



SECTION 1: Identification of the substance or mixture and of the company

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.

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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.

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.

Upon a correct use, according to our experience no significant hazards to man or environment are reasonably foreseen.

2.2. Label elements

Not applicable.

2.3. Other hazards

Not classified as PBT or vPvB.

SECTION 3: Composition/information on ingredients

3.1. Substances

This product is a mixture.

3.2. Mixtures

Mixture based on Polyethylene terephthalate glycol (PETG) copolyester (EC No 607-767-6, CAS No. 25640-14-6).

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation If inhaled: keep patient calm, remove to fresh air, and summon medical help.

Skin contact Areas affected by molten material should be quickly placed under cold running water.

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

Not available.

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

Note to a doctor: In case of inhalation of decomposition products: treat according to symptoms (decontamination, vital functions), no known specific antidote.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing Media Water, dry extinguishing media, foam, carbon dioxide.

Unsuitable extinguishing Media None.

5.2. Special hazards arising from the substance or mixture

Thermal decomposition, burning or faulty handling may diffuse noxious gases and vapours.

5.3. Advice for firefighters

In case of fire, wear a self contained breathing apparatus. Dispose of fire residues and contaminated extinguishing water in accordance to local regulations.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Not necessary.

6.2. Environmental precautions

See section 12.

6.3. Methods and material for containment and cleaning up

Collect by mechanical tools.

6.4. Reference to other sections

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SECTION 7: Handling and storage



7.1. Precautions for safe 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 (VDI guidelines 3673, 2263) (Germany) MAK -value (mill): 6 mg/m³.

7.2. Conditions for safe storage, including any incompatibilities

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

7.3 Specific end use(s)

No further relevant information available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No information available.

8.2. Exposure controls

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

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

Individual protection measures, such as personal protective equipment (PPE)

Eye/face protection	Safety glasses or complete face protection.
Hand protection	Safety gloves, in case rough edges may cause cuts.
Respiratory protection	Dust filter type P1 in case of fine dust creation.
General safety and hygiene measures	None.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Disc and plates, solid.
Colour	Translucent or colored.
Odour	Odourless.
Water solubility	Insoluble.
Solubility other	Inorganic solvents.
Melting point	>70°C ISO 306.
Flash point	>400°C ASTM E-659/DIN 51794.
Flammability	None.
Density	1.27 g/cm ³ ISO1183.
Bulk density	Not applicable.

9.2. Other information

No further details as regards the safety-relevant parameters are required.

SECTION 10: Stability and reactivity

10.1. Reactivity

Information not available.

10.2. Chemical stability

Stable under normal condition.

10.3. Possibility of hazardous reactions

Thermal decomposition, burning or faulty handling may diffuse noxious gases and vapours.

10.4. Conditions to avoid

Avoid thermal decomposition, do not overheat.

10.5. Incompatible materials

Product reacts with oxidising agents.

10.6. Hazardous decomposition product(s)

Thermal decomposition starts at 270°C.

Thermal decompositions release monomers, carbon dioxide, carbon monoxide, steam.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

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

Test on material:

LD50, oral: (male rat)	>3.200 mg/kg (highest dose rate tested).
LD50, oral: (male mouse)	>3.200 mg/kg (highest dose rate tested).
LD50, dermal: (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.
Irritation of eyes (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.

SECTION 12: Ecological information

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

12.1. Toxicity

Not available.

12.2. Persistence and degradability

Not available.

12.3. Bioaccumulative potential

Not available.

12.4. Mobility in soil

Not available.

12.5. Results of PBT and vPvB assessment

Not available.

12.6. Other adverse effects

No known significant effects or critical hazards.

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.

13.1. Waste treatment methods

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

Disposal code:

European Waste Catalogue: 120 105 (plastic filings and swarf).

European Waste Catalogue: 170 203 (scap-parts and plastic oddments).

SECTION 14: Transport information

Not dangerous according to current transportation regulations.

14.1. UN-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. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

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 was prepared in accordance with the Commission Regulation (EU) no. 453/2010 and Commission Regulation (EU) no. 2015/830.

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. R20/3E dated 01/07/2020 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.

This safety data sheet is subject to revision. Visit our web site www.leone.it for an updated version of the present sheet.

Legend

ASTM E-659: American Society for Testing and Materials, Standard Test Method for Autoignition Temperature of Chemicals.

CAS No.: Chemical Abstract Service Registry number.

DIN 51794: German Institute for Standardization, Testing of mineral oil hydrocarbons; determination of ignition temperature.

EC No.: European Inventory of Existing Commercial Chemical Substances.

IBC Code: International Bulk Chemicals Code.

ISO306: International Organization for Standardization, Plastics - Thermoplastic materials - Determination of Vicat softening temperature.

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

LD50 Lethal Dose 50: the dose required to kill half the members of a tested population after a specified test duration.

MAK (Maximale Arbeitsplatz-Konzentration): Maximum Workplace Concentration.

PBT: Persistent, Bioaccumulative And Toxic Substances.

VDI Verein Deutscher Ingenieure.

vPvB: Very Persistent And Very Bioaccumulative Substances.