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

1.1. Product identifier

Orthodontic and implantology products and instruments, listed by type of product and stainless steel alloy utilized for their production:

Screws and expanders	AISI 301, 302, 303, 304L, 316L+S, 630
Bites	AISI 301, 302, 304
Wires and wire products	AISI 301, 302, 304, 316L Leowire®
Bands	AISI 304L, 305L
Brackets and accessories	AISI 316L, 316L+S, 630, 304
Tubes and accessories	AISI 316L, AISI 304
Face masks	AISI 302, 303
Mandibular advancement devices	AISI 301, 302, 303, 304

Class II correctors	AISI 302, 303, 304, 304L
Extraoral facebows and lip bumpers	AISI 302, 304L
Orthodontic pliers and instruments	AISI 301, 302, 303, 410, 420, 420F PLUS
Orthodontic implants	AISI 316L (ISO 5832-1)
Burs	AISI 420, 420F, 440A,440B,420MOD, 630MOD, AISI 420, 420F, 440A,440B,420MOD, 630MOD , AISI 420B, AISI 420C
Taps and cutting instruments	AISI 316L (ISO 5832-1), 420, 420F, 630MOD
Accessories for dental implants	AISI 303
Accessory instruments for implants and burs	AISI 303, 420F, AISI 420B, AISI 420C

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, or as instruments and accessories for dentistry.

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

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.
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.

2.2. Label elements

Not applicable.

2.3. Other hazards

No PBT, vPvB or endocrine disrupting substances present at a concentration ≥ 0.1%

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical composition %

Steel type	Elements									
	C	Si	Mn	P	S	Cr	Mo	Ni	Others	Fe
AISI 301	≤0.15	≤1.00	≤2.00	≤0.045	≤0.030	16.0-18.0	-	6.00-8.00	-	rest
AISI 302	≤0.15	≤1.00	≤2.00	≤0.045	≤0.030	17.0-19.0	-	8.00-10.00	-	rest
AISI 303	≤0.15	≤1.00	≤2.00	≤0.200	≥0.150	17.0-19.0	-	8.00-10.00	Zr or Mo ≤0.60	rest
AISI 304	≤0.08	≤1.00	≤2.00	≤0.045	≤0.030	18.0-20.0	-	8.00-10.50	-	rest
AISI 304L	≤0.03	≤1.00	≤2.00	≤0.045	≤0.030	18.0-20.0	-	8.00-12.00	-	rest
AISI 305L	≤0.08	≤1.00	≤2.00	≤0.045	≤0.030	17.0-19.0	-	10.50-13.00	-	rest
AISI 316L	≤0.03	≤1.00	≤2.00	≤0.045	≤0.030	16.0-18.0	2.00-3.00	10.00-14.00	-	rest
AISI 316L+S	≤0.03	≤1.00	≤2.00	≤0.045	0.10-0.20	17.0-19.0	2.00-3.00	11.00-14.00	Cu 1-2	rest
AISI 316L (ISO 5832-1)	≤0.03	≤1.00	≤2.00	≤0.025	≤0.010	17.0-19.0	2.25-3.00	13.00-15.00	N ≤0.10; Cu ≤0.50	rest
AISI 410	≤0.15	≤1.00	≤1.00	≤0.040	≤0.030	11.5-13.5	-	-	-	rest
AISI 420	≥0.15	≤1.00	≤1.00	≤0.040	≤0.030	12.0-14.0	-	-	-	rest
AISI 420F	≥0.15	≤1.00	≤1.25	≤0.060	≥0.15	12.0-14.0	≤0.6	-	-	rest
AISI 420F PLUS	0.20-0.26	≤1.00	≤2.00	≤0.040	0.15-0.27	12.5-14.0	1.00-1.50	0.75-1.50	-	rest
AISI 420B	0.26-0.35	≤1,00	≤1,00	≤0.040	≤0.030	12.0-14.0	-	≤1.00	-	≤1.00
AISI 420C	0.43-0.50	≤1.00	≤1.00	≤0.04	≤0.03	12.5-14.5	-	-	-	rest
AISI 440A	0.60-0.75	≤1.00	≤1.00	≤0.040	≤0.030	16.0-18.0	≤0.75	-	-	rest

AISI 630	≤0.07	≤0.70	≤1.50	≤0.040	≤0.015	15.0-17.0	≤0.6	3.0-5.0	5xC≤Nb≤0.45; Cu 3-5	rest
Steel type	**Elements**									
Leowire®	**C**	**Si**	**Mn**	**P**	**S**	**Cr**	**Mo**	**Ni**	**Others**	**Fe**
AISI 630MOD	≤0.03	≤0.50	≤0.50	≤0.015	≤0.015	11.0-12.5	≤0.50	7.50-9.50	Cu 1.50-2.50; Nb+Ta 0.10-0.50; Ti 0.90-1.40	rest
AISI 420MOD	0.35-0.50	≤1.00	≤1.00	≤0.040	≤0.015	14.0-16.0	1.00-2.50	-	N 0.1-0.3; V ≤1.50	rest
AISI 440B	0.85-0.95	≤1.00	≤1.00	≤0.040	≤0.015	17.0-19.0	0.90-1.30	-	V 0.07-0.12;	rest
EC no.	215-609-9	231-130-8	231-105-1	231-768-7	231-722-6	231-157-5	231-107-2	231-111-4	Cu 231-159-6; Nb 231-113-5 N 231-783-9; Zr 231-176-9 Ta 231-135-5; Ti 231-142-3	
CAS no.	1333-86-4	7440-21-3	7439-96-5	7723-14-0	7704-34-9	7440-47-3	7439-98-7	7440-02-0	Cu 7440-50-8; Nb 7440-25-7 N 7727-37-9; Zr 7440-67-7 Ta 7440-25-7; Ti 7440-32-6	7439-89-6
Hazard statements	-	-	-	-	-	-	-	H317-H351	-	-

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation Remove to fresh air; if the condition persists, seek medical attention.

Skin contact Wash thoroughly with soap and water-if necessary, consult a doctor.

Eye contact Remove the contact lenses. Wash thoroughly for several minutes with plenty of water. If necessary, consult a physician.

Ingestion After ingestion, rinse the mouth with plenty of water (only if the person is conscious), do not induce vomiting, and seek immediate medical attention.

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

Dust contact with eyes and skin may cause mechanical irritation. May cause gastrointestinal effects if ingested. Suspected of damaging male fertility. Causes damage to the brain and central nervous system with prolonged or repeated exposure. Excessive exposure to welding fumes, gases or dusts may cause eye, nose or throat irritation. Inhalation of dust or fumes may cause an allergic respiratory reaction. Inhalation of fumes can cause metal fume fever (metallic taste in the mouth, dryness and irritation of the throat, chills and fever). Causes lung damage with prolonged or repeated inhalation. Can cause an allergic skin reaction. Can cause cancer.

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

Immediate medical attention is required for respiratory allergic reactions.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing Media Fire extinguisher, sand, sodium chloride

Unsuitable extinguishing Media CO_2, water

5.2. Special hazards arising from the substance or mixture

In case of fire, the following can develop: Carbon dioxide (CO_2) Carbon monoxide Formaldehyde.

5.3. Advice for firefighters

See Section 8 for personal protective equipment.

Protective respirator with independent air supply. Depending on the size of the fire use full protection if necessary. Dispose of contaminated firefighting water according to official regulations.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

In case of accidental spill or release, wear personal protective equipment specified in Section 8 to avoid contamination.

Ensure sufficient ventilation, remove sources of ignition.

Avoid dust formation with solid or powdered products.

Leave the danger zone if possible, use existing emergency plans if necessary.

No special measures are required.

6.1.2. For emergency responders

See section 8 for suitable protective equipment.

6.2. Environmental precautions

Do not disperse into sewers or groundwater.

6.3. Methods and material for containment and cleaning up

Collect mechanically and arrange for disposal in appropriate containers.

6.4. Reference to other sections

Safe handling: see section 7.

Personal protection: see section 8

Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Not applicable for solid stainless steels.
When handling in an open container, local exhaust ventilation must be used. Avoid the development of dust. Do not breathe dust. Ensure adequate ventilation in critical areas.
Wash contaminated clothing before reuse. Before breaks and after work, wash hands and face thoroughly, and take a shower if necessary. Do not eat, drink, or smoke in the workplace.

7.2. Conditions for safe storage, including any incompatibilities
Store the product closed and in a dry place. Do not store at temperatures above 40°C.

7.3 Specific end use(s)
Metals (including their alloys)

SECTION 8: Exposure controls/personal protection

8.1. Control parameters
The materials are incorporated into the product and should not result in any exposure under normal handling conditions.

Components	TLV ACGIH TWA
Carbon (C)	50 ppm (monoxide).
Silicon (Si),	10 mg/m^3.
Manganese (Mn)	5 mg/m^3.
Chromium (Cr),	0.5 mg/m^3.
Molybdenum (Mo)	10 mg/m^3.
Copper (Cu)	1 mg/m^3 (powder). 0.2 mg/m^3 (fumes).
Iron (Fe)	5 mg/m^3.
Nitrogen (N)	3 mg/m^3.
Nickel (Ni)	1 mg/m^3.

8.2. Exposure controls
8.2.1. Appropriate engineering controls
Apply the most common precautionary measures for handling chemicals. If operations generate dust, fumes, or mists, use ventilation to keep exposure to airborne contaminants below exposure limits.

8.2.2. Individual protection measures, such as personal protective equipment
General hygiene measures for handling chemicals apply. Wash hands before breaks and at the end of work.

Eye/face protection	Always wear safety glasses when grinding or cutting; wear face shields when welding or burning.
Hand protection	Not normally necessary. Depending on the operation. When welding or burning, wear appropriate clothing, such as aprons and welding gloves.
Skin protection	Protective work clothing (e.g., EN ISO 20345 safety shoes, long-sleeved protective work clothing).
Respiratory protection	If the process causes dust or fumes to be released above the permissible exposure limit, respirators approved for protection against airborne dust or fumes must be used. Respirators must be used in accordance with 29CFR 1910.134.

8.2.3. Environmental exposure controls
No additional information.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Solid
Colour	Silver, metallic gray
Odour	Odourless
Melting point/freezing point	1325-1530 °C
Boiling point or initial boiling point and boiling range	No information is available on this parameter.
Flammability	Non-flammable
Lower and upper explosion limit	Non-combustible
Flash point	>200 °C
Auto-ignition temperature	>300 °C
Decomposition temperature	No information is available on this parameter.
pH	No information is available on this parameter.
Kinematic viscosity	No information is available on this parameter.
Water solubility	Insoluble
Partition coefficient n-octanol/water (log value)	Does not apply to mixtures.
Vapour pressure	No information is available for this parameter.
Density and/or relative density	7.5-8.5 g/cm3 (20°C).

Relative vapour density	Not applicable to solids
Particle characteristics	No information is available on this parameter.

9.2. Other information
There is no additional information.
9.2.1. Information with regard to physical hazard classes
There is no additional information.
9.2.2. Other safety characteristics
There is no additional information.

SECTION 10: Stability and reactivity
10.1. Reactivity
There is no additional information.
10.2. Chemical stability
Stable when stored and handled properly.
10.3. Possibility of hazardous reactions
It may cause oxygen deficiency or generate dangerous gases when in contact with water, acids, or other chemicals.
10.4. Conditions to avoid
Areas not ventilated during cutting, welding, combustion, or brazing; avoid generating airborne dust and fumes; keep the area well ventilated.
10.5. Incompatible materials
Oxidizers and strong acids.
10.6. Hazardous decomposition products
At temperatures above the melting point, hazardous fumes containing metal oxides and other alloying elements, including hexavalent chromium, may be released.

SECTION 11: Toxicological information
11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	Not expected during normal use. May cause gastrointestinal effects.
Acute toxicity (dermal)	Eyes: Dust particles or filaments may cause abrasive injuries to the eyes. Skin: May cause irritation.
Acute toxicity (inhalation)	Excessive exposure to fumes, gases, or dust can cause irritation to the eyes, nose, and throat. High concentrations of fumes and ducts containing iron oxide, manganese, copper, and selenium can also cause metal fume fever. Typical symptoms include a metallic taste in the mouth, dryness and irritation of the throat, chills, and fever, usually lasting 12 to 48 hours.
Skin corrosion/irritation	The powder has an irritating effect.
Serious eye damage/irritation	The powder has an irritating effect.
Respiratory or skin sensitisation	May cause allergic reactions (Nickel)
Germ cell mutagenicity	The Registry of Toxic Effects of Chemical Substances (RTECS) contains genotoxic data for nickel.
Carcinogenicity	Nickel compounds are classified by the IARC as 1A carcinogenic to humans and by the NTP as known to be carcinogenic to humans. Cobalt compounds are classified by the IARC as 2B possibly carcinogenic to humans. None of the other components listed at 0.1% or more are classified as carcinogens or potential carcinogens by OSHA, NTP, or IARC.
Reproductive toxicity	Unknown
STOT-single exposure	Based on the available data, the classification criteria are not met.
STOT-repeated exposure	Causes damage to the lungs, kidneys, and liver in case of prolonged or repeated exposure. Route of exposure: inhalation.
Aspiration hazard	Unknown

11.2 Information on other hazards
As the product is not very soluble in water, it is separated in biological purifiers mainly by mechanical means.
This consideration is based on what is known about products of similar composition or structure.

SECTION 12: Ecological information

12.1. Toxicity

No information available at this time. As with all foreign substances, do not allow entry into rainwater drainage systems.

12.2. Persistence and degradability

No data available

12.3. Bioaccumulative potential

No data available

12.4. Mobility in soil

No data available

12.5. Results of PBT and vPvB assessment

The substances contained in the mixture do not meet the criteria for identification as PBT and vPvB substances according to Annex XIII of the REACH Regulation.

12.6. Endocrine disrupting properties

This product does not contain any substances that have endocrine properties in non-target organisms, as none of the ingredients meet the criteria.

12.7 Other adverse effects

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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 its proper disposal in compliance with current regulations.

SECTION 14: Transport information

14.1. UN number or ID number

Goods that are not dangerous according to transport regulations.

14.2. UN proper shipping name

Goods that are not dangerous according to transport regulations.

14.3. Transport hazard class(es)

Goods that are not dangerous according to transport regulations.

14.4. Packing group

Goods that are not dangerous according to transport regulations.

14.5. Environmental hazards

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14.6. Special precautions for user

Goods that are not dangerous according to transport regulations.

14.7. Maritime transport in bulk according to IMO instruments

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).

Some products are 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

No chemical safety assessment is required for mixtures.

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. Z01/9E 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.

Hazard statements
H317: May cause an allergic skin reaction.
H351: Suspected of causing cancer.

Legend
STOT RE - Specific target organ toxicity - repeated exposure
ACGIH: Association Advancing Occupational and Environmental Health.
AISI: American Iron and Steel Institute, association of North American steel producers.
CAS No.: numerical identifier that uniquely identifies a chemical substance, assigned by the Chemical Abstract Service.
EC No.: European Register of Chemical Substances in Commerce.
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.
TLV: Threshold Limit Value.
TWA: Time-Weighted Average.
vPvB: Very Persistent and Very Bioaccumulative.
CLP: Classification, labeling, and packaging (Regulation (EC) No. 2008 on the classification, labeling, and packaging of substances and mixtures)
CMR: Carcinogenic, mutagenic, toxic to reproduction
EC: European Community
EEC: European Economic Community
EN: European standards
REACH: Registration, Evaluation, Authorization, and Restriction of Chemicals (REGULATION (EC) No. 2006 on the registration, evaluation, authorization, and restriction of chemicals)
GHS: Globally Harmonized System of Classification and Labelling of Chemicals.