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1. Identification of the preparation and of the company

1.1 Identification of the preparation

Orthodontic solders.

1.2 Use of the preparation

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

1.3 Company identification

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 (0)55.30.44.1 - Fax ++39 (0)55 374808.

1.4 Emergency telephone

++39 (0)55.30.44.1. An answering machine is on during closing time.

2. Hazards identification

Hazards regarding the brazing alloys depend on the way of use. Little quantities of metal fumes and oxides may be generated during heating, but within the limits allowed. Anyway, given the risk of metal fume oxidation, it is recommended to provide suitable protective equipment and a good local exhaust during working.

Overheating of the alloys may liberate dangerous concentration of fumes.

3. Composition/information on ingredients

Silver based brazing alloy.

Information on ingredients and composition %

Chemical name	EC ¹ Number	%	CAS ² Number	Hazard symbols ³	R ³ Phrases
Silver	231-131-3	55	7440-22-4	-	-
Copper	231-159-6	21	7440-50-8	-	-
Zinc	231-175-3	22	7440-66-6	F	R15-17
Tin	231-141-8	2.0	7440-31-5	-	-

4. First aid measures

- Inhalation: inhalation of large quantities of zinc oxide fumes and /or copper and zinc oxide fumes may cause metal fume fever. Symptoms are similar to the flue ones and appear after a latency period that can last up 10 hours. Usually symptoms disappear within the following 24 hours.

If large quantities of fumes are inhaled, remove to the open air. If necessary seek for medical help.

- Ingestion: not applicable.
- Eye contact: not applicable.
- Skin contact: a prolonged skin contact with metal alloys may cause sensitisation

5. Fire-fighting measures

Not inflammable. Protect breathing tract from fumes generated by alloys in melted state.

Explosion hazards are not known.

6. Accidental release measures

Not applicable.

7. Handling and storage

No special precautions are required. A proper storage is recommended in order to avoid material contamination.

8. Exposure controls/personal protection

8.1. Exposure limit value⁴

European Union. Silver, professional exposure limits (TWA): 0.1 mg/m³ (ACGIH⁵: 0.01 mg/m³).

European Union. Copper fumes (as Cu), professional exposure limits (TWA): 0.2 mg/m³.

³ Hazards related to the ingredients of the product are indicated in section 2, information to be shown on the label are indicated in section 15. Explanation of hazardous symbols and Risk phrases is indicated in section 15 and 16.

¹ Number of European Catalogue. The EC number is made of a sequence of 7 figures, whose first group of 3 figures begins with 2 or 4 depending on which substance is included in the EINECS (European Inventory of Existing Commercial Chemical Substances) or in the ELINCS (European List of Notified Chemical Substances), or it begins with 5 if the substance is included in the list of "ex-polymers."

² CAS Number (Chemical abstract service).

⁴ The "occupational exposure limit", if not otherwise specified, is the average limit or serious concentration in the time of a chemical agent in the air inside the breathing area of a worker related to a specific period of time (Directive 98/24/EC on health and safety protection of the workers against the consequential risks from chemical agents during the job); the TWA (time weighted average) indicator is the serious average concentration in the time for a working day of 8 hours..

⁵ ACGIH: American Conference of Governmental Industrial Hygienists, USA.



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European Union. Zinc oxide fumes (as Zn), professional exposure limits (TWA): 5.0 mg/m³; short term exposure limit (STEL⁶): 10.0 mg/m³.

European Union. Inorganic compounds of tin (as Sn), professional exposure limits (TWA): 2.0 mg/m³; short term exposure limit (STEL): 4.0 mg/m³.

8.2.2. Exposure controls

Periodic controls of the workplace are recommended in order to not exceed maximum levels of exposition to polluting substances. Controls must be done by using personal samplers to be worn by the workers or portable samplers positioned in the working area of the brazing staff.

9. Physical and chemical properties

9.1. General information

Appearance: solid form in wire, tape, rod

Odour: not applicable.

9.2. Health, safety and environmental information

pH: not applicable
Flash point: not applicable
Explosive properties: not applicable
Comburent properties: not applicable
Melting range: 630-660°C.

10. Stability and reactivity

Stable under normal conditions of temperature and pressure.

Incompatibility: not determined.

Conditions to avoid: uncontrolled exposure at high temperatures.

Hazardous decomposition products: heavy metal oxides.

Polymerization risks: not determined.

11. Toxicological information

Some toxicological information on ingredients at section 3.

Italy. Zinc and copper are part of the substances listed by Decree no. 482 dated June 9 1975 for the acknowledgement of occupational diseases caused by metals and metal alloys.

Italy. Zinc is part of the substances listed by Decree DM April 27 2004, concerning the obligation to notify any occupational disease.

During working process a breathing apparatus suited to protect from welding fumes (activated carbons) should be worn by workers at risk of inhalation. The type of breathing apparatus to be used has to be decided on the basis of the surveys made in the workplace.

A good local exhaust should be provided during welding procedures.

12. Ecological information

In case the local aspiration is canalized to outdoor, exhaust is subject to national and local regulations. In Italy operate in accordance with the D.P.R. no. 203 dated May 24 1988.

Verify the applicability of possible simplified procedures.

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.

It is a special, non-hazardous waste.

14. Transport information

The product is not classified as dangerous to transport.

15. Regulatory information

- Health, safety and environmental information shown on the label according to European Directives on hazardous materials and substances

None.

- Information related to further dispositions

This product is CE marked in accordance with the essential requirements of 93/42EEC Directive, Annex I, on medical devices.

⁶ STEL, Short Term Exposure Limit, generally calculated at 15 minutes.



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16. Other information

The safety data sheet has been written according to relevant European provisions, on the basis of information received by the supplier of preparation.

Hazard symbols or risk phrases shown on section 3, and safety phrases:

Hazard symbols: F Easily flammable

Risk phrases: R15 Contact with water liberates extremely flammable gases

R17 Spontaneously flammable in air

Safety phrases: S8 Keep container dry

S30 Never add water to this product

refer to fumes of some ingredients of the preparation and are not shown on the label.

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 drawn herein is based on our knowledge at the date of the issue.

The information is exclusively provided related to the product herewith specified 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 doesn't imply any liberty to break patent rights.

Previous safety data sheet n. R09/3E dated 17/05/2001 is to be considered cancelled. 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 sheet.

This safety data sheet is subject to revision.

Visit our web site www.leone.it for an updated version of the present sheet.