



SAFETY DATA SHEET no. Z05/5E
STAINLESS STEEL ALLOY WITH LOW NICKEL
CONTENT

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1. Identification of the preparation and of the company

1.1 Identification of the preparation

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 Use of the preparation

The above mentioned products are intended for the manufacture of orthodontic prosthesis.

1.3 Company identification

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 (0)55.30.44.1 – Fax ++39 (0)55 374808.

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 an stainless steel alloys with low nickel content, 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 IARC¹ 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: According to European Directive 99/45/CE and further modifications, products with a nickel content not exceeding 1% are not labelled as hazardous products.

3. Composition/information on ingredients

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 | balance |
| "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; | balance |
| CAS ² Number of elements | 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 ingredients³ basing upon their concentration in the product

| EC ⁴ Number | - | - | 231-105-1 | - | - | - | - | - | - | - |
|-----------------------------|---|---|-----------|---|---|---|---|---|---|---|
| Hazard symbols ⁵ | - | - | Xn | - | - | - | - | - | - | - |
| R ⁵ Phrases | - | - | R48/20 | - | - | - | - | - | - | - |

¹ IARC (International Agency for Research on Cancer).

² CAS Number (Chemical abstract service).

³ The occupational exposure limits (OEL), if known, are listed in section 8.

⁴ Number of European Catalogue. The EC number is made of a sequence of 7 figures, whose first group of 3 figures begins with 2 or 4 depending on which substance is included in the EINECS (European Inventory of Existing Commercial Chemical Substances) or in the ELINCS (European List of Notified Chemical Substances), or it begins with 5 if the substance is included in the list of "ex-polymers."

⁵ Hazards related to the ingredients of the product are indicated in section 2, information to be shown on the label are indicated in section 15

Explanation of hazardous symbols and Risk phrases is indicated in section 15 and 16.

4. First aid measures

- Not applicable to the finished products which this safety data sheet refers to.
- The following warnings are applied in case the products are modified through processes involving a change in the state of the raw material:

Inhalation: move person to fresh air until recovered. Consult a physician.

Ingestion: while ingestion of large enough quantities to cause health effects is unlikely, consult a physician if it occurs

Eye contact: flush thoroughly with water, consult a physician.

5. Fire-fighting measures

- The finished products this safety data sheet refers to, are not flammable.
- The following warnings are applied in case the products are modified through processes involving a change in the state of the raw material:

Metal dust dispersed in the air may cause fire or explosion hazards. Molten metal may ignite combustibles

Suitable extinguishing media: use fire-fighting measures suitable to the environment.

Unsuitable extinguishing media: not applicable.

Special hazards caused by material, its combustion's products or flue gases: fume of metal oxide.

Protection for fire-fighters: wear a self-contained breathing apparatus.

Further information: collect contaminated fire fighting water separately. It must not enter the sewerage.

6. Accidental release measures

- The finished products this safety data sheet refers to, if dispersed, may be picked up with mechanical means.
- The following warnings are applied in case the products are modified through processes involving a change in the state of the raw material:

Personal precautions: avoid breathing in of fumes/dust and use protection as described at section 8.

Protection precautions: do not allow product to reach sewage system or water bodies.

Measures for cleaning: collect dust and waste material. Dispose of according to section 13.

7. Handling and storage

7.1 Handling

- The finished products this safety data sheet refers to, have to be restricted to skilled and licensed professionals, in accordance with the intended use.
- The following warnings are applied in case the products are modified through processes involving a change in the state of the raw material:

Prevent formation of dust. If dust/fume is developed, avoid breathing in of dust/fumes. Avoid skin and eye contact.

Make sure that all applicable workplace limits are observed.

7.2 Storage

Specific storage measures are not necessary.

8. Exposure controls/personal protection

8.1. Exposition limit values⁶

Exposure limits for finished products related to this safety data sheet are not known. Exposure limits, if applicable, apply to dust and fume of some constituent elements and certain of their compounds as generated from the working processes listed in section 2.

Exposure limits are stated by local laws, consult your Occupational Safety and Health Authorities.

Herewith the limits outlined by ACGIH⁷ in the USA:

Carbon (C), occupational exposure limit (TWA): 50ppm (monoxide)

Silicon (Si), occupational exposure limit (TWA): 10 mg/m³

Manganese (Mn), occupational exposure limit (TWA): 5.0 mg/m³

Chromium (Cr), occupational exposure limit (TWA): 0.5 mg/m³

Molybdenum (Mo), occupational exposure limit (TWA): 10 mg/m³

Iron (Fe), occupational exposure limit (TWA): 5.0 mg/m³(oxide)

Nitrogen (N), occupational exposure limit (TWA): 3ppm (dioxide)

Nickel (Ni), occupational exposure limit (TWA): 1.0 mg/m³; 0.5 mg/m³ in Germany; 1.0 mg/m³ in Italy.

8.2. Exposure control

The following control measures should be taken in case the product undergoes the working processes listed in section 3.

- Personal protection:

⁶ The "occupational exposure limit", if not otherwise specified, is the average limit or serious concentration in the time of a chemical agent in the air inside the breathing area of a worker related to a specific period of time (Directive 98/24/EC on health and safety protection of the workers against the consequential risks from chemical agents during the job); the TWA (time weighted average) indicator is the serious average concentration in the time for a working day of 8 hours.

⁷ ACGIH: American Conference of Governmental Industrial Hygienists, USA.

Ventilation: should the processes generate dust or fumes, use a local ventilation and suction system, to maintain the concentrations of dust and fumes transported by the air below the limit values outlined by the local authorities.

- Respiratory protection: if gases/vapours are formed. Gas filter for gases/vapours of inorganic compounds (e.g. in accordance with European EN 14387 Type B). Breathing protection if dusts are formed. Particle filters with medium efficiency for solid and liquid particles (e.g. in accordance with EN 143 or 149, Type P2 or FFP2).
- Eye protection: Safety glasses with side-shields (frame goggles, e.g. in accordance with EN 166).
- Environmental precautions: do not allow product to reach sewage system or water bodies.
- Cleaning methods: collect dust and waste material. Dispose of according to section 13.
- General safety and hygiene measures: wearing of closed work clothing is recommended. No eating, drinking, smoking or tobacco use at the place of work.

Handle in accordance with good industrial hygiene and safety practice of chemical products.

9. Physical and chemical properties

9.1. General information

Appearance: massive form, metal-silver grey colour
Odour: odourless.

9.2. Health, safety and environmental information

Boiling point: not determined
Melting point: not determined
Density at 20°C: > 3 g/cm³
Solubility in water: insoluble
pH: not applicable
Flash point: not applicable
Auto ignition temperature: not applicable
Lower explosion limit: not applicable.

10. Stability and reactivity

- Conditions to avoid: none.
- 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.
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

This product is CE marked 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 *Manganese*:

Hazard symbols: Xn harmful



Risk phrases: R48/20 Harmful: danger of serious damage to health by prolonged exposure through inhalation

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. Z05/4E dated 29/06/2004 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.