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.
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

This product is 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 (EC) no. 1907/2006, 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.

Hazard Statements	EUH210	To avoid risks to human health and the environment, comply with the instructions for use.
Precautionary Statements	P101	If medical advice is needed, have product container or label at hand.
	P102	Keep out of reach of children.
	P103	Read label before use.
	P201	Obtain special instructions before use.
	P263	Avoid contact during pregnancy/while nursing.
	P280	Wear protective gloves/protective clothing/eye protection/face protection.
	P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.

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

Ingredients	%W/W	EC no.	CAS no.	Hazard Class and Category Code(s)	Hazard statement Codes()
Silver	54-56	231-131-3	7440-22-4	-	-
Zinc	22-24	231-175-3	7440-66-6	Aquatic Chronic 4	H413 EUH401
Copper	20-22	231-159-6	7440-50-8	-	-
Tin	1-3	231-141-8	7440-31-5	-	-

SECTION 4: First aid measures

4.1. Description of first aid measures

No episode of damage to the personnel assigned to use the product. In case of necessity, will adopt the following general measures.

Inhalation	IF INHALED: Fresh air supply (e.g. if possible move outdoors). If necessary, apply artificial respiration, consult a doctor.
Skin contact	IF ON SKIN (or hair): Wash with copious water. If the irritation persists, call a physician.
Eye contact	IF IN EYES: Wash with copious water. If the irritation persists, call a physician.
Ingestion	Consult physician immediately. Induce vomiting only under physician instruction. Do not give anything orally without medical authorization if subject is unconscious.

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

No episodes of damage to health ascribable to the product have been reported.

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

Not available.

SECTION 5: Firefighting measures

5.1. Extinguishing media

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

Fire or explosion hazards. The product is non-flammable and non-combustible.

5.3. Advice for firefighters

Protective clothing for fire-fighting as a self-contained, open-circuit compressed air breathing apparatus (ref. standard EN 137). Flameproof equipment (EN 469) fireproof boots (HO A29or A30).

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid the formation of dust spraying the product with water, if there are not contraindications. DO NOT breathe vapors/mists and gases. Wear suitable protective equipment to prevent contamination of the skin, eyes and clothing (See Section 8). These information are valid for workers and emergency operations.

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 spillage using no sparkling mechanical means the leaked product, place it in containers for recovery and disposal. Eliminate the remainder using jets of water if there are no contraindications. Ensure adequate ventilation of the contaminated place. Check the compatibility of the material of the containers in Section 7. The disposal of contaminated material must be made in accordance with the provisions of Section 13.

6.4. Reference to other sections

See Section 8 and Section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Handle the product after consultation with all other sections of this SDS. Avoid discharges into the environment. Do not eat, drink or smoke during use. Wash hands after use.

7.2. Conditions for safe storage, including any incompatibilities

Keep the product in clearly labeled containers. Store in closed containers in well-ventilated area, out of direct sunlight.

7.3. Specific end uses

Welding and soldering: Refer to the safety regulations for each type of heating method. Make sure in any case the presence of a suction system fumes. Use appropriate clothing to end use (heat protective gloves, glasses with special UV protection, safety shoes, fireproof clothing).

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

	Type threshold value	TWA/8h	STEL/15 min	
Granular silver	TLV-ACGIH	0.1 mg/m^3.		
Zinc	TLV-ACGIH	0.1 mg/m^3.	0.4 mg/m^3.	Breathable.
Copper	TLV-ACGIH	0.2 mg/m^3.	2 mg/m^3.	Inhalable.
Tin	TLV-ACGIH	2 mg/m^3.		

8.2. Exposure controls

Whereas the use of adequate technical equipment must always take priority over personal protection equipment, ensure good ventilation in the workplace through effective local aspiration.

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

Eye/face protection — Wear protective airtight goggles (ref. Standard EN 166).

Hand protection — In case of prolonged contact with the product, use work gloves resistant to penetration (ref. Standard EN 374). For the final selection of glove's material evaluate the process and any additional products derived from it. Please remember that the latex gloves may result in irritation phenomena.

Respiratory protection — If the threshold value for one or more of the substances present in the preparation is exceeded, wear a facial mask with FFP1 filter class or higher, according to risk management procedure (standard EN 149). The use of respiratory tract protection equipment is necessary to reduce worker exposure in absence of technical measures to reduce the exposure value considered. The protection provided by masks is in any case limited. If the substance is odorless or its olfactory threshold is higher than the related TLV-TWA, and in case of emergency, wear a compressed air breathing apparatus open circuit (ref. Standard EN 137) or a respirator in socket outdoor air (ref. EN138 standard). For the correct choice of respiratory protection device, refer to standard

	EN529.
Body protection	Wear work clothes with long sleeves and safety footwear for professional use category I (ref. Directive 89/686 / EEC and standard EN ISO 20344). Wash with soap and water after removing protective clothing.

Environmental exposure controls

Emissions from production processes, including those from ventilation should be checked for compliance of environmental protection legislation. Product residues should not be discharged without control in the sewage system or water courses.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Solid.
Colour	Silver.
Odour	Odourless.
pH:	Not applicable.
Melting point:	>650°C.
Boiling point	Not applicable.
Boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not applicable.
Solid an gas flammability	Not applicable.
Explosive limits (Lower)	Not applicable.
Explosive limits (Upper)	Not applicable.
Flammable limits (Lower)	Not available.
Flammable limits (Upper)	Not available.
Vapour tension	Not available.
Vapour density	Not available.
Solubility	Insoluble.
octanol-water partition coefficient	Not applicable.
Auto ignition temperature	Non applicable.
Decomposition temperature	999°C.
Viscosity	Not applicable.
Explosive properties	Not applicable.
Oxidizing properties	Not applicable.

9.2. Other information

No other information.

SECTION 10: Stability and reactivity

10.1. Reactivity

There are no particular 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.

Zinc powder, risk of explosion with: ammonium nitrate, ammonium sulfide, barium peroxide, lead azide, chlorates, chromium trioxide, sodium hydroxide solutions, oxidizing agents, performic acid, acids, tetrachloromethane, water. Can react dangerously with: alkali hydroxides, bromine pentafluoride, calcium chloride in solution, fluorine, hexachloroethane, nitrobenzene, potassium dioxide, carbon disolfluoro, silver. It reacts with Acids and strong alkalis developing hydrogen.

10.4. Conditions to avoid

None in particular, however the usual precautions used for chemical products should be respected.

10.5. Incompatible materials

Powder Zinc: strong alkalis, strong acids and water.

10.6. Hazardous decomposition product(s)

Information not available.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

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.

SECTION 12: Ecological information

12.1. Toxicity

Zinc
LC50-fish: 7.1 mg/l/96h Nothobranchius guentheri.
EC50- crustaceans: 2.8 mg/l/48h Daphnia magna.
EC50- algae and aquatic plants: 0.015 mg/l/72h Pseudokirchneriella subcapitata.

12.2. Persistence and degradability

Zinc
Solubility in water: 0.1-100 mg/l.
Biodegradability: not available.
Copper
Solubility in water: <0.1 mg/l.
Biodegradability: not available.

12.3. Bioaccumulative potential

The product has low potential for bioaccumulation.

12.4. Mobility in soil

The product is predicted to have high mobility in soil.

12.5. Results of PBT and vPvB assessment

Not classified as PBT or vPvB.

12.6. Other adverse effects

No other information.

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

For solid waste, consider the possibility of a sanitary landfill disposal. Disposal must be performed through an authorized waste management firm, in compliance with national and local regulations.
Uncleaned packaging
Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

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.
Seveso Category: 9i
D. Lgs. 152/2006 and amendments

Emissions according part V attached I
Tab. B Class 3 21%

15.2. Chemical safety assessment

No chemical safety assessment has been carried out.

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. R09/5E dated 16/01/2017 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.

Frasi H

H413: May cause long-lasting harmful effects to aquatic life.
EUH401:To avoid risks to human health and the environment, comply with the instructions for use.

Legend

ACGIH: American Conference of Governmental Industrial Hygienists.
CAS No.: Chemical Abstract Service Registry number.
EC No.: European Inventory of Existing Commercial Chemical Substances.
EC50: Half maximal Effective Concentration: Refers to the concentration of toxicant which induces a response halfway between the baseline and maximum after a specified exposure time.
EN ISO 20344: Personal protective equipment - Test methods for footwear.
EN137 Respiratory protective devices. Self-contained open-circuit compressed air breathing apparatus with full face mask. Requirements, testing, marking.
EN138: Respiratory protective devices. Specification for fresh air hose breathing apparatus for use with full face mask, half mask or mouthpiece assembly.
EN149 Respiratory protective devices. Filtering half masks to protect against particles. Requirements, testing, marking.
EN166 Personal eye protection – Specifications.
EN469: Protective clothing for firefighters. Performance requirements for protective clothing for firefighting.
EN529 Respiratory protective devices - Recommendations for selection, use, care and maintenance - Guidance Document.
HOA29/A30: UK Home Office specification A29 (rubber boots) or A30 (leather boots).
IBC Code: International Bulk Chemicals Code.
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.
TLV: Threshold Limit Value.
TWA: Time Weighted Average.
vPvB: Very Persistent And Very Bioaccumulative Substances.
WEL: Work Place Exposure Limits.