

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Product Description: Elastomer 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, 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 product is not considered as dangerous in the form it is supplied, but ingestion or inspiration of pieces or fragments may happen during use.

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 ≥ 0.1 %.

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

SECTION 3: Composition/information on ingredients**3.2. Mixtures**

This product is made up for 99% of Polyurethane.

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 Not applicable.

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 Not applicable.

Unsuitable extinguishing Media Not applicable.

5.2. Special hazards arising from the substance or mixture

By fire are released: carbon monoxide, carbon dioxide, traces of HCN (hydrocyanic acid) and MDI (diphenylmethane diisocyanate).

5.3. Advice for firefighters

None.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures**

Not applicable.

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

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SECTION 7: Handling and storage**7.1. Precautions for safe handling**

Not applicable.

7.2. Conditions for safe storage, including any incompatibilities

Store in sealed containers. Storage temperature: ambient. Protect from atmospheric moisture. Keep dry.

7.3. Specific end use(s)

None.

SECTION 8: Exposure controls/personal protection**8.1. Control parameters**

Not applicable.

8.2. Exposure controls

Not applicable.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state	Solid.
Colour	Various.
Odour	Odourless.
Melting point	200-227°C.
Boiling point or initial boiling point and boiling range	Not applicable.
Flammability	/
Lower and upper explosion limit	/
Flash point	>250°C.
Auto-ignition temperature	>210°C.
Decomposition temperature	>230°C.
pH	Not applicable.
Kinematic viscosity	/
Solubility in water	Insoluble.
Partition coefficient n-octanol/water (log value)	/
Vapour pressure	Not applicable.
Density and/or relative density	1.1.
Relative vapour density	/
Particle characteristics	/

9.2. Other information**9.2.1. Information with regard to physical hazard classes**

Explosive properties	Not explosive.
Oxidising Properties	Not applicable.

9.2.2. Other safety characteristics

% volatile by volume	Not applicable.
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SECTION 10: Stability and reactivity**10.1. Reactivity**

Non-reactive material.

10.2. Chemical stability

Stable under normal conditions. Decomposes at >230°C.

10.3. Possibility of hazardous reactions

Hazardous Polymerization: will not occur.

10.4. Conditions to avoid

Heat & Direct Sunlight.

10.5. Incompatible materials

Direct contact with open flames, self-igniting and explosive materials.

10.6. Hazardous decomposition products

By fire: carbon monoxide, carbon dioxide, traces of HCN (hydrocyanic acid) and MDI (diphenylmethane diisocyanate).

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	No evidence of irritant effects from normal handling use.
Serious eye damage/irritation	Eye contact: mechanical irritation.

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 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.

11.2.2. Other information

According to our experience and information the product is not injurious to the health, if properly used.

SECTION 12: Ecological information**12.1. Toxicity**

Low toxicity to aquatic organisms.

12.2. Persistence and degradability

The product is non-biodegradable.

12.3. Bioaccumulative potential

Not applicable.

12.4. Mobility in soil

The product has low mobility in soil.

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

Effect on effluent treatment: unlikely to affect biological treatment processes.

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

Dispose of in accordance with all federal, state, and local 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 elevated temperatures and moisture.

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. K03-5E 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.

REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006.

vPvB: Very Persistent And Very Bioaccumulative Substances.