



## 1. Identification of the preparation and of the company

### 1.1 Identification of the preparation

Elastic chains for ligatures, elastic tube for ligatures, elastic wire for ligatures, elastic ligatures (standard, in modules, in mini modules and Slide™), tie-back, radio-opaque separators (standard and in modules).

### 1.2 Use of the preparation

Devices for the ligation and/or traction of brackets, tubes and accessories for fixed orthodontic applications, or for the separation of teeth before banding (radio-opaque separators).

### 1.3 Company identification

Leone s.p.a.

I – 50019 Sesto Fiorentino – Firenze - Via P. a Quaracchi, 50

e-mail: [research@leone.it](mailto:research@leone.it) – <http://www.leone.it>

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 products are not generally considered hazardous in the form in which they are furnished, nevertheless it is possible the ingestion or the inhalation of pieces or fragments during use.

In case of fire, for the treatment of burns caused by contact with melted material, seek for medical advice.

## 3. Composition/information on ingredients

Thermoplastic polyurethane.

Hazardous ingredients: none.

Radio-opaque separators have been loaded with medical grade barium (10-12%).

## 4. First aid measures

In case of ingestion or inhalation of pieces or fragments seek for medical advice. Products are not radio-opaque with the only exception for separators.

In case of fire, for the treatment of burns caused by contact with melted material, seek for medical advice.

## 5. Fire-fighting measures

Extinguishing media: water, foam, dry chemical.

In case of fire or flameless combustion use self-breathing apparatus.

## 6. Accidental release measures

Pick up by mechanical means.

## 7. Handling and storage

Keep dry and at temperatures below 40°C.

## 8. Exposure controls/personal protection

No special protection measures are required.

## 9. Physical and chemical properties

### 9.1. General information

Appearance: solid

Odour: odourless.

### 9.2. Health, safety and environmental information

Softening temperature: 180-200°C / 200-225°C (for radio-opaque separators)

Density: approx. 1.2 g/cm<sup>3</sup>

Outward density: 700-800 kg/m<sup>3</sup>

Vapour pressure: not applicable

Viscosity: not applicable

Solubility in water: insoluble

pH: not applicable

Ignition temperature for external event: > 210°C

Auto-ignition temperature: not applicable

Limit of explosiveness: not applicable.



## 10. Stability and reactivity

Thermal decomposition: starting from 230°C. In case of thermal decomposition, which can happen during a fire or for overheating, harmful gases and vapours can be generated.

Hazardous decomposition products: combustion with insufficient oxygen or incomplete combustion generate toxic mixtures of gases containing for the most part CO and CO<sub>2</sub>. Other hazardous decomposition products are nitric oxides, amines, nitriles, aromatic and aliphatic hydrocarbons, aldehydes, hydrocyanic and isocyanic acids, as well as small quantities of ketones and acids.

Hazardous reactions: no hazardous reactions have been observed.

## 11. Toxicological information

Toxic gases/fumes are given off during burning or decomposition and may cause allergic skin and respiratory reactions. Melted product is flammable and produces intense heat and dense smoke and may cause burns.

According to our experience, if properly used, the product is not hazardous to health.

## 12. Ecological information

The product is not soluble in water.

Due to the consistence and the insolubility in water ecological problems are not foreseen, if the product is properly used. The product is not easily biodegradable.

## 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.

Recycling possibility must be evaluated in accordance with local and national regulations.

## 14. Transport information

Not dangerous for transport. Sensitive to temperature exceeding 40°C.

## 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 no. K02/3E of 15/04/2003 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](http://www.leone.it) for an updated version of the present sheet.