



1. Identification of the preparation and of the company

1.1 Identification of the preparation

No-Mix orthodontic adhesive, paste.

1.2 Use of the preparation

For bonding orthodontic brackets, tubes and accessories to teeth, for fixed orthodontic appliances.

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.

For potential health hazards: see section 11.

No significant hazards to man or environment are reasonably foreseen.

3. Composition/information on ingredients

- Silica and other inert fillers
- bisGMA resin
- Polymethylene dimethacrylate resin
- Benzoyl peroxide
- Polymerization inhibitors (UV absorbers and inorganic pigments).

Hazardous ingredients: none.

4. First aid measures

- Inhalation: no harm anticipated from material in quantities as packaged.
- Skin contact: wash with water and soap.
- Eye contact: flush with copious amounts of water.
- Ingestion: induce vomiting if large amount of material is swallowed.

5. Fire-fighting measures

- Suitable extinguishing media: water contact acceptable.
- Extinguishing media which should not be used: none.
- Special exposure hazards from combustion products: none in quantities as packaged.
- Special protective equipment for fire-fighters: none.

6. Accidental release measures

- Personal precautions: avoid contact of skin and eyes. Wash hands with water and soap if contact occurs.
- Environmental precautions: dispose in accordance with local regulations.
- Methods of cleaning up: wipe up with soap, water and paper towels.

7. Handling and storage

7.1 Handling

Handling precautions: not applicable.

7.2 Storage

Safe storage conditions: Store at temperature not exceeding 24°C.

Other restrictions or recommendations: avoid exposure to moisture and light.

8. Exposure controls/personal protection

Respiratory protection and ventilation: not required

Protecting clothing or equipment: not required under normal handling.

Unusual work/hygienic practices: avoid prolonged contact with skin; wash with soap and water.



9. Physical and chemical properties

9.1. General information

Appearance: light paste
Odour: slight odour.

9.2. Health, safety and environmental information

Boiling point /range: not applicable
Melting point/range: not applicable
Specific gravity (H₂O=1): approx. 3.0
Solubility in water: virtually insoluble
pH: not applicable
Flash point: not applicable
Auto-ignition temperature : not applicable
Flammability: no
Explosive limits in air: not applicable
Oxidizing properties: none
Vapour pressure (mm Hg): negligible at room temperature
Vapour density (air=1): not applicable
Reactivity in water: not reactive.

10. Stability and reactivity

- Stability: generally stable .
- Conditions of instability: avoid exposure to high temperatures.
- Incompatibility with various substances: not applicable.
- Hazardous decomposition products: not applicable.
- Hazardous polymerization: none in quantities as packaged.
- Conditions to avoid: avoid exposure to light and temperatures above 24°C.

11. Toxicological information

- Potential acute health effects: possibility of skin irritation or sensitization if not washed off promptly.
- Potential chronic health effects: possibility of skin sensitization or irritation upon prolonged or repeated exposure.
- Signs and symptoms of exposure: skin/eye irritation.
- Medical conditions generally aggravated by exposure: none known.
- Carcinogenic or potential carcinogenic effects: no ingredient listed as a carcinogen.
- Other potential health effects: none known.

12. Ecological information

No ecological damage or impact anticipated upon exposure to the environment in quantities as packaged.

13. Disposal considerations

Do not dispose into sink.

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.

14. Transport information

None. The product is not hazardous within the meaning of transport regulations.

Special provisions for transport: avoid elevated temperatures and high intensity light.

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 Directive 93/42/EC, 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. F04/4E of 17/05/2001 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.