



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

### 1.1 Identification of the preparation

Light-cure cement with fluoride release.

### 1.2 Use of the preparation

For cementation of bands in fixed orthodontic appliances.

### 1.3 Company identification

Leone s.p.a.

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

e-mail: [research@leone.it](mailto:research@leone.it) – <http://www.leone.it>

Tel. ++39 (0)55.30.44.1 – Fax ++39 (0)55 374808.

### 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.*

Potential health hazards: see section 11.

No significant hazards to man or environment are reasonably foreseen.

## 3. Composition/information on ingredients

- Powdered glass
- Mixture of hydrophilic and hydrophobic aliphatic dimethacrylates
- Silica
- Camphoroquinone (polymerization initiator)
- Tertiary aliphatic amine (polymerization activator)
- Fluorescent agent
- Polyacrylic acid.

Hazardous ingredients: none.

## 4. First aid measures

- Inhalation: no harm anticipated.
- Ingestion: no harm perceived, however, if large quantities are accidentally swallowed, seek medical attention and advise of fluoride presence in material.
- Skin contact: wash with copious water.
- Eye contact: flush out with copious amounts of water; seek medical attention if irritation persists.

## 5. Fire-fighting measures

- Suitable extinguishing media: water contact acceptable.
- Extinguishing media which should not be used: none.
- Special exposure hazards from combustion products: none.
- Special protective equipment for fire-fighters: none.

## 6. Accidental release measures

- Personal precautions: avoid exposure to moisture.
- Environmental precautions: no precautionary measures required.
- Methods of cleaning up:
  - Small quantities: wipe up and dispose of as “household” trash. Do not dispose into sink.
  - Large quantities: dispose in accordance with local regulations.

## 7. Handling and storage

### 7.1 Handling

Handling precautions: avoid exposure to moisture and light.

### 7.2 Storage

Safe storage conditions: store at temperature not exceeding 28°C.

Other restrictions or recommendations: none.

## 8. Exposure controls/personal protection

Respiratory protection and ventilation: not applicable.

Protecting clothing or equipment: not required under normal handling.

Unusual work/hygienic practices: wash with water if skin contact occurs.



## 9. Physical and chemical properties

### 9.1. General information

Appearance: light yellow paste  
Odour: characteristic, slight.

### 9.2. Health, safety and environmental information

Boiling point /range: not applicable  
Melting point/range: not applicable  
Specific gravity (H<sub>2</sub>O=1): approx. 2  
Solubility in water: negligible  
pH: not applicable  
Flash point: not applicable  
Auto-ignition temperature: not applicable  
Flammability: under extreme conditions  
Explosive limits in air: not applicable  
Oxidizing properties: none  
Vapour pressure (mm Hg): negligible at room temperature  
Vapour density (air=1): not applicable  
Reactivity in water: none  
Other data: none.

## 10. Stability and reactivity

- Stability: stable except when exposed to light or extreme temperatures
- Conditions of instability: exposure to light.
- Incompatibility with various substances: none known.
- Hazardous polymerization: may occur when large quantities are involved and only upon exposure to intense light.
- Hazardous decomposition products: none known.
- Conditions to avoid: avoid exposure to light.

## 11. Toxicological information

- Potential acute health effects: none known
- Potential chronic health effects none known.
- Signs and symptoms of exposure: none known.
- Medical conditions generally aggravated by exposure: none known.
- Carcinogenic or potential carcinogenic effects: no ingredient listed as a carcinogen.
- Other potential health effects: none known.

## 12. Ecological information

No ecological damage or impact anticipated when handled as indicated.

## 13. Disposal considerations

Do not dispose into sink.

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

The product is not hazardous within the meaning of transport regulations.

Special provisions for transport: avoid elevated temperatures and high intensity light

## 15. Regulatory information

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

None.

- 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.



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. E08/1E of 15/06/2001 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.