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

1.1. Product identifier

Product description: Wires, archwires, springs and wire products in Nickel Titanium alloy.

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

Identified Use: Professional use: The above mentioned products are 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

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.
The products referred to in this sheet are in the form of solid metal bonds and, when used under normal conditions and in accordance with their intended use, are not generally considered hazardous to humans or the environment. Use in a manner that does not comply with the instructions for use may alter the performance of the products and present potential health and safety hazards. The product may release hazardous substances during mechanical operations that present the following hazards:

classification:

Physical	**Health**
Polvere combustibile	Skin sensitizer Category 1 Carcinogen Category 1 Specific target organ toxicity - repeated exposure Category 1 (lungs)

2.2. Label elements

According to Regulation (EC) no. 1272/2008 [CLP], not applicable.

2.3. Other hazards

Not classified as PBT or vPvB.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical composition %

Type of alloy	Elements											
	C	Si	Mn	P	S	Cr	Mo	Ni	Co	Ti	others	Fe
Nichel titanium	≤0.1	-	-	-	-	-	-	<60	-	rest	N≤0.01; H≤0.01; O≤0.1	≤0.5
CAS No.	1333-86-4	-	-	-	-	-	-	7440-02-0	-	7440-32-6	N 7727-37-9; H 1333-74-0; O 7782-44-7	7439-89-6

The rhodium coated archwires have the following chemical composition%: Ni 50-60, Rh ≤ 1, Cu ≤ 10, Co ≤ 4, Ti rest. CAS No.: Rh 7440-16-6, Cu 7440-50-8, Co 7440-48-4 EC No.: Rh 231-125-0, Cu 231-159-6, Co 231-158-0.

Information on hazardous ingredients basing upon their concentration in the preparation												
EC No.	215-609-9							231-111-4		231-142-3	N 231-783-9; H 215-605-7; O 231-956-9	231-096-4
Hazard class and category codes								Skin Sens. 1				
Hazard statements	-	-	-	-	-	-	-	H351 H317	-	-	-	-

SECTION 4: First aid measures

4.1. Description of first aid measures

No special first aid measures are required for the product in solid form; in the case of molten product, the following measures should be taken into consideration.

Inhalation: In case of overexposure to dust or fumes, transport the injured person to fresh air and consult a doctor.
Skin contact: Wash exposed skin with soap and water. If irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.
Eye contact: Rinse eyes thoroughly with water, keeping eyelids open. Consult a doctor if irritation persists.
Ingestion: If dust is ingested, consult a doctor.

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

Main symptoms/effects, acute and delayed: Contact with dust in the eyes and on the skin may cause 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). Causes lung damage in case of prolonged or repeated inhalation.
May cause an allergic skin reaction.
May cause cancer.

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

Immediate medical attention is not generally required.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing Media	Use any appropriate means for the surrounding fire. Particles, dust, or finely divided pieces resulting from the processing of this product may burn or ignite spontaneously at room temperature. Use a Class D dry powder fire extinguisher.
Unsuitable extinguishing Media	The use of water on burning metal can generate hydrogen gas and pose a risk of explosion.

5.2. Special hazards arising from the substance or mixture

The very fine, high-surface-area material resulting from grinding, sanding, polishing, or similar processes of this product may spontaneously ignite at room temperature.
Deposited dust presents a fire hazard. Minimize the generation and accumulation of dust.
Combustion may produce the following hazardous decomposition products: Titanium dioxide, a Group 2B carcinogen according to IARC. Copper fumes may cause metal fume fever.

5.3. Advice for firefighters

Firefighters must wear full emergency gear and a 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. If dust is present, wet and collect it to minimize the generation of dust in the air, or vacuum it up with a high-efficiency vacuum cleaner. If using a vacuum cleaner, explosion-proof equipment 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. Do not eat, drink, or smoke while using this material. Wash contaminated clothing before reuse. Wash thoroughly with soap and water after handling. Minimize dust generation and accumulation. Keep dust away from open flames, hot surfaces, and ignition sources. Follow good housekeeping practices to keep surfaces, including overhead areas such as pipes, drop ceilings, ducts, etc., free of settled dust. Provide adequate precautions, such as grounding and bonding, or inert atmospheres.
Empty containers retain product residue. Follow all SDS precautions for handling empty containers.

7.2. Conditions for safe storage, including any incompatibilities

Store in a dry place. Keep away from hydrofluoric acid, fluorine, chlorine, bromine, halogenated hydrocarbons, carbon tetrachloride, carbon tetrafluoride, freon, strong acids, and strong bases.

7.3 Specific end use(s)

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exhibition guidelines:

Chemical name	ACGIH TLV	OSHA PEL
Nichel	0.2 mg/m^3 TWA inhalable fraction.	1.0 mg/ m^3 TWA

Titanium	None established.	Non stabilito.
Copper	1.0 mg/m^3 TWA (Dust). 0.2 mg/m^3 TWA (Fume).	1,0 mg/m^3 TWA (Dust). 0,1 mg/m^3 TWA (Fume).

8.2. Exposure controls

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

Eye/face protection	Wear safety glasses with side shields.
Skin and body protection	Wear heavy-duty protective gloves. Heavy-duty/fire-retardant clothing is recommended when working with hot products.
Respiratory protection	Use appropriate respirators if exposure limits are exceeded or where dust and fumes are excessive. The choice of respirators depends on the type, form, and concentration of contaminants. Select a respirator according to good industrial hygiene practices.
Other	Protective clothing to prevent contamination of personal clothing. Thermal protection, as required when working with superheated material.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Solid
Colour	Metallic gray or silver.
Odour	Odourless
Melting point/freezing point	1000 °C / 1860 °F
Boiling point or initial boiling point and boiling range	Not applicable
Flammability	Fine powders of the product may spontaneously ignite at room temperature.
Lower and upper explosion limit	Not applicable
Flash point Auto-ignition temperature	Not applicable Not applicable
Decomposition temperature pH Kinematic viscosity Water solubility Partition coefficient n-octanol/water (log value) Vapour pressure Density and/or relative density Relative vapour density Particle characteristics	Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable 5,8 - 7,5 Not applicable Not applicable

9.2. Other information

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SECTION 10: Stability and reactivity

10.1. Reactivity

Not reactive under normal conditions.

10.2. Chemical stability

Stable in massive form. Fine powders may ignite spontaneously at ambient temperatures.

10.3. Possibility of hazardous reactions

It dissolves in hydrofluoric acid and ignites in the presence of fluorine.

10.4. Conditions to avoid

Avoid dust formation.

10.5. Incompatible materials

Avoid hydrofluoric acid, fluorine, chlorine, bromine, halogenated hydrocarbons, carbon tetrachloride, carbon tetrafluoride, freon, strong acids, and strong bases.

10.6. Hazardous decomposition products

Thermal decomposition can produce titanium, copper, and nickel oxides. Titanium oxide is carcinogenic (IARC Group 2B). Copper can cause metal fume fever.

SECTION 11: Toxicological information

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

Acute toxicity (oral)	Ingestion: May cause gastrointestinal effects if swallowed.
Skin corrosion/irritation	May cause mechanical irritation or abrasions. May cause an allergic skin reaction.
Serious eye damage/irritation	Dust particles or filings can cause abrasive injuries to the eyes.
Respiratory or skin sensitisation	Excessive exposure to fumes, gases, or dust may cause irritation of the nose or throat. Inhalation of fumes may cause fume fever (metallic taste in the mouth, dryness and irritation of the throat, chills, and fever).

	Causes irritation to the lungs through prolonged or repeated inhalation.
Germ cell mutagenicity	Unknown
Carcinogenicity	No component is considered carcinogenic.
Reproductive toxicity	Unknown
STOT-single exposure	Unknown
STOT-repeated exposure	Unknown
Aspiration hazard	Unknown

11.2 Information on other hazards
Long-term exposure to dust can cause lung damage (fibrosis) with symptoms of exposure such as coughing, breathing difficulties, and reduced breathing capacity. Causes lung damage in case of prolonged exposure or repeated inhalation.

11.2.2. Other information
Numerical toxicity measurements:
Nickel
Oral LD50 (rat) > 9000 mg/kg.
Titanium
LD50 Oral (rat) > 5000 mg/kg.
Copper
LD50 Oral (rat) >2000 mg/kg LD50 Dermal (rat)>2000 mg/kg (structurally related chemicals).
LC50 Inhalation (rat) >5.11 mg/l/4 hours.

SECTION 12: Ecological information
12.1. Toxicity
Nickel: 96 hr. LC50 Oncorhynchus mykiss 15.3 mg/l.
Titanium: 96 hr. LC50 Oncorhynchus mykiss >100 mg/l.
Copper: 96 hr. LC50 Oncorhynchus mykiss 190 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 percentage 0.1%.
12.6. Endocrine disrupting properties
Based on available data, the product does not contain substances listed in the main European lists of potential endocrine disruptors with effects on the environment under assessment.
12.7. Other adverse effects
No data available.

SECTION 13: Disposal considerations
The waste is not considered hazardous. Dispose of in accordance with local and national regulations. In Italy, dispose of in accordance with Legislative Decree No. 152 of April 3, 2006, “Environmental Regulations,” application of European Directives on environmental protection, and subsequent amendments and additions, 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 its proper disposal in compliance with current regulations.

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

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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. Z03/8E 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.
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.
EC No.: European Chemicals Agency.
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.
PBT: Persistent, Bioaccumulative and Toxic: hazardous chemicals.
PNEC: Predicted No Effect Concentration.
TA: Ames Test.
TWA: Time-weighted average.
vPvB: Very persistent and very bioaccumulative.
WEL: Occupational exposure limit value.
ACGIH: Association Advancing Occupational and Environmental Health.
IARC: International Agency for Research on Cancer.
OSHA: Occupational Safety and Health Administration.
NTP: National Toxicology Program, U.S. Department of Health and Human Services.
TLV: Threshold Limit Value.
GHS: Globally Harmonized System of Classification and Labelling of Chemicals.