

SECTION 1 : IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product name : Polistone

1.2. Relevant identified uses of the substance or mixture and uses advised against

Polistone is a class IV high strength formulated hemihydrate die stone plaster, used for prosthetic works.

1.3. Details of the supplier of the safety data sheet

Manufacturer/supplier

Polident d.o.o., Dental Products Industry
Volčja Draga 42, 5293 Volčja Draga,
Slovenija

Tel.: 00386 5 3304840,

Fax: 00386 5 3304870

E-mail: polident@polident.si

Information provided by

00386 5 3304859

1.4 Emergency telephone number

00386 5 3304840 - Polident d.o.o., Dental Products Industry (from 8 a.m. to 4 p.m.)

SECTION 2 : HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

In compliance with EC regulation No. 1272/2008 and its amendments:

This mixture does not present a physical hazard. Refer to the recommendations regarding the other products present on the site.

This mixture does not present a health hazard with the exception of possible occupational exposure thresholds (see section 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:

In compliance with EC regulation No. 1272/2008 and its amendments.

No labelling requirements for this mixture.

2.3 Other hazards:

The mixture does not contain substances classified as 'Substances of Very High Concern' (SVHC) $\geq 0.1\%$ published by the European Chemicals Agency (ECHA) under article 57 of REACH: <http://echa.europa.eu/fr/candidate-list-table>

The mixture satisfies neither the PBT nor the vPvB criteria for mixtures in accordance with annexe XIII of the REACH regulations EC 1907/2006.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

3.2. Mixtures

Composition :

Identification	(EC) 1272/2008	Note	%
CALCIUM SULFATE (CASO₄ + 0,5H₂O)	Not classified	[1]	[1] 90 \leq x % < 100
INDEX: PLASTER 1 CAS: 7778-18-9 EC: 231-900-3 REACH: 1-2119444918-26-(0066)			

[1] Substance for which maximum workplace exposure limits are available.

SECTION 4 : FIRST AID MEASURES

As a general rule, in case of doubt or if symptoms persist, always call a doctor.

NEVER induce swallowing by an unconscious person.

4.1 Description of first aid measures:

In the event of splashes or contact with eyes:

Wash thoroughly with water for 15 minutes holding the eyelids open.

If there is any redness, pain or visual impairment, consult an ophthalmologist.

In the event of splashes or contact with skin:

Wash with soap and water.

In the event of swallowing:

Seek medical attention, showing the label.

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

No specific symptoms or effects have been reported.

4.3 Indication of any immediate medical attention and special treatment needed:

None

SECTION 5 : FIREFIGHTING MEASURES

Non-flammable.

5.1 Extinguishing media:

Suitable extinguishing media:

Any means suitable for extinguishing surrounding fire.

Unsuitable extinguishing media:

None.

5.2 Special hazards arising from the substance or mixture:

None.

5.3 Advice for firefighters:

Product itself does not burn.

Special protective equipment for fire-fighters: None.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:

Consult the safety measures listed under headings 7 and 8.

For first aid worker

For first aid worker:

First aid workers will be equipped with suitable personal protective equipment (See section 8).

6.2 Environmental precautions:

Prevent any material from entering drains or waterways.

6.3 Methods and material for containment and cleaning up:

Retrieve the product by dry mechanical means (brush/vacuuming): do not generate dust.

6.4 Reference to other sections:

No data available.

SECTION 7 : HANDLING AND STORAGE

7.1 Precautions for safe handling:

Do not generate dust.

Fire prevention:

N/A Product itself does not burn.

Recommended equipment and procedures:

For personal protection, see section 8.

Observe precautions stated on label and also industrial safety regulations.

Prohibited equipment and procedures:

N/A

7.2 Conditions for safe storage, including any incompatibilities:

Avoid the exposure to moisture

Packaging

Store in original packaging.

7.3 Specific end use(s):

No data available.

SECTION 8 : EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Occupational exposure limits :

- ACGIH TLV (American Conference of Governmental Industrial Hygienists, Threshold Limit Values, 2010) :

CAS TWA:	STEL:	Ceiling:	Definition:	Criteria:
7778-18-9	10 mg/m3	-	-	I

- Belgium (Order of 19/05/2009, 2010) :

CAS TWA:	STEL:	Ceiling:	Definition:	Criteria:
7778-18-9	10 mg/m3	-	-	-

- France (INRS - ED984 :2012):

CAS VME-ppm:	VME-mg/m3:	VLE-ppm:	VLE-mg/m3:	Notes:	TMP N°:
7778-18-9	-	10	-	-	-

Derived no effect level (DNEL) or derived minimum effect level (DMEL):

CALCIUM SULFATE (CASO4 + 0,5H2O) (CAS: 7778-18-9)

SAFETY DATA SHEET

according to Regulation 1907/2006/EC

POLISTONE

Final use:	Workers.
Exposure method:	Inhalation.
Potential health effects:	Short term systemic effects.
DNEL:	5082 mg of substance/m3
Final use:	Man exposed via the environment.
Exposure method:	Ingestion.
Potential health effects:	Short term systemic effects.
DNEL:	11.4 mg/kg body weight/day
Exposure method:	Ingestion.
Potential health effects:	Long term systemic effects.
DNEL:	1.52 mg/kg body weight/day
Exposure method:	Inhalation.
Potential health effects:	Short term systemic effects.
DNEL:	3811 mg of substance/m3
Exposure method:	Inhalation.
Potential health effects:	Long term systemic effects.
DNEL:	
Predicted no effect concentration (PNEC):	CALCIUM SULFATE (CASO4 + 0,5H2O) (CAS: 7778-18-9)
Environmental compartment:	Waste water treatment plant.
PNEC:	100 mg/l

8.2 Exposure controls

Personal protection measures, such as personal protective equipment

Pictogram(s) indicating the obligation of wearing personal protective equipment (PPE): None

Do not generate dust. Use personal protective equipment that is clean and has been properly maintained.

Ensure that there is adequate ventilation, especially in confined areas.

Eye protection:	Avoid contact with eyes. In case of splashing, wear protective goggles in accordance with standard EN166.
Hand protection:	Wear suitable protective gloves in the event of prolonged or repeated skin contact.
Body protection:	Work clothing.
Respiratory protection:	Avoid breathing dust. Type of FFP mask: Wear a disposable half-mask dust filter in accordance with standard EN149.

SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties:

General information:

Physical state: Powder

Important health, safety and environmental information

pH: N/A, mixed with water 7-9

Boiling point: N/A

Flash point (50°C): N/A

Vapour pressure: N/A

Density: 600-1200.

Water solubility: Soluble. app. 2g/l

Melting point/melting range: N/A

Self-ignition temperature: no self ignition/ not explosive

Decomposition point/decomposition range :

in CaSO4 x ½ H2O und H2O ca. 140°C (ca. 413 K)

in CaO und SO3 ca. 1000°C (ca. 1273 K)

9.2 Other information:

No data available.

SECTION 10 : STABILITY AND REACTIVITY

10.1	Reactivity:	No data available.
10.2	Chemical stability:	This mixture is stable under the recommended handling and storage conditions in section 7.
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:	Avoid : - formation of dusts
10.5	Incompatible materials:	None known.
10.6	Hazardous decomposition products:	Decomposition > 1000°C : Sulfurtrioxide and Calciumoxide

SECTION 11 : TOXICOLOGICAL INFORMATION

11.1	Information on toxicological effects:	No data available.
Acute toxicity:	Not classified	

11.1.1 Substances

Acute toxicity :

CALCIUM SULFATE (CASO₄ + 0,5H₂O) (CAS: 7778-18-9)

Oral route: LD₅₀ > 1581 mg/kg

Species : Rat

OECD Guideline 420 (Acute Oral Toxicity Fixed Dose Method)

Inhalation route: LC₅₀ > 2.61 mg/l

Species: Rat

OECD Guideline 403 (Acute Inhalation Toxicity)

Skin corrosion/skin irritation:

CALCIUM SULFATE (CASO₄ + 0,5H₂O) (CAS: 7778-18-9)

Corrosivity: No observed effect.

Species: Rabbit

OECD Guideline 404 (Acute Dermal Irritation / Corrosion)

Species: Rabbit

OECD Guideline 404 (Acute Dermal Irritation / Corrosion)

Serious damage to eyes/eye irritation :

SULFATE DE CALCIUM CASO₄ + 0,5H₂O (CAS: 7778-18-9)

Species: Rabbit

OECD Guideline 405 (Acute Eye Irritation / Corrosion)

Species: Rabbit

OECD Guideline 405 (Acute Eye Irritation / Corrosion)

Species: Rabbit

OECD Guideline 405 (Acute Eye Irritation / Corrosion)

Species: Rabbit

OECD Guideline 405 (Acute Eye Irritation / Corrosion)

Respiratory or skin sensitisation:

CALCIUM SULFATE (CASO₄ + 0,5H₂O) (CAS: 7778-18-9)

Local lymph node stimulation test : Non-Sensitiser.

Species: Guinea pig

OECD Guideline 406 (Skin Sensitisation)

Guinea Pig Maximisation Test (GMPT) : Non-sensitiser.

Species: Guinea pig

OECD Guideline 406 (Skin Sensitisation)

Buehler Test: Non-sensitiser.

Species: Guinea pig

OECD Guideline 406 (Skin Sensitisation)

Germ cell mutagenicity:

SULFATE DE CALCIUM CASO₄ + 0,5H₂O (CAS: 7778-18-9)

No mutagenic effect.

Mutagenesis (in vivo): Negative.

Species: Mouse

OECD Guideline 474 (Mammalian Erythrocyte Micronucleus Test)

Mutagenesis (in vitro): Negative.

Carcinogenicity :

CALCIUM SULFATE (CASO4 + 0,5H2O) (CAS: 7778-18-9)

Carcinogenicity Test: Negative.

No carcinogenic effect.

Reproductive toxicant:

CALCIUM SULFATE (CASO4 + 0,5H2O) (CAS: 7778-18-9)

No toxic effect for reproduction

Study on development : Species : Rat

OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity

Screening Test) Mutagénèse (in vivo): Negative.

11.1.2. Mixture

No toxicological data available for the mixture.

SECTION 12 : ECOLOGICAL INFORMATION

12.1 Toxicity

12.1.1 Substances

CALCIUM SULFATE (CASO4 + 0,5H2O) (CAS: 7778-18-9)

Fish toxicity: LC50 > 79 mg/l

Species: Others

DuraHon of exposure: 96 h

OECD Guideline 203 (Fish, Acute Toxicity Test)

Crustacean toxicity: EC50 > 79 mg/l

Species: Daphnia sp.

DuraHon of exposure: 48 h

OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test)

Algae toxicity: ECr50 > 79 mg/l

Species: Selenastrum capricornutum

DuraHon of exposure: 72 h

OECD Guideline 201 (Alga, Growth Inhibition Test)

12.1.2 Mixtures:

No aquatic toxicity data available for the mixture.

12.2 Persistence and degradability

12.2.1 Substances

CALCIUM SULFATE (CASO4 + 0,5H2O) (CAS: 7778-18-9)

Biodegradability: no degradability data is available, the substance is considered as not degrading quickly.

12.3 Bioaccumulative potential:

No data available.

12.4 Mobility in soil:

No data available.

12.5 Results of PBT and vPvB assessment:

No data available.

12.6 Other adverse:

No data available.

SECTION 13 : DISPOSAL CONSIDERATIONS

Proper waste management of the mixture and/or its container must be determined in accordance with Directive 2008/98/EC.

13.1 Waste treatment methods

Do not pour into drains or waterways.

Waste :

Waste management is carried out without endangering human health, without harming the environment and, in particular without risk to water, air, soil, plants or animals.

Recycle or dispose of waste in compliance with current legislation, preferably via a certified collector or company.

Do not contaminate the ground or water with waste, do not dispose of waste into the environment.

Soiled packaging:

Empty container completely. Keep label(s)

SECTION 14 : TRANSPORT INFORMATION

Exempt from transport classification and labelling.

Transport product in compliance with provisions of the ADR for road, RID for rail, IMDG for sea and ICAO/IATA for air transport.

SECTION 15 : REGULATORY INFORMATION

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

Classification and labelling information included in section 2:

The following regulations have been used:

- EU Regulation No. 1272/2008 amended by EU Regulation No. 487/2013.
- EU Regulation No. 1272/2008 amended by EU Regulation No. 758/2013.
- EU Regulation No. 1272/2008 amended by EU Regulation No. 944/2013.
- EU Regulation No. 1272/2008 amended by EU Regulation No. 605/2014

Container information:

No data available.

Particular provisions:

No data available.

15.2 Chemical safety assessment: A chemical safety assessment has been carried out.

SECTION 16 : OTHER INFORMATION

Since the user's working conditions are not known by us, the information supplied on this safety data sheet is based on our current level of knowledge and on national and community regulations.

The mixture must not be used for other uses than those specified in section 1 without having first obtained written handling instructions.

It is at all times the responsibility of the user to take all necessary measures to comply with legal requirements and local regulations.

The information in this safety data sheet must be regarded as a description of the safety requirements relating to the mixture and not as a guarantee of the properties thereof.

Abbreviations :

DNEL : Derived No-Effect Level

PNEC : Predicted No-Effect Concentration

ADR : European agreement concerning the international carriage of dangerous goods by Road.

IMDG : International Maritime Dangerous Goods.

IATA : International Air Transport Association.

ICAO : International Civil Aviation Organisation

RID : Regulations concerning the International carriage of Dangerous goods by rail.