

SECTION 1: Identification of the substance/mixture and of the company/undertaking

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, 48/50

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.

www.leone.it/emergency (EU and international telephone numbers).

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 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

According to the available data, the product does not contain PBT or vPvB substances in a proportion $\geq 0.1\%$.

The product does not contain substances with endocrine-disrupting properties in a concentration $\geq 0.1\%$.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

These products are made of thermoplastic polyurethane.

Medical grade Barium Sulfate (BaSO_4) (5-10%) was added to the Radio-opaque separators.

According to Regulation (EC) no. 1272/2008 [CLP], these products 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 In case of inhalation of pieces or fragments seek for medical advice. Products are not radiopaque.

Skin contact In case of fire due, to the melted material, medical advice is necessary.

Ingestion In case of ingestion of pieces or fragments seek for medical advice. Products are not radiopaque.

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 None.

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

/

6.2. Environmental precautions

/

6.3. Methods and material for containment and cleaning up

Pick up by mechanical means. If melted, allow the material to cool and place it in a suitable container marked for disposal.

6.4. Reference to other sections

Section 13.

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

8.2.1. Appropriate engineering controls

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

8.2.2. Individual protection measures, such as personal protective equipment

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

Physical state	Solid at 20 °C at 1.013 hPa.
Colour	Coloured, various.
Odour	Odourless.
Melting point/freezing point	200-230°C.
Boiling point or initial boiling point and boiling range	Not established.
Flammability	Not established.
Lower and upper explosion limit	Not applicable.
Flash point	250 °C.
Auto-ignition temperature	>210 °C.
Decomposition temperature	>230 °C.
pH	Not applicable.
Kinematic viscosity	Not established.
Solubility in water	Insoluble.
Partition coefficient n-octanol/water (log value)	Not established.
Vapour pressure	Not applicable.
Density and/or relative density	1.1 g/cm ³
Relative vapour density	Not established.
Bulk density	500 – 700 kg/m ³ .
Particle characteristics	Not established.

9.2. Other information

None.

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 products

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 hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity	None known.
Skin corrosion/irritation	None known.
Serious eye damage/irritation	None known.
Respiratory or skin sensitisation	None known.
Germ cell mutagenicity	None known.
Carcinogenicity	No ingredient listed as a carcinogen.
Reproductive toxicity	None known
STOT-single exposure	None known
STOT-repeated exposure	None known
Aspiration hazard.	None known

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

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.

11.2.2. Other information

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 easily biodegradable. 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.

12.3. Bioaccumulative potential

/

12.4. Mobility in soil

Not applicable.

12.5. Results of PBT and vPvB assessment

According to the available data, the product does not contain PBT or vPvB substances in a proportion ≥ 0.1 %.

12.6. Endocrine disrupting properties

Not applicable.

12.7 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 including those of Decree-Law No. 153 of 17 October 2024.

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 or ID 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. Maritime transport in bulk according to IMO instruments

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 has been prepared in accordance with REACH Regulation (EC) 1907/2006 as amended by Regulation (EU) 2020/878.

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. K02-6E dated 31/01/2023 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.

Certain subsections of some sections are omitted because, as permitted by Annex II, Part B of Regulation (EU) 2020/878, they are not applicable.

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

Legend

CLP: Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008.

IMO: International Maritime Organization.

PBT: Persistent, Bioaccumulative and Toxic substances.

vPvB: Very Persistent and Very Bioaccumulative.