



## 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, 48/50

e-mail: [research@leone.it](mailto: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](http://www.leone.it/emergency) (EU and international telephone numbers).

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

In accordance with Regulation (EC) No. 1272/2008 [CLP].

This product does not meet the criteria for classification as hazardous under Titles I and II of Regulation (EC) No. 1272/2008 on the classification, labeling, and packaging of substances and mixtures.

The products referred to in this data sheet are in the form of solid metal bonds and, when used under normal conditions and in accordance with their intended use, are not generally considered hazardous to humans or the environment. Use in a manner that does not comply with the instructions for use may alter the performance of the products and present potential health and safety hazards. The product may release hazardous substances during mechanical operations such as cutting, grinding, and/or sanding. In the event of heat/chemical treatment, the product may release hazardous substances. Under certain conditions, the product's dust is explosive.

### 2.2. Label elements

Not applicable.

### 2.3. Other hazards

No PBT, vPvB, or endocrine disrupting substances present in concentrations  $\geq 0.1\%$

## SECTION 3: Composition/information on ingredients

### 3.2. Mixtures

Chemical composition %

Steel type	Elements									
	C	Si	Mn	P	S	Cr	Mo	Ni	Others	Fe
Biosteel®	0.15-0.25	0.20-0.60	9.5-12.5	$\leq 0.020$	$\leq 0.010$	16.5-18.0	2.7-3.7	$\leq 0.05$	N 0.45-0.55; Cu $\leq 0.25$	rest
"No-Nichel"	$\leq 0.20$	$\leq 1.0$	10.0-12.0	-	-	16.5-17.5	3.00-3.50	$\leq 0.1$	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 Cu 7440-50-8	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 Cu 231-159-6	231-096-4
Hazard class and category code	-	-	STOT RE 2	-	-	Aquatic Chronic 4	-	-	-	-
Frasi H	-	-	H373	-	-	H413	-	-	-	-

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

Inhalation Generally, no route of exposure. In case of inhalation, rest and fresh air.

Skin contact Wash thoroughly with soap and water; contact a doctor if necessary.

Eye contact Remove contact lenses. Rinse thoroughly for 15 minutes under running water, keeping your eyelids open. Contact a doctor if necessary.

Ingestion Generally, no route of exposure. Rinse mouth and drink plenty of water. Contact a doctor if necessary.

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

Symptoms: No further symptoms and/or effects are known at this time.

Hazards: No further symptoms and/or effects are known at this time.

### 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

For personal protective measures, see section 8.

Special protective measures: Use a self-contained breathing apparatus.

Additional information: The hazard depends on the flammable substances and the conditions of the fire. Fire residues and contaminated firefighting water must be disposed of in accordance with local regulations.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

Avoid the formation of dust.

#### 6.1.2. For emergency responders

See section 8 for appropriate protective equipment and material specifications.

### 6.2. Environmental precautions

Suppress gases/vapors/mists with water spray. Suppress dust with water spray.

Prevent entry into the drainage system.

### 6.3. Methods and material for containment and cleaning up

Small quantities: Collect using suitable means and dispose of.

Residues: Collect using suitable means and dispose of.

### 6.4. Reference to other sections

Information on exposure control/personal protection and disposal considerations is provided in Sections 8 and 13.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Avoid dust formation.

Fire and explosion protection: the accumulation of fine dust can lead to a risk of explosion in the presence of air.

### 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

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

Components	EC No.	CAS No.	WEL-TWA values
Nickel	231-111-4	7440-02-0	0,5 mg/m <sup>3</sup>
Chromium	231-157-5	7440-47-3	2 mg/m <sup>3</sup> (OEL (EU)). 0,5 mg/m <sup>3</sup> (OEL (IT)).
Silicon	231-130-8	7440-21-3	Inhalable fraction: 10 mg/m <sup>3</sup> Respirable fraction: 4 mg/m <sup>3</sup>

Components	EC No.	CAS No.	PNEC
Nickel	231-111-4	7440-02-0	Fresh water: 3.55 µg/l Sea water: 8.6 µg/l Wastewater treatment plant: 0.33 mg/l Soil: 29.9 mg/kg.
Chromium	231-157-5	7440-47-3	Freshwater: 6.5 µg/l Sediment (freshwater): 205.7 mg/kg dw Soil: 21.1 mg/kg dw



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Molybdenum	231-107-2	7439-98-7	Freshwater: 12.7 mg/l Seawater: 1.91 mg/l Sediment (freshwater): 22.6 mg/kg dw Sediment (seawater): 1.98 mg/kg dw Soil: 39 mg/kg dw
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**DNEL components**

Nickel			
DNEL	Oral	Inhalation	Dermal
Operator - Long Term - Systemic Effects	-	0,05 mg/m3	-
Operator - Long Term - Local Effects	-	0,05 mg/m3	0,07 mg/cm2
Operator - Short Term - Local Effects	-	4 mg/m3	-
Operator - Short Term - Systemic Effects	-	680 mg/m3	-
Consumer - Long Term - Local Effects	-	0,00002 mg/m3	-
Consumer - Long Term - Systemic Effects	0,02 mg/kg	0,00002 mg/m3	-
Consumer - Short Term - Systemic Effects	0,012 mg/kg	-	-
Consumer - Short Term - Local Effects	-	2,4 mg/m3	-

Chromium			
DNEL	Oral	Inhalation	Dermal
Consumer - Long Term - Local Effects	-	0,027 mg/m3	-
Consumer - Long Term - Local Effects	-	0,5 mg/m3	-

Rame			
DNEL	Oral	Inhalation	Dermal
Operator - Long Term - Systemic Effects	-	18,2 mg/m3	273 mg/kg
Consumer - Long Term - Systemic Effects	-	-	137 mg/kg

Molybdenum			
DNEL	Oral	Inhalation	Dermal
Operator - Long Term - Systemic Effects	-	11,17 mg/m3	-
Consumer - Long Term - Systemic Effects	4,85 mg/kg	3.33 mg/m3	-

**No-Nichel**

Components with limit values to be observed in the workplace

The emission and quantity of the substance indicated depend on the processing conditions. Provide adequate ventilation for indoor use to prevent the accumulation of formaldehyde in the workplace, thus avoiding exceeding occupational exposure limits.

Components	EC No.	CAS No.	TWA values
Manganese	231-105-1	7439-96-5	Respirable fraction: 0.05 mg/m3 (OEL (IT)). / 0.05 mg/m3 (OEL (EU)) Inhalable fraction: 0.2 mg/m3 (OEL (IT)). / 0.2 mg/m3 (OEL (EU))
Molybdenum	231-107-2	7439-98-7	Inhalable particles: 3 mg/m <sup>3</sup> (OEL (IT))
Chromium	231-157-5	7440-47-3	2 mg/m3 (OEL (EU)). 0,5 mg/m3 (OEL (IT)).
Formaldehyde	50-00-0	50-00-0	0,1 ppm (OEL (IT))

**Components with PNEC**

Components	EC No.	CAS No.	PNEC
Iron	231-096-4	7439-89-6	It has not been possible to derive any PNEC values, as no specific studies have been conducted. The product is a naturally occurring substance whose molecular structure appears to have no harmful effects.
Molybdenum	231-107-2	7439-98-7	Fresh water: 12.7 mg/l. Sea water: 1.91 mg/l. Occasional emissions: PNEC value not available. Wastewater treatment plant: 21.7 mg/l. Sediment (freshwater): 22,600 mg/kg. Sediment (seawater): 1,984 mg/kg. Soil: 39 mg/kg. Oral (secondary poisoning): No PNEC value available.



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Manganese	231-105-1	7439-96-5	Freshwater: 0.034 mg/l Seawater: 0.0034 mg/l Sediment (freshwater): 3.3 mg/kg Sediment (seawater): 0.34 mg/kg Soil: 3.4 mg/kg Wastewater treatment plant: 100 mg/l Occasional emissions: 0.028 mg/l
Chromium	231-157-5	7440-47-3	Sediment (freshwater): 205.7 mg/kg Freshwater: 0.0065 mg/l Soil: 21.1 mg/kg Oral (secondary poisoning): No PNEC (oral) derived, as no accumulation in organisms is expected.

**Components with DNEL**

Iron			
DNEL	Oral	Inhalation	Dermal
Operator - Long term - Local effects	-	3 mg/m <sup>3</sup> .	-
Consumer - Long term - Local effects	-	-	-
Consumer - Long term - Systemic effects	0,71 mg/kg.	1,5 mg/m <sup>3</sup> .	-

Molybdenum			
DNEL	Oral	Inhalation	Dermal
Operator - Long term - Local effects	-	11,17 mg/m <sup>3</sup> .	-
Consumer - Long term - Systemic effects	4,85 mg/kg.	3,33 mg/m <sup>3</sup> .	-

Manganese			
DNEL	Oral	Inhalation	Dermal
Operatore - Lungo termine - Effetti sistemici	-	0,02 mg/m <sup>3</sup> .	0,00414 mg/kg.
Consumer - Long term - Systemic effects	-	0,041 mg/m <sup>3</sup> .	0,0021 mg/kg.

Chromium			
DNEL	Oral	Inhalation	Dermal
Operator - Long term - Local effects	-	0,5 mg/m <sup>3</sup> .	-
Consumer - Long term - Local effects	-	0,027 mg/m <sup>3</sup> .	-

## 8.2. Exposure controls

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

Eye protection	Safety glasses with side protection (cage glasses) (e.g., EN 166)
Hand protection	Wear chemical-resistant protective gloves. Due to the wide variety of types, it is advisable to follow the manufacturers' instructions for use.
Respiratory protection	In case of gas or vapor development. Filter for gases/vapors of inorganic compounds (e.g., EN 14387 Type B). Protect the respiratory tract in case of dust formation. Filter for solid and liquid particles with medium retention capacity (e.g., EN 143 or 149, Type P2 or FFP2).
Body protection	Choose the appropriate protective equipment according to the activity and exposure, e.g., apron, boots, suitable clothing (in accordance with EN 14605 in case of splashes or EN 13982 in case of dust).
Hygienic measures	It is recommended to wear closed work clothes. Do not eat, drink, or smoke during use. The usual precautions for handling chemicals must be observed.

### 8.2.3. Environmental exposure controls

No information is available at this time.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Propriety	No-Nichel	Biosteel
Physical state	Solid.	Solid .
Colour	Gray	Metallic gray
Odour	Odourless	Odourless
Melting point	165°C	1325-1530°C
Boiling point	The product is not volatile	No information is available on



		this parameter.
Flammability	Not easily flammable.	No information is available on this parameter.
Lower and upper explosion limits	Not relevant for the purposes of classification and labeling of solids.	Not applicable to solids
Flash point	Not applicable, the product is a solid	No information is available on this parameter.
Auto-ignition temperature	236 °C	Not applicable to solids
Decomposition temperature	> 200 °C Thermal decomposition is possible at temperatures above the indicated temperature. Severe overheating may release gaseous decomposition products.	No information is available on this parameter.
pH	The substance/mixture is not soluble (in water), not applicable	No information is available on this parameter.
Kinematic viscosity	Not applicable, the product is a solid	No information is available on this parameter.
Water solubility	Insoluble	Insoluble
Partition coefficient n-octanol/water (log value)	not applicable to mixtures	not applicable to mixtures
Vapour pressure	negligible, not applicable	No information is available on this parameter.
Density	No information is available for absolute density. Instead, apparent density was established as a more relevant value.	7,7-8,3 g/cm <sup>3</sup> (20°)
Relative vapour density	The product is not volatile.	Not applicable to solids
Particle characteristics	/.	No information is available on this parameter.

## 9.2. Other information

There is no additional information.

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No dangerous reactions if the storage and handling requirements/instructions are observed.

Metal corrosion: not applicable. No corrosive effect on metal is to be expected.

### 10.2. Chemical stability

The product is stable if the handling and storage requirements/instructions are observed.

Depolymerization at high temperatures.

### 10.3. Possibility of hazardous reactions

Strongly exothermic reaction with acids. Violent decomposition is possible.

The product is stable if the requirements/instructions for handling and storage are observed.

### 10.4. Conditions to avoid

Avoid all sources of ignition: heat, sparks, open flames. Avoid prolonged exposure to extreme heat..

### 10.5. Incompatible materials

Materials to avoid: inorganic acids, plastics containing halogenated flame retardants.

### 10.6. Hazardous decomposition products

Formaldehyde.

In case of prolonged or high thermal load above the decomposition temperature, hazardous decomposition products may form.

## SECTION 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Tossicità acuta (ingestione)

Praticamente non tossico per una singola ingestione. Il prodotto non è stato testato. L'indicazione è dedotta dalle proprietà dei singoli componenti.

Tossicità acuta (contatto con pelle/occhi)

Sulla base dei dati disponibili, i criteri per la classificazione non sono soddisfatti.



Tossicità acuta (inalazione)	Praticamente non tossico per una singola inalazione.
Corrosione cutanea/irritazione cutanea	Può causare un'irritazione meccanica. Il prodotto non è stato testato.
Gravi danni oculari/irritazione oculare	Può causare un'irritazione meccanica. Il prodotto non è stato testato
Sensibilizzazione respiratoria o cutanea	Sulla base dei dati disponibili, i criteri per la classificazione non sono soddisfatti.
Mutagenicità sulle cellule germinali	Sulla base dei dati disponibili, i criteri per la classificazione non sono soddisfatti.
Cancerogenicità	Sulla base dei dati disponibili, i criteri per la classificazione non sono soddisfatti.
Tossicità per la riproduzione	Sulla base dei dati disponibili, i criteri per la classificazione non sono soddisfatti.
Tossicità specifica per organi bersaglio (STOT) — esposizione singola	Non classificato, per mancanza di dati.
Tossicità specifica per organi bersaglio (STOT) — esposizione ripetuta	Non classificato, per mancanza di dati.
Pericolo in caso di aspirazione.	Non rilevante

## 11.2 Information on other hazards

### 11.2.1. Endocrine disrupting properties

The product does not contain any substance identified as having endocrine-disrupting properties beyond the legal limits, in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605. The product does not contain any substances above the legal limits included in the list established in accordance with Article 59(1) of Regulation (EC) No. 1907/2006 for having endocrine-disrupting properties or identified as having endocrine-disrupting properties, in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

### 11.2.2. Other information

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## SECTION 12: Ecological information

### 12.1. Toxicity

Aquatic toxicity: The product is unlikely to be harmful to aquatic organisms. The product has not been tested. The information is derived from substances/products of similar composition or structure.

Terrestrial toxicity assessment:

Toxic effects have been observed in studies on organisms living in the soil.

### 12.2. Persistence and degradability

Due to its low water solubility, the product is largely separated mechanically in wastewater treatment plants.

### 12.3. Bioaccumulative potential

The product has not been examined. Given the consistency and very low water solubility of the product, its bioavailability is unlikely.

Chromium: Accumulation in organisms is modest.

Cobalt: No significant accumulation in organisms is expected.

### 12.4. Mobility in soil

Absorption into the soil: Absorption into the solid phase of the soil is possible.

### 12.5. Results of PBT and vPvB assessment

Based on available data, the product does not contain PBT or vPvB substances in a percentage  $\geq 0.1\%$ .

### 12.6. Endocrine disrupting properties

The product does not contain any substance identified as having endocrine-disrupting properties beyond the legal limits, in accordance with the criteria established in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605. The product does not contain any substances above the legal limits included in the list established in accordance with Article 59(1) of Regulation (EC) No. 1907/2006 for having endocrine-disrupting properties or identified as having endocrine-disrupting properties, in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

### 12.7. Other adverse effects

The product does not contain substances listed in Regulation 1005/2009/EC on substances that deplete the ozone layer.

The product has been assessed based on the available data on its components. For some components, the data is incomplete. Based on our current knowledge and experience, no hazards are expected that have not been taken into account in this labeling.





### 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 proper disposal in accordance with current regulations.

Check for reuse possibilities.

After chemical-physical pre-treatment, it must be sent for special treatment, e.g.:  
controlled landfill.

Local administrative regulations regarding wastewater treatment must be observed.

The waste code according to the European Waste Catalogue cannot be specified as it depends on the use.

Contaminated packaging:

Contaminated packaging must be emptied as thoroughly as possible and then, after adequate washing, can be reused.

Contaminated empty packaging must be treated in the same way as the substance it contained.

### SECTION 14: Transport information

Not dangerous according to current transportation regulations.

#### 14.1. UN number or ID 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

No one known

#### 14.7. Maritime transport in bulk according to IMO instruments

No bulk maritime transport is planned.

### 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 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. Z05/8E dated 31/01/2023 is to be considered obsolete. In comparison to the preceding revision, meaningful changes have not been effected but only a slight variations of the percentage of Biosteel® alloy elements.



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](http://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.: numerical identifier that uniquely identifies a chemical substance, assigned by the Chemical Abstract Service.

DNEL: exposure levels below which the substance has no dangerous effects on human health.

EC No.: European Chemicals Trade Register.

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

EN 149: Maintenance-free dust respirators.

EN 166: Personal eye protection - Specifications.

EN 13982: Protective clothing for use against solid particles.

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

EN 14605: Protective suits resistant to liquid penetration.

GHS: Globally Harmonized System of Classification and Labelling of Chemicals.

IMO: International Maritime Organization.

PBT: Persistent, Bioaccumulative, and Toxic: hazardous chemicals.

PNEC: Predicted No-Effect Concentration.

STOT RE: Specific Target Organ Toxicity - Repeated Exposure.

TWA: Time-Weighted Average.

vPvB: Very Persistent and Very Bioaccumulative.