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

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.
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

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 >=0.1%.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

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

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 use(s)

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/m^3 – TWA/8h

Copper
Cas: 7440-50-8
ACGIH 0,2 mg/m^3 – TWA/8h Fume, as Cu
VME 1,0 mg/m^3 – TWA 8/h

Predicted no-effect concentration for environment - PNEC
Reference value in fresh water: 7,8 µg/1.
Reference value in sea water: 5,2 µg/1.
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/1.
Reference value for Terrestrial compartment: 65 mg/kg.

Health- derived no effect level- DNEL

	Effects for the consumers		Effects for workers	
Exposition way	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/m^3 – TWA/8h Breathable
MAK (DE) 0,4 mg/m^3 – STEL/15 min

Tin
Cas:7440-31-5
ACGIH 2 mg/m^3- TWA/8h
ACGIH 2,5 mg/m^3 – STEL/15min
VLEP (FR) 10mg/m^3 – TWA 8/h

Predicted no-effect concentration for environment - PNEC
Reference value in fresh water: 2 mg/1.
Reference value in sea water: 0,2 mg/1.
Reference value for STP Microorganisms: 55 mg/1

Health- derived no effect level- DNEL

	Effects for the consumers	Effects for workers
Exposition way	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
8.2.2. Individual protection measures, such as personal protective equipment
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.

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	Yellowish.
Odour	Odourless.
Odor threshold	Not established.
Melting point	>630°C.
Boiling point or initial boiling point and boiling range	Not available.
Flammability	Not available.
Lower and upper explosion limit	Not available.
Flash point	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
pH	Not available.
Kinematic viscosity	Not available.
Solubility	Not available.
Partition coefficient n-octanol/water (log value)	Not available.
Vapour pressure	8,8 – 9,6.
Density and/or relative density	Not available.

Relative vapour density	Not available.
Particle characteristics	Not available.

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Explosive properties	Not available.
Oxidising properties	Not available.

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 products

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 hazard classes as defined in Regulation (EC) No 1272/2008

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

11.2.1. Endocrine disrupting properties

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

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 including those of Decree-Law No. 153 of 17 October 2024.
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 (RID), by sea (IMDG Code) and by air (IATA).
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
Not applicable.
14.7. Maritime transport in bulk according to IMO instruments
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.

Restrictions related to the product or contained substances according to Annex XVII EC Regulation 1907/2006
Points 75
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 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. R09-7E dated 16/10/2023 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.

Legend

ACGIH: American Conference of Governmental Industrial Hygienists.
ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.
CAS No.: numerical identifier that uniquely identifies a chemical substance, assigned by the Chemical Abstract Service.
CLP: Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008.
EC-Number: EINECS and ELINCS Number (see also EINECS and ELINCS).
EC10: Effect concentration for 10% of the sample.
EC50: 50 % effective concentration. Corresponds to the concentration of a tested substance capable of causing 50 % effect changes (e.g. on growth) during a specified time interval.
EN166 Personal eye protection – Specifications.
EN344: Safety footwear, protective footwear and work footwear for professional use - Additional requirements and test methods.
IATA : International Air Transport Association.
IMDG Code: International Maritime Dangerous Goods Code.
IMO: International Maritime Organisation.
LC10: Lethal concentration for 10% of the sample.
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.
MAK: Maximum concentration in the workplace.
NOEC: Concentration with no observed (adverse) effects.
PBT: Persistent, Bioaccumulative And Toxic Substances.
REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006.
RID: Regulations concerning the International Carriage of Dangerous Goods by Rail.
STEL: Short Term Exposure Limit.
STP: Waste water treatment plant.
SVHC: Substances that may have serious effects on human health and the environment.
TWA: Time-weighted average concentration of a chemical agent in the air within the breathing zone of a worker for an 8-hour working day.
VLEP: Occupational exposure limit value for chemicals in France.
VME: Average exposure value.
vPvB: Very Persistent And Very Bioaccumulative Substances.