



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

1.1. Product identifier

Product Description: Orthodontic solders.

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

Identified Use Material for the soldering of orthodontic devices with melting range: 630-660°C.

1.3. Details of the supplier of the safety data sheet

Leone s.p.a.

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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

This product is not classified as dangerous in accordance with Regulation (EC) No.1272/2008 (CLP) on classification, labelling and packaging of substances and mixtures. The product thus requires a safety data sheet according to Regulation (EU) no. 2020/878, as amended.

Further information on health and / or the environment are given in Sections 11 and Sections 12 of this sheet.

2.2. Label elements

No labeling required in accordance with Regulation (EC) no. 1272/2008 Annex-I-1.3.4.

2.3. Other hazards

Avoid inhaling the fumes that develop during brazing operations by using fume hoods and/or protective masks. Workers must use and carefully store the individual means of protection made available to them or in any case provided by the employer and comply with the safety regulations. Before the start of welding and brazing operations, workers must in any case be aware of the safety regulations to be observed and are obliged to scrupulously observe these regulations. The workers' bodies must be protected with suitable clothing. Welding and brazing operations can present a danger of developing dangerous metal oxides and metal fumes (fine particles in the millimetre range).

Avoid excessive heating of the product and/or workpieces to be brazed. Do not eat and/or drink at the workplace. According to available data, the product does not contain any PBT or vPvB substances above 0.1 %. The product does not contain SVHC substances. The product does not contain endocrine disrupting substances in concentrations $\geq 0.1\%$.

SECTION 3: Composition/information on ingredients

3.1. Substances

This product is a mixture.

3.2. Mixtures

Ingredients	% W/W	EC no.	CAS no.	Classification 1272/2008/EC (CLP)
Silver	54-56	231-131-3	7440-22-4	-
Zinc	22-24	231-175-3	7440-66-6	-
Copper	20-22	231-159-6	7440-50-8	-
Tin	1-3	231-141-8	7440-31-5	-

SECTION 4: First aid measures

There are no known hazardous effects on human health for the product as supplied, in solid form. However, compliance with good hygiene and safety regulations is recommended.

4.1. Description of first aid measures

Inhalation	Welding fumes: remove the person from the hazardous area and breathe fresh air. If symptoms persist, consult a doctor.
Skin contact	In case of contact with hot product: Use appropriate first aid methods.
Eye contact	Not likely, due to the solid form of the product. Welding fumes: Flush eyes for several minutes with running water, holding the eyelids wide open.
Ingestion	No likely, due to the solid form of the product

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

Welding fumes: Irritation of nose, throat, eyes, and mucous membranes. Inhalation of excessive amounts of copper and/or zinc oxide fumes can cause metal fume fever. Symptoms are similar to those of flu and appear after a latency period of up to 10 hours. Symptoms normally disappear within the next 24 hours.

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

Not available.



SECTION 5: Firefighting measures

The product is not flammable.

5.1. Extinguishing media

Suitable extinguishing Media General media: water, chemical powder, CO₂, etc.

Unsuitable extinguishing Media None.

5.2. Special hazards arising from the substance or mixture

Avoid breathing combustion products.

5.3. Advice for firefighters

General information:

Cool the product with water jets to prevent decomposition and the development of substances potentially hazardous to health. Collect extinguishing water which must not be discharged into drains. Dispose of contaminated extinguishing water and fire residue in accordance with current regulations.

Equipment:

Complete fire protection equipment.

SECTION 6: Accidental release measures

The product in its solid state presents no particular danger of accidental spillage.

6.1. Personal precautions, protective equipment, and emergency procedures

Generally unnecessary.

6.2. Environmental precautions

Do not allow product to reach sewage system, ground water levels or any water course.

6.3. Methods and material for containment and cleaning up

Collect the material manually.

The disposal of contaminated material must be made in accordance with the provisions of Section 13.

6.4. Reference to other sections

For information on safe handling, refer to Section 7.

For information on personal protective equipment, refer to Section 8.

For information on disposal, refer to Section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Handling the product as supplied, in its solid state, does not require any special precautions. However, it is recommended to handle the product after consulting all other sections of this MSDS. Do not eat, drink, or smoke during use. During use (brazing) avoid breathing the fumes that develop, ensuring adequate ventilation.

7.2. Conditions for safe storage, including any incompatibilities

Store in original packaging, in a dry, well-ventilated place.

7.3. Specific end uses

During brazing, keep the workplace well-ventilated or use appropriate mechanical air extraction methods. If necessary, wear a suitable respiratory mask.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Silver

Cas:7440-22-4

ACGIH 0,1 mg/m³ – TWA/8h

Copper

Cas: 7440-50-8

ACGIH 0,2 mg/m³ – TWA/8h Fume, as Cu

VME 1,0 mg/m³ – TWA 8/h

Predicted no-effect concentration for environment - PNEC

Reference value in fresh water: 7,8 µg/l.

Reference value in sea water: 5,2 µg/l.

Reference value for fresh water sediments: 87 mg/kg.

Reference value for sea water sediments: 676 mg/kg.

Reference value for STP Microorganisms: 230 µg/l.

Reference value for Terrestrial compartment: 65 mg/kg.



Health- derived no effect level- DNEL

Exposition way	Effects for the consumers		Effects for workers	
	Long systemic	Short systemic	Long systemic	Short systemic
Oral	41 µg/kg bw/d		137 mg/kg bw/d	
Dermic	137 mg/kg bw/d	273 mg/kg bw/d		273 mg/kg bw/d

Zinc

Cas:7440-66-6

MAK (DE) 0,1 mg/m³ – TWA/8h Breathable

MAK (DE) 0,4 mg/m³ – STEL/15 min

Tin

Cas:7440-31-5

ACGIH 2 mg/m³- TWA/8h

ACGIH 2,5 mg/m³ – STEL/15min

VLEP (FR) 10mg/m³ – TWA 8/h

Predicted no-effect concentration for environment - PNEC

Reference value in fresh water: 2 mg/l.

Reference value in sea water: 0,2 mg/l.

Reference value for STP Microorganisms: 55 mg/l

Health- derived no effect level- DNEL

Exposition way	Effects for the consumers	Effects for workers
	Long systemic	Long systemic
Oral	5 mg/kg bw/d	
Dermic	80 mg/kg bw/d	10 mg/kg bw/d
Inhalation	17 mg/m ³	71 mg/m ³

8.2. Exposure controls

Eye/face protection	It is advisable to wear sealed safety glasses with side shields (ref. Standard EN 166).
Hand protection	It is advisable to protect hands with work gloves.
Respiratory protection	Ensure a well-ventilated workplace by means of mechanical air extraction and/or exhaust air systems. If these measures are not sufficient to keep the concentration of the product below the exposure limit values, wear a suitable respirator.
Body protection	Waterproof safety footwear and professional, long-sleeved, waterproof work clothes are recommended (ref. EN 344).
General hygiene measures	No information available.

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	Yellowish.
Odour	Odourless.
pH:	Not available.
Melting point:	>630°C.
Boiling point	Not available.
Boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Solid an gas flammability	Not available.
Explosive limits (Lower)	Not available.



Explosive limits (Upper)	Not available.
Flammable limits (Lower)	Not available.
Flammable limits (Upper)	Not available.
Vapour tension	Not available.
Vapour density	8,8 – 9,6.
Solubility	Not available.
octanol-water partition coefficient	Not available.
Auto ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Explosive properties	Not available.
Oxidizing properties	Not available.

9.2. Other information

There is no additional information.

SECTION 10: Stability and reactivity

10.1. Reactivity

There are no risks of reaction with other substances in normal conditions of use.

10.2. Chemical stability

The product is stable in normal conditions of use and storage.

10.3. Possibility of hazardous reactions

In normal conditions of use and storage are not predictable hazardous reactions.

10.4. Conditions to avoid

None.

10.5. Incompatible materials

Information not available.

10.6. Hazardous decomposition product(s)

At high temperatures it can develop dangerous fumes.

SECTION 11: Toxicological information

In the absence of experimental toxicological data on the product itself any product health hazards were evaluated based on the properties of the substances contained, according to the criteria laid down by the relevant regulations for the classification. Consider, therefore, the concentrations for the individual dangerous substances listed in Section 3, to assess toxicological effects resulting from exposure to the product.

Acute effects: exposure to fumes is harmful to the health of the operator, causing rapid poisoning by exposure to metal oxides; it can be harmful by dermal absorption and ingestion. By inhalation of the product, poisoning may manifest itself, depending on the case, with different symptoms, which may include burning and irritation of the eyes, mouth, nose and throat, coughing, difficulty breathing, dizziness, headache, nausea, and vomiting. In severe cases, inhalation of the product may cause inflammation and oedema of the larynx and bronchi, chemical pneumonia, and pulmonary oedema, increased or decreased heart rate, excessive salivation or sputum of blood, loss of consciousness, behavioural disturbances (depression or euphoria). Fumes from the welding process may cause irritation of the eyes and skin.

11.1. Information on toxicological effects

Metabolism, kinetics, mechanism of action and other information

No information available.

Information on likely routes of exposure

The product is supplied in a solid state and is intended for use as a brazing filler material: the most likely route of exposure is inhalation during product use (melting of the brazing alloy).

Immediate, delayed, and chronic effects from short- and long-term exposure

See section 4.2.

Interactive effects

No information available.

Acute toxicity

Substance	CAS	Method	Value	Unit of measure/Notes
Ag-Cu-Zn-Sn		LD50- oral LC50- inhalation LD50-dermic	Not classified Not classified Not classified	
Silver	7440-22-4	LD50-oral LC50-inhalation LD50-dermic	>2000	Mg/kg - Rat



Copper	7440-50-8	LD50- oral LC50- inhalation LD50-dermic	>2000	Mg/kg - Rat
Zinc	7440-66-6	LD50- oral LC50- inhalation LD50-dermic		
Tin	7440-31-5	LD50- oral LC50- inhalation LD50-dermic	>2000 >5 >2000	Mg/kg – Rat Mg/1/4h – Rat Mg/kg – Rat

Skin corrosion / skin irritation

Does not meet the classification criteria for this hazard class.

Serious eye damage / eye irritation

Does not meet the classification criteria for this hazard class.

Respiratory or skin sensitisation

Does not meet the classification criteria for this hazard class.

Germ cell mutagenicity

Does not meet the classification criteria for this hazard class.

Carcinogenicity

Does not meet the classification criteria for this hazard class.

Reproductive toxicity

Does not meet the classification criteria for this hazard class.

Specific Target Organ Toxicity (STOT) - Single Exposure

Does not meet the classification criteria for this hazard class.

Specific Target Organ Toxicity (STOT) - Repeated Exposure

Does not meet the classification criteria for this hazard class.

Aspiration hazard

Does not meet the classification criteria for this hazard class.

11.2 Information on other hazards

Based on available data, the product does not contain any substances on the main European lists of potential or suspected endocrine disruptors with effects on human health under evaluation.

SECTION 12: Ecological information

12.1. Toxicity

SUBSTANCE	CAS	METHOD	VALUE	UNIT OF MEASURES	NOTES
Silver	7440-22-4	LC10-Fish LC50- Fish EC10-Crustaceans EC50-Crustaceans EC10-Algae/Aquatic Plants EC50- Algae/Aquatic Plants NOEC-Fish NOEC- Crustaceans NOEC- Algae/Aquatic Plants			
Copper	7440-50-8	LC10- Fish LC50- Fish EC10- Crustaceans EC50- Crustaceans EC10- Algae/Aquatic Plants EC50- Algae/Aquatic Plants NOEC-Fish NOEC- Crustaceans NOEC Algae/Aquatic Plants	193	µg/l	Pimephales promelas



Zinc	LC10- Fish	7,1	Mg/1/96h	Nothobranchius guentheri
	LC50- Fish			
	EC10- Crustaceans	2,8	Mg/1/48h	Daphina magna
	EC50- Crustaceans			
Tin	EC10- Algae/Aquatic Plants	0,015	Mg/1/72h	Pseudokirchneriella subcapitata
	EC50- Algae/Aquatic Plants			
	NOEC- Fish			
	NOEC- Crustaceans			
	NOEC- Algae/Aquatic Plants			
Tin	LC10- Fish	>12,4	µg/1	Pimephales promelas
	LC50- Fish			
	EC10- Crustaceans	1303	µg/1	Daphina magna
	EC50- Crustaceans			
	EC10- Algae/Aquatic Plants	>19,2	µg/1	Pseudokirchneriella subcapitata
	EC50- Algae/Aquatic Plants			
	NOEC- Fish			
NOEC- Crustaceans				
NOEC- Algae/Aquatic Plants				

12.2. Persistence and degradability

Information not available.

12.3. Bioaccumulative potential

Information not available.

12.4. Mobility in soil

Information not available.

12.5. Results of PBT and vPvB assessment

According to the available data, the product does not contain any PBT or vPvB substances above 0.1%.

12.6. Endocrine-disrupting properties

Based on available data, the substance is not listed in the main European lists of potential or suspected endocrine disrupters with environmental effects under evaluation.

12.7. Other adverse effects

Information not 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. According to European Directive 2008/98/EC, waste does not require special supervision.

13.1. Waste treatment methods

Reuse if possible.

The hazardousness of waste containing some of this product must be assessed in accordance with current legislation. Disposal must be performed through an authorized waste management firm, in compliance with national and local regulations.

Contaminated packaging

Not relevant information.

SECTION 14: Transport information

The product is not to be regarded as dangerous in the sense of the regulations in force for the transport of dangerous goods by road (A.D.R.), by rail (ADR), by sea (IMDG Code) and by air (IATA).

14.1. UN-number or ID Number

Not applicable.

14.2. Shipping name ONU

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. Maritime transport in bulk according to IMO Acts

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.

Category Seveso - Directive 2012/18/EU

None

Restrictions related to the product or contained substances according to Annex XVII EC Regulation 1907/2006

Points 75

Regulation (EU) 2019/1148 on the marketing and use of explosives precursors

Not applicable

Substance on Candidate List (Art. 59 REACH)

According to the available data, the product does not contain SVHC substances in a percentage above 0.1%.

Substances subject to authorization (Annex XIV REACH)

None

Substances subject to export notification - Regulation (EU) 649/2012

None

Substances subject to the Rotterdam Convention

None

Substances subject to the Stockholm Convention

None

Health Controls

Information not available.

15.2. Chemical safety assessment

A chemical safety assessment was not prepared for the mixture and the substances it contains.

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. R09/6E 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.

This safety data sheet is subject to revision. Visit our web site www.leone.it for an updated version of the present sheet.

Legend

ACGIH: American Conference of Governmental Industrial Hygienists.

CAS No.: Chemical Abstract Service Registry number.

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

EN166 Personal eye protection – Specifications.

LC50: Lethal Concentration 50: lethal concentration of substance for 50% of organisms of a certain population during a certain exposure period.

LD50 Lethal Dose 50: the dose required to kill half the members of a tested population after a specified test duration.

PBT: Persistent, Bioaccumulative And Toxic Substances.

STEL: Short Term Exposure Limit.

TWA: Time Weighted Average.

vPvB: Very Persistent And Very Bioaccumulative Substances.



NOEC: Concentration with no observed (adverse) effects.

SVHC: Substances that may have serious effects on human health and the environment.

EN 344: General requirements and test methods for safety shoes, protective shoes and work shoes for professional use.

EC10: Effect concentration for 10% of the sample.

EC50: Concentration to produce 50% of the maximum effect.

LC10: Lethal concentration for 10% of the sample.

IMO: International Maritime Organisation.

IMDG: International Maritime Dangerous Goods Code.

MAK: Maximum workplace concentration.

VLEP: Occupational exposure limit value for chemicals in France.