



1. Identification of the preparation and of the company

1.1 Identification of the preparation

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

Expansion screws	AISI ¹ 301, 303, 316L+S, 630	Extraoral facebows and lip bumpers	AISI 302, 304L
Bites	AISI 301, 302, 304	Orthodontic pliers and instruments	AISI 302, 303, 410, 420, 420F PLUS
Wires and wire products	AISI 301, 304, 316L Leowire [®]	Orthodontic implants	AISI 316L (ISO 5832-1) ²
Bands	AISI 304L, 305L	Burs	AISI 420, 420F, 440A, 440B, 420MOD, 630MOD
Brackets and accessories	AISI 316L, 316L+S, 630	Taps and cutting instruments	AISI 316L (ISO 5832-1), 420, 420F, 630MOD
Tubes	AISI 316L	Accessories for dental implants	AISI 303
Face masks	AISI 302, 303	Accessory instruments for implants and burs	AISI 303, 420F

1.2 Use of the preparation

The above mentioned products are intended for the manufacture of orthodontic appliances, or as instruments and accessories for dentistry.

1.3 Company identification

Leone s.p.a.

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1.4 Emergency telephone

++39 (0)55.30.44.1. An answering machine is on during closing time.

2. Hazards identification

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.

Prolonged and repeated exposure to dust and fumes, generated from successive working processes of the products involving grinding, melting, brazing, thermal treatment, welding and pickling or any other process that causes a release of dust or fumes, could cause potential human health hazards.

The following is a list of potential health effects for hazardous elements that are possibly contained in stainless steel alloys and which may be inhaled, swallowed or get in contact with skin and eyes.

Iron oxide: it has caused irritation of the eyes, nose, and skin of test animals. It may have the same effect on humans.

Chromium: ferrochrome alloys have been associated with lung changes in workers exposed to these alloys. Chromium is classified by IARC³ as a suspect carcinogenic agent.

Manganese: inhalation of manganese fume may cause "metal fume fever" with symptoms of chills, fever, nausea, cough, dry throat, weakness, muscle aches and a sweet or metallic taste in the mouth. Prolonged or repeated exposure may affect the nervous system, with difficulty in walking and balancing, weakness or cramps in the legs. Hoarseness of the voice, trouble with memory or judgment, unstable emotions or unusual irritability. The respiratory system may also be affected by a pneumonia like illness with symptoms of coughing, fever, chills, body ache, chest pain and other common signs of pneumonia.

Nickel: fumes are respiratory irritants and may cause respiratory disease. Skin contact can also cause an allergic skin rash. Nickel and its compounds have been reported to cause cancer of the lungs and sinuses. Nickel is classified by IARC as a suspect carcinogenic agent.

Nickel is classified by EC Directive 67/548/EEC and further modifications as suspect carcinogen (category 3 – R40) and a skin sensitizer (R43). The classification rules of the European Directive 99/45/EC and further modifications state that all preparations containing 1% Nickel or more must be automatically classified as suspect carcinogen (R40).

¹ AISI (American Iron and Steel Institute).

² The ISO (International Organization for Standardization) 5832-1 standard "Implant for surgery – Metallic materials – Part 1: Wrought stainless steel", specifies the characteristic of, and corresponding test methods for, wrought stainless steel for use in the manufacture of surgical implants.

³ IARC (International Agency for Research on Cancer).

- Material to avoid: none.
- Hazardous reactions: not known.
- Hazardous decomposition products: metal oxide fume.

11. Toxicological information

Acute toxicity: see hazards outlined in section 2.

Sensitization: possible by skin contact.

Chronic toxicity: see hazards outlined in section 2.

12. Ecological information

Do not dispose of in the environment; slightly hazardous for water.

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.

Do not dispose of together with household garbage, do not allow product to reach sewage and water bodies.

Recycling possibility must be verified in accordance with local and national regulations.

14. Transport information

The product is not hazardous within the meaning of transport regulations.

15. Regulatory information

- Health, safety and environmental information shown on the label according to European Directives on hazardous materials and substances

There is no obligation to label the product.

- Information related to further dispositions

The products which wear the CE marking on the label are in accordance with the essential requirements of 93/42EEC Directive, Annex I, on medical devices.

16. Other information

The safety data sheet has been written according to relevant European provisions, on the basis of information received by the supplier of preparation.

Hazard symbols or risk phrases shown on section 3, related to *nickel*:

Hazard symbols:	Xn	Harmful
Risk phrases:	R 40	Limited evidence of a carcinogenic effect
	R 43	May cause sensitization by skin contact

further advice on the preparation:

Safety phrases:	S 22	Do not breathe dust
	S 36/37	Wear suitable protective clothing and gloves

are not shown on the product label.

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 drawn herein is based on our knowledge at the date of the issue.

The information is exclusively provided related to the product herewith specified 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 doesn't imply any liberty to break patent rights.

Previous safety data sheet n. Z01/6E dated 17/05/2001 is to be considered cancelled. 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.