



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

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, 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.

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 hazards

Not classified as PBT or vPvB.

SECTION 3: Composition/information on ingredients

3.1. Substances

This product is a mixture.

3.2. Mixtures

Intra-and extra oral elastics	
Chemical name: butadiene, methyl, homopolymer	
Components	%
Natural latex	95-98
Sulfur	0-1
Zinc oxide	0-1
Polymeric hindered phenol	1-2
Dithiocarbonate derivitive	0-1

Cotton thread for elastic ligatures		
Components	%	CAS no./ EC no.
Natural latex rubber	39-48	-
Polyester resin (AFC material)	47-55	31831-53-5/608-670-1
Cotton	5-6	-

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 Not applicable.

Skin contact Not applicable.

Eye contact Not applicable.

Ingestion Not applicable.

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 Carbon dioxide, foam, dry chemicals.

Unsuitable extinguishing Media Not applicable.

5.2. Special hazards arising from the substance or mixture

Overexposure to thermal decomposition products may cause health hazard.

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

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

Keep away from flame or excessive heat.

7.2. Conditions for safe storage, including any incompatibilities

Storage temperature: ambient.

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 at the work place. The following information is given as general guidance.

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

Industrial Hygiene	Not required.
Respiratory protection	Not required if local ventilation is adequate.
Eye protection	Not required.
Protective Equipment	Not required.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance:	Solid.
Colour	Amber and F. D. A. Allowable neon colours.
Odour	Rubber odour.
pH	Not applicable.
Boiling point	Not applicable.
Melting/freezing point:	Not applicable
Vapour pressure mmHg	Not applicable.
Specific gravity (H ₂ O=1)	0.95.
Bulk density	Not applicable.
%volatile by volume	Not applicable.
Solubility in water	Insoluble.

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 flame or excessive heat.

10.5. Incompatible materials

Not known.

10.6. Hazardous decomposition product(s)

By fire, oxides of carbon when burned.



SECTION 11: Toxicological information

11.1. Information on toxicological effects

Potential Acute Health Effects

Inhalation: no significant health hazard.

Signs and Symptoms of Exposure

Eye contact: no irritation.

Medical Conditions Generally Aggravated by Exposure

Not applicable.

Carcinogenic or Potential Carcinogenic Effects

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

Other Potential Health Effects

No ingredient listed as a carcinogen.

Potential Chronic Health Effects

Not known.

Not known.

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

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 excessive heat.

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/not indicated.



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. K07/2E 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

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.: Chemical Abstract Service Registry number.

EC No.: European Inventory of Existing Commercial Chemical Substances.

IBC Code: International Bulk Chemicals Code.

PBT: Persistent, Bioaccumulative And Toxic Substances.

vPvB: Very Persistent And Very Bioaccumulative Substances.