



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

1.1. Product identifier

Product Description: Glass ionomer cement.

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

Identified Use Professional use: For cementation of bands in fixed orthodontic appliances.

1.3. Details of the supplier of the safety data sheet

Leone s.p.a.

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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. The information contained herein is to be referred to the raw material which these products are manufactured with; for this purpose some instructions and indications are related to the personnel employed in the manufacturing processes and not to the final user.

2.2. Label elements

Precautionary statement(s)	P280	Wear protective gloves, protective clothing, eye protection.
	P305+351+338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.

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

Hazardous ingredient(s)	%W/W	EC no.	CAS no.	Hazard Class and Category Code(s)	Hazard statement Code (s)
Fluoro-aluminosilicate glass	50-100%	-		Eye Irritation, 2	H319
Polyacrylic acid	10-25%	-		Eye Irritation, 2	H319
(+) – Tartaric acid	5-10%	201-766-0	87-69-4	Eye damage, 1	H318

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation If inhaled: seek medical treatment in case of complaints.

Skin contact immediately rinse with water.

Eye contact Rinse opened eye for several minutes under running water. If symptoms persists consult a doctor.

Ingestion If symptoms persist consult a doctor.

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

No further information available.

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

No further information available.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing Media Carbon dioxide, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

Unsuitable extinguishing Media None.

5.2. Special hazards arising from the substance or mixture

No further relevant information available.

5.3. Advice for firefighters

Protective equipment: No special measures required.



SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Not required.

6.2. Environmental precautions

Do not allow to enter sewers/surface or ground water.

6.3. Methods and material for containment and cleaning up

Pick up mechanically.

6.4. Reference to other sections

See Section 7, Section 8 and Section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

For dental use only.

7.2. Conditions for safe storage, including any incompatibilities

Keep container tightly sealed. See storage instruction on package.

7.3 Specific end use(s)

No further relevant information available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the work place.

8.2. Exposure controls

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

Eye protection

Safety glasses.

Hand protection

Protective gloves. The selection of suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material cannot be calculated in advance and has, therefore, to be checked prior to the application.

Respiratory protection

Not required.

Hygienic measures

The usual precautionary measures should be adhered to general rules for handling chemicals.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Solid.

Colour

White.

Odour and odour threshold

Characteristic, undetermined.

pH

Not applicable.

Melting point

Undetermined.

Boiling point

Undetermined.

Flash point

Not applicable.

Flammability

Not determined.

Decomposition temperature

Not determined.

Self-igniting

Product is not self igniting.

Danger of explosion

Product does not present an explosion hazard.

Density

Not determined.

Relative density

Not determined.

Vapour density

Not applicable.

Evaporation rate

Not applicable.

Solubility in water

Soluble.

Partition coefficient (n-octanol/water)

Not determined.

Dynamic viscosity

Not applicable.

Kinetic viscosity

Not applicable.

Solid content

100% solid.

9.2. Other information

No further details as regards the safety-relevant parameters are required.

SECTION 10: Stability and reactivity

10.1. Reactivity

Information not available.



10.2. Chemical stability

No decomposition if used according to specification.

10.3. Possibility of hazardous reactions

No dangerous reaction known.

10.4. Conditions to avoid

No further information available.

10.5. Incompatible materials

None.

10.6. Hazardous decomposition product(s)

No dangerous decomposition product known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity: not available.

Primary irritant effect: no irritant effect.

In the eye: no irritant effect.

On the skin: no irritating effect.

Sensitization: no sensitizing effects known.

Additional toxicological information: the product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparation as issued in the latest version.

SECTION 12: Ecological information

12.1. Toxicity

Aquatic toxicity: no further relevant information available.

12.2. Persistence and degradability

No further relevant information available.

12.3. Bioaccumulative potential

No further relevant information available.

12.4. Mobility in soil

Not available.

Additional information: water hazard class 1 (German Regulation): slightly hazardous for water. Do not allow undiluted product or large quantity of it to reach ground water, water course of sewage system.

12.5. Results of PBT and vPvB assessment

Not available.

12.6. Other adverse effects

No further relevant information available.

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

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

Uncleaned packaging

Disposal must be made according to official regulations.

Recommended cleansing: water, if necessary add cleansing agent.

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).

This product is CE marked in accordance with the essential safety and performance requirements of Annex I of the European regulation on medical devices.

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. E07/4E dated 05/03/2013 is to be considered cancelled. 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.

Hazard statements

H318: Causes serious eye damage.

H319: Causes serious eye irritation.

Legend

CAS No.: unique numerical identifier assigned by Chemical Abstracts Service.

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.