



1. Identification of the preparation and of the company

1.1 Identification of the preparation

Ceramic brackets.

1.2 Use of the preparation

Direct bonding aesthetic brackets utilized in fixed orthodontic prostheses.

1.3 Company identification

Leone s.p.a.

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Tel. ++39 (0)55.30.44.1 – Fax ++39 (0)55 374808.

1.4 Emergency telephone

++39 (0)55.30.44.1. An answering machine is on during closing time.

2. Hazards identification

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.

The products are not generally considered hazardous in the form they are shipped, anyway during use ingestion or inhalation of pieces or fragments may be possible.

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

3. Composition/information on ingredients

Chemical family: Pure Alumina (Aluminium Oxide) 99,998% - CAS¹:Number: 1344-28-1.

Hazardous components²: none in the form the product is shipped.

4. First aid measures

In case of ingestion or inhalation of pieces or fragments, seek medical advice.

In case of releasing dust as described under section 2, the following first aid procedures are recommended.

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

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

Eye contact: flush thoroughly with water, consult a physician.

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

5. Fire-fighting measures

Non flammable.

Extinguishing media: none.

Fire and explosion hazards: none.

Special fire-fighting procedures: none.

6. Accidental release measures

Sweep up to avoid slipping hazards.

Environmental precautions: none; dispose of in accordance with local and national regulations.

7. Handling and storage

7.1 Handling

Specific measures are not necessary.

7.2 Storage

Specific measures are not necessary.

8. Exposure controls/personal protection

- Occupational exposure limits³ 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.

- Respiratory protection: only required when cutting, grinding or welding.

- Skin protection: only required when cutting, grinding or welding.

¹ CAS Number (Chemical abstract service).

² Occupational exposure limit (OEL, occupational exposure limits), if known, are listed in section 8.

³ The "occupational exposure limit", if not otherwise specified, is the average limit or serious concentration in the time of a chemical agent in the air inside the breathing area of a worker related to a specific period of time (Directive 98/24/EC on health and safety protection of the workers against the consequential risks from chemical agents during the job); the TWA (time weighted average) indicator is the serious average concentration in the time for a working day of 8 hours.



- Eye protection: only required when cutting, grinding or welding.
- Other means of protection: none.

9. Physical and chemical properties

9.1. General information

Appearance/status:	solid
Colour:	translucent
Odour:	odourless.

9.2. Health, safety and environmental information:

Boiling point:	not known
Melting point	1950°C
Solubility in water:	insoluble
Flash point:	not flammable
Specific gravity (H ₂ O=1)	2.5-5.0
Vapour density:	>1.

10. Stability and reactivity

Stability: stable.
Conditions to avoid: none.
Incompatibility (materials to avoid): none.
Polymerization Hazard: it doesn't occur.

11. Toxicological information

This material is not hazardous in normal storage and handling.

12. Ecological information

No ecological effects are known.

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.

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

14. Transport information

Not dangerous according to current transportation regulations.

15. Regulatory information

- Health, safety and environmental information shown on the label according to European Directives on hazardous materials and substances

None.

- Information related to further dispositions

This product is CE marked in accordance with the essential requirements of 93/42EEC Directive, Annex I, on medical devices.

16. Other information

The safety data sheet has been written according to relevant European provisions, on the basis of information received by the supplier of preparation.

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 drawn herein is based on our knowledge at the date of the issue.

The information is exclusively provided related to the product herewith specified 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 doesn't imply any liberty to break patent rights.

Previous safety data sheet n. F13/1E dated 14/11/2006 has to be considered cancelled. 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.