

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1. Product identifier**

Product description: Thermoforming discs and plates.

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

Identified Use Professional use: Products for thermoforming technique for invisible orthodontic aligners and for aesthetic orthodontic post-therapy retainers.

**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](mailto: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](http://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 has not been classified as a hazardous substance or preparation in accordance with Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of December 16, 2008, on classification, labeling, and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No. 1907/2006.

**2.2. Label elements**

Not applicable.

**2.3. Other hazards**

No PBT, vPvB, or endocrine disrupting substances present in concentrations  $\geq 0.1\%$

**SECTION 3: Composition/information on ingredients****3.2. Mixtures**

Blend based on polyethylene terephthalate copolymer (CAS No. 25640-14-6)

**SECTION 4: First aid measures****4.1. Description of first aid measures**

Inhalation	If gas is inhaled during combustion of the product, move the patient to fresh air. Consult a doctor.
Skin contact	In case of burns from molten material, immediately immerse in cold water. If material sticks to the skin, do not remove it from the skin; consult a doctor and treat the injury as a thermal burn. Consult a doctor.
Eye contact	In case of contact with eyes, rinse immediately with plenty of water. After initial rinsing, remove any contact lenses and continue rinsing the affected eyes for at least 15 minutes under running water, keeping the eyelids open. Seek medical advice.
Ingestion	Ingestion during handling is unlikely. Remove material from mouth. If swallowed, do not induce vomiting; seek medical advice immediately.

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

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

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**SECTION 5: Firefighting measures****5.1. Extinguishing media**

Suitable extinguishing Media Water, dry powder extinguishers, foam, sand, ABC chemical powder.

Unsuitable extinguishing Media None.

**5.2. Special hazards arising from the substance or mixture**

Non-toxic products: Carbon dioxide (CO<sub>2</sub>), carbon monoxide (CO), and volatile organic compounds.

**5.3. Advice for firefighters**

In case of fire or risk of exposure to vapors or fumes, wear appropriate respiratory equipment.

**SECTION 6: Accidental release measures****6.1. Personal precautions, protective equipment and emergency procedures****6.1.2. For emergency responders**

Risk of slipping on smooth surfaces.

**6.2. Environmental precautions**

This product is not soluble in water. Due to its structure, the product should not be harmful to aquatic life. Not biodegradable. Consult a specialist for safe waste disposal in accordance with local or national regulations.

### **6.3. Methods and material for containment and cleaning up**

Clean and collect the released product by hand or with vacuum equipment. Clean with brooms and shovels.

### **6.4. Reference to other sections**

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## **SECTION 7: Handling and storage**

### **7.1. Precautions for safe handling**

The sheets must be handled with care (do not drag them) or using vacuum equipment. Avoid contact with hot or molten material. Avoid the formation of dust, otherwise, in some cases, there may be a risk of explosion. To reduce the potential risk of dust explosion, isolate and ground electrical equipment and avoid the accumulation of dust. Use safety tools that do not produce sparks and explosion-proof electrical equipment.

### **7.2. Conditions for safe storage, including any incompatibilities**

The product must be stored in closed rooms that guarantee normal environmental conditions. Keep away from sources of heat and/or ignition.

### **7.3 Specific end use(s)**

No further information is available.

## **SECTION 8: Exposure controls/personal protection**

### **8.1. Control parameters**

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### **8.2. Exposure controls**

Eye/face protection	Wear glasses with side protection, EN-166.
Hand protection	Sharp edges can cause cuts. Wear industrial gloves, EN-388.
Respiratory protection	If there is a risk of overexposure to dust, vapors, or fumes (during product processing), wear a suitable respirator with filter (recommended filter type: P1, EN-143).
Personal protection	If there is a risk of overexposure to dust, vapors, or fumes (during product processing), wear a suitable respirator with filter (recommended filter type: P1, EN-143).
Body protection	Coverall (EN-340).
Hygiene measures	During the operation, eating, drinking, and smoking are prohibited.

Exposure limit

Particles (respirable dust particles) E (2008): VLA-ED: 3 mg/m<sup>3</sup>.

Particles (inhalable dust particles) E (2008): VLA-ED: 10 mg/m<sup>3</sup>.

### **8.2.3. Environmental exposure controls**

Not regulated.

## **SECTION 9: Physical and chemical properties**

### **9.1. Information on basic physical and chemical properties**

Physical state	Solid
Colour	Transparent or colored
Odour	Odourless
Melting point/freezing point	>240
Boiling point or initial boiling point and boiling range	/.
Flammability	/.
Lower and upper explosion limit	/.
Flash point	/.
Auto-ignition temperature	>450
Decomposition temperature	>280
pH	/.
Kinematic viscosity	/.
Solubility	Soluble in organic solvents
Water solubility	Insoluble
Partition coefficient n-octanol/water (log value)	/.
Vapour pressure	/.
Density and/or relative density	1,27 g/cm <sup>3</sup>
Relative vapour density	/.
Particle characteristics	/.

### **9.2. Other information**

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## **SECTION 10: Stability and reactivity**

### **10.1. Reactivity**

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### **10.2. Chemical stability**

The product is stable under normal operating conditions (storage, handling, and use).

### **10.3. Possibility of hazardous reactions**

Thermal decomposition, combustion, or improper handling may release harmful gases and vapors.

### **10.4. Conditions to avoid**

Avoid the formation and/or accumulation of dust.

Avoid proximity to or contact with flames or sparks.

Avoid overheating the product.

Do not heat to temperatures above thermal decomposition.

### **10.5. Incompatible materials**

Avoid contact with highly oxidizing materials.

### **10.6. Hazardous decomposition products**

Non-toxic products: Carbon dioxide (CO<sub>2</sub>), carbon monoxide (CO), and volatile organic compounds.

## **SECTION 11: Toxicological information**

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

Acute toxicity (oral)	No data available
Acute toxicity (dermal)	No data available
Acute toxicity (inhalation)	No data available
Skin corrosion/irritation	During the heating process, it may cause skin irritation.
Serious eye damage/irritation	Durante il processo di riscaldamento può causare irritazioni e agli occhi.
Respiratory or skin sensitisation	During the heating process, it may cause irritation to the respiratory tract.
Germ cell mutagenicity	Based on the available data, the classification criteria are not met.
Carcinogenicity	Based on the available data, the classification criteria are not met.
Reproductive toxicity	Based on the available data, the classification criteria are not met.
STOT-single exposure	Based on the available data, the classification criteria are not met.
STOT-repeated exposure	Based on the available data, the classification criteria are not met.
Aspiration hazard	Based on the available data, the classification criteria are not met.

### **11.2 Information on other hazards**

Based on our experience and the information available to us, the product is not harmful to health, provided it is handled and processed correctly in accordance with the instructions provided.

## **SECTION 12: Ecological information**

### **12.1. Toxicity**

Due to its low solubility, the product should not be hazardous.

### **12.2. Persistence and degradability**

The product is slowly biodegradable.

### **12.3. Bioaccumulative potential**

The product has a low potential for bioaccumulation in the environment.

### **12.4. Mobility in soil**

Due to its physical and chemical properties, the product has low mobility in soil. The product has a density of up to 1 g/cm<sup>3</sup> and sinks in water. Due to its low solubility, the product should not be hazardous to aquatic life. Due to its low solubility, the product should not be hazardous to aquatic life.

### **12.5. Results of PBT and vPvB assessment**

Based on available data, the product does not contain PBT or vPvB substances in a percentage  $\geq 0.1\%$ .

### **12.6. Endocrine disrupting properties**

Based on available data, the product does not contain any substances listed in the main European lists of potential or suspected endocrine disruptors with environmental effects under evaluation.

### **12.7 Other adverse effects**

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## **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 October 17, 2024.

### **13.1. Waste treatment methods**

It is the responsibility of the disposer to determine the toxicity and physical characteristics of the material for the correct classification of waste and its proper disposal in accordance with current regulations.

Where possible, recycling is preferred to destruction or incineration. The product is suitable for recycling. The condition for recycling is the collection and reuse of the same material. Disposal must be carried out in accordance with local or national regulations.

#### SECTION 14: Transport information

Not classified as dangerous for transport regulations.

##### 14.1. UN number or ID number

Not applicable.

##### 14.2. UN proper shipping name

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##### 14.3. Transport hazard class(es)

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##### 14.4. Packing group

Not applicable.

##### 14.5. Environmental hazards

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##### 14.6. Special precautions for user

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##### 14.7. Maritime transport in bulk according to IMO instruments

Not subject to transport restrictions.

#### 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

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#### 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. R20/4E 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](http://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.

CLP: Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008.

EC No.: European Chemicals Agency.

ISO306: International Organization for Standardization, plastics, thermoplastics, determination of softening temperature (Vicat method).

ISO1183: International Organization for Standardization, Methods for determining the density of non-cellular plastics.

PBT: Persistent, Bioaccumulative, and Toxic: hazardous chemicals.

vPvB: Very Persistent and Very Bioaccumulative.

EN 166: Personal eye protection - Specifications.

EN 388: Gloves against mechanical hazards.

EN 143: Dust filters.

VLA-ED: Indicative Occupational Exposure Limit Value.

IMO: International Maritime Organisation.