--|--------------------------------|
| 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 | >250 °C (ASTM D 1929-68) |
| Auto-ignition temperature | data not available |
| Decomposition temperature | >250 °C |
| 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 | 1,6 g/cm ³ at 20 °C |
| Relative vapour density | data not available |
| Particle characteristics | data not available |

9.2. Other information

| | |
|----------------------|--|
| Bulk density | 0,620-0,670 g/cm ³ at 20 °C |
| Ignition temperature | >400 °C (ASTM D 1929-68) |

SECTION 10: Stability and reactivity

10.1. Reactivity

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

10.2. Chemical stability

The product is stable under normal conditions.

Decomposition can occur at elevated temperatures (>250°C), releasing potentially irritating vapours (methyl 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

Niso znani.

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. Methyl methacrylate, methyl acrylate.

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

Methyl methacrylate

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

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Methyl methacrylate

| Route of exposure | Parameter | Value | Exposure time | Species | Sex |
|-------------------|------------------|-------------|---------------|---------|-----|
| Dermal | LD ₅₀ | >5000 mg/kg | | Rabbit | |

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.

Dibenzoyl peroxide

| Route of exposure | Result | Method | Exposure time | Species | Sex |
|-------------------|-------------|--------|---------------|---------|-----|
| Dermal | Sensitizing | | | | |

Methyl methacrylate

| Route of exposure | Result | Method | Exposure time | Species | Sex |
|-------------------|-------------|----------|---------------|---------|-----|
| Dermal | Sensitizing | OECD 429 | | Mouse | |

Germ cell mutagenicity

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 | Result | Species | Sex |
|-------------------|-----------|-------|------------|---------|-----|
| Inhalation | | | 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.

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

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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 | |

Methyl methacrylate

| Parameter | Method | Value | Exposure time | Species | Environment |
|------------------|----------|-----------|---------------|-----------------------------------|-------------|
| LC ₅₀ | OECD 203 | >79 mg/l | 96 hours | Fish (Oncorhynchus mykiss) | |
| EC ₅₀ | OECD 202 | 69 mg/l | 48 hours | Daphnia (Daphnia magna) | |
| EC ₅₀ | OECD 201 | >100 mg/l | 72 hours | Algae (Selenastrum capricornutum) | |
| NOEC | OECD 201 | >100 mg/l | 72 hours | Algae (Selenastrum capricornutum) | |

Chronic toxicity

Dibenzoyl peroxide

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

Methyl methacrylate

| Parameter | Method | Value | Exposure time | Species | Environment |
|-----------|----------|----------|---------------|-------------------------|-------------|
| NOEC | OECD 210 | 9.4 mg/l | 32 days | Fish (Danio rerio) | |
| NOEC | OECD 202 | 37 mg/l | 21 days | Daphnia (Daphnia magna) | |

12.2. Persistence and degradability

Product is solid, chemically inert and non-biodegradable. No negative effects are known.

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

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

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.

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SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste is non-hazardous. 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

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. |

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

EUH208 Contains Methyl methacrylate, 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 |
| 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 K _{ow} | 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

SAFETY DATA SHEET

PoliDent

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



POLIHOT POWDER

| | | | |
|---------------|--------------------|---------|-----|
| Creation date | 21st November 2019 | Version | 2.0 |
| Revision date | 31st January 2023 | | |

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 version from 21.11.2019.

Changes were made in sections:

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.