

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Product description: Ceramic brackets.

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified Use Professional use: Direct bonding aesthetic brackets used in fixed orthodontic prosthesis.

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 under Titles I and II of Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

The products generally are not considered as hazardous in the form they are supplied, nevertheless ingestion or inhalation of pieces or fragments may occur during use.

Further grinding or cutting or any other procedure that causes a release of dust, hazardous levels of dust may be generated.

2.2. Label elements

Not applicable.

2.3. Other hazardsAccording 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**

Ingredient(s)	Product identifier	%W/W	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Aluminum Oxide (Al ₂ O ₃)	CAS-No.: 1344-28-1 EC-No.: 215-691-6	99.9	-

The *Ghiaccio* brackets have Zirconia micro beads on the base.

Other trace elements may also be present in minute amounts. These small quantities (less than 0.1%) are frequently referred to as “trace” or “residual” elements; generally they originate in the raw material used.

According to Regulation (EC) no. 1272/2008 [CLP], no dangerous ingredients.

SECTION 4: First aid measures**4.1. Description of first aid measures**

In case of releasing dust as described under Chapter 2 the following first aid procedures are recommended:

Inhalation Move person to fresh air until recovered, consult a physician.

Eye contact Flush thoroughly with water, consult a physician.

Skin contact Wash with water and mild detergent, consult a physician.

Ingestion While ingestion of large enough quantities to cause health effects is unlikely, consult a physician if it occurs.

4.2. Most important symptoms and effects, both acute and delayed

Not available.

4.3. Indication of any immediate medical attention and special treatment needed

Not available.

SECTION 5: Firefighting measures

Non-flammable.

5.1. Extinguishing media

Suitable extinguishing Media None.

Unsuitable extinguishing Media None.

5.2. Special hazards arising from the substance or mixture

None.

5.3. Advice for firefighters

None.

SECTION 6: Accidental release measures

Sweep up to avoid slipping hazards.

6.1. Personal precautions, protective equipment and emergency procedures

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6.2. Environmental precautions

Not applicable.

6.3. Methods and material for containment and cleaning up

Not applicable.

6.4. Reference to other sections

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SECTION 7: Handling and storage

7.1. Precautions for safe handling

None.

7.2. Conditions for safe storage, including any incompatibilities

Not specific measure required.

7.3 Specific end use(s)

No further relevant information available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Component	OSHA PEL(mg per m ³)	ACGIH TLV (mg per m ³)
Aluminum Oxide	15 TWA Total Dust	10 TWA Total Dust
	5 TWA Respirable Fraction	1 TWA Respirable Fraction

8.2. Exposure controls

8.2.2. Individual protection measures, such as personal protective equipment

Eye/face protection Only required when cutting, grinding or welding.

Skin protection Only required when cutting, grinding or welding.

Respiratory protection Only required when cutting, grinding or welding.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Solid
Colour	Translucent
Odour	Odourless
Melting point	2053 °C
Boiling point or initial boiling point and boiling range	>2977 °C
Flammability	/
Lower and upper explosion limit	/
Flash point	Not flammable
Auto-ignition temperature	/
Decomposition temperature	/
pH	/
Kinematic viscosity	/
Solubility	Insoluble
Partition coefficient n-octanol/water (log value)	/
Vapour pressure	/
Density and/or relative density	3.99 (water=1)
Relative vapour density	>1
Particle characteristics	/

9.2. Other information

No further details as regards the safety-relevant parameters are required.

SECTION 10: Stability and reactivity

10.1. Reactivity

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10.2. Chemical stability

Stable.

10.3. Possibility of hazardous reactions

None.

10.4. Conditions to avoid

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10.5. Incompatible materials

None.

10.6. Hazardous decomposition products

Will not occur.

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

Acute toxicity	This material is not hazardous in normal storage and handling.
Skin corrosion/irritation	None known.
Serious eye damage/irritation	Exposure to dust may cause irritation to eyes.
Respiratory or skin sensitisation	Exposure to dust may cause irritation to lungs.
Germ cell mutagenicity	None known.
Carcinogenicity	None known.
Reproductive toxicity	None known.
STOT-single exposure	Exposure to dust may cause irritation to eyes, lungs, and gastrointestinal tract.
STOT-repeated exposure	Over exposure to dust via inhalation for prolonged periods could cause pneumoconiosis and/or nervous system disorder.
Aspiration hazard.	None known.

11.2 Information on other hazards

No further information available.

SECTION 12: Ecological information

No ecological effects are known.

12.1. Toxicity

Information not available.

12.2. Persistence and degradability

Information not available.

12.3. Bioaccumulative potential

Not available.

12.4. Mobility in soil

Not available.

12.5. Results of PBT and vPvB assessmentAccording to the available data, the product does not contain PBT or vPvB substances in a proportion ≥ 0.1 %.**12.6. Endocrine disrupting properties**

Not available.

12.7 Other adverse effects

Not available.

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

The possibility of recycling is to be verified according to local and national 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

Not applicable.

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 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. F13-4E 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

ACGIH: American Conference of Governmental Industrial Hygienists.

CAS No.: numerical identifier that uniquely identifies a chemical substance, assigned by the Chemical Abstract Service.

CLP: Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008.

EC-Number: EINECS and ELINCS Number (see also EINECS and ELINCS).

IMO: International Maritime Organization.

OSHA: European Agency for Safety and Health at work.

OSHA PEL: OSHA permissible exposure limits.

PBT: Persistent, Bioaccumulative And Toxic Substances.

REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006.

TLV: Threshold Limit Value. Guideline developed by ACGIH. This value represents the maximum concentration of a chemical in the air to which most workers can be continuously exposed during their working life without suffering adverse health effects.

TWA: Time-weighted average concentration of a chemical agent in the air within the breathing zone of a worker for an 8-hour working day.

vPvB: Very Persistent And Very Bioaccumulative Substances.