



SECTION 1: Identification of the substance or mixture and of the company

1.1. Product identifier

Product Description: Thermoretractile protective tube.

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified Use Professional use: Protective device for orthodontic archwires or wires.

1.3. Details of the supplier of the safety data sheet

Leone s.p.a.

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

e-mail: research@leone.it – <http://www.leone.it>

Tel. +39 055.30.44.1 – Fax +39 055 374808.

1.4. Emergency telephone number

+39 055.30.44.1. An answering machine is on during closing time.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

According to Regulation (EC) no. 1272/2008 [CLP].

This product does not meet the criteria for classification as hazardous in accordance with Titles I and II of Regulation (EC) no. 1272/2008 on classification, labelling and packaging of substances and mixtures.

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

2.2. Label elements

Not applicable.

2.3. Other hazards

Not classified as PBT or vPvB.

SECTION 3: Composition/information on ingredients

3.1. Substances

This product is a mixture.

3.2. Mixtures

Cross linked ethylene co-polymer.

According to Regulation (EC) no. 1272/2008 [CLP], this product does not meet the criteria for classification as hazardous in accordance with Titles I and II.

No hazardous components are listed.

SECTION 4: First aid measures

4.1. Description of first aid measures

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

Skin contact Not applicable.

Eye contact 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.

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

4.2. Most important symptoms and effects, both acute and delayed

Not applicable.

4.3. Indication of any immediate medical attention and special treatment needed

None necessary.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing Media Water, carbon dioxide, foam, dry chemicals.

Unsuitable extinguishing Media Not applicable.

5.2. Special hazards arising from the substance or mixture

None, it can only be combusted with difficulty.

5.3. Advice for firefighters

Use self contained breathing apparatus if exposed to fumes.

SECTION 6: Accidental release measures



6.1. Personal precautions, protective equipment and emergency procedures

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.

6.2. Environmental precautions

Dispose of in accordance with all federal, state, and local regulations.

6.3. Methods and material for containment and cleaning up

Remove by mechanical means.

6.4. Reference to other sections

..

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Do not heat above 325°C.

7.2. Conditions for safe storage, including any incompatibilities

Not applicable.

7.3. Specific end use(s)

None.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Not applicable.

8.2. Exposure controls

Appropriate engineering controls

Do not eat, drink or smoke at the work place. The following information is given as general guidance.

Individual protection measures, such as personal protective equipment (PPE)

Protective Equipment	Protective gloves are not required.
Respiratory protection	Not required if local ventilation is adequate.
Eye protection	Protective glasses are required during tube processing.
Industrial Hygiene	Use the good manufacturing practices (GMP) during tube handling and processing.

Special precautions

Make sure the heat shrink equipment will not allow tubing to be heated above 325°C.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Solid.
Colour	Clear almost transparent.
Odour	Odourless.
Boiling point	Not Applicable.
Melting point	105°C.
Vapour pressure mmHg	Not applicable.
Specific gravity (H ₂ O=1)	0.935.
Flammability point	335°C-350°C Method used: ASTM D1929.
Vapour density (air=1)	Not applicable.
Evaporation rate	Not applicable.
Solubility in water	Insoluble.

9.2. Other information

None.

SECTION 10: Stability and reactivity

10.1. Reactivity

Non-reactive material.

10.2. Chemical stability

Stable.

10.3. Possibility of hazardous reactions

Hazardous Polymerization: will not occur.

10.4. Conditions to avoid

Temperature above 325°C.

10.5. Incompatible materials

Not known.

10.6. Hazardous decomposition product(s)



Not applicable.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Potential Acute Health Effects

Not known below 325°C.

Probable eye, ear, nose and throat irritation when exposed to fumes from tubing heating above 325°C.

Signs and Symptoms of Exposure

If tubing is exposed to temperatures above 325°C and fumes are inhaled, eye, ear, nose and throat irritation, itching and tearing of eyes and soreness in nose with coughing.

Medical Conditions Generally Aggravated by Exposure
Carcinogenic or Potential Carcinogenic Effects

Not known effect below 325°C.

No ingredient listed as a carcinogen (NTP, IARC monographs, OSHA regulated).

Other Potential Health Effects

Not known.

Potential Chronic Health Effects

Not known.

SECTION 12: Ecological information

Ecological problems are not expected from a correct use.

12.1. Toxicity

Not applicable.

12.2. Persistence and degradability

Not applicable.

12.3. Bioaccumulative potential

Not applicable.

12.4. Mobility in soil

Not applicable.

12.5. Results of PBT and vPvB assessment

Not applicable.

12.6. Other adverse effects

Not applicable.

SECTION 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.

13.1. Waste treatment methods

Incineration recommended with complete combustion conditions.

SECTION 14: Transport information

Not dangerous according to current transportation regulations.

14.1. UN-number

Not Applicable.

14.2. UN proper shipping name

Not Applicable.

14.3. Transport hazard class(es)

Not Applicable.

14.4. Packing group

Not Applicable.

14.5. Environmental hazards

Not Applicable.

14.6. Special precautions for user

Avoid temperatures above 325°C.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture



Regulation (EC) no. 1272/2008 (Classification, labeling and packaging of substances and mixtures) and subsequent amendments, amending and repealing Directive 67/548/EEC and 1999/45/EC, and amending Regulation (EC) no. 1907/2006.

Directive 2009/161/EU (third list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Commission Directive 2000/39/EC).

This product is CE marked in accordance with the essential safety and performance requirements of Annex I of the European regulation on medical devices.

15.2. Chemical safety assessment

Not applicable/not indicated.

SECTION 16: Other information

This Safety data sheet was prepared in accordance with the Commission Regulation (EU) no. 453/2010 and Commission Regulation (EU) no. 2015/830.

The safety data sheet has been written according to relevant European provisions, on the basis of information received by the supplier of the mixture.

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 relates only to specific product designated 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 does not imply any liberty to break patent rights.

Previous safety data sheet no. K05/4E dated 16/01/2017 is to be considered obsolete. 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 sheets.

This safety data sheet is subject to revision. Visit our web site www.leone.it for an updated version of the present sheet.

Legend

ASTM: American Standard Materials. ASTM D1929 - 16 Standard Test Method for Determining Ignition Temperature of Plastics

IARC: International Agency for Research on Cancer.

IBC Code: International Bulk Chemicals Code.

NTP: National Toxicology Program, U.S. Department of Health and Human Services.

OSHA: Occupational Safety and Health Administration.

PBT: Persistent, Bioaccumulative And Toxic Substances.

vPvB: Very Persistent And Very Bioaccumulative Substances.