

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

**1.1. Product identifier** 

Product Description: Solders for stainless steel.

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

Identified Use Professional use: Material for the soldering of orthodontic devices with melting range: 680-705°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: <u>research@leone.it</u> – <u>http://www.leone.it</u> 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 (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.

Carcinogenicity, cat. 2	H351
Specific target organ toxicity (STOT) – Repeated exposure, cat. 2	H373
Skin sensitizing, cat. 1	H317

#### 2.2. Label elements

Exempt from labelling according to 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 products 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**

#### 3.1. Substances

3.2. Mixtures

This product is a mixture.

Ingredients	%W/W	EC no.	CAS no.	Hazard class(es) and category code(s)	H statements
Silver	49	231-131-3	7440-22-4	-	-
Copper	16	231-159-6	7440-50-8	-	-
Zinc	23	231-175-3	7440-66-6	-	-
Manganese	7,50	231-105-1	7439-96-5	-	-
Nickel	4,50	231-111-4	7440-02-0	Carcinogenicity, cat.2 STOT RE. 1 Skin Sens 1	H351 H372 H317

## **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 let them 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: rinse eves for a few minutes with running water, holding the evelids wide open.					



Ingestion Not likely, given the solid form of the product.

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

Welding fumes: irritation of the nose, throat, eyes, and mucous membrane. 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 ten hours. Symptoms normally disappear within the next 24 hours.

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

Avoid the formation of dust spraying the product with water if there are no contraindications.

Wear appropriate personal protective equipment.

**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 Type threshold value: ACGIH-TWA. TWA/8h: 0.1 mg/m<sup>3</sup>

Copper

Cas: 7440-50-8 Type threshold value: ACGIH-TWA. TWA/8h: 0.2 mg/m<sup>3</sup> Fume, as Cu VME-TWA = TWA/8h: 1.0 mg/m3



Predicted no-effect concentration for environment - PNEC Reference value in fresh water: 7.8 mg/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

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

## Zinc

Cas: 7440-66-6 Type threshold value: MAK-TWA(DE) TWA/8h: 0,1 mg/m3 Breathable MAK-STEL(DE) = STEL/15 min: 0.4 mg/m3

## Manganese

Cas: 7439-96-5 Type threshold value: TLV-TWA(DK) TWA/8h: 0.1 mg/m3 Breathable TLV-STEL(DK) = STEL 15 min: 0.2 mg/m3 VLEP-TWA(FR)= TWA/8h: 1 mg/m3 Breathable TLV-TWA = TWA/8h: 0.5 mg/m3 Breathable TLV-STEL = STEL/15 min: 3 mg/m3 NGV/KGV-TWA = TWA/8h: 0.2 mg/m3 Breathable

Predicted no-effect concentration for environment - PNEC Reference value in fresh water: 0.034 mg/1. Reference value in sea water: 0.003 mg/l. Reference value for fresh water sediments: 3.3 mg/kg/d. Reference value for sea water sediments: 0.34 mg/kg/d. Reference value for fresh water, intermittent release: 0.028 mg/1. Reference value for STP Microorganisms: 100 mg/1. Reference value for Terrestrial compartment: 3.4 mg/kg/d.

Health- derived no effect level- DNEL

	Effects for the consumers		Effects for workers		
Exposition way	Long Local	Long systemic	Long Local	Short Local	Long Systemic
Inhalation	0.041 mg/m3	0.041 mg/m3	0.2 mg/m3	0.2 mg/m3	$0.2 \text{ mg/m}^3$ .
Dermic					0.004 mg/kg bw/d

## Nickel

Cas:7440-02-0 Type threshold value: ACGIH-TWA TWA/8h: 1,5 mg/m<sup>3</sup> Inhalable VLEP-TWA(B)= TWA/8h: 0,2 mg/m<sup>3</sup> Inhalable TLV-TWA(BG)= TWA/8h: 0,05 mg/m<sup>3</sup> Breathable VME/VLE-TWA(CH)= TWA/8h: 0,05 mg/m<sup>3</sup> TLV-TWA(CZ)= TWA/8h: 0,05 mg/m<sup>3</sup> TLV-STEL(CZ)= STEL 15 min: 1 mg/m<sup>3</sup> AGW-TWA(D)= TWA/8h: 0,006 mg/m<sup>3</sup> AGW-STEL(D)= STEL 15 min: 0,048 mg/m<sup>3</sup> TLV-TWA(DK)= TWA/8h: 0,05 mg/m<sup>3</sup> VLA-TWA(E)= TWA/8h: 1 mg/m<sup>3</sup> TLV-TWA(EST)= TWA/8h: 0,5 mg/m<sup>3</sup> VLEP-TWA(FR)= TWA/8h: 1 mg/m<sup>3</sup>



HTP-TWA(FIN)= TWA/8h: 1 mg/m<sup>3</sup>  $AK-TWA(H) = TWA/8h: 0,1 \text{ mg/m}^3$ AK-STEL(H) =STEL 15 min: 0,1 mg/m<sup>3</sup> GVI/KGVI- $TWA(HR) = TWA/8h: 0.5 \text{ mg/m}^3$  $OELV-TWA(IRL) = TWA/8h: 0.5 \text{ mg/m}^3$  $RD-TWA(LT) = TWA/8h: 0.5 \text{ mg/m}^3$  $RV-TWA(LV) = TWA/8h: 0.05 \text{ mg/m}^3$ TLV-TWA(N) = TWA/8h:  $0.05 \text{ mg/m}^3$  $TGG-TWA(NL) = TWA/8h: 0.1 \text{ mg/m}^3$ NDS/NDSCh-TWA(PL) = TWA/8h:  $0,25 \text{ mg/m}^3$ TLV-TWA(RO)= TWA/8h:  $0,1 \text{ mg/m}^3$ TLV-STEL(RO) = STEL 15 min:  $0.5 \text{ mg/m}^3$ NGV/KGV-TWA(S)= TWA/8h: 0,5 mg/m<sup>3</sup> NPEL-TWA(SK)= TWA/8h: 0,5 mg/m<sup>3</sup> MW-TWA(SLO)= TWA/8h: 0,5 mg/m<sup>3</sup>Inhalable MW-STEL(SLO) =STEL 15 min: 2 mg/m<sup>3</sup> WEL-TWA(UK) = TWA/8h:  $0.5 \text{ mg/m}^3$ 

Predicted no-effect concentration for environment - PNEC Reference value in fresh water: 0.0071 mg/1. Reference value in sea water: 0.0086 mg/1. Reference value for fresh water sediments: 109 mg/kg/d. Reference value for sea water sediments: 109 mg/kg/d. Reference value for STP Microorganisms: 0.3 mg/1. Reference value in food chain: 0.12 mg/kg. Reference value for Terrestrial compartment: 29.9 mg/kg/d.

#### Health- derived no effect level- DNEL

	Effects for the consumers		Effects for workers		
Exposition way	Long Local	Long systemic	Long Local	Short Local	Long Systemic
Inhalation	0.06 mg/m3	0.06 mg/m3	0.05 mg/m3	11.9 mg/m3	0.05 mg/m3
Dermic	0.035 mg/cm2		0.035 mg/cm2		
Oral		0.011 mg/kg bw/d			

## 8.2. Exposure controls

Eye/face protection	It is advisable to wear sealed safety glasses with side protectors (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 product concentration 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	Information not available.

Environmental exposure controls Information not 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:	>680°C.			
Boiling point	Not available.			



**Boiling** range Not available. Flash point Evaporation rate Explosive limits (Upper) Explosive limits (Lower) Flammable limits (Upper) Flammable limits (Lower) Vapour tension Vapour density Solubility Octanol-water partition coefficient Auto ignition temperature Decomposition temperature Viscosity Explosive properties Oxidizing properties 9.2. Other information

Not available. Not available.

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.

# **11. 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 id harmful to the health of the operator, causing rapid poisoning by exposure to metal oxides; may 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 Information not 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 Information not available.



Acute toxicity

Substance	CAS	Method	Value	Unit of measures / notes
Ag-Cu-Zn-Mn- Ni		LD50- oral LC50- inhalation LD50-dermic	Not classified Not classified Not classified	i
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		
Manganese	7439-96-5	LD50- oral LC50- inhalation LD50-dermic	>2000 >5,14	Mg/kg – Rat Mg/1/4h
Nickel	7440-02-0	LD50- oral LC50- inhalation LD50-dermic	>9000	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 sensitization Skin sensitization

<u>Germ cell mutagenicity</u> Does not meet the classification criteria for this hazard class.

<u>Carcinogenicity</u> Suspected of causing cancer.

<u>Reproductive toxicity</u> Does not meet the classification criteria for this hazard class.

<u>Specific Target Organ Toxicity (STOT) - Single Exposure</u> Does not meet the classification criteria for this hazard class.

<u>Specific target organ toxicity (STOT) - Repeated Exposure</u> Causes damage to organs.

<u>Aspiration hazard</u> 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 disrupters with effects on human health under evaluation.



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# **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
Manganese		LC10- Fish LC50- Fish EC10- Crustaceans EC50- Crustaceans EC10- Algae/Aquatic Plants EC50- Algae/Aquatic Plants NOEC- Fish NOEC- Crustaceans NOEC- Algae/Aquatic Plants	>3,6 >1,6 4,5	Mg/1/96h Mg/1/48h Mg/1/72h	Oncorhynchus mykiss Daphina magna Desmodesmus subspicatus
Nickel		LC10- Fish LC50- Fish EC10- Crustaceans EC50- Crustaceans EC10- Algae/Aquatic Plants EC50- Algae/Aquatic Plants NOEC- Fish NOEC- Crustaceans NOEC- Algae/Aquatic Plants			

## 12.2. Persistence and degradability

Information not available.

12.3. Bioaccumulative potential

Information not available.

12.4. Mobility in soil

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 in percentages 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 effects on the environment under evaluation.

# 12.7. 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

Reuse if possible.

The hazardousness of waste containing some of this product must be assessed in accordance with current legislation. Disposal must be entrusted to a company authorized to handle waste, in accordance with national and possibly local regulations.

<u>Contaminated packaging</u>. 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, labelling 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 27 Nickel 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. R10/9E 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 <u>www.leone.it</u> for an updated version of the present sheet.

#### Hazard statements

Text of the hazard statements (H) mentioned in sections 2 and 3 of the sheet:

H351: Suspected of causing cancer.

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

H317: May cause allergic skin reaction.

## Legend

ACGIH: American Conference of Governmental Industrial Hygienists.

CAS No.: Unique numerical identifier assigned by Chemical Abstracts Service.

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.

STOT RE: Specific target organ toxicity - repeated exposure.

TLV: threshold limit value.

TWA: Time weighted average.

vPvB: Very Persistent And Very Bioaccumulative Substances.

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.

VLEP: Occupational exposure limit value for chemicals in France.

OEL: Occupational Exposure Limit.

MAK: Maximum Workplace Concentration.

WEL: Occupational Exposure Limit Value.

IMDG: International Maritime Code for the Transport of Dangerous Goods.

NOEC: Concentration with no observed (adverse) effects.