



## 1. Identification of the preparation and of the company

### 1.1 Identification of the preparation

Glass ionomer cement.

### 1.2 Use of the preparation

For cementation of bands in fixed orthodontic appliances.

### 1.3 Company identification

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### 1.4 Emergency telephone

++39 (0)55.30.44.1. An answering machine is on during closing time.

## 2. Hazards identification

*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.*

Hazards to man or environment:

- Potential health hazards: irritant in case of eye, skin and inhalation contact.
- Environmental hazards: no environmental risks have been detected.

Effects and symptoms:

- Inhalation: irritating to respiratory system .
- Skin contact: irritating to skin.
- Eye contact: irritating to eyes.

## 3. Composition/information on ingredients

Preparation: mixture of polyacrylic acid, silicates, tartaric acid and additives.

Information on hazardous ingredients<sup>1</sup> and composition %:

Chemical name	EC <sup>2</sup> Number	%	CAS <sup>3</sup> Number	Hazard <sup>4</sup> symbols	R <sup>4</sup> Phrases
Polyacrylic acid	-	22-24	87913-09-5	Xi	R 36/37/38

## 4. First aid measures

- Inhalation: move to fresh air, in case of indisposition or nausea contact a doctor.
- After ingestion: seek immediately for medical advice. Information for the doctor: material for dental use.
- After skin contact: rinse thoroughly with water.
- After eye contact: rinse thoroughly with water, if necessary contact a physician.

## 5. Fire-fighting measures

- Suitable fire extinguishing agents: foam, carbon dioxide and powder fire extinguishers.
- Unsuitable fire extinguishing agents: water.
- Particular hazards: none.
- Fire fighting protective equipment: no data available.

## 6. Accidental release measures

- Personal precautions: avoid eye and/or skin contact.
- Environmental precautions: do not let the material get in contact with sewerage systems.
- Methods of cleaning up: wipe up mechanically, use common absorbents.

## 7. Handling and storage

### 7.1 Handling

Product handling must be executed only by qualified staff in dental offices or dental laboratories.

Instructions for safe handling: see instructions for use.

Instructions on fire and explosion protection: no special precautions are required.

### 7.2 Storage

Store in containers tightly closed at room temperature, in good ventilated rooms.

<sup>1</sup> The occupational exposure limits (OEL), if known, are listed in section 8.

<sup>2</sup> Number of European Catalogue. The EC number is made of a sequence of 7 figures, whose first group of 3 figures begins with 2 or 4 depending on which substance is included in the EINECS (European Inventory of Existing Commercial Chemical Substances) or in the ELINCS (European List of Notified Chemical Substances), or it begins with 5 if the substance is included in the list of "ex-polymers."

<sup>3</sup> CAS Number (Chemical abstract service).

<sup>4</sup> Hazards related to the ingredients of the product are indicated in section 2, information to be shown on the label are indicated in section 15. Explanation of hazardous symbols and Risk phrases is indicated in section 15 and 16.



Do not store together with food and keep out of the reach of children.

## 8. Exposure controls/personal protection

Professional equipment control: hazards related to place of work are not known.

Breathing protection: do not breath or inhale vapour or dust.

Hand protection: use of protective gloves is recommended.

Eye protection: use of protective glasses is recommended.

Personal protective equipment: dental office or laboratory working clothes.

Hygiene measures: washing hands.

## 9. Physical and chemical properties

### 9.1. General information

Appearance:	powder
Form:	solid
Colour:	pale blue
Odour:	almost odourless.

### 9.2. Health, safety and environmental information

Boiling point/area:	no data available
Melting point:	no data available
Vapour pressure:	no data available
Specific gravity (H <sub>2</sub> O=1)	no data available
Solubility in water (20°C):	no data available
pH:	no data available
Flash point:	no data available
Auto-ignition temperature:	no data available
Lower explosion limit:	no data available
Upper explosion limit:	no data available
Viscosity:	no data available
Change of state:	no data available
Flammability:	no data available
Autoignition:	no data available
Explosion hazards:	no data available.

## 10. Stability and reactivity

- Conditions to be avoided: none if used in the recommended way.
- Material to be avoided: none if used in the recommended way.
- Hazardous products of decomposition: none if used in the recommended way.
- Further details: none.

## 11. Toxicological information

No toxicological data are available on the product.

General information: during long-standing product application risks have not become known.

## 12. Ecological information

No ecological information on the product are available.

## 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.

## 14. Transport information

None. The product is not hazardous within the meaning of transport regulations.

## 15. Regulatory information

- Health, safety and environmental information shown on the label according to European Directives on hazardous materials and substances

No special label required.

- Information related to further dispositions

This product is CE marked in accordance with the essential requirements of Directive 93/42/EC, Annex I, on medical devices.



## **16. Other information**

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

Hazard symbols or risk phrases shown on section 3:

Hazard symbols: Xi Irritating

Risk phrases: R 36/37/38 Irritating to eyes, respiratory system and skin

are specific for some ingredients and not shown on the product label.

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 drawn herein is based on our knowledge at the date of the issue.

The information is exclusively provided related to the product herewith specified 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 doesn't imply any liberty to break patent rights.

Previous safety data sheet n. E07/2E of 17/05/2001 has 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](http://www.leone.it) for an updated version of the present sheet.