



1. Identification of the preparation and of the company

1.1 Identification of the preparation

Labial archwire tube.

1.2 Use of the preparation

Protective device for labial archwires or orthodontic wires.

1.3 Company identification

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1.4 Emergency telephone

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

2. Hazards identification

The information contained herein is to be referred to the raw material which these products are manufactured with; for this purpose some instructions and indications are related to the personnel employed in the manufacturing processes and not to the final user.

- Ingestion: not toxic.
- Skin contact: not toxic.
- Eye contact: mechanical irritation.
- Inhalation: when thermally decomposed by heating above 280°C, or by smoking tobacco or cigarettes contaminated with polymer dust, it may cause polymer fume fever. Symptoms are flu, with chills and fever, which may not occur until several hours after exposure and pass off within 36-48 hours, even in absence of treatment.
- Chronic effects: none known.
- Medical conditions aggravated by exposure: none.

3. Composition/information on ingredients

Material: tetrafluoroethylene homopolymer (CAS¹ Number 9002-84-0).

Hazardous components: none.

4. First aid measures

- Skin contact: if molten polymer contacts skin, cool rapidly with cold water. Do not attempt to peel polymer from skin. Seek medical advice.
- Eye contact: flush eyes with plenty of water. Seek medical advice if symptoms persist.
- Inhalation: if exposed to fumes from overheating or combustion, move to fresh air. Seek medical advice if symptoms persist.

5. Fire-fighting measures

- Flash ignition temperature: it does not flash. Open Cup method.
- Unusual fire and explosion hazards: toxic fluorine compounds evolve in fire.
- Hazardous combustion products: hydrogen fluoride (HF), carbonyl fluoride, carbon monoxide and low molecular weight fluorocarbons.
- Special fire fighting instructions: the product does not burn without an external flame. Wear self-contained breathing apparatus and clothing to protect from hydrogen fluoride fumes which react with water to form hydrofluoric acid. Wear neoprene gloves when handling refuse from a fire.
- Extinguishing media: water, carbon dioxide, foam, dry chemical.

6. Accidental release measures

Pick up by mechanical means.

7. Handling and storage

Use the good manufacturing practices (GMP) during tube handling and processing.

8. Exposure controls/personal protection

8.1 Exposition limit values²

USA. Hydrogen fluoride, occupational exposure limit (TWA): 3ppm [Occupational Safety and Health Administration (OSHA) Regulation 29 CFR 1910.1000, Table Z-2].

¹ Numero CAS (Chemical abstract service).

² 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.



8.2. Exposure control

8.2.1. Professional exposure control

Breathing protection: use respirator when temperature exceeds 280°C if ventilation is inadequate to maintain hydrogen fluoride (HF) concentration below the permissible exposure limit.

Hand and skin protection: gloves and long sleeve shirt are recommended when handling hot polymer.

Eye protection: protective glasses are recommended.

8.2.2. Environmental exposure control

Use local exhaust to completely remove vapours and fumes generated during hot processing at the work area.

Further protections: avoid contamination of cigarettes or tobacco with polymer dust.

9. Physical and chemical properties

9.1. General information

Appearance: solid

Odour: odourless

9.2. Health, safety and environmental information

Melting point : 342°C

Solubility in water: insoluble

Flammability point: not applicable (Open Cup method)

% volatile by volume: not applicable

Specific gravity: 21 - 23

10. Stability and reactivity

- Conditions to avoid: if there is a source of ignition the product burns in an atmosphere composed of 95% oxygen.

- Materials to avoid: melted alkali metals, interhalogens.

- Hazardous decomposition products: at temperature exceeding 280°C the fine dust may liberate toxic gases such as hydrogen fluoride (HF) and fluoride olefins. Dusts formed during overheating may cause polymer fume fever (see section 2, Inhalation).

11. Toxicological information

See section 10, Hazardous decomposition products.

12. Ecological information

Ecological problems are not expected from a correct use.

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.

By incineration, acid gaseous product must be removed by alkaline scrubbing.

14. Transport information

Not dangerous for 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.

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.

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 no. K04/02E of 15/05/2001 has 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.