



1. Identification of the preparation and of the company

1.1 Identification of the preparation

Wires, archwires and wire products in titanium molybdenum alloy.

1.2 Use of the preparation

The products above mentioned are intended for the manufacture of orthodontic prosthesis.

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 products this safety data sheet refers to, are in the form of massive metallic alloy and when used under usual conditions and in accordance with the intended use, they are generally not considered hazardous to man or environment.

A different use of the product not conforming to the indications of use, may alter the performances of the product and induce potential hazards to health and safety.

In case the products undergo to any process that causes the change in the state of the raw material, the following health hazards shall be applied to the personnel involved in the raw material's processing and not to the final user.

Prolonged and repeated exposure to dust and fumes, generated from successive working processes of the products involving grinding, melting, brazing, thermal treatment, welding and pickling or any other process that causes a release of dust or fumes, could cause potential human health hazards.

The following is a list of potential health effects for hazardous elements that are possibly contained in titanium molybdenum alloys and which may be inhaled, swallowed or get in contact with skin and eyes.

Products made of titanium or titanium alloy are not ignitable, corrosive or reactive.

Dusts have a moderate fire and explosive hazard when exposed to heat, flame, electric current or static electricity.

Titanium is considered as a relatively non-toxic metal.

3. Composition/information on ingredients

Chemical composition %

Type of alloy	Elements											
	C	Si	Mn	P	S	Cr	Mo	Ni	Co	Ti	Others	Fe
Titanium molybdenum	-	-	-	-	-	-	10-20	-	-	70-80	Sn 4-8; Zr 5-10	-
CAS ¹ Number of elements	-	-	-	-	-	-	7439-98-7	-	-	7440-32-6	Sn 7440-31-5; Zr 7440-67-7	-

4. First aid measures

- Not applicable to the finished products which this safety data sheet refers to.

- The following warnings are applied in case the products are modified through processes involving a change in the state of the raw material:

Inhalation: move person to fresh air until recovered. Consult a physician.

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

Skin contact: wash with water and mild soap.

Eye contact: flush thoroughly with water, consult a physician.

5. Fire-fighting measures

- The finished products this safety data sheet refers to, are not flammable.

- The following warnings are applied in case the products are modified through processes involving a change in the state of the raw material:

Metal dust dispersed in the air may cause fire or explosion hazards. Molten metal may ignite combustibles.

Suitable extinguishing media: use fire-fighting measures suitable to the environment.

Unsuitable extinguishing media: water and CO₂.

Special hazards caused by material, its combustion's products or flue gases: fume of metal oxide.

¹ CAS Number (Chemical abstract service).



Protection for fire-fighters: wear a self-contained breathing apparatus.

Further information: collect contaminated fire fighting water separately. It must not enter the sewerage.

6. Accidental release measures

- The finished products this safety data sheet refers to, if dispersed, may be picked up with mechanical means.
- The following warnings are applied in case the products are modified through processes involving a change in the state of the raw material:

Personal precautions: avoid breathing in of fumes/dust and use protection as described at section 8.

Protection precautions: do not allow product to reach sewage system or water bodies.

Measures for cleaning: collect dust and waste material. Dispose of according to section 13.

7. Handling and storage

7.1 Handling

- The finished products this safety data sheet refers to, have to be restricted to skilled and licensed professionals, in accordance with the intended use.

- The following warnings are applied in case the products are modified through processes involving a change in the state of the raw material:

Prevent formation of dust. If dust/fume is developed, avoid breathing in of dust/fumes. Avoid skin and eye contact.

Make sure that all applicable workplace limits are observed.

7.2 Storage

Specific storage measures are not necessary.

8. Exposure controls/personal protection

8.1. Exposition limit values²

Exposure limits for finished products related to this safety data sheet are not known. Exposure limits, if applicable, apply to dust and fume of some constituent elements and certain of their compounds as generated from the working processes listed in section 2.

Exposure limits are stated by local laws, consult your Occupational Safety and Health Authorities.

Herewith the limits outlined by ACGIH³ in the USA:

Molybdenum (Mo), occupational exposure limit (TWA): 10 mg/m³(oxide)

Tin (Sn), occupational exposure limit (TWA): 2.0 mg/m³

Zirconium (Zr), occupational exposure limit (TWA): 5.0 mg/m³

Titanium (Ti), occupational exposure limit (TWA): 10 mg/m³.

8.2. Exposure control

The following control measures should be taken in case the product undergoes the processes listed in section 2.

- Personal protection:

Ventilation: should the processes generate dust or fumes, use a local ventilation and suction system, to maintain the concentrations of dust and fumes transported by the air below the limit values outlined by the local authorities.

Respiratory protection: should the processes generate dust or fumes higher than the maximum exposure limit, special approved breathing apparatus against dust and fumes transported by the air should be worn.

Protective equipment: gloves and protective barrier creams may be necessary to prevent skin sensitization and dermatitis. If your processes involve grinding or any other action that causes the release of dust or fumes, approved protective or safety glasses should be worn.

- Environmental precautions: do not allow product to reach sewage system or water bodies.

- Cleaning methods: collect dust and waste material. Dispose of according to section 13.

9. Physical and chemical properties

9.1. General information

Appearance: massive form, metal-silver grey colour

Odour: odourless.

9.2. Health, safety and environmental information

Boiling point: not applicable

Melting point: non determined

Density at 20°C: non determined

Solubility in water:: insoluble

pH: not applicable

² The "occupational exposure limit", if not otherwise specified, is the average limit or serious concentration in the time of a chemical agent in the air inside the breathing area of a worker related to a specific period of time (Directive 98/24/EC on health and safety protection of the workers against the consequential risks from chemical agents during the job); the TWA (time weighted average) indicator is the serious average concentration in the time for a working day of 8 hours.

³ ACGIH: American Conference of Governmental Industrial Hygienists, USA.



Flash point: non determined
Auto ignition temperature: non determined
Lower explosion limit: non determined.

10. Stability and reactivity

- Conditions to avoid: none.
- Material to avoid: none.
- Hazardous reactions: not known.
- Hazardous decomposition products: metal oxide fume.

11. Toxicological information

See section 2.

12. Ecological information

Do not dispose of in the environment; slightly hazardous for water.

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.

Do not dispose of together with household garbage, do not allow product to reach sewage and water bodies.

Recycling possibility must be verified in accordance with local and national regulations.

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.

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 no. Z06/1E dated 18/06/2001 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.