

# SAFETY DATA SHEET

PoliDent

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



## Polystone

Creation date	27th October 2020	Version	3.0
Revision date	10th March 2023		

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

- 1.1. Product identifier**  
Substance / mixture Polystone  
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.  
**Most serious adverse physico-chemical effects**  
This mixture does not present a physical hazard. Refer to the recommendations regarding the other products present on the site.  
**Most serious adverse effects on human health and the environment**  
This mixture does not present a health hazard with the exception of possible occupational exposure thresholds (see paragraphs 3 and 8).  
This mixture does not present an environmental hazard. No known or foreseeable environmental damage under standard conditions of use.
- 2.2. Label elements**  
none
- 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.

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### 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 CASO4 x 0,5 H2O	90-<100	not classified as dangerous	1

#### 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 an inhalation hazard.

In case of inhalation: Move person into fresh air and keep at rest. Get medical attention if symptoms occur.

##### If on skin

Remove contaminated clothes. Wash with plenty of soap and water. Provide medical treatment if skin irritation persists.

##### If in eyes

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

##### If swallowed

DO NOT INDUCE VOMITING! 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

Alcohol-resistant foam, carbon dioxide, powder, water spray jet, water mist.

##### Unsuitable extinguishing media

not available

#### 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. 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. Do not allow run-off of contaminated fire extinguishing material to enter drains or surface and ground water.

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### 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 an appropriate manner. Dispose of the collected material according to the instructions in the section 13. Do not generate dust. Ventilate the room.

#### 6.4. Reference to other sections

See the Section 7, 8 and 13.

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

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 no 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 <sup>3</sup>	Inhalable fraction - the part of the total suspended substance inhaled by the worker.
	KTV (15 min)	20 mg/m <sup>3</sup>	
dust - alveolar fraction (CAS: 7778-18-9)	8 hours	1,25 mg/m <sup>3</sup>	Alveolar fraction - respirable fraction which can penetrate the sac alveolar.
	KTV (15 min)	2,5 mg/m <sup>3</sup>	

#### Slovenia

Uradni list RS, Št. 72/2021

Substance name (component)	Type	Value	Note
calcium sulfate CASO <sub>4</sub> x 0,5 H <sub>2</sub> O (CAS: 7778-18-9)	8 hours	6 mg/m <sup>3</sup>	Alveolar fraction - respirable fraction which can penetrate the sac alveolar.

#### DNEL

calcium sulfate CASO<sub>4</sub> x 0,5 H<sub>2</sub>O

Workers / consumers	Route of exposure	Value	Effect	Value determination	Source
Workers	Inhalation	21.17 mg/m <sup>3</sup>	Chronic effects systemic		ECHA REACH

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calcium sulfate CASO<sub>4</sub> x 0,5 H<sub>2</sub>O

Workers / consumers	Route of exposure	Value	Effect	Value determination	Source
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 <sup>3</sup>	Acute effects systemic		ECHA REACH
Consumers	Inhalation	3811 mg/m <sup>3</sup>	Acute effects systemic		ECHA REACH
Consumers	Inhalation	5.29 mg/m <sup>3</sup>	Chronic effects systemic		ECHA REACH

### PNEC

calcium sulfate CASO<sub>4</sub> x 0,5 H<sub>2</sub>O

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 (powder)
Colour	data not available
Odour	data not available
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	data not available
Auto-ignition temperature	data not available
Decomposition temperature	140 °C (CaSO <sub>4</sub> x ½ H <sub>2</sub> O + H <sub>2</sub> O)
Decomposition temperature	1000 °C (CaO + SO <sub>3</sub> )
pH	7-9 (10% solution) (mixed with water)
Kinematic viscosity	data not available
Solubility in water	soluble (app. 2 g/l)
Partition coefficient n-octanol/water (log value)	data not available

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Vapour pressure data not available  
Density and/or relative density  
Density data not available  
Relative density 600 - 1200  
Relative vapour density data not available  
Particle characteristics data not available

### 9.2. Other information

Spontaneous ignition no self ignition  
Explosive properties The product does not have explosive properties.

## 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

Mixing with an aqueous solution of sodium carbonate will result in the formation of carbon dioxide.

### 10.4. Conditions to avoid

The product is stable and no degradation occurs under normal use.  
Avoid formation of dusts.

### 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.  
Decomposition > 1000°C : Sulfurtrioxide and Calciumoxide

## 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.

calcium sulfate CASO4 x 0,5 H2O

Route of exposure	Parameter	Method	Value	Exposure time	Species	Sex
Oral	LD <sub>50</sub>	OECD 420	>1581 mg/kg		Rat	
Inhalation	LC <sub>50</sub>	OECD 403	>2.61 mg/l		Rat	

#### Skin corrosion/irritation

Based on available data the classification criteria are not met.

calcium sulfate CASO4 x 0,5 H2O

Route of exposure	Result	Method	Exposure time	Species
Oral	Not irritating	OECD 404		Rabbit

#### Serious eye damage/irritation

Based on available data the classification criteria are not met.

calcium sulfate CASO4 x 0,5 H2O

Route of exposure	Result	Method	Exposure time	Species
Eye	Not irritating	OECD 405		Rabbit

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### Respiratory or skin sensitisation

Based on available data the classification criteria are not met.  
calcium sulfate CASO4 x 0,5 H2O

Route of exposure	Result	Method	Exposure time	Species	Sex	Source
Dermal	Not sensitizing	OECD 406		Guinea-pig		
Dermal	Not sensitizing			Guinea-pig		Local lymph node stimulation test

### Germ cell mutagenicity

Based on available data the classification criteria are not met.  
calcium sulfate CASO4 x 0,5 H2O

Result	Method	Exposure time	Specific target organ	Species	Sex	Source
Negative				Mouse		in vivo
Negative	OECD 474					in vitro

### Carcinogenicity

Based on available data the classification criteria are not met.  
calcium sulfate CASO4 x 0,5 H2O

Route of exposure	Parameter	Value	Result	Species	Sex
			Negative		

### Reproductive toxicity

Based on available data the classification criteria are not met.  
calcium sulfate CASO4 x 0,5 H2O

Effect	Parameter	Method	Value	Result	Species	Sex	Source
		OECD 422		Negative	Rat		in vivo

### 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

No aquatic toxicity data available for the mixture.  
calcium sulfate CASO4 x 0,5 H2O

Parameter	Method	Value	Exposure time	Species	Environment
ECr <sub>50</sub>	OECD 201	>79 mg/l	72 hours	Algae (Selenastrum capricornutum)	
LC <sub>50</sub>	OECD 203	>79 mg/l	96 hours	Fish	
EC <sub>50</sub>	OECD 202	>79 mg/l	48 hours	Daphnia (Daphnia sp.)	

### 12.2. Persistence and degradability

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### Biodegradability

calcium sulfate CASO4 x 0,5 H2O

Parameter	Value	Exposure time	Environment	Result
				Hardly biodegradable

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

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.

### Waste management legislation

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

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### SECTION 15: Regulatory information

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

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 been carried out.

### SECTION 16: Other information

#### Other important information about human health protection

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

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

ADR	European agreement concerning the international carriage of dangerous goods by road
BCF	Bioconcentration Factor
CAS	Chemical Abstracts Service
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substance and mixtures
EC	Identification code for each substance listed in EINECS
EC <sub>50</sub>	Concentration of a substance when it is affected 50% of the population
EINECS	European Inventory of Existing Commercial Chemical Substances
EmS	Emergency plan
EU	European Union
EuPCS	European Product Categorisation System
IATA	International Air Transport Association
IBC	International Code For The Construction And Equipment of Ships Carrying Dangerous Chemicals
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods
IMO	International Maritime Organization
INCI	International Nomenclature of Cosmetic Ingredients
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
LC <sub>50</sub>	Lethal concentration of a substance in which it can be expected death of 50% of the population
LD <sub>50</sub>	Lethal dose of a substance in which it can be expected death of 50% of the population
log K <sub>ow</sub>	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

#### Training guidelines

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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 from 27.10.2020

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](http://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.