



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

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, 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

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

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

Components	%W/W	EC no.	CAS no.	Hazard Class and Category Code(s)	Hazard statement Code (s)
Fluorinated ethylene propylene	-	607-524-4	25067-11-2		
Water	-	231-791-2	7732-18-5		
Ethylbenzene	-	202-849-4	100-41-4	Flam. Liq. 2 Asp. Tox. 1 Acute Tox. 4 STOT RE 2	H225 H304 H332 H373
Xylene	<9	215-535-7	1330-20-7	Flam. Liq. 3 Acute Tox. 4 Skin Irrit. 2	H226 H312 H315
Glycerine	-	200-289-5	56-81-5		
Octyl phenoxyethoxyethanol surfactant	-	618-541-1	9036-19-5	Acute Tox. 4 Eye dam. 1 Aquatic Chronic 3	H302 H318 H412
Titanium dioxide	-	236-675-5	13463-67-7		
Aluminium hydroxide	-	244-492-7	21645-51-2		
Amorphous silica	-	231-545-4	7631-86-9		

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation If affected by inhalation of vapour or spray mist, remove to fresh air. If breathing difficulties persists or occurs later, consult a physician.

Skin contact In case of skin contact wash with water and soap. If irritation occurs contact a physician.

Eye contact In case of eye contact. immediately flush with plenty of water for at least 15 minutes, call a physician.

Ingestion In the unlikely event of digestion, do not induce vomiting. Call a physician immediately and have names of ingredients available.

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

Inhalation May cause nose and throat irritation. May cause nervous system depression characterized by the following progressive steps: headache, dizziness, nausea staggering gate, confusion and unconsciousness. Report have associated prolonged overexposure to solvents with permanent brain and



nervous system damage. Inhalation of fumes for over breathing of PTFE may cause polymer fume fever, a flu-like illness with fever, chills and sometimes cough for approximately 24 hours duration. Protection against acute exposure should also provide protection against any potential chronic effects. Smoker should avoid contamination of tobacco products, and should wash their hand before smoking. Significant skin permeation after contact appears unlikely.

- Skin contact Repeated or prolonged liquid contact may cause skin irritation or with discomfort or dermatitis.
- Eye contact May cause irritation or burning of the eyes.
- Ingestion Gastro-intestinal distress.

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

Not applicable.

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing Media Carbon dioxide, foam, dry chemical.
- Unsuitable extinguishing Media None.

5.2. Special hazards arising from the substance or mixture

When heated above the flashpoint, emits flammable vapours which, when mixed in with air, can burn or be explosive. Fine mists or spray may be flammable at temperatures below the flash point. At temperatures above 400°C (750°F), small amounts of hydrogen fluoride, can be evolved; amounts increase when temperature increase. Hydrogen fluoride is toxic and can cause skin and eye irritation. High concentration can cause lung damage. Explosive reaction can occur above 426°C (800°F) with finely divided fluorocarbon and metal powder (aluminum or magnesium). Avoid any dust buildup such as can occur with grinding, buffing or grit blasting.

5.3. Advice for firefighters

Full protective equipment, including self-contained breathing apparatus, is recommended. Water from fog nozzles may be used to cool closed containers to prevent pressure build up.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Ventilate area, remove source of ignition. Prevent skin contact and breathing of vapour. Wear a properly fitted vapour/particulate respirator (NIOSH/MSHA TC-23C) or a positive pressure supplied air respirator (NIOSH/MSHA TC-19), eye protection, gloves and protecting clothing.

6.2. Environmental precautions

Do not allow material to contaminate ground water system.

6.3. Methods and material for containment and cleaning up

Confine and remove with inert absorbent.

6.4. Reference to other sections

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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Store in well ventilated area. Keep container tightly closed.

7.2. Conditions for safe storage, including any incompatibilities

Do not store above 48°C (120°F). Keep away from heat, sparks, flame static discharge and other source of ignition. Vapors may cause flash fire. Close container after each use.

7.3 Specific end use(s)

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Components	EC no.	CAS no.	(exposure limits) ACGIH	(exposure limits) ACGIH (STEL)
Fluorinated ethylene propylene	607-524-4	25067-11-2		
Water	231-791-2	7732-18-5		
Ethylbenzene	202-849-4	100-41-4	100 ppm.	125 ppm/15 minutes.
Xylene	215-535-7	1330-20-7	100 ppm.	150 ppm/15 minutes.
Glycerine	200-289-5	56-81-5	10 mg/m ³ .	
Octyl phenoxy polyethoxy ethanol surfactant	618-541-1	9036-19-5		
Titanium dioxide	236-675-5	13463-67-7	10 mg/m ³ .	
Aluminium hydroxide	244-492-7	21645-51-2		
Amorphous silica	231-545-4	7631-86-9	10 mg/m ³ total dust.	



8.2. Exposure controls

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

Eye/face protection	Goggles are preferred to prevent eye irritation. If safety glasses are substituted, include splash guards or side shields.
Respiratory protection	Do not breathe vapors or mist. Wear a properly-fitted negative-pressure, air-purifying, organic vapor respirator (NIOSH/MSHA TC-23C) and particulate filter (NIOSH TC-84A) during application and until all vapors and spray mists are exhausted. In confined spaces and in situations where continuous spray operations are typical, or if it is impossible to properly fit a negative pressure respirator, wear a positive-pressure, supplied air respirator (NIOSH/MSHA TC-19C). In all cases follow respirator manufacturer's directions for respirator use. Do not permit anyone without proper protection in the painting area. Provide sufficient ventilation in volume and pattern to keep contaminants below applicable OSHA (ACGIH) requirements.
Protective clothing	Wear coveralls and impermeable gloves (e.g. neoprene). Do not reuse coveralls while solvent odor is retained in them.
Hygienic measures	Observe label precautions, keep away from heat sparks and flame. Close container after each use. Ground containers when pouring. Do not transfer contents to unmarked bottles. Wash thoroughly after handling and before eating and smoking. Do not store above 48°C (120°F). Do not sand, flame cut, braze or weld dry coating without NIOSH/MSHA TC-23C, TC-19C or TC-84A approved respirator or appropriate ventilation.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Viscous liquid.
Colour	Beige.
Evaporation rate	Slower than ether.
Solubility in water	Appreciable.
Boiling range	135°C-292°C.
Vapour density	Heavier than air.
Percent volatile by volume	55%.
Gallon weight	5 kg.
Flash point	Below 37.7°C (100°F).
Flammable limits	1-7%.

9.2. Other information

No further details as regards the safety-relevant parameters are required.

SECTION 10: Stability and reactivity

10.1. Reactivity

Not known under normal usage conditions.

10.2. Chemical stability

Stable.

10.3. Possibility of hazardous reactions

Not applicable.

10.4. Conditions to avoid

Keep away from heat, sparks, flame static discharge and other source of ignition. Vapors may cause flash fire.

10.5. Incompatible materials

None reasonably foreseeable.

10.6. Hazardous decomposition product(s)

CO, CO₂, smoke, oxides of any heavy metals, hazardous polymerization will not occur.



SECTION 11: Toxicological information

11.1. Information on toxicological effects

See section 4.2.

Potential Acute Health Effects

Skin irritation, eye irritation, nose and throat irritation, nervous system depression characterized by the following progressive steps: headache, dizziness, nausea staggering gait, confusion and unconsciousness, fume fever.

Medical Conditions Generally Aggravated by Exposure

Individuals with preexisting disease of the central nervous system, kidneys, liver, cardiovascular system, lungs or bone marrow may have increased susceptibility to the toxicity of excessive exposures of Xylene. Xylene can be absorbed through the skin in harmful amounts and can cause kidney or liver injury.

Carcinogenic or Potential Carcinogenic Effects

This product contain tetrafluoroethylene which is known to cause cancer by the state of California.

Reproduction toxicity

Canada classifies Xylene as a developmental toxin as high exposure to Xylene, in some animal studies have been reported to cause health effects on the developing fetus/embryo. These effects were often at levels toxic to the adult animal. The significance of effect to human is not known.

Potential Chronic Health Effects

There are some report in the literature of persistent pulmonary effects in individuals, especially smokers, who have had repeated episodes of polymer fume fever. Because of complicated facts such as mixed exposures and smoking history, these finding are uncertain. Report have associated prolonged overexposure to solvents with permanent brain and nervous system damage

SECTION 12: Ecological information

12.1. Toxicity

Not available.

12.2. Persistence and degradability

Not available.

12.3. Bioaccumulative potential

Not available.

12.4. Mobility in soil

Not available.

12.5. Results of PBT and vPvB assessment

Not available.

12.6. 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.

13.1. Waste treatment methods

Do not allow material to contaminate ground water system. Incinerate absorbed material in accordance with federal, state and local requirements. Do not incinerate in closed containers.

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

Not applicable.

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. Z04/4E 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.

Hazard statements

H225: Highly flammable liquid and vapour.

H304: May be fatal if swallowed and enters airways.

H332: Harmful if inhaled.

H373: May cause damage to organs through prolonged or repeated exposure.

H226: Flammable liquid and vapour.

H312: Harmful in contact with skin.

H315: Causes skin irritation.

H302: Harmful if swallowed.

H318: Causes serious eye damage.

H412: Harmful to aquatic life with long-lasting effects.

Legend

ACGIH: Association Advancing Occupational and Environmental Health.

CAS No.: Chemical Abstract Service Registry number.

DNEL: Derived No-Effect Level.

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

IBC Code: International Bulk Chemicals Code.

MSHA: Mine Safety and Health Administration.

NIOSH: National Institute for Occupational Safety and Health.

OSHA: Occupational Safety and Health Administration.

PBT: Persistent, Bioaccumulative And Toxic Substances.

STEL: Short Term Exposure Limit.

STOT RE: Specific Target Organ Toxicity-Repeated Exposure.

vPvB: Very Persistent And Very Bioaccumulative Substances.