



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

1.1. Product identifier

Orthodontic products, listed by type of product and chromium-cobalt alloy utilized for their production:

Crozat wires: chromium-cobalt alloys.

Wires for archwires: Leoloy® alloys.

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified Use The above mentioned products are intended for the manufacture of orthodontic appliances.

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 material does not pose any health hazard to humans through inhalation, swallowing or skin contact in the form in which they are marketed. The alloying and additive elements are metallurgically bonded in the material. Health hazards arising as a result of machining and thermal processing (e.g. milling, turning, welding, cutting, grinding) should be taken into consideration when fumes and/or inhalable dust are created (cf. exposure limits in accordance with Section 8.2.1). During product handling, a risk of cutting and crushing injury can occur.

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	Co	Ti	others	Fe
Chromium-cobalt	≤0.30	≤1.0	≤1.0	≤0.05	≤0.01	18.0-22.0	9.0-11.0	33.0-36.0	rest	0.1-2.0		0.1-2.0
Leoloy®	≤0.30	≤1.0	1.0-3.0	≤0.05	≤0.01	19.0-21.0	6.0-8.0	14.0-16.0	38.0-42.0	-	-	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	7440-48-4	7440-32-6	-	7439-89-6

Information on hazardous ingredients basing upon their concentration in the preparation

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	231-158-0	231-142-3		231-096-4
Hazard statements	-	-	-	-	-	-	-	H317 H351 H372	-	-	-	-

SECTION 4: First aid measures

4.1. Description of first aid measures

First aid measures relate to dust and fumes.

Inhalation IF INHALED: Fresh air supply (e.g. if possible move outdoors), if applicable consult a doctor.

Skin contact IF ON SKIN (or hair): wash with water and mild detergent.

Eye contact IF IN EYES: With eye lids open, rinse in running water and if applicable consult a doctor. No material-specific precautions are required.

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

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

No information available.

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

None necessary.



SECTION 5: Firefighting measures

5.1. Extinguishing media

Product does not burn. Fire fighting method for surrounding areas must be discussed. 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.

5.2. Special hazards arising from the substance or mixture

Combustion's products or flue gases: fume of metal oxide.

5.3. Advice for firefighters

Use a breathing apparatus. Collect contaminated fire fighting water separately. It must not enter the sewerage.

SECTION 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.

6.1. Personal precautions, protective equipment and emergency procedures

Avoid breathing fumes and dust and use protection as described in Section 8.

6.2. Environmental precautions

Do not allow product to reach sewage system or water bodies.

6.3. Methods and material for containment and cleaning up

Collect dust and waste material. Dispose of according to Section 13.

6.4. Reference to other sections

See sections 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

During thermal processing and/or machining, extraction at the machine / at the workplace, use ventilation measures. TRGS 528, welding, and TRGS 900 (exposure limit values for air at the workplace) are the applicable documents. As cobalt-base alloys products may have sharp edges, cut-proof gloves should be used when handling.

Prevent formation of dust. If dust/fume is developed, avoid breathing dust/fume. Avoid skin and eye contact. Make sure that all applicable workplace limits are observed.

7.2. Conditions for safe storage, including any incompatibilities

Not applicable.

7.3 Specific uses, use restrictions

Not applicable.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

The exposure limits refer to the dust and fumes occurring during machining and processing under special work conditions. The exposure limits are established at national level, it is therefore recommended to consult the local authority for the Occupational Safety and Health Authorities.

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.

Herewith the limits outlined by ACGIH 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).

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

Cobalt (Co), occupational exposure limit (TWA): 0.05 mg/m³.

Titanium (Ti), occupational exposure limit (TWA): 10 mg/m³.

8.2. Exposure controls

Appropriate engineering controls

Never eat, drink, smoke, or sniff when working.

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

Eye/face protection Where fumes and dust are created, wear protective goggles.



Hand protection	Dependent upon the respective machining or processing operation.
Respiratory protection	If exposure limits are not adhered to despite implementation of the latest measures to capture dust and fumes and provide ventilation, then suitable personal protection equipment must be provided. Suitable filtration devices may be used for short periods.
Other	Do not breathe in dust, fumes or aerosols. Do not clean contaminated clothing by blowing or brushing.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Massive form.
Colour	Metal-silver grey colour.
Odour	Odourless.
pH	Not applicable.
Melting point	2400°C-2600°C.
Boiling point	Not determined.
Flash point	Not applicable.
Density at 20°C	7.5-8.5 g/cm ³ .
Solubility in water	Insoluble.
Auto ignition temperature	Not applicable.
Lower explosion limit	Not applicable.

9.2. Other information

Not applicable.

SECTION 10: Stability and reactivity

10.1. Reactivity

Cobalt-base alloys are not reactive under normal atmospheric conditions. Vapour can only escape when in molten form and during welding (i.e. when heating to very high temperatures).

10.2. Chemical stability

Cobalt-base alloys are stable.

10.3. Possibility of hazardous reactions

Not known.

10.4. Conditions to avoid

None.

10.5. Incompatible materials

Avoid contact with strong acids like HNO₃/HCl and mixtures of these together with FeCl₃ (danger of corrosion), formation of nitrous gases possible.

10.6. Hazardous decomposition product(s)

Not known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Excessive exposure to dust/fumes can irritate the eyes and upper bronchial tract.

Occupational medical experience has shown that handling cobalt-base alloys products does not result in sensitization in case of normal short periods of skin contact.

SECTION 12: Ecological information

12.1. Toxicity

None of the substances contained in cobalt-base alloys should be emitted under normal or reasonably foreseeable application conditions. Under normal foreseeable application conditions including disposal, any risk from exposure may be deemed negligible to humans or to the environment.

12.2. Persistence and degradability

Not applicable.

12.3. Bioaccumulative potential

Not applicable.

12.4. Mobility in soil

Not applicable.

12.5. Results of PBT and vPvB assessment

Not classified as PBT or vPvB.

12.6. Other adverse effects

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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

Return to the cobalt-base alloys manufacturer through the scrap dealer for recycling.

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

No chemical safety assessment is required for the product.

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. Z02/5E 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

H317: May cause an allergic skin reaction.

H351: Suspected of causing cancer.

H372: Causes damage to organs through prolonged or repeated exposure.



Legend

ACGIH: Association Advancing Occupational and Environmental Health.

CAS No.: Chemical Abstract Service Registry number.

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

IBC Code: International Bulk Chemicals Code.

PBT: Persistent, Bioaccumulative And Toxic Substances.

TRGS 528: Technische Regeln für Gefahrstoffe Schweißtechnische Arbeiten, Technical Rules for Hazardous Substances welding work.

TRGS 900: Technische Regeln für Gefahrstoffe Arbeitsplatzgrenzwerte, Technical Rules for Hazardous Substances occupational exposure limit.

TWA: Time weighted average.

vPvB: Very Persistent And Very Bioaccumulative Substances.