

SECTION 1: Identification of the substance/mixture and of the company/undertaking

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, 48/50

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.

www.leone.it/emergency (EU and international telephone numbers).

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

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	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 aiders must ensure that they are protected.

Never pour anything into the mouth of an unconscious person.

First aid measures relating to dust and fumes.

Inhalation Generally no route of exposure.

Skin contact Wash thoroughly with soap and water - if necessary, consult a doctor.

Eye contact Remove contact lenses.

Wash thoroughly for several minutes with plenty of water. If necessary, consult a doctor.

Ingestion Generally no route of exposure.

Rinse mouth thoroughly with water. If necessary, consult a doctor.

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

Where applicable, delayed symptoms and effects are listed in section 11 and the route of absorption in section 4.1. In some cases, symptoms of poisoning may only appear after a prolonged period/several hours.

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

Symptomatic treatment.

SECTION 5: Firefighting measures

5.1. Extinguishing media

The finished products referred to in this sheet are not flammable. Consider fire prevention measures for surrounding areas. The following warnings apply if the products are modified by processes that change the state of the raw material: metal powders dispersed in the air may cause fire and explosion hazards. Molten metal may ignite combustibles.

Suitable extinguishing Media Fire extinguisher, sand

Unsuitable extinguishing Media CO₂, water

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

For personal protective equipment, see Section 8.

Use a self-contained breathing apparatus. Collect water used for extinguishing separately so that it does not enter the sewer system.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

In case of accidental spillage or release, wear the personal protective equipment specified in section 8 to avoid contamination. Ensure adequate ventilation, remove sources of ignition.

Avoid dust formation with solid or powdered products.

Leave the danger zone if possible, use existing emergency plans if necessary. No special measures are required.

6.1.2. For emergency responders

See Section 8 for suitable protective equipment and material specifications.

6.2. Environmental precautions

Avoid entry into the drainage system.

6.3. Methods and material for containment and cleaning up

Collect mechanically and dispose of in accordance with section 13.

6.4. Reference to other sections

For personal protective equipment, see Section 8, and for disposal instructions, see Section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

General recommendations:

Eating, drinking, smoking, and storing food are prohibited in the workplace. Follow the instructions on the label and the instructions for use.

When handling heated material:

Ensure good ventilation.

Avoid inhalation and contact with eyes or skin.

Notes on general hygiene measures in the workplace:

General hygiene measures for handling chemicals apply. Wash hands before breaks and at the end of work.

Keep away from food, beverages, and animal feed.

Remove contaminated clothing and protective equipment before entering areas where food is consumed.

7.2. Conditions for safe storage, including any incompatibilities

Keep the product closed and only in its original packaging. Store in a dry place.

7.3 Specific uses, use restrictions

No information available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

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

Chemical name: Cobalt		Contents %: <70
WEL-TWA: 0,1 mg/m ³	WEL-STEL: ---	---

Chemical name: Chrome		Contents %: <40
WEL-TWA: 0,5 mg/m ³ (WEL), 2 mg/m ³ (EU)	WEL-STEL: ---	---

Chemical name: Silicon		Contents %:
WEL-TWA: 10 mg/m ³ (total inhalable dust), 4 mg/m ³ (residual dust)	WEL-STEL: ---	---

Chemical name: Tungsten		Contents %:
WEL-TWA: 5 mg/m ³	WEL-STEL: 10 mg/m ³	---

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Ensure good ventilation. This can be achieved by local exhaust ventilation or general air extraction.

If this is not sufficient to keep the concentration below the WEL or AGW values, appropriate respiratory protection must be worn.

8.2.2. Individual protection measures, such as personal protective equipment

General hygiene measures for handling chemicals apply. Wash hands before breaks and at the end of work.

Keep away from food, beverages, and animal feed.

Remove contaminated clothing and protective equipment before entering areas where food is consumed.

Eye/face protection In case of fumes and/or dust release, wear protective goggles.

Skin protection Not normally necessary.

Hand protection Not normally necessary. To prevent skin sensitization and dermatitis, gloves and barrier creams may be necessary.

Respiratory protection In case of smoke and/or dust emissions, wear approved safety masks.

8.2.3. Environmental exposure controls

No information available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Solid
Colour	Silver, grey
Odour	Odourless
Melting point/freezing point	No information is available on this parameter.
Boiling point or initial boiling point and boiling range	No information is available on this parameter.
Flammability	No information is available on this parameter.
Lower and upper explosion limit	Does not apply to solids.
Flash point	Does not apply to solids.
Auto-ignition temperature	Does not apply to solids.
Decomposition temperature	No information is available on this parameter.
pH	No information is available on this parameter.
Kinematic viscosity	No information is available on this parameter.
Water solubility	Insoluble
Partition coefficient n-octanol/water (log value)	Does not apply to mixtures.
Vapour pressure	Does not apply to solids.
Density and/or relative density	No information is available on this parameter.
Relative vapour density	No information is available on this parameter.
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

Not applicable

10.2. Chemical stability

Stable when stored and handled properly.

10.3. Possibility of hazardous reactions

No dangerous reactions are known.

10.4. Conditions to avoid

See also section 7.

10.5. Incompatible materials

See also section 7.

Avoid contact with strong acids.

10.6. Hazardous decomposition products

See also section 5.2

No decomposition if used as directed.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral)

Based on the available data, the classification criteria are not met.

Acute toxicity (dermal)

Based on the available data, the classification criteria are not met.

Acute toxicity (inhalation)

Based on the available data, the classification criteria are not met.

Skin corrosion/irritation

Based on the available data, the classification criteria are not met.

Serious eye damage/irritation

Based on the available data, the classification criteria are not met.

Respiratory or skin sensitisation

Germ cell mutagenicity

Carcinogenicity

Reproductive toxicity

STOT-single exposure

STOT-repeated exposure

Aspiration hazard

Based on the available data, the classification criteria are not met.

Based on the available data, the classification criteria are not met.

No component is considered carcinogenic.

Based on the available data, the classification criteria are not met.

Based on the available data, the classification criteria are not met.

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Based on the available data, the classification criteria are not met.

11.2 Information on other hazards

11.2.1. Endocrine disrupting properties

Does not apply to mixtures.

11.2.2. Other information

No other relevant information on health effects is available.

SECTION 12: Ecological information

12.1. Toxicity

For further information on environmental effects, see Section 2.1 (classification).

12.2. Persistence and degradability

No information available

12.3. Bioaccumulative potential

No information available

12.4. Mobility in soil

No information available

12.5. Results of PBT and vPvB assessment

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

12.6. Endocrine disrupting properties

Does not apply to mixtures.

12.7 Other adverse effects

No information is available on other adverse effects on the environment.

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

Pay attention to local and national regulations. Empty the container completely.

Uncontaminated packaging can be recycled.

Dispose of packaging that cannot be cleaned in the same way as the substance.

SECTION 14: Transport information

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

Unless otherwise specified, general measures for safe transport must be followed.

14.7. Maritime transport in bulk according to IMO instruments

Non-hazardous material according to transport regulations.

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 mixtures.

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. Z02/7E dated 31/01/2023 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 sheets.

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 for an updated version of the present sheet.

Hazard Statements

H317: May cause an allergic skin reaction.

Legend

CAS Chemical Abstracts Service

CLP Classification, labeling, and packaging (REGULATION (EC) No. 1272/2008 on classification, labeling, and packaging of substances and mixtures)

n.a. not applicable

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

OECD Organization for Economic Cooperation and Development org. organic

OSHA Occupational Safety and Health Administration (USA)

PBT persistent, bioaccumulative, and toxic

REACH Registration, Evaluation, Authorization, and Restriction of Chemicals (Regulation (EC) No. 1907/2006 concerning the registration, evaluation, authorization, and restriction of chemicals)

STOT RE 2: Specific target organ toxicity – repeated exposure, category 2.

STOT SE 3: Specific target organ toxicity – single exposure, category 3 – respiratory tract irritation.

TWA: time-weighted average.

vPvB: very Persistent very Bioaccumulative

STOT: Specific target organ toxicity

REACH: Registration, Evaluation, Authorization, and Restriction of Chemicals, Regulation (EC) No. 1907/2006.

IMO: International Maritime Organization.