SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product description: Wires, archwires and wire products in titanium molybdenum alloy.

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

Identified Use: Professional use: The products above mentioned are intended for the manufacture of orthodontic prosthesis.

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.
www.leone.it/emergency (EU and international telephone numbers).

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

In accordance with Regulation (EC) No. 1272/2008 [CLP].
This product does not meet the criteria for classification as hazardous under Titles I and II of Regulation (EC) No. 1272/2008 on the classification, labeling, and packaging of substances and mixtures.
During processing, dust and fumes are generated with the following hazards:
May form combustible dust concentrations (non-hazardous) in the air during processing.

2.2. Label elements

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2.3. Other hazards

No PBT, vPvB, or endocrine-disrupting substances present in concentrations ≥ 0.1%.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Components	%W/W	EC no.	CAS no.
Titanium	50-99	231-142-3	7440-32-6
Molybdenum	0-37	231-107-2	7439-98-7
Zirconium	0-15	231-176-9	7440-67-7
Tin	0-8	231-141-8	7440-31-5

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation: Use local ventilation and/or respiratory protection to limit exposure to airborne dust. In case of sudden overexposure: take the injured person to fresh air, start artificial respiration if the injured person is not breathing. Consult a doctor if necessary.

Skin contact: Repeated exposure or contact may irritate the skin. Avoid frequent and prolonged contact. Wear appropriate protective clothing and gloves. Wash exposed skin with soap and water. If skin irritation occurs: Consult a doctor. Wash contaminated clothing before reuse.

Eye contact: Rinse thoroughly with water, keeping your eyes wide open. Consult a doctor if irritation persists.

Ingestion: If dust is ingested, contact a doctor.

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

Contact with dust in the eyes and on the skin may cause mechanical irritation. May cause gastrointestinal effects if swallowed. Excessive exposure to welding fumes, gases, or dust may cause irritation to the eyes, nose, or throat. Inhalation of fumes may cause metal fume fever (metallic taste in the mouth, dryness and irritation of the throat, chills, and fever).

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

Immediate medical attention is generally not required.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing Media: Not flammable in the form in which it is distributed. Use appropriate extinguishing media for the surrounding fire. Finely divided particles, dust, or pieces resulting from the processing of this product may burn or ignite. Use dry sand, dry graphite, or inert gas to smother the fire.

Unsuitable extinguishing Media: Do not use water or carbon dioxide on burning metal as an explosion may occur.

5.2. Special hazards arising from the substance or mixture

Very fine dust on a large surface area, resulting from grinding, polishing, buffing, or similar processes involving this product, may ignite and burn. Fine particles resulting from the processing of this product may form combustible dust-air mixtures. Settled dust poses a fire hazard. Resuspension of dust in the air due to vibration, traffic, material handling, etc. in high concentrations in the presence of an ignition source may cause a dust explosion. Minimize dust generation and accumulation.
Combustion may produce the following hazardous decomposition products. Titanium dioxide is an IARC Group 2B carcinogen.

5.3. Advice for firefighters

Firefighters must wear full emergency equipment and NIOSH-approved positive pressure breathing apparatus for all fires involving chemicals.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Wear appropriate protective clothing and equipment (see section 8). Avoid contact with skin, eyes, or clothing. Do not breathe dust or fumes.

6.2. Environmental precautions

Avoid release into the environment. Report releases as required by local, state, and federal authorities.

6.3. Methods and material for containment and cleaning up

Collect the material and place it in a container for disposal or reprocessing at the address. If dust is present, wet it and collect it in order to minimize the generation of airborne dust, or vacuum it up with a high-efficiency vacuum cleaner. If using a vacuum cleaner, an explosion-proof device is required. Non-sparking tools must be used. Do not allow dust deposits to accumulate on surfaces, as they can form an explosive mixture if released into the atmosphere in sufficient concentrations.
Avoid dispersing dust into the air (e.g., cleaning dusty surfaces with compressed air).

6.4. Reference to other sections

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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid contact with eyes, skin, and clothing. Avoid creating and breathing dust. Wear protective clothing and equipment as described in Section 8. Use only with adequate ventilation. Wash contaminated clothing before reuse. Wash thoroughly with soap and water after use. Minimize dust generation and accumulation. Keep dust away from open flames, hot surfaces, and sources of ignition. Follow good housekeeping practices to keep surfaces, including overhead areas such as pipes, ceilings, ducts, etc., free of dust. Provide adequate precautions, such as electrical grounding and inert atmospheres.
Empty containers retain product residues. Follow all SDS precautions when handling empty containers.

7.2. Conditions for safe storage, including any incompatibilities

Store in a dry place. Keep away from acids, oxidizing agents, and halogens.

7.3 Specific end use(s)

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Components	ACGIH TLV	OSHA PEL
Titanium	None established	None established
Molybdenum	10 mg/m^3 TWA (inhalable) 3 mg/m^3 TWA (respirable)	15 mg/m^3 TWA (total dust)
Zirconium	5 mg/m^3 TWA. 10 mg/m^3 Ceiling.	5 mg/m^3 TWA.
Tin	2 mg/m^3 TWA.	2 mg/m^3 TWA.

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Use local exhaust or general ventilation as required to minimize exposure
to dust and fumes and to keep contaminant concentrations below applicable occupational limits.

8.2.2. Individual protection measures, such as personal protective equipment

Eye/face protection	Safety glasses with side shields.
Hand/skin protection	Wear protective gloves. Fireproof clothing is appropriate when working with the product at high temperatures.
Respiratory protection	Use NIOSH-certified respirators if exposure limits are exceeded or where dust or fume exposure is excessive. The choice of respiratory protection depends on the type of contaminant, its form, and its concentration. Select and use respirators in accordance with OSHA 1910.134 and good industrial hygiene practices.
Other	Wear protective clothing to prevent contamination of personal clothing. Thermal

protection is necessary when working with heated material.

8.2.3. Environmental exposure controls

Provide local exhaust ventilation in areas where fumes or metal dust are present.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Solid
Colour	Metallic gray.
Odour	Odourless
Melting point/freezing point	1660 °C / 3020 °F
Boiling point or initial boiling point and boiling range	Not applicable
Flammability	Not applicable
Lower and upper explosion limit	Not applicable
Flash point	Not applicable
Auto-ignition temperature	Not applicable
Decomposition temperature	Not applicable
pH	Not applicable
Kinematic viscosity	Not applicable
Water solubility	Insoluble
Partition coefficient n-octanol/water (log value)	Not applicable
Vapour pressure	/.
Density and/or relative density	Not applicable
Relative vapour density	4.47.
Particle characteristics	/.

9.2. Other information

No further details are required regarding safety-related parameters.

SECTION 10: Stability and reactivity

10.1. Reactivity

It is not normally reactive.

10.2. Chemical stability

Stable.

10.3. Possibility of hazardous reactions

None expected.

10.4. Conditions to avoid

Avoid dust formation.

10.5. Incompatible materials

Acids, oxidizing agents and halogens.

10.6. Hazardous decomposition products

Extreme heat from fire or processing (e.g. welding, brazing, machining, etc.) may produce toxic or irritating airborne particulate, including metal and metallic oxide fumes. Reaction with water, steam, acids, etc. can evolve hydrogen, which is highly dangerous fire and explosion hazard.

SECTION 11: Toxicological information

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

Acute toxicity (oral)	None expected under normal conditions of use. May cause gastrointestinal effects if swallowed.
Acute toxicity (dermal)	It can cause mechanical irritation or abrasions.
Acute toxicity (inhalation)	Excessive exposure to fumes, gases, or dust may cause irritation to the nose or throat. Inhalation of dust or fumes may cause metal fume fever (metallic taste in the mouth, dryness and irritation of the throat, chills, and fever).
Skin corrosion/irritation	May cause mechanical irritation or abrasions
Serious eye damage/irritation	Dust particles or filings can cause abrasive injuries to the eyes.
Respiratory or skin sensitisation	Based on the available data, the classification criteria are not met.
Germ cell mutagenicity	Based on the available data, the classification criteria are not met
Carcinogenicity	None of the components are listed as carcinogenic or potentially carcinogenic by OSHA, NTP, or IARC.
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	La sovraesposizione a lungo termine alla polvere può causare danni ai polmoni (fibrosi) con sintomi di tosse, mancanza di respiro e diminuzione della capacità respiratoria.
Aspiration hazard	Based on the available data, the classification criteria are not met.

11.2 Information on other hazards

Numerical measures of toxicity

Titanium
Oral rat LD50 > 5000 mg/kg.
Molybdenum
Oral rat LD50 > 2000 mg/kg.
Inhalation rat LC50 > 3.92 mg/l.
Dermal rat LD50 > 2000 mg/kg.
Zirconium
Oral rat LD50 > 5000 mg/kg.
Inhalation rat LC50 > 4.3 mg/l/4 hr.
Tin
Oral rat LD50 >2000 mg/kg.
Dermal rat LD50 >2000 mg/kg.
Inhalation rat LC50 4.75 mg/l/4 hr.

SECTION 12: Ecological information

12.1. Toxicity

Titanium: 96 hr. LC50 Oncorhynchus mykiss >100 mg/l.
Molybdenum: 96 hr. LC50 Pimephales promelas 609.1 mg/l.
Zirconium: 96 hr. LC50 Danio rerio >100 mg/l, 48 hr. EC50 daphnia magna >100 mg/l.
Tin: 96 hr. LC50 Pimephales promelas >12.4 µg/l.

12.2. Persistence and degradability

Biodegradation is not applicable to inorganic compounds.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

Based on available data, the product does not contain PBT or vPvB substances in a 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

No data available

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

It is the responsibility of the disposer to determine the toxicity and physical characteristics of the material for the correct classification of waste and proper disposal in accordance with current regulations.
Dust: When transported by air, titanium dust can burn. Once ignited, titanium is very difficult to extinguish. Before disposal, titanium residues must be stabilized (solidified or diluted with sand or other non-combustible substances) to prevent ignition. Titanium alloys can be disposed of in landfills as industrial waste.

SECTION 14: Transport information

14.1. UN number or ID number

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14.2. UN proper shipping name

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14.3. Transport hazard class(es)

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14.4. Packing group
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14.5. Environmental hazards
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14.6. Special precautions for user
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14.7. Maritime transport in bulk according to IMO instruments
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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 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. Z06/4E 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
ACGIH: Association Advancing Occupational and Environmental Health.
CAS No.: numerical identifier that uniquely identifies a chemical substance, assigned by the Chemical Abstract Service.
EC50: the concentration that produces 50% of the maximum effect.
EC No.: European Chemicals Register.
IARC: International Agency for Research on Cancer.
LC50, Lethal Concentration 50: lethal concentration for 50% of organisms in a given population for a certain exposure time.
LD50, Lethal Dose 50: a substance, administered in a single dose, capable of killing 50% of a sample population of guinea pigs.
NIOSH: National Institute for Occupational Safety and Health, National Institute for Occupational Safety and Health (U.S.).
NTP: National Toxicology Program, U.S. Department of Health and Human Services.
OSHA: Occupational Safety and Health Administration of the US federal government.
PBT: Persistent, Bioaccumulative, and Toxic: hazardous chemicals.
PEL: Permissible exposure limits.
TLV: Threshold limit value.
TWA: Time-weighted average.
vPvB: Very persistent and very bioaccumulative.
IMO: International Maritime Organisation.