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

1.1. Product identifier

Product description: thermoforming discs Three-Layer

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

Identified Use: Professional use: Products for thermoforming techniques for the manufacture of dental aligners

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

In accordance with Regulation (EC) No. 1272/2008 [CLP].
This product does not meet the criteria for classification as hazardous under Titles I and II of Regulation (EC) No. 1272/2008 on the classification, labeling, and packaging of substances and mixtures.
When used correctly, no significant danger to humans or the environment is reasonably expected.

2.2. Label elements

Signal word: Warning
Hazard statements: If fine particles are generated during further processing, handling or by other means, product may form combustible dust concentrations in air.

2.3. Other hazards

No one identified.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Ingredienti	**%W/W**
Copolyester	**20 - 80**
Polyurethane	**20 - 80**

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation: Remove exposed person to fresh air if adverse effects are observed. Treat symptomatically.If symptoms persist, call a physician.

Skin contact: Wash skin thoroughly with soap and water. If skin irritation or rash occurs: Get medical attention. Launder contaminated clothing before reuse. For contact with molten product, do not remove contaminated clothing. Flush skin immediately with large amounts of cold water. If possible submerge area in cold water. Pack with ice. Do not attempt to peel polymer from skin. Seek medical attention immediately.

Eye contact: If hot melted material should splash into the eyes, flush eyes immediately with water for 15 minutes while holding the eyelids open. Immediately call a poison center or doctor. Any material that contacts the eye should be washed out immediately with water. If easy to do, remove contact lenses.

Ingestion: Treat symptomatically. Get medical attention.

Personal Protection for First-aid Responders:
When providing first aid always protect yourself against exposure to chemicals or blood born diseases by wearing gloves, masks and eye protection. After providing first aid wash your exposed skin with soap and water.

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

See section 11.

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

Treat symptomatically.

SECTION 5: Firefighting measures

No unusual fire or explosion hazards noted.

5.1. Extinguishing media

Suitable extinguishing Media: Water spray, Dry chemical, Carbon dioxide (CO2)

Unsuitable extinguishing Media Not determined.

5.2. Special hazards arising from the substance or mixture

See section 10 for additional information.

5.3. Advice for firefighters

Special fire fighting procedures:

Thermoplastic polymers can burn. Protect product from flames; maintain proper learance when using heat devices, etc. Irritating or toxic substances will be emitted upon burning, combustion or decomposition. Large masses of molten polymer held at elevated temperatures for extended periods of time may auto-ignite.

Special protective equipment for firefighters:

Wear full protective firegear including self-containing breathing apparatus operated in the positive pressure mode with full facepiece, coat, pants, gloves and boots.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Keep unauthorized personnel away.

See Section 8 of the SDS for Personal Protective Equipment.

6.2. Environmental precautions

Avoid release to the environment. Prevent further leakage or spillage if safe to do so.

6.3. Methods and material for containment and cleaning up

Pick up free solid for recycle and/or disposal.

6.4. Reference to other sections

See sections 8 and 13 for additional information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Contact with heated material may cause thermal burns. Wash thoroughly after handling. Refer to Processing Guide and/or contact your local Technical Service representative for melt processing temperature range. For most thermoplastic polyurethanes, melt processing is in the range of 177 - 232 deg. C (350 - 450 deg. F), however, some products may process at different temperatures. Heating above the maximum handling temperature can generate hazardous decomposition products (see Section 10).

Fume condensates may include hazardous contaminants from additives. Condensate may be combustible and should be periodically removed from exhaust hoods, ductwork, and other surfaces. Impervious gloves should be worn during cleanup operations to prevent skin contact.

Post thermal processing activities necessary to produce molded articles (such as cutting, sanding, sawing, grinding, drilling, or regrinding) may create dust or "fines."

Powders, dust, and/or fines may pose a dust explosion hazard. Avoid breathing dust. Loading and unloading operations may cause nuisance dust to form. Electrostatic buildup may occur when pouring or transferring this product from its container. The spark produced may be sufficient to ignite vapors of flammable liquids. Always transfer product by means which avoid static buildup. Avoid pouring product directly from its container into combustible or flammable solvent.

Conduct any operations emitting fumes or vapors (including thermo- forming, heat joining, cutting and or sealing of articles and clean up) under well-ventilated conditions. Avoid breathing process vapors. Do not hold product for extended periods of time at elevated temperatures or allow thick masses of hot polymer to accumulate because they can decompose emitting hazardous gasses. Do not taste, swallow, or chew products. Wash thoroughly after processing. Do not store or consume food in processing areas. The major offgasses from normal melt processing are expected to be water vapor and carbon dioxide. Other trace volatile organic components may also be emitted.

Do not steam sterilize articles made with thermoplastic polyurethanes. Methylene dianiline can be generated as a result.

Avoid breathing dust/fume/gas/mist/vapors/spray. Avoid contact with eyes, skin, and clothing. Observe good industrial hygiene practices. Provide adequate ventilation. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace. Launder contaminated clothing before reuse. Avoid environmental contamination.

Maximum Handling Temperature: Not determined.

7.2. Conditions for safe storage, including any incompatibilities

Store in dry, well ventilated place away from sources of heat and direct sunlight. Store away from incompatible materials.

See section 10 for incompatible materials.

Maximum Storage Temperature: Not determined.

7.3 Specific end use(s)

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

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8.2. Exposure controls

None of the components have assigned exposure limits.

8.2.1. Appropriate engineering controls

Thermal processing operations should be ventilated to control gases and fumes given off during processing. No special requirements under ordinary conditions of use and with adequate ventilation.

8.2.2. Individual protection measures, such as personal protective equipment

Use personal protective equipment as necessary.

8.2.2.1 Eye and face protection as required.

If contact is likely, safety glasses with side shields are recommended.

8.2.2.2 Skin protection

To avoid burns from contact with molten product, use thermal insulating gloves. Suitable gloves can be recommended by the glove supplier. Gloves, coveralls, apron, boots as necessary to minimize contact. Do not wear rings, watches or similar apparel that could entrap the material. Long sleeve shirt is recommended.

8.2.2.3 Respiratory protection

Under normal use conditions, respirator is not usually required. Use appropriate respiratory protection if exposure to dust particles, mist or vapors is likely. Cutting operations may create small particles from this product. If inhalation of particles cannot be avoided, wear a dust respirator. Consult with an industrial hygienist to determine the appropriate respiratory protection for your specific use of this material. A respiratory protection program compliant with all applicable regulations must be followed whenever workplace conditions require the use of a respirator.

Hygiene measures: Observe good industrial hygiene practices. Avoid contact with skin. Contaminated work clothing should not be allowed out of the workplace

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Solid
Form	Sheets
Color	Trasparent
Odour	Odorless
Odor Threshold:	No data available.
Ph	No data available.
Melting point	No data available.
Boiling point	No data available.
Flash point	No data available.
Evaporation rate	No data available.
Flammability (solid, gas)	No data available.
Upper/lower limit on flammability or explosive limits	
Flammability Limit - Upper (%)	No data available.
Flammability Limit – Lower (%)	No data available.
Vapor pressure	No data available.
Vapor density (air=1)	No data available.
Relative density	>1.1 (20 °C)
Solubility(ies)	
Solubility in Water	Insoluble in water
Solubility (other)	No data available.
Partition coefficient (n-octanol/water):	No data available.
Autoignition Temperature	No data available.
Decomposition Temperature	No data available.
Viscosity	No data available.
Explosive properties	No data available.
Oxidizing properties	No data available.
Pour Point Temperature	No data available.

9.2. Other information

Bulk density: No data available.

SECTION 10: Stability and reactivity

10.1. Reactivity

No data available.

10.2. Chemical stability
Material is stable under normal conditions.

10.3. Possibility of hazardous reactions
Will not occur.

10.4. Conditions to avoid
Minimize dust generation and accumulation.

10.5. Incompatible materials
Strong oxidizing agents, avoid contact with reactive chemicals.

10.6. Hazardous decomposition products
May generate carbon monoxide, carbon dioxide (CO2), May also include isocyanates and small amounts of hydrogen cyanide. Thermal decomposition or combustion may generate smoke, carbon monoxide, carbon dioxide nitrogen oxides, and other products of incomplete combustion.

SECTION 11: Toxicological information
Inhalation: No data available.
Ingestion: No data available.
Skin Contact: No data available.
Eye contact: No data available.

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008
Acute toxicity (Oral)
Product: May cause irritation of the gastrointestinal tract. Not classified for acute toxicity based on available data.
Acute toxicity (Dermal)
Product: Not classified for acute toxicity based on available data.
Acute toxicity (Inhalation)
Product: Overexposure to vapors or mist may cause dizziness, headache, nausea, and/or flu-like symptoms. Persons with sensitive airways (e.g., asthmatics) may react to vapors. Not classified for acute toxicity based on available data.
Skin Corrosion/Irritation:
Product: Remarks: Contact with heated material may cause thermal burns. Pre-existing skin conditions may be aggravated by prolonged or repeated exposure. Not classified as a primary skin irritant.
Serious Eye Damage/Eye Irritation:
Product: Remarks: Not classified as a primary eye irritant.
Respiratory sensitization:
Product: Remarks: Under decomposition conditions, isocyanates may be generated from this product. Isocyanates can cause skin sensitization and/or respiratory sensitization.
Skin sensitization:
Product: Remarks: Under decomposition conditions, isocyanates may be generated from this product. Isocyanates can cause skin sensitization and/or respiratory sensitization.
Germ Cell Mutagenicity: No data available
Chronic Effects Carcinogenicity: No data available
Reproductive toxicity: No data available
Specific Target Organ Toxicity – Single Exposure: No data available
Specific Target Organ Toxicity – Repeated exposure: No data available
Aspiration Hazard: No data available

11.2 Information on other hazards
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SECTION 12: Ecological information

12.1. Toxicity
Toxicity to Aquatic Plants No data available
Toxicity to soil dwelling organisms No data available
Sediment Toxicity No data available
Toxicity to Terrestrial Plants No data available
Toxicity to Above-Ground Organisms No data available
Toxicity to microorganisms No data available

12.2. Persistence and degradability
Biodegradation No data available

12.3. Bioaccumulative potential
Bioconcentration Factor (BCF) No data available
Partition Coefficient n-octanol / water (log Kow) No data available

12.4. Mobility in soil

No data available

12.5. Results of PBT and vPvB assessment

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

12.6. Endocrine disrupting properties

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

12.7 Other adverse effects

Harmful to aquatic life with long lasting effects.

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 compliance with current regulations.

SECTION 14: Transport information

IATA

Not regulated.

IMDG

Not regulated.

Shipping descriptions may vary based on mode of transport, quantities, temperature of the material, package size, and/or origin and destination. It is the responsibility of the transporting organization to follow all applicable laws, regulations and rules relating to the transportation of the material. For transportation, steps must be taken to prevent load shifting or materials falling, and all relating legal statutes should be obeyed. Review classification requirements before shipping materials at elevated temperatures.

14.1. UN number or ID number

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14.2. UN proper shipping name

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14.3. Transport hazard class(es)

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14.4. Packing group

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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

Unknown.

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.

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 No.: European Chemicals Trade Register.
PBT: Persistent, Bioaccumulative, and Toxic: hazardous chemicals.
vPvB: Very Persistent Very Bioaccumulative.
IATA: International Air Transport Association.
IMDG Code: International Maritime Dangerous Goods Code.
CLP: Classification, Labelling and Packaging Regulation; Regulation (EC) No. 1272/2008.
IMO: International Maritime Organization.
REACH: Registration, Evaluation, Authorization, and Restriction of Chemicals, Regulation (EC) No. 1907/2006.
GHS: Globally Harmonized System of Classification and Labelling of Chemicals.