



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

### 1.1 Identification of the preparation

Elastomer protective tube.

### 1.2 Use of the preparation

Protective device for orthodontic archwires or wires.

### 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 considered as dangerous in the form they are supplied, but ingestion or inspiration of pieces or fragments may happen during use.

## 3. Composition/information on ingredients

Thermoplastic polyurethane.

Hazardous ingredients: none.

## 4. First aid measures

In case of ingestion or inhalation of pieces or fragments take medical advice. The products are not radio-opaque.

## 5. Fire-fighting measures

Not applicable.

## 6. Accidental release measures

Pick up by mechanical means.

## 7. Handling and storage

Store at ambient temperature and protect from moisture.

## 8. Exposure controls/personal protection

No special precautions are needed.

## 9. Physical and chemical properties

### 9.1. General information

Appearance: solid

Odor: odorless.

### 9.2. Health, safety and environmental information

Boiling point: not applicable

Melting point: 200-227°C

Vapor pressure: not applicable

Specific gravity (H<sub>2</sub>O=1): about 1.2 g/cm<sup>3</sup>

Solubility in water: insoluble

Flammability point: not applicable

% volatile by volume: not applicable.

## 10. Stability and reactivity

- Stability: stable.

- Hazardous polymerization: will not occur.

- Incompatibilities: not known.

- Instability conditions: not known.

- Decomposition products by fire: carbon monoxide, carbon dioxide, traces of HCN (hydrocyanic acid) and MDI (diphenylmethane diisocyanate).

## 11. Toxicological information

Toxic gases and 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 and information the product is not injurious to the health, if properly used.



## 12. Ecological information

Ecological problems are not expected from a correct use.

## 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.

## 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. K03/2E of 17/05/2001 has to be considered cancelled. In comparison to the preceding revision, the raw material has changed and adjustments to the European provisions which regulate the compilation of safety data sheet have been effected.

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.