

SAFETY DATA SHEET

PoliDent

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



POLIDUR

Creation date 03rd April 2023
Revision date Version 1.0

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

- 1.1. Product identifier** POLIDUR
Substance / mixture mixture
- 1.2. Relevant identified uses of the substance or mixture and uses advised against**
Mixture's intended use
Model making in dentistry.
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
EUH210 Safety data sheet available on request.
- 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**
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: 7778-18-9 EC: 231-900-3 Registration number: 01-2119444918-26	calcium sulfate	75-100	not classified as dangerous	1
CAS: 21645-51-2 EC: 244-492-7 Registration number: 01-2119529246-39	Aluminium hydroxide	2-5	not classified as dangerous	

SAFETY DATA SHEET

PoliDent

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



POLIDUR

Creation date	03rd April 2023	Version	1.0
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Notes

1 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

There are not any particular first aid measures required. If any health problems are manifested or if in doubt, inform a doctor and show him information from this safety data sheet.

If inhaled

Under normal conditions of intended use, this material is not expected to be hazardous by inhalation. In case of inhalation: move the person to fresh air and let him rest. If symptoms occur, seek medical attention.

If on skin

Remove contaminated clothes. Wash with plenty of soap and water. Provide medical treatment if skin irritation persists. The product generally does not irritate the skin.

If in eyes

Immediately flush the eyes with running water, open the eyelids; if the affected person wears contact lenses, remove them immediately. The running water should be heated (20-30°C). Depending on the situation, call medical rescue service or ensure medical treatment.

If swallowed

Rinse out the mouth with clean water. Never give anything by mouth to an unconscious person. In the event of issues, find medical help.

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

If inhaled

Not expected.

If on skin

Not expected.

If in eyes

Not expected.

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

Non-flammable.

Unsuitable extinguishing media

There are no special features.

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. The product itself does not burn.

5.3. Advice for firefighters

Self-Contained Breathing Apparatus (SCBA) with chemical resistant gloves. Use a self-contained breathing apparatus and full-body protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Follow the instructions in the Sections 7 and 8. Do not inhale dust. Prevent contact with skin and eyes.

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.

6.3. Methods and material for containment and cleaning up

Place the product mechanically in closed tightly containers. Dispose of the collected material according to the instructions in the section 13. Avoid dusting. Ventilate the room.

SAFETY DATA SHEET

PoliDent

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



POLIDUR

Creation date 03rd April 2023
Revision date Version 1.0

6.4. Reference to other sections

See the Section 7, 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

No special measures are required. Use personal protective equipment as per Section 8. Observe valid legal regulations on safety and health protection. Do not inhale dust. Protect from moisture.

7.2. Conditions for safe storage, including any incompatibilities

Store in tightly closed containers in cold, dry and well ventilated areas designated for this purpose.

Store in a dry place. Protect from moisture.

Keep only in original packaging.

7.3. Specific end use(s)

not available

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
dust - inhalable fraction (CAS: 7778-18-9)	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	
dust - alveolar fraction (CAS: 7778-18-9)	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	

Slovenia

Uradni list RS, Št. 72/2021

Substance name (component)	Type	Value	Note
calcium sulfate (CAS: 7778-18-9)	8 hours	6 mg/m ³	Alveolar fraction - respirable fraction which can penetrate the sac alveolar.

DNEL

calcium sulfate

Workers / consumers	Route of exposure	Value	Effect	Value determination	Source
Workers	Inhalation	21.17 mg/m ³	Chronic effects systemic		ECHA REACH
Consumers	Oral	1.52 mg/kg bw/day	Chronic effects systemic		ECHA REACH
Consumers	Oral	11.4 mg/kg bw/day	Acute effects systemic		ECHA REACH
Workers	Inhalation	5082 mg/m ³	Acute effects systemic		ECHA REACH
Consumers	Inhalation	3811 mg/m ³	Acute effects systemic		ECHA REACH
Consumers	Inhalation	5.29 mg/m ³	Chronic effects systemic		ECHA REACH

SAFETY DATA SHEET

PoliDent

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



POLIDUR

Creation date 03rd April 2023
Revision date Version 1.0

PNEC

calcium sulfate

Route of exposure	Value	Value determination	Source
Microorganisms in sewage treatment	100 mg/l		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.

Eye/face protection

Protective glasses with side shields. EN166 - Personal Eye Protection Standard.

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. Use barrier creams for skin protection, they should, however, not be applied once exposure has occurred. Other protection: Protective antistatic clothing made of natural fibres (cotton) or synthetic fibres resistant to elevated temperatures.

Respiratory protection

Use a mask with anti-dust filter when the exposition limits of the substances are exceeded or at the place with insufficient ventilation. Filter FFP. EN 14387.

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 (prah)
Colour	blue
Odour	without fragrance
Melting point/freezing point	1,450 °C (DIN ISO 3016)
Boiling point or initial boiling point and boiling range	data not available
Flammability	It is not flammable.
Lower and upper explosion limit	data not available
Flash point	data not available
Auto-ignition temperature	data not available
Decomposition temperature	data not available
pH	6-8 (undiluted at 20 °C)
Kinematic viscosity	data not available
Solubility in water	2,4 g/l (20 °C)
Partition coefficient n-octanol/water (log value)	data not available
Vapour pressure	data not available
Density and/or relative density	
Density	2,31-2,97 g/cm ³ at 20 °C (DIN 51757)
Relative vapour density	data not available
Particle characteristics	data not available

9.2. Other information

Spontaneous ignition	The product is not self-igniting.
Explosive properties	The product is not explosive.
Bulk density: 700-1.100 kg/m ³	
EU-VOC: 0,0000 %	
EU-VOC: 0,0000 g/l	
Solids content: 100,0 %	

SAFETY DATA SHEET

PoliDent

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



POLIDUR

Creation date 03rd April 2023
Revision date Version 1.0

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.

10.3. Possibility of hazardous reactions

No dangerous reactions are known.

10.4. Conditions to avoid

The product is stable and no degradation occurs under normal use.
Prevent the formation of dust. Avoid contact with moisture.

10.5. Incompatible materials

It is not 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.

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.

Aluminium hydroxide

Route of exposure	Parameter	Value	Exposure time	Species	Sex
Oral	LD ₅₀	>2000 mg/kg		Rat	

calcium sulfate

Route of exposure	Parameter	Value	Exposure time	Species	Sex
Oral	LD ₅₀	>2000 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.

Respiratory or skin sensitisation

Based on available data the classification criteria are not met.

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

SAFETY DATA SHEET

PoliDent

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



POLIDUR

Creation date 03rd April 2023
Revision date Version 1.0

Acute toxicity

The product is not classified as dangerous for the environment. Do not allow it to enter groundwater, waterways or sewers.

calcium sulfate

Parameter	Value	Exposure time	Species	Environment
LC ₅₀	>79 mg/l	96 hours	Fish (<i>Oryzias latipes</i>)	
LC ₅₀	79-2980 mg/l	96 hours	Fish	
LC ₅₀	79-1970 mg/l	48 hours	Daphnia (<i>Daphnia magna</i>)	
EC ₅₀	>79 mg/l	72 hours	Algae (<i>Selenastrum capricornutum</i>)	
EC ₅₀	>1000 mg/l	3 hours	Bacteria (<i>Aktivno blato</i>)	

12.2. Persistence and degradability

Data not available.

12.3. Bioaccumulative potential

Not available.

12.4. Mobility in soil

Not available.

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

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.

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

10 13 99 wastes not otherwise specified

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.

SAFETY DATA SHEET

PoliDent

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



POLIDUR

Creation date 03rd April 2023
Revision date Version 1.0

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. Commission Regulation (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

15.2. Chemical safety assessment

A chemical safety assessment has not been carried out.

SECTION 16: Other information

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

EUH210 Safety data sheet available on request.

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 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
OEL	Occupational Exposure Limits
PBT	Persistent, Bioaccumulative and Toxic
ppm	Parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals

SAFETY DATA SHEET

PoliDent

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



POLIDUR

Creation date	03rd April 2023	Version	1.0
Revision date			

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

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.

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.