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

Product identifier

Product Description: Labial archwire tube.

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

Identified Use Professional use: Protective device for labial archwires or orthodontic wires.

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

According to Regulation (EC) no. 1272/2008 [CLP].
This product does not meet the criteria for classification as hazardous in accordance with Titles I and II of Regulation (EC) no. 1272/2008 on classification, labelling and packaging of substances and mixtures.
In case the products undergo to any process that causes the change in the state of the raw material, the information in this safety data sheet are to be referred to the raw material. Thus, the following health hazards shall be applied to the personnel involved in the raw material's processing and not to the final user.

2.2. Label elements

Not applicable.

2.3. Other hazards

According to the available data, the product does not contain PBT or vPvB substances in a proportion ≥ 0.1 %.
The product does not contain substances with endocrine-disrupting properties in a concentration ≥ 0.1%.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Hazardous components: none.
Tetrafluoroethylene homopolymer (EC No.: 500-721-5, CAS No.: 162491-88-5).

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation If exposed to fumes from overheating or combustion, move to fresh air. Seek medical advice if symptoms persist.
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.

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

Overheating fume 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.

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

Non applicable.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing Media Water, carbon dioxide, foam and dry chemical.

5.2. Special hazards arising from the substance or mixture

Hazardous combustion products: hydrogen fluoride (HF), carbonyl fluoride, carbon monoxide and low molecular weight fluorocarbons.

5.3. Advice for firefighters

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.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

See Section 8.

6.2. Environmental precautions

Not applicable.

6.3. Methods and material for containment and cleaning up
Pick up by mechanical means.
6.4. Reference to other sections
/

SECTION 7: Handling and storage
7.1. Precautions for safe handling
Use the Good Manufacturing Practices (GMP) during tube handling and processing.
7.2. Conditions for safe storage, including any incompatibilities
Avoid atmospheres to 95% oxygen.
7.3 Specific end use(s)
/

SECTION 8: Exposure controls/personal protection
8.1. Control parameters
USA. Hydrogen fluoride, occupational exposure limit (TWA): 3ppm [Occupational Safety and Health Administration (OSHA) Regulation 29 CFR 1910.1000, Table Z-2].
8.2. Exposure controls
8.2.2. Individual protection measures, such as personal protective equipment

Eye/face protection	Protective glasses are recommended.
Skin/ Hand protection	Gloves and long sleeve shirt are recommended when handling hot polymer.
Respiratory protection	Use respirator when temperature exceeds 280°C if ventilation is inadequate to maintain hydrogen fluoride (HF) concentration below the permissible exposure limit.

8.2.3. Environmental exposure controls
Use local exhaust to completely remove vapours and fumes generated during hot processing at the work area.
Avoid contamination of cigarettes or tobacco with polymer dust.

SECTION 9: Physical and chemical properties
9.1. Information on basic physical and chemical properties

Physical state	Solid
Colour	Not applicable
Odour	Odourless
Melting point	342°C
Boiling point or initial boiling point and boiling range	Not applicable
Flammability	Not applicable
Lower and upper explosion limit	Not applicable
Flash point	Not applicable
Auto-ignition temperature	Not applicable
Decomposition temperature	Not applicable
pH	Not applicable
Kinematic viscosity	Not applicable
Solubility in water	Insoluble
Partition coefficient n-octanol/water (log value)	Not applicable
Vapour pressure	Not applicable
Density and/or relative density	Not applicable
Relative vapour density	Not applicable
Particle characteristics	Not applicable

9.2. Other information
9.2.2. Other safety characteristics

% volatile by volume	Not applicable
Specific gravity	21-23

SECTION 10: Stability and reactivity
10.1. Reactivity
Not reactive upon a correct use.
10.2. Chemical stability
Stable.
10.3. Possibility of hazardous reactions
None expected.
10.4. Conditions to avoid
If there is a source of ignition the product burns in an atmosphere composed of 95% oxygen.
10.5. Incompatible materials

Materials to avoid: melted alkali metals, interhalogens.

10.6. Hazardous decomposition product(s)

A 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.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity	Ingestion: Non-toxic. Skin contact: Non-toxic. Eye contact: Mechanical irritation. Inhalation: Inhalation of fumes can cause polymer fume fever. Symptoms are flu, with chills and fever, which does not occur until several hours after exposure and subsides within 36-48 hours, even without treatment.
Skin corrosion/irritation	None known.
Serious eye damage/irritation	Mechanical irritation.
Respiratory or skin sensitisation	None known.
Germ cell mutagenicity	None known.
Carcinogenicity	No ingredient listed as a carcinogen.
Reproductive toxicity	None known
STOT-single exposure	None known
STOT-repeated exposure	None known
Aspiration hazard.	None known

11.2 Information on other hazards

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SECTION 12: Ecological information

Ecological problems are not expected from a correct use.

12.1. Toxicity

Not applicable.

12.2. Persistence and degradability

Not applicable.

12.3. Bioaccumulative potential

Not applicable.

12.4. Mobility in soil

Not applicable.

12.5. Results of PBT and vPvB assessment

According to the available data, the product does not contain PBT or vPvB substances in a proportion ≥ 0.1 %.

12.6 Endocrine disrupting properties

Not applicable.

12.7. Other adverse effects

Not applicable.

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 Directive 2008/98/EC waste does not requires particular monitoring.

13.1. Waste treatment methods

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

SECTION 14: Transport information

Not dangerous according to current transportation regulations.

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.

15.2. Chemical safety assessment
Not applicable.

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. K04-5E 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.
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
CAS No.: numerical identifier that uniquely identifies a chemical substance, assigned by the Chemical Abstract Service.
EC-Number: EINECS and ELINCS Number (see also EINECS and ELINCS).
IMO: International Maritime Organization.
PBT: Persistent, Bioaccumulative And Toxic Substances.
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.
vPvB: Very Persistent And Very Bioaccumulative Substances.