



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

### 1.1 Identification of the preparation

Thermoretractile protective tube.

### 1.2 Use of the preparation

Protective device for orthodontic arches or wires.

### 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.*

- Hazards to man

Exposure to fumes generated by heating up of the tube at temperature exceeding 325°C may cause irritation to eyes, ears, nose and throat.

Possible ingestion or inspiration of pieces or fragments during use.

- Effects and symptoms

Inhalation: not probable.

Ingestion: not probable.

Skin contact: none observed in CLASS VI<sup>1</sup> test.

Carcinogenicity : not applicable.

- Signs and symptoms of exposure

Inhalation of fumes generated by heating up of the tube at temperature exceeding 325°C may cause: irritation to eyes, ears, nose and throat; itching and lacrimation of the eyes; inflammation of the respiratory tract with cough.

- Medical conditions generally aggravated by exposure

None known below 325°C.

## 3. Composition/information on ingredients

Material: crosslinked ethylene co-polymer.

Hazardous components: none.

## 4. First aid measures

If exposed to the heating up of the tube at temperature exceeding 325°C, move to the open air, rinse eyes with water and seek medical advice.

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

## 5. Fire-fighting measures

- Suitable fire extinguishing media: water, carbon dioxide, foam, dry chemicals.

- Special fire fighting procedures: use self contained breathing apparatus if exposed to fumes.

- Unusual fire and explosion hazards: none, it can only be combusted with difficulty.

## 6. Accidental release measures

Pick up by mechanical means.

## 7. Handling and storage

Handling and storage: no precaution.

Other precautions: do not heat above 325°C.

## 8. Exposure controls/personal protection

### 8.1 Professional exposure control

Respiratory protection: not required if local ventilation is adequate.

Hand protection: protective gloves are not required.

Eye protection: protective glasses are required during tube processing.

Other protective clothing or equipment: not required.

### 8.2 Environmental exposure control

Local exhaust: needed for the oven processing equipment.

<sup>1</sup> United States Pharmacopeia (USP) XIX biological tests.



Special precautions: make sure the heat shrink equipment will not allow tubing to be heated above 325°C.  
Unusual work/hygienic practices: use the good manufacturing practices (GMP) during tube handling and processing.

## 9. Physical and chemical properties

### 9.1. General information

Appearance: clear almost transparent.

### 9.2. Health, safety and environmental information

Boiling point: not applicable  
Melting point: 105°C  
Vapour pressure mm HG: not applicable  
Specific gravity (H<sub>2</sub>O=1): 0.935  
Flammability point: 335-350°C Method used: ASTM<sup>2</sup> D1929  
Vapour density (AIR=1): not applicable  
Evaporation rate: not applicable  
Solubility in water: insoluble.

## 10. Stability and reactivity

- Stability: stable.
- Conditions to avoid: temperatures above 325°C.
- Materials to avoid: none known.
- Polymerization hazard: it doesn't occur.

## 11. Toxicological information

No toxicological information on the product and the fumes generated by heating up of the tube at temperature exceeding 325°C are available.

## 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.

## 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.

<sup>2</sup> ASTM: American Standard Materials. ASTM D1929 - 96(2001)e1 Standard Test Method for Determining Ignition Temperature of Plastics.



Previous safety data sheet no. K05/02E 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](http://www.leone.it) for an updated version of the present sheet.