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01. Identification of the preparation and of the company

1.1 Identification of the preparation

Thermoforming discs and plates.

1.2 Use of the preparation

Products for thermoforming technique for invisible orthodontic aligners and for aesthetic orthodontic post-therapy retainers.

1.3 Company identification

Leone s.p.a.

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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

No obligation to label in accordance to Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 and further modification, concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.

3. Composition/information on ingredients

Chemical nature:

Polyethylene terephthalate Glycol (PETG) Copolyester - CAS¹ Number 25640-14-6

Anti-UV additives, colorants.

Hazardous ingredients:

None.

4. First aid measures

If inhaled:

On inhalation of decomposition products: keep patient calm, remove to fresh air, and summon medical help

On skin contact: areas affected by molten material should be quickly placed under cold running water and summon medical help.

Note to physician: on inhalation of decomposition products: treat according to symptoms (decontamination, vital functions), no known specific antidote.

5. Fire-fighting measures

Suitable extinguishing media: water, dry extinguishing media, foam, carbon dioxide.

Special protective equipment: in case of fire, wear a self contained breathing apparatus.

Further information: dispose of fire residues and contaminated extinguishing water in accordance to local regulations.

6. Accidental release measures

Methods for cleaning up: pick up mechanically.

7. Handling and storage

7.1. Handling

Ensure good ventilation and local exhaustion of the working area.

In case of mechanical operations (drill, saw, mill) the instructions/limited values for handling fine dust are to be observed (VDI² guidelines 3673, 2263) (Germany) MAC³-value (mill): 6 mg/m³.

7.2 Storage

In original packing, keep away from sunlight and in a dry place.

8. Exposure controls/personal protection

Personal protective equipment:

In case of usual handling, no special protective equipment will be necessary.

Under consideration of applied work technique it may be mandatory to use:

Respiratory protection: dust filter type P1 in case of fine dust creation

Skin protection: safety gloves, in case rough edges may cause cuts

¹ CAS Number (Chemical abstract service)

² Verein Deutscher Ingenieure

³ MAC: maximum concentration on workplace



Eye protection: safety glasses or complete face protection.

General safety and hygiene measures:
None.

9. Physical and chemical properties

9.1. General information

Form: discs and plates
Colour: transparent
Odour: odourless.

9.2. Health, safety and environmental information

Change in physical state
Softening point > 70 °C ISO 306
Ignition temperature > 400 °C ASTM E-659 / DIN 51794
Fire promoting properties none
Density 1.27 g/cm³ ISO 1183
Bulk density n. a. kg/m³
Solubility in water insoluble
Solubility in other solvents soluble in organic solvents.

10. Stability and reactivity

Start of thermal decomposition: at 270°C.
Thermal decomposition, burning or faulty handling may diffuse noxious gases and vapours.
Thermal decompositions release monomers, carbon dioxide, carbon monoxide, steam.
Avoid thermal decomposition, do not overheat.
Incompatibility: material reacts with oxidising agents.

11. Toxicological information

Acute toxicity: no data existing, except those mentioned below. Water-insoluble.

Material Tests:

LD ⁴ ₅₀ , oral: (male rat)	>3.200 mg/kg (highest dose rate tested)
LD ₅₀ , oral: (male mouse)	>3.200 mg/kg (highest dose rate tested)
Dermal LD ₅₀ : (Guinea pig)	>1.000 mg/kg
Skin irritation (Guinea pig)	slight
Irritation of eyes (rabbit, unwashed eyes)	slight
Irritation of eyes (rabbit, washed eyes)	slight
Guinea pig	none.

Additional information:

In our experience and according to information available to us the product is not harmful to health provided it is correctly handled and processed according to the given recommendations.

12. Ecological information

Behaviour and environmental effects:

Due to the consistency of the product, and its insolubility in water, it will apparently not be bio-available.

13. Disposal consideration

The product is qualified for material recycling. After suitable treatment the material can again be melted and processed. 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.

Disposal code:

European Waste Catalogue: 120105 (plastic filings and swarf)
European Waste Catalogue: 170203 (scrap-parts and plastic oddments).

14. Transport information

The product is not hazardous within the meaning of transport regulations.

⁴ LD₅₀ Lethal Dose, dose of substance which results to be lethal for 50% of organisms used in a toxicity test.



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 Directive 93/42/EC, 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 the 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

This first edition safety data sheet is subject to revision.

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