



1. Identification of the preparation and of the company

1.1 Identification of the preparation

Latex intra/extra-oral elastics and elastic cotton thread.

1.2 Use of the preparation

Orthodontic products for intra-and extra oral practices in conjunction with fixed or removable appliances.

1.3 Company identification

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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.

Medical conditions aggravated by exposure: no known hazards.

Persons allergic to fruits or persons with spina bifida may be allergic to natural rubber.

Exposure limits: none.

Potential health effects: none.

Routes of entry: not applicable.

Human effects and symptoms of overexposure: not applicable.

(Acute) Inhalation: no significant health hazards.

(Chronic) Inhalation: none.

(Acute) eye contact: not irritant.

(Chronic) eye contact: none.

Carcinogenicity: none.

3. Composition/information on ingredients

| Intra-and extra oral elastics | |
|---|-------|
| Chemical name: butadiene, methyl, homopolymer | |
| Components | % |
| Natural latex | 95-98 |
| Sulfur | 0-1 |
| Zinc oxide | 0-1 |
| Polymeric hindered phenol | 1-2 |
| Dithiocarbonate derivitive | 0-1 |

All components are non-hazardous.

| Cotton thread for elastic ligatures | | |
|---|-------|-------------------------|
| Components | % | CAS ¹ Number |
| Natural latex rubber | 39-48 | - |
| Polyester resin (AFC material) ² | 47-55 | 31831-53-5 |
| Cotton | 5-6 | - |
| | | |
| | | |

4. First aid measures

Inhalation: not applicable.

Ingestion: not applicable.

Skin contact: not applicable.

Eye contact: not applicable.

5. Fire-fighting measures

Flash point: not applicable.

Flammable limits: not applicable.

Extinguishing media: foam, CO₂, dry chemical.

Special fire fighting procedures: overexposure to thermal decomposition products may cause health hazard.

An approved, self-contained breathing apparatus should be worn.

6. Accidental release measures

Contain and remove by mechanical means.

¹ CAS Number (Chemical abstract service).

² Cfr. EFSA (European Food Safety Authority) Journal (2005) 201, Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on a request from the Commission related to a 7th list of substances for food contact materials.



7. Handling and storage

7.1. Handling

Special sensitivity: not applicable.

7.2 Storage

Storage temperature: ambient. Keep away from flame or excessive heat.

8. Exposure controls/personal protection

Eye protection requirements: not required.

Skin protection requirements: not required.

Respirator requirements: not required.

Ventilation requirements: adequate ventilation practice.

Additional protective measures: none.

9. Physical and chemical properties

9.1. General information

Appearance/status: solid

Odour: rubber odour.

9.2. Health, safety and environmental information

pH: not applicable

Boiling point: not applicable

Melting point: not applicable

Solubility in water: insoluble

Specific gravity (H₂O=1): 0.95

% volatile by volume: not applicable

Vapour pressure: not applicable.

10. Stability and reactivity

Stability: stable.

Hazardous polymerization: it does not occur.

Incompatibility: not applicable.

Instability conditions: flames or excessive heat.

Hazardous decomposition products: by fire, oxides of carbon when burned.

11. Toxicological information

Toxicity tests have not been conducted on this product.

12. Ecological information

None.

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.

14. Transport information

Not dangerous for transport.

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.

Caution: these products contain natural rubber latex which may cause allergic reactions.

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. K07/1E 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.