SECTION 1: Identification of the substance/mixture and of the company/undertaking

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, 48/50
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.
www.leone.it/emergency (EU and international telephone numbers).

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.
For potential health hazards: See Section 11 below.
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

Not applicable.

2.3. Other hazards

According to the available data, the product does not contain PBT or vPvB substances in a proportion ≥ 0.1 %.
The product does not contain substances with endocrine-disrupting properties in a concentration ≥ 0.1%.

SECTION 3: Composition/information on ingredients

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

Exposure hazards in case of fire: None in quantities as packaged.

5.3. Advice for firefighters

Not required.

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 are necessary.

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

8.2.2. Individual protection measures, such as personal protective equipment

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

Physical state:	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.
Odor threshold:		Not established.
Melting point/freezing point:		Not applicable.
Boiling point or initial boiling point and boiling range:	Glass Ionomer Powder:	Not applicable.
	Glass Ionomer Liquid:	approx. 105°C.
Flammability:		None.
Lower and upper explosion limit:		Not applicable.
Flash point:		Not applicable.
Auto-ignition temperature:		Not applicable.
Decomposition temperature		Not established.
pH		No data available.
Kinematic viscosity		Not established.
Solubility	Glass Ionomer Powder:	Negligible in water.
	Glass Ionomer Liquid:	Soluble in water.
Partition coefficient n-octanol/water (log value)		Not established.
Vapour pressure:	Glass Ionomer Powder:	Negligible at ambient temperature.
	Glass Ionomer Liquid:	ca 720 mm Hg at 100°C.
Density and/or relative density:	Glass Ionomer Powder:	ca 3.0.

	Glass Ionomer Liquid:	ca 1.1.
Relative vapour density	Glass Ionomer Powder:	Not applicable.
	Glass Ionomer Liquid:	ca 0.62.
Particle characteristics		/

9.2. Other information
None.

SECTION 10: Stability and reactivity

10.1. Reactivity
Glass Ionomer Powder: None known
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
lass Ionomer Powder: Not applicable
Glass Ionomer Liquid: Contact with alkaline materials
10.6. Hazardous decomposition products
None.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity	None.
Skin corrosion/irritation	None.
Serious eye damage/irritation	None.
Respiratory or skin sensitisation	None known.
Germ cell mutagenicity	None known.
Carcinogenicity	No ingredient listed as a carcinogen.
Reproductive toxicity	None known.
STOT-single exposure	None known.
STOT-repeated exposure	None known.
Aspiration hazard.	None known.

11.2 Information on other hazards
None known.

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
According to the available data, the product does not contain PBT or vPvB substances in a proportion ≥ 0.1 %.
12.6. Endocrine disrupting properties
Not applicable.
12.7 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 including those of Decree-Law No. 153 of 17 October 2024.
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 or ID 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. Maritime transport in bulk according to IMO instruments

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 has been prepared in accordance with REACH Regulation (EC) 1907/2006 as amended by Regulation (EU) 2020/878.
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. E07-7E dated 31/01/2023 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 sheets.
Certain subsections of some sections are omitted because, as permitted by Annex II, Part B of Regulation (EU) 2020/878, they are not applicable.
This safety data sheet is subject to revision. Visit our web site www.leone.it for an updated version of the present sheet.

Legend
CLP: Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008.
IMO: International Maritime Organization.
PBT: Persistent, Bioaccumulative and Toxic substances.
vPvB: Very Persistent and Very Bioaccumulative.