

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

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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**

According to Regulation (EC) no. 1272/2008 [CLP].

This product does not meet the criteria for classification as hazardous in accordance with Titles I and II of Regulation (EC) no. 1272/2008 on classification, labelling and packaging of substances and mixtures.

Products are generally classified as “articles” and do not constitute a hazardous material in their solid form. The product does not present risks to human health in the form in which it is placed on the market (solid metallic).

During processing, dusts and fumes generated have the following hazards: combustible dust.

Skin Sensitizer Cat. 1
Carcinogen Cat. 1
STOT RE Cat. 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**3.1. Substances**

This product is a mixture.

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**

Inhalation If overexposed to dust or fumes remove victim to fresh air and get medical attention.

Skin contact Wash exposed skin with soap and water. If skin irritation or rash occurs: Get medical attention.
Launder contaminated clothing before reuse.

Eye contact Flush eyes thoroughly with water, holding open eyelids. Get medical attention if irritation persists.

Ingestion If dust is swallowed, seek medical attention.

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

Eye and skin contact with dust may cause mechanical irritation. May cause gastrointestinal effects if swallowed.

Excessive exposure to welding fumes, gases or dust may cause irritation of eyes, nose or throat. Inhalation of fumes may result in metal fume fever (metallic taste in mouth, dryness and irritation of throat, chills and fever). Causes damage to lungs through 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 generally not required.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing Media Not flammable in the form as distributed. Use any media that is appropriate for the surrounding fire.
Finely divided particles, dusts or pieces resulting from processing of this product may burn or spontaneously ignite at room temperature. Smother with salt (NaCl) or class D dry powder fire extinguisher. Do not spray water on burning metal as an explosion may occur.

Unsuitable extinguishing Media None.

5.2. Special hazards arising from the substance or mixture

Very fine, high surface area material resulting from grinding, buffing, polishing, or similar processes of this product may ignite spontaneously at room temperature. Settled dust presents a fire hazard. Minimize the generation and accumulation of dust. Burning may produce the following hazardous decomposition products: Titanium dioxide an IARC Group 2B carcinogen. Copper fumes may produce metal fume fever.

5.3. Advice for firefighters

Firefighters should wear full emergency equipment and NIOSH approved positive pressure self-contained breathing apparatus for all fires involving chemical products.

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 fume.

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

Pick up material and place into a container for disposal or reprocessing. If dust is present, wet down and collect in a manner to minimize the generation of airborne dusts or vacuum with a high efficiency vacuum cleaner. If a vacuum is used, explosion proof equipment is required. Non-sparking tools should be used. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentrations. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).

6.4. Reference to other sections

See Section 8.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid contact with eyes, skin and clothing. Avoid creating and breathing dusts. Wear protective clothing and equipment as described in Section 8. Use only with adequate ventilation. Do not eat, drink or smoke when using this material. Launder contaminated clothing before re-use. Wash thoroughly with soap and water after handling. Minimize the generation and accumulation of dust. Keep dust away from open flames, hot surfaces and sources of ignition. Follow good housekeeping practices to keep surfaces, including areas overhead such as piping, drop ceilings, ductwork, etc. free from settled dust. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. Empty containers retain product residues. Follow all SDS precautions in handling empty containers.

7.2. Conditions for safe storage, including any incompatibilities

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

7.3 Specific end use(s)

No further relevant information available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Appropriate engineering control

Use local exhaust or general ventilation as required to minimize exposure to dust and fumes; and to maintain the concentration of contaminants below occupational applicable limits.

Components	ACGIH TLV
Nichel	0.2 mg/m ³ TWA inhalable fraction.
Titanium	None established.



Copper	1.0 mg/m ³ TWA (Dust). 0.2 mg/m ³ TWA (Fume).
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8.2. Exposure controls

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

Eye/face protection	Safety glasses with side shields.
Skin and body protection	Wear protective gloves. Fire/flame resistant/retardant clothing may be appropriate during hot work with the product.
Respiratory protection	Use approved respirator if exposure limits are exceeded or where dust/fume exposures are excessive. Selection of respiratory protection depends on the contaminant type, form and concentration. Select and use respirators in accordance with good industrial hygiene practice.
Other	Protective clothing as needed to prevent contamination of personal clothing. Thermal protection as needed when working with heated material.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Solid.
Colour	Metallic gray, or silver.
Odour	Odourless.
Odour threshold	Not applicable.
pH	Not applicable.
Melting point	1000 °C (1860 ° F).
Boiling Point	Not applicable.
Flash point	Not applicable.
Evaporation rate	Not applicable.
Flammability (solid, gas)	Fine product dusts may ignite spontaneously at room temperature.
Lower explosive limit	Not applicable.
Vapour pressure	Not applicable.
Vapour density	Not applicable.
Relative density	5.8 - 7.5.
Solubility	Not soluble.
Auto ignition temperature	Not applicable.
Partition coefficient: n-octanol/water	Not applicable.
Decomposition temperature	Not applicable.
Viscosity	Not applicable.

9.2. Other information

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

SECTION 10: Stability and reactivity

10.1. Reactivity

Not normally reactive.

10.2. Chemical stability

Stable in massive form. Fine product dusts may ignite spontaneously at room temperature.

10.3. Possibility of hazardous reactions

Dissolves in hydrofluoric acid, Ignites in the presence of fluorine.

10.4. Conditions to avoid

Avoid dust formation.

10.5. Incompatible materials

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

10.6. Hazardous decomposition product(s)

Thermal decomposition may produce oxides of titanium, copper and nickel. Titanium dioxide is an IARC Group 2B carcinogen. Copper fumes may cause metal fume fever.



SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute Toxicity	Ingestion: May cause gastrointestinal effects if swallowed. Inhalation: Excessive exposure to fumes, gases or dust may cause irritation of nose or throat. Inhalation of fumes may result in metal fume fever (metallic taste in mouth, dryness and irritation of throat, chills and fever). Causes damage to lungs through prolonged or repeated inhalation. Eye: Dust particles or filings may cause abrasive injury to the eyes. Skin: May cause mechanical irritation or abrasions. May cause an allergic skin reaction.
Chronic effect	Long-term overexposure to dust may cause lung damage (fibrosis) with symptoms of coughing, shortness of breath and diminished breathing capacity. Causes damage to lungs through prolonged or repeated inhalation.
Carcinogenicity	Nickel compounds are classified by IARC as Carcinogenic to Humans (IARC-1), and by the NTP as Known to Be a Human Carcinogen (NTP-K). None of the other components are listed as a carcinogen or potential carcinogen by OSHA, NTP or IARC.

Numerical measures of toxicity

Nichel

Oral rat LD50 > 9000 mg/kg.

Titanium

Oral rat LD50 > 5000 mg/kg.

Copper

Oral rat LD50 >2000 mg/kg; Dermal rat LD50 >2000 mg/kg (structurally similar chemical).

Inhalation rat LC50 >5.11 mg/l/4 hour.

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

Not available.

12.4. Mobility in soil

Not available.

12.5. Results of PBT and vPvB assessment

Not available.

12.6. Other adverse effects

Not 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.

13.1. Waste treatment methods

It is the responsibility of the waste generator to determine the toxicity and physical characteristics of the material to determine the proper waste identification and disposal in compliance with applicable regulations.

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. Z03/6E dated 05/03/2013 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.

Legend

ACGIH: Association Advancing Occupational and Environmental Health.

CAS No.: Chemical Abstract Service Registry number.

EC50: Half maximal Effective Concentration: Refers to the concentration of toxicant which induces a response halfway between the baseline and maximum after a specified exposure time.

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

IARC: International Agency for Research on Cancer.

IBC Code: International Bulk Chemicals Code.

LC50: Lethal Concentration 50: lethal concentration of substance for 50% of organisms of a certain population during a certain exposure period.

LD50 Lethal Dose 50: the dose required to kill half the members of a tested population after a specified test duration.

OSHA: Occupational Safety and Health Administration.

NIOSH: National Institute for Occupational Safety and Health.

NTP: National Toxicology Program, U.S. Department of Health and Human Services.

PBT: Persistent, Bioaccumulative And Toxic Substances.

STOT RE: Specific Target Organ Toxicity-Repeated Exposure.

TLV: Threshold Limit Value.

TWA: Time Weighted Average.

vPvB: Very Persistent And Very Bioaccumulative Substances.