

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

Product description: Archwire coating Memoria® Natura®, preformed ligature ties Natura®, ligature preformed wire Natura®, Kobayashi ligature ties Natura®.

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

Identified Use Professional use: For coating of wire devices intended for the manufacture of orthodontic 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**

The coating is in solid form and therefore no toxic effects caused by the material in the solid state as it is supplied or during the normal orthodontic practices have been detected.

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.

2.2. Label elements

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2.3. Other hazards

No PBT, vPvB, or endocrine disrupting substances present in concentrations $\geq 0.1\%$

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

Diethylene glycol butyl ether	1 <5%	CAS 112-34-5
Titanium dioxide	1 <5%	CAS 13463-67-7
Ethylene glycol 2-ethylhexyl ether	1-<5%	CAS 1559-35-9
Methyl ethyl ketone	0.1-1.0%	CAS 78-93-3
(As glycol ethers)	*	CAS 112-34-5

SECTION 4: First aid measures**4.1. Description of first aid measures**

No information available

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

Inhalation	If vapors or mists are inhaled, move to fresh air. If symptoms occur, contact a poison control center, emergency room, or doctor for treatment information.
Skin contact	In case of contact with skin, wash immediately and thoroughly with water for 15 minutes and then wash with soap and water.
Eye contact	In case of contact with eyes, rinse immediately and thoroughly with water for at least 15 minutes. Redness, itching, burning sensation, and visual disturbances may indicate excessive contact of the liquid material with the eyes.
Ingestion of liquid material	Gently clean or rinse the inside of the mouth with water. A conscious person may be given sips of water. Never give anything by mouth to an unconscious person. Contact a poison control center, emergency room, or doctor immediately, as further treatment will be necessary.
Other	The effects of long-term exposure have not been determined.

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 Use Class B fire extinguishers (carbon dioxide, dry chemicals, or universal aqueous film-forming foam) designed to extinguish NFPA Class II combustible liquid fires.

Unsuitable extinguishing Media Water mist may be ineffective. Water mist may be used to cool closed containers to prevent pressure build-up and possible self-ignition or explosion when exposed to extreme heat. If water is used, fog nozzles are preferable.

5.2. Special hazards arising from the substance or mixture

Closed containers may explode or burst (due to the accumulation of pressurized vapor) when exposed to extreme heat. Keep away from heat, sparks, flames, and other sources of ignition. Extreme heat includes, but is not limited to, flame cutting, brazing, and welding.

5.3. Advice for firefighters

Complete protective clothing and a self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Inhalation	In case of insufficient ventilation, use an appropriate respirator.
Skin contact	Wear protective clothing and gloves made of impermeable material.
Eye contact	Wear protective eyewear against chemical splashes.

6.1.1. For non-emergency personnel

Provide general dilution ventilation or local exhaust ventilation in volume and pattern to maintain the concentration of the listed ingredients below the suggested minimum exposure limits, LEL limit, and to remove decomposition products during welding or flame cutting on surfaces coated with this product.

Clean or discard contaminated clothing and shoes.

6.2. Environmental precautions

Do not allow material to contaminate ground water system.

6.3. Methods and material for containment and cleaning up

See point 6.2.

6.4. Reference to other sections

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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Do not store at temperatures above 120°F (48°C). Store in a well-ventilated area. Keep containers tightly closed.

7.2. Conditions for safe storage, including any incompatibilities

Do not store at temperatures above 120° F. Store large quantities in buildings designed and protected for the storage of NFPA Class II combustible liquids.

7.3 Specific end use(s)

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

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8.2. Exposure controls

Inhalation	In case of insufficient ventilation, use an appropriate respirator.
Skin contact	Wear protective clothing and gloves made of waterproof material.
Eye contact	Wear protective eyewear against chemical splashes.
Other equipment	Clean or discard contaminated clothing and shoes. Ventilation requirements: Provide general dilution ventilation or local exhaust ventilation in volume and pattern to maintain the concentration of the listed ingredients below the suggested minimum exposure limits, LEL limit, and to remove decomposition products during welding or flame cutting on surfaces coated with this product.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Viscous liquid
Colour	Beige
Odour	Characteristic odor of the chemical family and all solvents listed in this document.
Melting point/freezing point	Not applicable
Boiling point	From 169 a 527 °F
Flash point	106 °F (41 °C)
Auto-ignition temperature	Combustible
Decomposition temperature	/.
pH	/.
Kinematic viscosity	/.
Solubility in water	79.3%

Partition coefficient n-octanol/water (log value)	no information
Vapor pressure	no information
Vapor pressure at 20°C	17.6 mm Hg
Density and/or relative density	no information
Relative vapor density	Heavier than air
Particle characteristics	/.

9.2. Other information

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SECTION 10: Stability and reactivity

10.1. Reactivity

No information available

10.2. Chemical stability

This material is normally stable.

10.3. Possibility of hazardous reactions

May produce hazardous decomposition products when heated. Welding, brazing, or flame cutting on surfaces coated with this product may produce fumes including: carbon monoxide, nitrogen oxides.

10.4. Conditions to avoid

None

10.5. Incompatible materials

Avoid contact with strong alkalis, strong mineral acids, or strong oxidizing agents.

10.6. Hazardous decomposition products

Carbon monoxide, carbon dioxide, lower molecular weight polymer fractions

SECTION 11: Toxicological information

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

Acute toxicity	Harmful if swallowed
Skin corrosion/skin irritation	May cause moderate skin irritation.
Serious eye damage/eye irritation	Causes eye irritation
Respiratory or skin sensitization	Vapor and mist can be harmful if inhaled.
Germ cell mutagenicity	Based on the available data, the classification criteria are not met..
Carcinogenicity	No component is considered carcinogenic.
Reproductive toxicity	Based on the available data, the classification criteria are not met.
STOT-single exposure	Based on the available data, the classification criteria are not met.
STOT-repeated exposure	Based on the available data, the classification criteria are not met.
Aspiration hazard	Vapor and mist can be harmful if inhaled.

11.2 Information on other hazards

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SECTION 12: Ecological information

12.1. Toxicity

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12.2. Persistence and degradability

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12.3. Bioaccumulative potential

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12.4. Mobility in soil

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12.5. Results of PBT and vPvB assessment

Based on available data, the product does not contain PBT or vPvB substances in percentage 0.1%.

12.6. Endocrine disrupting properties

Based on available data, the product does not contain any substances listed in the main European lists of potential or suspected endocrine disruptors with environmental effects under evaluation.

12.7 Other adverse effects

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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 October 17, 2024.

13.1. Waste treatment methods

Waste materials must be disposed of in accordance with federal, state, provincial, and local environmental control regulations. Empty containers must be recycled or disposed of through an approved waste management facility.

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

Not applicable.

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

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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. Z04/6E 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

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

DNEL: exposure levels below which the substance has no dangerous effects on human health.

EC No.: European Chemicals Agency.

GHS: Globally Harmonized System of Classification and Labelling of Chemicals.

PBT: Persistent, Bioaccumulative, and Toxic: hazardous chemicals.

STOT RE: Specific Target Organ Toxicity - Repeated Exposure.

vPvB: Very Persistent and Very Bioaccumulative.

IMO: International Maritime Organization.

CLP: Regulation on the classification, labeling, and packaging of substances and mixtures.