

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

Product Description: Latex intra/extra-oral elastics and elastic cotton thread.

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

Identified Use Professional use: Orthodontic products for intra-and extra oral practices in conjunction with fixed or removable appliances.

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 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. Persons allergic to fruits or persons with spina bifida may be allergic to natural rubber.

2.2. Label elements

Not applicable.

2.3. Other hazardsAccording 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**

Intra-and extra oral elastics		Cotton thread for elastic ligatures		
Chemical name: 1,3 butadiene, 2-methyl, homopolymer				
Components	%	Components	%	CAS no./ EC no.
Natural latex	95-97	Natural latex rubber	39-48	-
Sulfur	0-1	Polyester resin (AFC material)	47-55	31831-53-5/608-670-1
Zinc oxide	0-1	Cotton	5-6	-
Polymeric hindered phenol	1-2			
Dithiocarbonate derivative	0-1			

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 No specific intervention is indicated as the compound is not likely to be hazardous by inhalation. Consult a physician if necessary. If exposed to fumes from overheating or combustion, move to fresh air. Consult a physician if symptoms persist.

Skin Contact Allergic reactions may occur in some people. Consult a physician if symptoms persist.

Eye Contact Flush thoroughly with water, consult a physician.

Ingestion While ingestion of large enough quantities to cause health effects is unlikely, consult a physician if it occurs.

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

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

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SECTION 5: Firefighting measures**5.1. Extinguishing media**

Suitable extinguishing Media Foam, Dry Chemical or water.

Unsuitable extinguishing Media Not applicable.

5.2. Special hazards arising from the substance or mixture

When exposed to flame, emits oxides of carbon and other acrid fumes such as sulfur dioxide and carbon monoxide. No explosive hazards.

5.3. Advice for firefighters

An approved, self-contained breathing apparatus should be worn.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Not applicable.

6.2. Environmental precautions

Not applicable.

6.3. Methods and material for containment and cleaning up

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

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

Keep closed to avoid contamination. Store at room temperature. Keep away from sunlight.

"Caution: some products are subject to expiry date."

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 at the workplace. The following information is given as general guidance.

8.2.2. Individual protection measures, such as personal protective equipment

FDA Label law requires labelling of medical devices with natural rubber latex in them. The warning reads "Caution: This product contains natural rubber latex with may cause allergic reaction".

Persons allergic to fruits or persons with spina bifida may be allergic to natural rubber.

Hand protection Workers exposed to latex gloves and other medical products containing natural rubber latex may develop allergic reactions such as skin rashes

Respiratory protection Exposure to natural rubber latex can cause respiratory symptoms, such as asthma and (rarely) shock.

Eye protection Natural rubber latex may cause ocular or sinus symptoms.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Solid
Colour	Colored
Odour	Rubber
Melting point/freezing point	Not applicable
Boiling point or initial boiling point and boiling range	Not applicable
Flammability	Not applicable
Lower and upper explosion limit	Not applicable
Flash point	Not applicable
Auto-ignition temperature	
Decomposition temperature	Not applicable
pH	Not applicable
Kinematic viscosity	Not applicable
Water solubility	Not applicable
Partition coefficient n-octanol/water (log value)	Not applicable
Vapour pressure	Not applicable
Density and/or relative density	0.95
Relative vapour density	Not applicable
Particle characteristics	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

High temperatures. Flames cause oxides of carbon.

10.5. Incompatible materials

Not applicable.

10.6. Hazardous decomposition products

Not applicable.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity	Inhalation: no significant health hazard. Eye contact: no irritation.
Skin corrosion/irritation	Does not meet the classification criteria for this hazard class.
Serious eye damage/irritation	Does not meet the classification criteria for this hazard class.
Respiratory or skin sensitisation	See Section 8.
Germ cell mutagenicity	Does not meet the classification criteria for this hazard class.
Carcinogenicity	No ingredient listed as a carcinogen.
Reproductive toxicity	Does not meet the classification criteria for this hazard class.
STOT-single exposure	Does not meet the classification criteria for this hazard class.
STOT-repeated exposure	Does not meet the classification criteria for this hazard class.
Aspiration hazard.	Does not meet the classification criteria for this hazard class.

11.2 Information on other hazards

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SECTION 12: Ecological information

12.1. Toxicity

<u>Method</u>	<u>Duration of exposure</u>
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LC50- Fish	48 h
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EC0- Batterie

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

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

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 excessive heat.

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/not indicated.

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. K07-4E 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

AFC: Cfr. EFSA (European Food Safety Authority) Journal (2005) 201, Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on a request from the Commission related to a 7th list of substances for food contact materials.

CAS No.: numerical identifier that uniquely identifies a chemical substance, assigned by the Chemical Abstract Service.

EC-Number: EINECS and ELINCS Number (see also EINECS and ELINCS).

IMO: International Maritime Organization.

LC50: Lethal Concentration 50: lethal concentration of substance for 50% of organisms of a certain population during a certain exposure period.

PBT: Persistent, Bioaccumulative And Toxic Substances.

vPvB: Very Persistent And Very Bioaccumulative Substances.