

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1. Product identifier**

Product Description: Extra hard plaster.

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

Identified Use Professional use: Plaster for orthodontic casts.

**1.3. Details of the supplier of the safety data sheet**

Leone s.p.a.

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Tel. +39 055.30.44.1 – Fax +39 055 374808.

**1.4. Emergency telephone number**

+39 055.30.44.1. An answering machine is on during closing time.

[www.leone.it/emergency](http://www.leone.it/emergency) (EU and international telephone numbers).**SECTION 2: Hazards identification****2.1. Classification of the substance or mixture**

According to Regulation (EC) no. 1272/2008 [CLP].

This product does not meet the criteria for classification as hazardous in accordance with Titles I and II of Regulation (EC) no. 1272/2008 on classification, labelling and packaging of substances and mixtures.

Upon a correct use, according to our experience no significant hazards to man or environment are reasonably foreseen.

**2.2. Label elements**

Labelling according to Regulation (EC) No. 1272/2008 [CLP]:

EUH phrases EUH210 Safety data sheet available on request

**2.3. Other hazards**According to the available data, the product does not contain PBT or vPvB substances in a proportion  $\geq 0.1$  %.The product does not contain substances with endocrine-disrupting properties in a concentration  $\geq 0.1$  %.**SECTION 3: Composition/information on ingredients****3.2. Mixtures**

Description: Calcium sulphate, mineral fillers, non-hazardous admixtures

Components	Product identifier	%W/W	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Calcium sulphate	CAS no: 7778-18-9 EC no: 231-900-3 REACH no: 01-2119444918-26-0066	90 - <100 %	Not classified

Full text of H-statements: see section 16.

**SECTION 4: First aid measures****4.1. Description of first aid measures**

First-aid measures general: If you feel unwell, seek medical advice. If possible, show him this sheet. Failing this, show him the packaging or label. Never give anything by mouth to an unconscious person. In case of loss of conscience place the victim in the recovery position.

First-aid measures after inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

First-aid measures after skin contact: Take off contaminated clothing and wash it before reuse. Wash with plenty of soap and water.

First-aid measures after eye contact: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

First-aid measures after ingestion: Rinse mouth. Drink water as a precaution. Get medical advice/attention if you feel unwell.

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

Not expected to present a significant hazard under anticipated conditions of normal use.

**4.3. Indication of any immediate medical attention and special treatment needed**

Treat symptomatically.

**SECTION 5: Firefighting measures****5.1. Extinguishing media**

Suitable extinguishing Media Adapt extinguishing agents to the environment. Foam. Dry powder. Carbon dioxide. Water spray. Sand.

Unsuitable extinguishing Media Do not use a heavy water stream.

## 5.2. Special hazards arising from the substance or mixture

The product itself does not burn. Product cures after contact with water.

## 5.3. Advice for firefighters

Firefighting instructions: Use water spray or fog for cooling exposed containers. Prevent fire-fighting water from entering environment.

Protection during firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

Provide adequate ventilation. Avoid breathing dust. Evacuate unnecessary personnel. Use personal protective equipment as required. Avoid dust formation.

### 6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.

### 6.3. Methods and material for containment and cleaning up

On land, sweep or shovel into suitable containers. Take up mechanically and dry and collect in suitable container for disposal.

### 6.4. Reference to other sections

Concerning personal protective equipment to use, see section 8. Concerning disposal elimination after cleaning, see section 13.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Precautions for safe handling: Ensure good ventilation of the workstation. Avoid dust formation. Avoid breathing dust. Avoid contact with skin and eyes.

Hygiene measures: Handle in accordance with good industrial hygiene and safety procedures. When using do not eat, drink or smoke. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Contaminated work clothing should not be allowed out of the workplace.

### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions: Store in original container. Store tightly closed in a dry and cool place.

Prohibitions on mixed storage: Keep away from food, drink and animal feedingstuffs.

Storage class: 13 - Non-flammable solids

### 7.3. Specific end use(s)

No additional information available.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

Components with critical values that require monitoring at the workplace:	
7778-18-9 Calcium sulphate	
OEL 8-hr (Ireland)	10 mg/m <sup>3</sup>

DNEL:	
7778-18-9 Calcium sulphate	
DNEL/DMEL (Workers)	
Long-term - systemic effects, inhalation	21.17 mg/m <sup>3</sup>
Acute - systemic effects, inhalation	5082 mg/m <sup>3</sup>
DNEL/DMEL (General population)	
Long-term - systemic effects, inhalation	5.29 mg/m <sup>3</sup>
Long-term - systemic effects, oral	1.52 mg/kg body weight/day
Acute - systemic effects, inhalation	3811 mg/m <sup>3</sup>
Acute - systemic effects, oral	11.4 mg/kg body weight/day
PNEC:	
7778-18-9 Calcium sulphate	
sewage treatment plant (STP):	100 mg/l

### 8.2. Exposure controls

#### 8.2.1. Appropriate engineering controls

Use adequate ventilation to keep vapour concentrations below applicable standard.

#### 8.2.2. Individual protection measures, such as personal protective equipment

Hand protection: Wear suitable gloves (EN 374). Nitrile rubber.  
Eye protection: Chemical goggles or safety glasses (EN 166).  
Respiratory protection: Where exposure through inhalation may occur from use, respiratory protection equipment is recommended. In case of dust formation use respirator with filter: FFP1 (EN 149).  
Skin and body protection: Wear suitable protective clothing.

**8.2.3. Environmental exposure controls**

Avoid release to the environment.

**SECTION 9: Physical and chemical properties****9.1. Information on basic physical and chemical properties**

Physical state	Solid, crystalline Powder / Granulate
Colour	Various
Odour	Characteristic, weak
Melting point/freezing point	No data available
Boiling point or initial boiling point and boiling range	No data available
Flammability	Not flammable
Lower and upper explosion limit	Not applicable
Flash point	Not applicable
Auto-ignition temperature	Not applicable
Decomposition temperature	Ca. 1000 °C
pH	7 – 9
Kinematic viscosity	Not applicable
Solubility	Water: 2 g/L
Partition coefficient n-octanol/water (log value)	Not applicable
Vapour pressure	No data available
Density and/or relative density	No data available
Relative vapour density	Not applicable.
Particle characteristics	No data available

**9.2. Other information****9.2.2. Other safety characteristics**

Explosive properties:	No explosive properties.
Oxidising properties:	No oxidising properties.
Bulk density:	600 – 1200 kg/m <sup>3</sup>

**SECTION 10: Stability and reactivity****10.1. Reactivity**

No dangerous reactions known under normal conditions of use.

**10.2. Chemical stability**

Stable under use and storage conditions as recommended in section 7. No decomposition if stored and applied as directed.

**10.3. Possibility of hazardous reactions**

No hazardous reactions known under normal conditions of use.

**10.4. Conditions to avoid**

No additional information available

**10.5. Incompatible materials**

Not known.

**10.6. Hazardous decomposition products**

Decomposition at temperatures > 1000 °C. Release of calcium oxide and sulphur trioxide.

**SECTION 11: Toxicological information****11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008**

Acute toxicity:	Not classified Based on available data, the classification criteria are not met
Skin corrosion/irritation:	Not classified Based on available data, the classification criteria are not met
Serious eye damage/irritation:	Not classified Based on available data, the classification criteria are not met
Respiratory or skin sensitisation	Not classified Based on available data, the classification criteria are not met
Germ cell mutagenicity:	Not classified Based on available data, the classification criteria are not met
Carcinogenicity:	Not classified

Reproductive toxicity:	Based on available data, the classification criteria are not met Not classified
Specific target organ toxicity (single exposure):	Based on available data, the classification criteria are not met Not classified
Specific target organ toxicity (repeated exposure):	Based on available data, the classification criteria are not met Not classified
Aspiration hazard:	Based on available data, the classification criteria are not met Not classified
	Based on available data, the classification criteria are not met

## 11.2 Information on other hazards

### 11.2.1. Endocrine disrupting properties

Based on available data, the classification criteria are not met.

## SECTION 12: Ecological information

### 12.1. Toxicity

Acute aquatic toxicity:

Not classified

Chronic aquatic toxicity:

Not classified

Ecology - general advice

Avoid release to the environment. Prevent entry to sewers and public waters.

### 12.2. Persistence and degradability

No additional information available.

### 12.3. Bioaccumulative potential

No additional information available.

### 12.4. Mobility in soil

No additional information available.

### 12.5. Results of PBT and vPvB assessment

According to the available data, the product does not contain PBT or vPvB substances in a proportion  $\geq 0.1$  %.

### 12.6. Endocrine disrupting properties

No additional information available.

### 12.7. Other adverse effects

No other effects known.

## SECTION 13: Disposal considerations

Dispose of in accordance with local and national regulations. In Italy dispose of according to Legislative Decree of April 3 2006 no. 152 "Regulations on environmental subject", application of European Directives on environmental protection, and subsequent modifications and integrations including those of Decree-Law No. 153 of 17 October 2024.

### 13.1. Waste treatment methods

Regional legislation (waste):

Dispose in a safe manner in accordance with local/national regulations.

Waste disposal recommendations:

When totally empty, containers are recyclable like any other packing.

European List of Waste (LoW) code	
10 12 00	wastes from manufacture of ceramic goods, bricks, tiles and construction products
10 12 06	discarded molds
10 13 00	wastes from manufacture of cement, lime and plaster and articles and products made from them
10 13 01	waste preparation mixture before thermal processing
10 13 06	particulates and dust (except 10 13 12 and 10 13 13)
17 08 00	gypsum-based construction material
17 08 02	gypsum-based construction materials other than those mentioned in 17 08 01

## SECTION 14: Transport information

The product is not considered dangerous according to the current regulations for the transport of dangerous goods by rail (ADR), sea (IMDG Code) and air (IATA).

### 14.1. UN number or ID number

Not applicable.

### 14.2. UN proper shipping name

Not applicable.

### 14.3. Transport hazard class(es)

Not applicable.

### 14.4. Packing group

Not applicable.

#### 14.5. Environmental hazards

Environmental hazards: No  
Marine pollutant: No  
Other information: No supplementary information available

#### 14.6. Special precautions for user

Not applicable.

#### 14.7. Maritime transport in bulk according to IMO instruments

Not applicable.

### SECTION 15: Regulatory information

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

Regulation (EC) no. 1272/2008 (Classification, labeling and packaging of substances and mixtures) and subsequent amendments, amending and repealing Directive 67/548/EEC and 1999/45/EC, and amending Regulation (EC) no. 1907/2006.

Directive 2009/161/EU (third list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Commission Directive 2000/39/EC).

EU-Regulations:	This mixture is classified as not hazardous according to regulation (EC) 1272/2008.
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Contains no substance on the REACH candidate list.

Contains no substance on the REACH Annex XIV List.

National regulations:

No additional information available

#### 15.2. Chemical safety assessment

A chemical safety assessment has been carried out.

### SECTION 16: Other information

This safety data sheet has been prepared in accordance with REACH Regulation (EC) 1907/2006 as amended by Regulation (EU) 2020/878.

The safety data sheet has been written according to relevant European provisions, on the basis of information received by the supplier of the mixture.

The product is intended for orthodontic and odontological use only. The use of the product has to be restricted to skilled and licensed professionals. The information relates only to specific product designated and is not intended as a warranty of quality.

Leone disclaims any responsibility arising out of the use of the information here furnished, or of the handling, the application or the manufacture of the product here described. The final user is called to verify the application and completeness of the information herein in relationship to the specific use and reliability of the rules and local applicable dispositions.

The present information does not imply any liberty to break patent rights.

Previous safety data sheet no. R08-6E dated 31/01/2023 is to be considered obsolete. In comparison to the preceding revision, meaningful changes have not been effected but only adjustments to the European provisions which regulate the compilation of safety data sheets.

Certain subsections of some sections are omitted because, as permitted by Annex II, Part B of Regulation (EU) 2020/878, they are not applicable.

This safety data sheet is subject to revision. Visit our web site [www.leone.it](http://www.leone.it) for an updated version of the present sheet.

#### Legend

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.

CAS No.: numerical identifier that uniquely identifies a chemical substance, assigned by the Chemical Abstract Service.

CLP: Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008.

DFG: German Research Foundation.

DMEL: Derived Minimal Effect level.

DNEL: Derived-No Effect Level.

EC-Number: EINECS and ELINCS Number (see also EINECS and ELINCS).

EN: European Standard.

EN 166: Personal eye-protection – Specifications.

EN 374: Protective gloves against dangerous chemicals and micro-organisms.

EN149: Respiratory protective devices – Filtering half masks to protect against particles.

IATA: International Air Transport Association.

IMDG: International Maritime Dangerous Goods Code.

IMO: International Maritime Organization.

PBT: Persistent, Bioaccumulative And Toxic Substances.

PNEC: Predicted No-Effect Concentration.

REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006.

STP: Wastewater treatment plant.

vPvB: Very Persistent And Very Bioaccumulative Substances.