



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

1.1. Product identifier

Product Description: 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 in modules.

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

Identified Use Professional: 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. 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.

Upon a correct use, according to our experience no significant hazards to man or environment are reasonably foreseen.

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.

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

These products are mixture.

3.2. Mixtures

These products are made of thermoplastic polyurethane.

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

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

No hazardous ingredients are listed.

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation IF INHALED: seek medical attention.

Skin contact Contact with the hot melt: Cool immediately with plenty of water. Do not remove product crusts which may have formed neither forcibly nor by applying any solvents to the skin involved. To obtain treatment for possible burns, and appropriate skin care, seek medical advice immediately.

Ingestion Seek medical attention.

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 In case of fire use water, foam, dry chemical.

Unsuitable extinguishing Media Do not use water jet.

5.2. Special hazards arising from the substance or mixture

Burning releases carbon monoxide, carbon dioxide, oxides of nitrogen and traces of hydrogen cyanide. In the event of fire and/or explosion do not breathe fumes.



5.3. Advice for firefighters

A self-contained breathing apparatus and suitable protective clothing should be worn in fire conditions. Do not allow contaminated extinguishing water to enter the soil, ground-water or surface waters.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation/exhaust extraction. Keep unauthorized persons away.

6.2. Environmental precautions

None.

6.3. Methods and material for containment and cleaning up

Pick up by mechanical means.

6.4. Reference to other sections

-.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Not applicable.

7.2. Conditions for safe storage, including any incompatibilities

Keep container tightly closed and dry. Protect from atmospheric moisture. Storage temperature < 40°C.

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 place. The following information is given as general guidance.

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

Eye/face protection	None.
Skin protection	Not required.
Respiratory protection	None.
Other	None.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Solid.
Colour	Coloured, various.
Odour	Odourless.
Softening temperature	180-200°C / 200-225°C (for radio-opaque separators).
Density	Approximately 1.2 g/cm ³ .
Outward density	700-800 kg/m ³ .
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.

9.2. Other information

Not applicable.

SECTION 10: Stability and reactivity

10.1. Reactivity

Not reactive.

10.2. Chemical stability

Stable.

10.3. Possibility of hazardous reactions

No hazardous reactions have been observed.



10.4. Conditions to avoid

Avoid temperature above 40°C and protect from moisture.

10.5. Incompatible materials

Not known.

10.6. Hazardous decomposition product(s)

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 CO₂. 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.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Potential Acute Health Effects	None known.
Signs and Symptoms of Exposure	None known.
Medical Conditions Generally Aggravated by Exposure	None known.
Carcinogenic or Potential Carcinogenic Effects	No ingredient listed as a carcinogen.
Other Potential Health Effects	None known.
Potential Chronic Health Effects	None known.

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.

SECTION 12: Ecological information

No ecological damage or impact by Environment exposure Intended for the amount contained in the package.

12.1. Toxicity

Not applicable.

12.2. Persistence and degradability

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.

12.3. Bioaccumulative potential

Not applicable.

12.4. Mobility in soil

Not applicable.

12.5. Results of PBT and vPvB assessment

Not classified as PBT or vPvB.

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

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

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 temperature above 40°C and keep dry.

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.

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. K02/4E dated 29/05/2009 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 sheet.

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

Legend

IBC Code: International Bulk Chemicals Code.

PBT: Persistent, Bioaccumulative And Toxic Substances.

vPvB: Very Persistent And Very Bioaccumulative Substances.