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

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
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

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, 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.

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

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 %

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	-	resto
AISI 302	≤0.15	≤1.00	≤2.00	≤0.045	≤0.030	17.0-19.0	-	8.00-10.00	-	resto
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	resto
AISI 304	≤0.08	≤1.00	≤2.00	≤0.045	≤0.030	18.0-20.0	-	8.00-10.50	-	resto
AISI 304L	≤0.03	≤1.00	≤2.00	≤0.045	≤0.030	18.0-20.0	-	8.00-12.00	-	resto
AISI 305L	≤0.08	≤1.00	≤2.00	≤0.045	≤0.030	17.0-19.0	-	10.50-13.00	-	resto
AISI 316L	≤0.03	≤1.00	≤2.00	≤0.045	≤0.030	16.0-18.0	2.00-3.00	10.00-14.00	-	resto
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	resto
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	resto
AISI 410	≤0.15	≤1.00	≤1.00	≤0.040	≤0.030	11.5-13.5	-	-	-	resto
AISI 420	≥0.15	≤1.00	≤1.00	≤0.040	≤0.030	12.0-14.0	-	-	-	resto
AISI 420F	≥0.15	≤1.00	≤1.25	≤0.060	≥0.15	12.0-14.0	≤0.6	-	-	resto
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	-	resto
AISI 440A	0.60-0.75	≤1.00	≤1.00	≤0.040	≤0.030	16.0-18.0	≤0.75	-	-	resto
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	resto
Leowire®	≤0.15	≤1.00	≤2.00	≤0.045	≤0.030	16.0-18.0	≤0.80	6.00-9.00	-	resto
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	resto

Steel type	Elements									
	C	Si	Mn	P	S	Cr	Mo	Ni	Others	Fe
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	resto
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;	resto
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: No need for first aid is anticipated under normal use conditions. If symptoms develop following exposure to fumes or dusts released from the processing of the product (e.g. machining, grinding, casting, sawing, blasting, polishing, buffing, brazing, soldering, welding or thermal cutting), immediately remove person from exposure. Seek medical attention if symptoms persist.

Skin contact: No need for first aid is anticipated under normal use conditions. Wash exposed skin with soap and water. If skin irritation or rash occurs: Get medical attention. Launder contaminated clothing before reuse.

Eye contact: No need for first aid is anticipated under normal use conditions. Flush eyes thoroughly with water, holding open eyelids. Get medical attention if irritation persists.

Ingestion: No need for first aid is anticipated under normal use conditions. 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. Suspected of damaging male fertility. Causes damage to brain and central nervous system (CNS) through prolonged or repeated exposure. Excessive exposure to welding fumes, gases or dust may cause irritation of eyes, nose or throat. Inhalation of dusts or fumes may cause an allergic respiratory response. 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 required for allergic respiratory response.

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 ignite.

Unsuitable extinguishing Media: Do not use water or CO_2 extinguishers, explosion may occure.

5.2. Special hazards arising from the substance or mixture

At temperatures above the melting point, hazardous fumes containing metal oxides and other alloying elements may be produced.

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. Collect contaminated fire fighting water separately. It must not enter the sewerage.

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 breath dust or fume.

6.2. Environmental precautions

Avoid release into the environmental. 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 it into a container for disposal or reprocessing. If dust is present, wet down and collect in order to to minimize the generation of airborne dusts or vacuum with a high efficiency vacuum cleaner. Avoid dispersal of dust in the air (i.e., clearing dust 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

Not applicable to stainless steel in solid state. For dusts or fumes created during processing use the following precautions: 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. Do no eat, drink or smoke when using this product.

7.2. Conditions for safe storage, including any incompatibilities

No special storage conditions for stainless steel in solid state. Store away from acids and incompatible materials.

7.3 Specific end use(s)

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

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

Appropriate engineering controls

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.

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

Eye/face protection	Safety glasses with side shields.
Skin/ Hand protection	Wear protective gloves. Fire/flame resistant/retardant clothing may be appropriate during hot work with the product.
Respiratory protection	Use NIOSH 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 OSHA 1910.134 and 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	Silver gray metal.
Odour	Odourless.
Odour threshold	Not applicable.
Boiling point	Not applicable.
Melting point	1371 - 1538 °C (2500-2800 ° F).
Density at 20°C	> 3 g/cm^3.
Solubility in water	Insoluble.
pH	Not applicable.
Flash point	Not applicable.
Auto ignition temperature	Not applicable.
Lower explosion limit	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.
10.3. Possibility of hazardous reactions
Can react with strong acids and form hydrogen gas
10.4. Conditions to avoid
None.
10.5. Incompatible materials
Oxidizers and strong acids.
10.6. Hazardous decomposition product(s)
At temperatures above the melting point, hazardous fumes containing metal oxides and other alloying elements may be liberated to include Hexavalent chromium.

SECTION 11: Toxicological information
11.1. Information on toxicological effects

Acute toxicity	Ingestion: None expected under normal use conditions. May cause gastrointestinal effects if swallowed. Inhalation: Excessive exposure to fumes, gases or dust may cause irritation of nose or throat. Inhalation of dusts or fumes may result in metal fume fever (metallic taste in mouth, dryness and irritation of throat, chills and fever). Eye: Dust particles or filings may cause abrasive injury to the eyes. Skin: May cause mechanical irritation or abrasions.
Potential Chronic Health Effects	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. Causes damage to brain and CNS through prolonged or repeated exposure. Suspected of damaging male fertility.
Carcinogenicity	Nichel compounds are classified by IARC as 1A Carcinogenic to Humans, and by the NTP as Known to Be a Human Carcinogen. Cobalt compounds are classified by IARC as 2B Possibly Carcinogenic to Humans. None of the other components listed at 0.1% or greater is listed as a carcinogen or potential carcinogen by OSHA, NTP or IARC.

Numerical measures of toxicity
Nickel
Oral rat LD50 > 9000 mg/kg
Chromium
Oral rat LD50 > 5000 mg/kg
Manganese
Oral rat LD50 > 2000 mg/kg,
Inhalation rat LC50 > 5.14 mg/L
Cobalt
Oral rat LD50 550 mg/kg,
Dermal rat LD50 > 2000 mg/kg

SECTION 12: Ecological information
12.1. Toxicity
Nichel: 96 hr. LC50 Oncorhynchus mykiss 15.3 mg/l
Manganese: 96 hr. LC50 Oncorhynchus mykiss LC50 > 3.6 mg/l
12.2. Persistence and degradability
Biodegradation is not applicable to inorganic compounds.
12.3. Bioaccumulative potential
No further information available.
12.4. Mobility in soil
No further information available.
12.5. Results of PBT and vPvB assessment
No further information available.
12.6. Other adverse effects
No further information 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. Z01/8E dated 16/01/2017 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.
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
ACGIH: Association Advancing Occupational and Environmental Health.
AISI: American Iron and Steel Institute.
ASTM: American Society for Testing and Materials.
CAS No.: Chemical Abstract Service Registry number.
EC No.: European Inventory of Existing Commercial Chemical Substances.

IARC: International Agency for Research on Cancer.
IBC Code: International Bulk Chemicals Code.
ISO 5832-1: International Organization for Standardization, Implants for surgery - Metallic materials - Part 1: Wrought stainless steel.
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.
NIOSH: National Institute for Occupational Safety and Health, National Institute for Occupational Safety and Health.
NTP: National toxicology program, U.S. Department of Health and Human Services.
OSHA: Occupational Safety and Health Administration, U. S..
PBT: Persistent, Bioaccumulative And Toxic Substances.
TLV: Threshold limit value.
TWA: Time Weighted Average.
vPvB: Very Persistent And Very Bioaccumulative Substances.