



## **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.

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

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

Tel. +39 055.30.44.1 – 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.

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.

For potential health hazards: See Section 11 below.

### **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**

Glass Ionomer Cement.

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 ingredients are listed.

## **SECTION 4: First aid measures**

### **4.1. Description of first aid measures**

Inhalation IF INHALED: No harm anticipated. Breathing of dust should be avoided.

Skin contact IF ON SKIN (or hair): Wash with copious amounts of water.

Eye contact IF IN EYES: Flush with copious amounts of water. Seek medical attention if irritation persists

Ingestion Glass Ionomer Powder: No harm perceived, however, if large quantities are accidentally swallowed, seek medical attention. Advise of fluoride presence in material.

Glass Ionomer Liquid: No hazard if small amounts are swallowed. If large amounts swallowed, ingest baking soda and seek medical attention.

### **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**

Glass Ionomer Powder: if large quantities are accidentally swallowed, seek medical attention. Advise of fluoride presence in material.

Glass Ionomer Liquid: If large amounts swallowed, ingest baking soda and seek medical attention.

## **SECTION 5: Firefighting measures**

### **5.1. Extinguishing media**

Suitable extinguishing Media In case of fire, water contact acceptable.

Unsuitable extinguishing Media None.

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

None in quantities as packaged.

### **5.3. Advice for firefighters**

None.



## **SECTION 6: Accidental release measures**

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

Glass Ionomer Powder: Avoid dusting and exposure to moisture.

Glass Ionomer Liquid: Avoid exposure to elevated temperatures.

### **6.2. Environmental precautions**

No precautionary measures required.

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

Wipe up with soap, water, and paper towels.

### **6.4. Reference to other sections**

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## **SECTION 7: Handling and storage**

### **7.1. Precautions for safe handling**

Glass Ionomer Powder: Avoid dusting and exposure to moisture.

Glass Ionomer Liquid: Avoid exposure to elevated temperatures.

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

Store at temperatures not exceeding 24°C, in dry conditions.

### **7.3. Specific end use(s)**

None.

## **SECTION 8: Exposure controls/personal protection**

### **8.1. Control parameters**

Not applicable.

### **8.2. Exposure controls**

#### Respiratory protection e ventilation:

Glass Ionomer Powder: Use dust mask if material is accidentally blown by air stream.

Glass Ionomer Liquid: Not required under normal handling.

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

Not required under normal handling.

Protective Equipment                      Not required under normal handling.

Industrial Hygiene

Glass Ionomer Powder: Avoid dusting, wash with water if skin contact occurs.

Glass Ionomer Liquid: Avoid spills, wash immediately with water if skin or eye contact occurs.

## **SECTION 9: Physical and chemical properties**

### **9.1. Information on basic physical and chemical properties**

|                   |                       |                           |
|-------------------|-----------------------|---------------------------|
| Appearance:       | Glass Ionomer Powder: | Fine powder.              |
|                   | Glass Ionomer Liquid: | Liquid.                   |
| Colour:           | Glass Ionomer Powder: | White.                    |
|                   | Glass Ionomer Liquid: | Clear.                    |
| Odour:            | Glass Ionomer Powder: | Odorless.                 |
|                   | Glass Ionomer Liquid: | Mild characteristic odor. |
| pH:               |                       | Not applicable.           |
| Melting point:    |                       | Not applicable.           |
| Boiling point:    | Glass Ionomer Powder: | Not applicable.           |
|                   | Glass Ionomer Liquid: | ca 105°C.                 |
| Flash point       |                       | Not applicable.           |
| Flammability      |                       | No.                       |
| Evaporating rate: |                       | Not established.          |



|   |  |   |
|---|--|---|
| Upper/Lower flammability or explosive limits: |  | Not applicable.   |
| Vapor pressure:                               | Glass Ionomer Powder:<br>Glass Ionomer Liquid: | Negligible at ambient temperatures.<br>ca 720 mm Hg at 100°C. |
| Vapor density:                                | Glass Ionomer Powder:<br>Glass Ionomer Liquid: | Not applicable.<br>ca 0.62.                                   |
| Relative density:                             | Glass Ionomer Powder:<br>Glass Ionomer Liquid: | ca 3.0.<br>ca 1.1.  |
| Solubility (ies):                             | Glass Ionomer Powder:<br>Glass Ionomer Liquid: | Negligible in water.<br>Soluble in water.                     |
| Auto-ignition temperature:                    |  | Not applicable.   |
| Partition coefficient: n-octanol/water:       |  | Not established.  |
| Decomposition temperature:                    |  | Not established.  |
| Viscosity:                                    |  | Not established.  |

## 9.2. Other information

None.

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

Glass Ionomer Powder: Not applicable

Glass Ionomer Liquid: Contact with alkaline materials

### 10.2. Chemical stability

Generally stable.

### 10.3. Possibility of hazardous reactions

Will not occur

### 10.4. Conditions to avoid

Glass Ionomer Powder: Moisture

Glass Ionomer Liquid: Elevated temperatures

### 10.5. Incompatible materials

Glass Ionomer Powder: Not applicable

Glass Ionomer Liquid: Contact with alkaline materials

### 10.6. Hazardous decomposition product(s)

None

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

|   |                                       |
|---|---------------------------------------|
| Potential Acute Health Effects                      | None                                  |
| Signs and Symptoms of Exposure                      | None                                  |
| 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.                           |
| Potential Chronic Health Effects                    | None                                  |

## SECTION 12: Ecological information

No ecological damage or impact anticipated upon exposure of material to the environment in quantities as packaged.

### 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**

Glass Ionomer Powder: Do not dispose into sink.

Glass Ionomer Liquid: Disposal into the sink is acceptable.

Dispose of in accordance with all federal, state, and local regulations.

### **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**

Avoid elevated temperatures and high intensity light.

#### **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/not indicated.

### **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. F07/5E dated 16/01/2017 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](http://www.leone.it) for an updated version of the present sheet.

### **Legend**

IBC Code: International Bulk Chemicals Code.

PBT: Persistent, Bioaccumulative And Toxic Substances.

vPvB: Very Persistent And Very Bioaccumulative Substances.