



SECTION 1: Identification of the substance or mixture and of the company

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.

I – 50019 Sesto Fiorentino – Firenze - Via P. a Quaracchi, 50

e-mail: research@leone.it – <http://www.leone.it>

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.

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

Not applicable.

2.3. Other hazards

Not classified as PBT or vPvB.

SECTION 3: Composition/information on ingredients

3.1. Substances

This product is a mixture.

3.2. Mixtures

Product name	%W/W	EC-no.	CAS no.	Hazard class and category code	Hazard statements code
Calcium sulphate hemi-hydrate	>98	600-067-1	10034-76-1	-	-
Sodium citrate	<1	213-618-2	994-36-5	-	-

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.

No hazardous components are listed.

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation IF INHALED: ensure the supply of fresh air.

Skin contact IF ON SKIN (or hair): Wash affected skin with hot water.

Eye contact IF IN EYES: flush eyes with plenty of water with eyelids wide open . in case of contact lens undergo a medical examination.

Ingestion Rinse the mouth and drink water.

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

Not applicable.

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

None necessary.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing Media The material is non-flammable , in case of fire involving the product , you can use the means of extinction recommended for the other materials involved.

Unsuitable extinguishing Media None.

5.2. Special hazards arising from the substance or mixture

None specific.

5.3. Advice for firefighters

Not required.



SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid formation of dust.

6.2. Environmental precautions

Keep wetted with nebulised water to avoid dust leakage.

6.3. Methods and material for containment and cleaning up

Pick up by mechanical means. Eliminate residuals with throws of water.

6.4. Reference to other sections

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SECTION 7: Handling and storage

7.1. Precautions for safe handling

In case of dust formation, arrange local or general dust suction.

7.2. Conditions for safe storage, including any incompatibilities

Store in a dry place.

7.3. Specific end use(s)

None.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

European Union. Calcium sulphate, professional exposure limits: 10 mg/m³.

8.2. Exposure controls

Appropriate engineering controls

Do not eat, drink or smoke at the work place. The following information is given as general guidance.

Individual protection measures, such as personal protective equipment (PPE)

Eye/face protection	Safety glasses.
Skin protection	Not necessary, eventually wear an apron.
Respiratory protection	Protective filter-dust mask.
Hand protection	Wear gloves.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Dust.
Colour	White.
Odour	Odourless.
pH	5-7 in suspension (10g/l at 20°C).
Melting point	1700°C.
Explosive properties and Comburent	Not explosive, nor comburent.
Flammability	No.
Solubility (Water)	Virtually insoluble.
Volatile substances or components	No.
Specific gravity (H ₂ O=1)	Approximately 2.6.

9.2. Other information

None.

SECTION 10: Stability and reactivity

10.1. Reactivity

Non-reactive material, under normal environmental condition.

10.2. Chemical stability

Stable under normal storage and handling conditions.

10.3. Possibility of hazardous reactions

During high temperature heating, the release of vapors of sulphurous anhydride is possible.

10.4. Conditions to avoid

None.

10.5. Incompatible materials

Not known.

10.6. Hazardous decomposition product(s)

Not known.



SECTION 11: Toxicological information

11.1. Information on toxicological effects

Potential Acute Health Effects

Skin irritation/corrosion: not irritating.

Ocular damage/irritation: slightly irritating.

Sensitization to the respiratory tract and skin: not available.

Signs and Symptoms of Exposure

Eye irritation.

Medical Conditions Generally Aggravated by Exposure

Not known.

Carcinogenic or Potential Carcinogenic Effects

No ingredient listed as a carcinogen.

Other Potential Health Effects

Not known.

Potential Chronic Health Effects

Not known.

SECTION 12: Ecological information

Generally not pollutant according to the classification of water pollution risks.

12.1. Toxicity

Not applicable.

12.2. Persistence and degradability

Not applicable.

12.3. Bioaccumulative potential

Not applicable.

12.4. Mobility in soil

Not applicable.

12.5. Results of PBT and vPvB assessment

Not applicable.

12.6. Other adverse effects

Not applicable.

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.

13.1. Waste treatment methods

This product is classified as a special non-hazardous waste and can be disposed of in landfills. Based on decisions of individual collection companies of municipal solid waste, it can be disposed of with household waste.

SECTION 14: Transport information

Not dangerous according to current transportation regulations.

14.1. UN 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

Not applicable.

14.6. Special precautions for user

Not applicable.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

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).

15.2. Chemical safety assessment

Not applicable.



SECTION 16: Other information

This Safety data sheet was prepared in accordance with the Commission Regulation (EU) no. 453/2010 and Commission Regulation (EU) no. 2015/830.

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. R08/4E dated 29/05/2009 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 sheet.

This safety data sheet is subject to revision. Visit our web site www.leone.it for an updated version of the present sheet.

Legend

CAS No.: Chemical Abstract Service Registry number.

EC-No.: European Inventory of Existing Commercial Chemical Substances.

IBC Code: International Bulk Chemicals Code.

PBT: Persistent, Bioaccumulative And Toxic Substances.

vPvB: Very Persistent And Very Bioaccumulative Substances.