



SECTION 1: Identification of the substance or mixture and of the company

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, 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.

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.

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 hazards

Not classified as PBT or vPvB.

SECTION 3: Composition/information on ingredients

3.1. Substances

This product is a mixture.

3.2. Mixtures

Pure Alumina (Aluminium Oxide) 99.998%.

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

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 in Section 2, the following first aid procedure 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 quantities enough 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

Not applicable.

6.2. Environmental precautions

Not applicable.

6.3. Methods and material for containment and cleaning up

Not applicable.

6.4. Reference to other sections

Not applicable.

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

Occupational exposure limits to Alumina Oxide in the form of dust as indicated in section 2:

Italy Occupational exposure limits are not known. USA: TWA 5.0 mg/m³.

8.2. Exposure controls

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

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

Appearance	Solid.
Colour	Translucent.
Odour	Odourless.
Water solubility	Insoluble.
Melting point	1950°C.
Boiling point	Not known.
Flash point	Not flammable.
Vapour density	>1.
Specific gravity	2.5-5 (water=1).

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 product(s)

Will not occur.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

This material is not hazardous.



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 assessment

Not available.

12.6. Other adverse effects

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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

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

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. 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.

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. F13/2E dated 29/05/2009 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 for an updated version of the present sheet.

Legend

IBC Code: International Bulk Chemicals Code.

PBT: Persistent, Bioaccumulative And Toxic Substances.

TWA: Time Weighted Average.

vPvB: Very Persistent And Very Bioaccumulative Substances.