



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

1.1. Product identifier

Orthodontic products listed by type and low nickel content stainless steel alloy employed for their production:

Low nickel content round wires	Biosteel®
EXTREMO brackets and accessories	"No-Nichel"
EXTREMO tubes	"No-Nichel"

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 prosthesis.

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. During machining or thermal processing (e.g. welding, dividing, grinding) dust and fumes can be produced which could entail a health risk if inhaled. Under defined conditions, the product may explode.

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	Altri	Fe
Biosteel®	≤0.10	≤1.0	16.0-20.0	≤0.050	≤0.050	16.0-20.0	1.80-2.50	≤0.30	N 0.7-1.0; V ≤0.20	rest
"No-Nichel"	≤0.20	≤1.0	10.0-12.0	-	-	16.5-17.5	3.00-3.50	≤0.1	N 0.75-0.90;	rest
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	N 7727-37-9 V 7440-62-2	7439-89-6

Information on hazardous ingredients basing upon their concentration in the product

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	N 231-783-9 V 231-171-1	231-096-4
Hazard class and category code	-	-	STOT RE 2	-	-	Aquatic Chronic 4	-	-	-	-
Frasi H	-	-	H373	-	-	H413	-	-	-	-

SECTION 4: First aid measures

No special measures required.

4.1. Description of first aid measures

For the product in solid form are not provided details of the first aid measures; in case of product in the molten state, adopt the following measures:

Inhalation If formaldehyde vapors inhaled: provide fresh air and heat, if necessary, call a doctor.
Skin contact Wash thoroughly with soap and water.
Eye contact With eye lids open, rinse in running water and if applicable consult a doctor. No material-specific precautions are required.
Ingestion Rinse the mouth and drink water.

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

Symptoms: Not significant symptoms, because the product is not classified.



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

Treatment: Symptomatic treatment.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing Media Dry powder, water spray, foam, carbon dioxide.

Unsuitable extinguishing Media None.

5.2. Special hazards arising from the substance or mixture

For temperature higher than 200 °C production of: formaldehyde ...%, harmful vapors.

5.3. Advice for firefighters

Protective equipment: Wear self-contained breathing apparatus.

Further information:

The risk is related to the burning substance and the fire conditions. The fire debris and contaminated fire extinguishing water must be disposed of according to local regulations.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid dust formation.

6.2. Environmental precautions

Suppress gases / vapours / mist with water spray. Reduce dust with water spray.

6.3. Methods and material for containment and cleaning up

For small amounts: Pick up with suitable device and dispose of.

Residues: Pick up with suitable device and dispose of.

6.4. Reference to other sections

See Section 8 and Section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid dust formation.

Fire and Explosion Protection: The fine powder build-up can lead, in the presence of air, the risk of explosion.

7.2. Conditions for safe storage, including any incompatibilities

Further information on storage conditions: Keep container dry.

The packed product is not damaged by low temperatures or frost and high temperatures.

The packed product is not damaged by high temperatures.

7.3 Specific end use(s)

For the identified use listed in Section 1, the recommendations of Section 7 must be observed.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Biosteel

Exposure limits: Source: TRGS 900, workplace exposure limits (status 2006, last supplemented and updated 2012). The general exposure limit applicable for dust is 3 mg/m³ (alveolar fraction) or 10 mg/m³ (inhalable fraction). If it is not possible to adhere to a dust concentration of 3 mg/m³ (A-dust), then precautionary medical examinations must be provided. Iron, iron (II) / (III) oxide is contained in the general dust exposure limit.

No-Nichel

Components with limit values to be respected in the workplace, according to ACGIH

Hazardous elements	EC no.	CAS no.	TWA Value
Manganese	231-105-1	7439-96-5	Respirable fraction: 0.02 mg/m ³ (OEL (IT)). Inhalable fraction: 0.1 mg/m ³ (OEL (IT)).
Molybdenum	231-107-2	7439-98-7	=
Chromium	231-157-5	7440-47-3	2 mg/m ³ (OEL (EU)). 0.5 mg/m ³ (OEL (IT)). The emission and the amount of the substance indicated depends on the processing conditions.
Formaldehyde	200-001-8	50-00-0	VLC 0.3 ppm (OEL (IT)).

Hazardous elements	EC no.	CAS no.	PNEC
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Iron	231-096-4	7439-89-6	It was not possible to derive any PNEC, since they were not carried out specific studies. The product is a substance that is found in nature and whose molecular structure appears to have no detrimental effect.
Molybdenum	231-107-2	7439-98-7	Fresh water: 12.7 mg/l. Sea water: 1.91 mg/l. Occasional emission: no PNEC value available. treatment plant: 21.7 mg/l. Sediment (fresh water): 22600 mg/kg. Sediment (sea water): 1984 mg/kg. Soil: 39 mg/kg. Oral, secondary poisoning: No PNEC value available.
Manganese	231-105-1	7439-96-5	Fresh water: 0.034 mg/l. Sea water: 0.0034 mg/l. Sediment (fresh water): 3.3 mg/kg. Sediment (sea water): 0.34 mg/kg. Soil: 3.4 mg/kg. Occasional emission: 100 mg/l. Treatment plant: 0.028 mg/l.
Chromium	231-157-5	7440-47-3	Sediment (fresh water): 205.7 mg/kg. Fresh water: 0.0065 mg/l. Soil: 21.1 mg/kg.

Components with DNEL

Iron			
DNEL	Oral	Inhalation	Dermal
Worker - Long Term - Local effects	-	3 mg/m ³ .	-
Consumer - Long Term - Local effects	-	-	-
Consumer - Long Term - Systemic effects	0.71 mg/kg.	1.5 mg/m ³ .	-

Molybdenum			
DNEL	Oral	Inhalation	Dermal
Worker - Long Term - Local effects	-	11.17 mg/m ³ .	-
Consumer - Long Term - Systemic effects	4.85 mg/kg.	3.33 mg/m ³ .	-

Manganese			
DNEL	Oral	Inhalation	Dermal
Worker - Long Term - Systemic effects	-	0.02 mg/m ³ .	0.00414 mg/kg.
Consumer - Long Term - Systemic effects	-	0.041 mg/m ³ .	0.0021 mg/kg.

Chromium			
DNEL	Oral	Inhalation	Dermal
Worker - Long Term - Local effects	-	0.5 mg/m ³ .	-
Consumer - Long Term - Local effects	-	0.027 mg/m ³ .	-

8.2. Exposure controls

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

Eye protection	When fumes and dust are created, wear protective glasses (EN166).
Hand protection	Wear protective gloves resistant to chemicals. Because of the great diversity of types, observe the operating instructions of the manufacturer.
Respiratory protection	In case of dust or vapour formation, use Filter for gases / vapors of inorganic compounds (eg. EN 14387 type B). In case of dust formation, Protect the respiratory system. Filter for solid and liquid particles with medium efficiency (eg. EN 143 or 149, Type P2 or FFP2).
Body protection	the protection must be chosen depending on activity and possible exposure, eg. apron, boots, chemical-protection suit (according to EN 14605 in case of splashes or EN 13982 in case of dust).
Hygienic measures	Always wear closed work clothing. When using do not eat, drink or smoke. Observe the general safety regulations when handling chemicals.



SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	No-Nichel	Biosteel
Appearance	Massive form.	Massive form.
Colour	Metal-silver grey colour.	metal-silver grey colour.
Odour	Odourless.	Odourless.
Melting point	165°C.	1325-1350°C.
Flash Pont	Not applicable.	-
Evaporation rate	Negligible, not applicable.	-
Flammability	Not easily flammable.	-
Upper explosion limit	Not available.	-
Self- igniting temperature	450°C.	-
Density	5.1 – 5.5 g/cm ³ at 15 °C.	7.7-8.3 g/cm ³ .
Solubility (water)	Insoluble.	Insoluble.
Partition coefficient (n-octanol/water)	Not applicable.	-
Decomposition temperature	>200°C.	-
Dynamic viscosity	Not applicable.	-
Kinetic viscosity	Not applicable.	-
Relative density	2500-2900 kg/m ³ .	-
Hygroscopic	Not hygroscopic.	-
Solid component	90%.	-

9.2. Other information

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

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reactions when stored and handled according to instructions.
Metal corrosion: not corrosive effect, not to predict a corrosive metal effect.

10.2. Chemical stability

The product is chemically stable.
Depolymerisation at high temperature.

10.3. Possibility of hazardous reactions

Highly exothermic reaction with acid. It is possible a violent decomposition.

10.4. Conditions to avoid

Avoid ignition sources: heat, sparks, open flame. Avoid prolonged explosion to extreme heat.

10.5. Incompatible materials

Organic acids, plastic materials with halogenated flame- retardant.

10.6. Hazardous decomposition product(s)

Formaldehyde.

In case of prolonged heat load or temperature above the decomposition temperature, hazardous products may be produced.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Based on our current knowledge and experience, other dangers, which are not taken into account by this labelling, are not expected. In the case of proper use and handled as prescriptions, based on our experience and the information available, no adverse health effect.

Acute toxicity

The product has not been fully tested. The statements have been derived from products with similar structure or composition. The product is practically non toxic for one ingestion, can cause mechanically irritation. Sensitization not investigated, due to exposure considerations. Not relevant danger in case of inhalation.

Acute Toxicity	(Based on Iron) Ingestion: Practically non toxic.
Irritation	Inhalation: Practically non toxic. (Based on Iron) Skin: not irritant. Eye: not irritant.
Sensitization	(Based on Iron) Animal test has shown no sensitization effects.
Germ cell Mutagenicity	(Based on Iron) In most of the experiments performed it was not encountered a mutagenic effect on the part of the substance.
Carcinogenic effects	(Based on Iron) No data are available on carcinogenic effects.
Toxic for reproduction	(Based on Iron) No data available. The chemical structure does not determine particular suspicion of such an effect.



Toxic for development

(Based on Iron) No data available. The chemical structure does not determine particular suspicion of such an effect.

STOT RE

(Based on Manganese) The substance can damage the central nervous system following repeated inhalation of large quantities.

SECTION 12: Ecological information

The product has not been fully tested. The ecotoxicological indications have been deducted from the individual components. The product has been evaluated considering the individual component data available. Based on our current knowledge and experience, other dangers, which are not taken into account by this labeling, are not expected.

12.1. Toxicity

Aquatic toxicity: probably non toxic for aquatic organism. The product has not been fully tested. The statements have been derived from products with similar structure or composition.

12.2. Persistence and degradability

Due to its low solubility in water the product is largely mechanically separated in sewage plant.

12.3. Bioaccumulative potential

The product has not been tested. Due to product's consistency and very low solubility in water, bioavailability is unlikely.

Chromium: can accumulate in humans.

12.4. Mobility in soil

Adsorption in soil: Adsorption to solid soil phase is possible.

12.5. Results of PBT and vPvB assessment

Not available.

12.6. Other adverse effects

No further relevant 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

After a chemical-physical pre-treatment must be started to a special treatment, eg.: controlled dump.

Uncleaned packaging:

Contaminated packaging should be emptied optimally and then, after being thoroughly cleaned, can be passed on for recycling. Contaminated empty containers are to be treated like the substance.

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. Z05/5E dated 29/05/2009 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.

Hazard statements

H373: May cause damage to organs through prolonged or repeated exposure.

H413: May cause long-lasting harmful effects to aquatic life.

Legend

ACGIH: Association Advancing Occupational and Environmental Health.

CAS No.: Chemical Abstract Service Registry number.

DNEL: Derived No-Effect Levels.

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

EN 143: Respiratory protective devices: Particle filters -Requirements, testing, marking.

EN 149: Maintenance Free Particulate Respirators.

EN 166: Personal eye protection – Specifications.

EN 13982: Protective clothing for use against solid particulates.

EN 14387: Respiratory protective devices - Gas filters and combined filters - Requirements, testing, marking.

EN 14605: Protective Suits resistant to penetration by liquids.

IBC Code: International Bulk Chemicals Code.

PBT: Persistent, Bioaccumulative And Toxic Substances.

PNEC: Predicted No Effect Concentration.

STOT RE: Specific Target Organ Toxicity-Repeated Exposure.

TWA: Time Weighted Average.

vPvB: Very Persistent And Very Bioaccumulative Substances.