



1. Identification of the preparation and of the company

1.1 Identification of the preparation

Archwire coating Memoria[®] Natura[®], preformed ligature ties Natura[®], ligature preformed wire Natura[®], Kobayashi ligature ties Natura[®].

1.2 Use of the preparation

For coating of wire devices intended for the manufacture of orthodontic appliances.

1.3 Company identification

Leone s.p.a.

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Tel. ++39 (0)55.30.44.1 – Fax ++39 (0)55 374808.

1.4 Emergency telephone

++39 (0)55.30.44.1. An answering machine is on during closing time.

2. Hazards identification

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.

- Inhalation: vapours and fumes may be harmful if inhaled.
- Skin contact: may cause moderate skin irritation. It is not supposed can be absorbed through the skin.
- Sensitization: not defined.
- Eye contact: may cause serious eye irritation.
- Chronic overexposure: dryness, itching, cracks, burning, blush and swelling are associated to an excessive skin contact before the product transformation. Redness, itching, burning sensation and visual disturbances may indicate excess of eye contact with liquid material.

3. Composition/information on ingredients

Information on ingredients and composition %

Chemical name	EC ¹ Number	%	CAS ² Number	Hazard symbols ³	R ³ Phrases
Diethylene glycol monobutyl ether	203-961-6	1-5	112-34-5	Xi	R36/37/38
Titanium dioxide	236-675-5	1-5	13463-67-7	-	-
Ethylene Glycol m-2-Ethylhexil Ether	216-323-7	1-5	1559-35-9	-	-
Methyl Ethyl Ketone	201-159-0	0.1-1.0	78-93-3	-	-

4. First aid measures

- Inhalation: if effected by inhalation of vapour or fume, remove to fresh air. If symptomatic, seek immediately for medical advice.
- Skin contact: wash immediately with plenty of water for at least 15 minutes followed by washing with soap and water.
- Eye contact: flush immediately with plenty of water for at least 15 minutes.
- Ingestion of liquid material: gently clean or rinse the inside of the mouth with water. Sips of water can be given to a conscious person. Don't give anything by mouth to an unconscious person. Immediately contact a physician.
- Further information: effects of a long term overexposure have not been detected.

5. Fire-fighting measures

- Suitable fire extinguishing methods: carbon dioxide, dry chemicals, AFFF (aqueous film forming foam).
- Unsuitable fire extinguishing methods: water spray may be ineffective. Water spray may be used to cool closed containers to prevent pressure build-up and possible auto-ignition or explosion when exposed to extreme heat. If water is used, fog nozzles are preferable.

¹ Number of European Catalogue. The EC number is made of a sequence of 7 figures, whose first group of 3 figures begins with 2 or 4 depending on which substance is included in the EINECS (European Inventory of Existing Commercial Chemical Substances) or in the ELINCS (European List of Notified Chemical Substances), or it begins with 5 if the substance is included in the list of "ex-polymers."

² CAS Number (Chemical abstract service).

³ Hazards related to the ingredients of the product are indicated in section 2, information to be shown on the label are indicated in section 15. Explanation of hazardous symbols and Risk phrases is indicated in section 15 and 16.



- Special hazards: because of the accumulation of vapour pressure, closed containers may explode when overheated. Keep away from heat, sparks, flames or other sources of ignition. Extreme heat includes, but not limited to, thermal cut, brazing and welding.
- Protection for fire-fighters: put on breathing apparatus.

6. Accidental release measures

Provide a good local ventilation. Only personnel equipped with proper respiratory, skin and eye protection should be permitted in the area. Remove all sources of ignition. Take up spilled material with sawdust, vermiculite or other absorbent material and put into containers for disposal.

7. Handling and storage

Do not store above 48°C. Store in buildings designed and protected for storage of combustible liquids.

8. Exposure controls/personal protection

8.1. Exposition limit values

Respiratory protection: where ventilation is inadequate, use a suitable respirator.

Skin protection: wear protective clothing and waterproof gloves.

Eye protection: wear chemical type splash goggles.

Further information: clean or throw away contaminated clothing and shoes.

8.2. Exposure control

Ventilation requirements: provide a good local exhaust ventilation to keep the concentration of product's components below the exposure limits and remove decomposition products during welding or flame cutting of surfaces coated with this product.

9. Physical and chemical properties

9.1. General information

Appearance: viscous liquid

Odour: typical.

9.2. Health, safety and environmental information

Boiling range: 76-275°C

Melting point: not applicable

Vapour pressure (20°C): 17.6 mm Hg

Solubility in water (20°C): 79.3%

Flammability range: 41°C

Density(20°C) 1.05

Vapour density: heavier than air.

10. Stability and reactivity

This product is normally stable and not subject to hazardous reactions.

- Thermal decomposition: may produce hazardous decomposition products when exposed to extreme heat. Soldering, brazing and thermal cut of surfaces coated with this product may generate fumes including: carbon monoxide, nitrogen oxides.

- Conditions to avoid: none known.

- Materials to avoid: avoid contact with strong alkalis, strong mineral acids or strong oxidising agents.

- Hazardous decomposition products: carbon monoxide, carbon dioxide, lower molecular weight polymer fractions.

11. Toxicological information

See section 2.

This product contains titanium dioxide. Animals inhaling massive quantities of titanium dioxide dust in a long term study developed long tumours. Studies with humans involved in the manufacture of this pigment indicate no increased risks of cancer from exposure. The possibility to inhale titanium dioxide dusts from coating is very limited.

Since overexposures are not expected, there is no significant hazard for man.

This product contains diethylene glycol monobutyl ether (DEGBE). Diethylene glycol monobutyl ether consumed in drink water at low levels by rats for 30 days caused microscopic injury to either the liver, kidney, spleen or testes.

12. Ecological information

No information available.

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.



14. Transport information

The product is not hazardous within the meaning of transport regulations.

15. Regulatory information

- Health, safety and environmental information shown on the label according to European Directives on hazardous materials and substances

There is no obligation to label the product.

- Information related to further dispositions

This product is CE marked in accordance with the essential requirements of 93/42EEC Directive, Annex I, on medical devices.

16. Other information

The safety data sheet has been written according to relevant European provisions, on the basis of information received by the supplier of preparation.

Hazard symbols or risk phrases shown on section 3 and safety phrases:

Hazard symbols:	Xi	Irritating
Risk phrases:	R 36/37/38	Irritating to eyes, respiratory system and skin
Safety phrases:	S 26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
	S 28	After contact with skin, wash immediately with plenty of ... (to be specified by the manufacturer)

are specific for some ingredients and not shown on the product label.

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 drawn herein is based on our knowledge at the date of the issue.

The information is exclusively provided related to the product herewith specified 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 doesn't imply any liberty to break patent rights.

Previous safety data sheet n. Z04/3 dated 17/05/2001 is to be considered cancelled. 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.