



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

### **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, 50

e-mail: [research@leone.it](mailto: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 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**

Not classified as PBT or vPvB.

## **SECTION 3: Composition/information on ingredients**

### **3.1. Substances**

This product is a mixture.

### **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.

### 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

Appearance	Solid.
Colour	Various.
Odour	Odourless.
Boiling point	Not Applicable.
Melting point	200-227°C.
Vapour pressure	Not Applicable.
Specific gravity (H <sub>2</sub> O=1)	About 1.2 g/cm <sup>3</sup> .
Solubility in water	Insoluble.
Flammability point	Not applicable.
% volatile by volume	Not applicable.

### 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

Avoid exposure to moisture.

### 10.5. Incompatible materials

Not Applicable.

### 10.6. Hazardous decomposition product(s)

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

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Potential Acute Health Effects	Acute eye contact: mechanical irritation.
Signs and Symptoms of Exposure	Not applicable.
Medical Conditions Generally Aggravated by Exposure	Not known.
Carcinogenic or Potential Carcinogenic Effects	No ingredient listed as a carcinogen.
Other Potential Health Effects	None known.
Potential Chronic Health Effects	Not known.

Contact with hot material will cause thermal burns. 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.

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



## SECTION 12: Ecological information

### 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

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

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. 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. K03/3E 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](http://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.