

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

1.1. Product identifier

Product Description: Light-cure cement with fluoride release.

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.

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

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

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 components are listed.

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation IF INHALED: No harm anticipated.

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

Eye contact IF IN EYES: Flush eye with copious amount water. If irritation persists consult a doctor.

Ingestion No harm perceived, however, if large quantities are accidentally swallowed, get medical attention.
Advise of fluoride presence in material.

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

None necessary.

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 specific.

5.3. Advice for firefighters

Not required.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid exposure to moisture.

6.2. Environmental precautions

No precautionary measures required.

6.3. Methods and material for containment and cleaning up

Small quantities: wipe up and dispose of as "household" trash. Do not dispose into sink.

Large quantities: dispose in accordance with all local, state and federal regulations.

6.4. Reference to other sections

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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid exposure to moisture and light.

7.2. Conditions for safe storage, including any incompatibilities

Store at temperatures not exceeding 28°C.

7.3. Specific end use(s)

None.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Not applicable.

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Do not eat, drink or smoke at the workplace. The following information is given as general guidance.

8.2.2. Individual protection measures, such as personal protective equipment

Respiratory protection	Not applicable.
Protective equipment	Not required under normal handling.
Industrial Hygiene	Wash with water if skin contact occurs.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Paste.
Colour	Light yellow.
Odour	Characteristic, slight.
Odor threshold	Not established.
Melting point/freezing point	Not applicable.
Boiling point or initial boiling point and boiling range	Not applicable.
Flammability	Under extreme conditions.
Lower and upper explosion limit	Not applicable.
Flash point	Not applicable.
Auto-ignition temperature	Not applicable.
Decomposition temperature	Not established.
pH	Not applicable.
Kinematic viscosity	Not established.
Solubility	Negligible in water.
Partition coefficient n-octanol/water (log value)	Not established.
Vapour pressure	Negligible at ambient temperatures.
Density and/or relative density	Approximately 2.
Relative vapour density	Not applicable.
Particle characteristics	/

9.2. Other information

9.2.2. Other safety characteristics

Evaporating rate: Not established.

SECTION 10: Stability and reactivity

10.1. Reactivity

Non-reactive material.

10.2. Chemical stability

Stable, except when exposed to light or extreme temperatures.

10.3. Possibility of hazardous reactions

Hazardous polymerization may occur when large quantities are involved and only upon exposure to intense light.

10.4. Conditions to avoid

Exposure to light.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

None known.

SECTION 11: Toxicological information**11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008**

Acute toxicity	None known.
Skin corrosion/irritation	None known.
Serious eye damage/irritation	None known.
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

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SECTION 12: Ecological information

No ecological damage or impact anticipated when handled as indicated.

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

Large quantities: dispose of in accordance with all federal, state, and local regulations. Do not dispose into sink.

Small quantities: dispose of into "household" trash.

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.

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. E08-4E 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.