



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

1.1. Product identifier

Product description: thermoforming hard/soft disc 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 bruxism splint and the realization of the anchorage support of complex appliances.

1.3. Details of the supplier of the safety data sheet

Leone s.p.a.

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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, EC No 607-767-6, CAS No. 25640-14-6) and Ethylene-vinyl acetate (EVA, CAS Number 24937-78-8).

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur.

Skin contact Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.

Eye contact Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.

Ingestion Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

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

Potential acute health effects: No known significant effects or critical hazards.

Over-exposure signs/symptoms: No specific data.

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

Note to a doctor: Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.

No specific treatment.

Protection of first aiders: No action shall be taken involving any personal risk or without suitable training.

See toxicological information (section 11).

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing Media Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing Media None.

5.2. Special hazards arising from the substance or mixture

No specific fire or explosion hazard.



Hazardous thermal decomposition products: carbon dioxide, carbon monoxide, halogenated compounds.

5.3. Advice for firefighters

Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training. Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Put on appropriate personal protective equipment.

For emergency responders If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For nonemergency personnel".

6.2. Environmental precautions

Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

6.3. Methods and material for containment and cleaning up

Small spill: Move containers from spill area. Vacuum or sweep up material and place in a designated, labeled waste container. Dispose of via a licensed waste disposal contractor.

Large spill: Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Vacuum or sweep up material and place in a designated, labeled waste container. Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

6.4. Reference to other sections

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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Protective measures: put on appropriate personal protective equipment (see Section 8).

Advice on general occupational hygiene: Eating, drinking, and smoking should be prohibited in areas where this material is handled, stored, and processed. Workers should wash hands and face before eating, drinking, and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

7.2. Conditions for safe storage, including any incompatibilities

Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination.

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

Appropriate engineering controls: Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

Environmental exposure controls: Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

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



Eye/face protection	Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases, or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.
Hand protection	Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary
Body Protection	Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
Other skin protection	Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
Respiratory protection	Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.
General safety and hygiene measures	Wash hands, forearms, and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Disc and plates, solid
Colour	Clear
Odour	Characteristic
pH	Not applicable
Melting point	Not available
Boiling point	Not available
Flash Point	Product does not sustain combustion
Lower and upper explosive (flammable) limits	Not available
Vapour pressure	Not available
Vapour density	Not available
Relative density	1,3 to 1,4
Solubility	Insoluble in the following materials: cold water and hot water
Solubility in water	Not available
Partition coefficient: n-octanol/water	Not available
Auto-ignition temperature	Not available
Viscosity	Not available.

9.2. Other information

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

SECTION 10: Stability and reactivity

10.1. Reactivity

No specific test data related to reactivity available for this product or its ingredients.

10.2. Chemical stability

The product is stable.

10.3. Possibility of hazardous reactions

Under normal conditions of storage and use, hazardous reactions will not occur.

10.4. Conditions to avoid

No specific data.

10.5. Incompatible materials

No specific data.

10.6. Hazardous decomposition product(s)

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on toxicological effects



Information on the likely routes of exposure: Not available.

Potential acute health effects:

Eye contact	No known significant effects or critical hazards
Inhalation	No known significant effects or critical hazards
Skin contact	No known significant effects or critical hazards
Ingestion	No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics:

Eye contact	No specific data
Inhalation	No specific data
Skin contact	No specific data
Ingestion	No specific data.

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure:

Potential immediate effects	Not available
Potential delayed effects	Not available.

Long term exposure

Potential immediate effects	Not available
.Potential delayed effects	Not available.

Potential chronic health effects: Not available.

General	No known significant effects or critical hazards
Carcinogenicity	No known significant effects or critical hazards
Mutagenicity	No known significant effects or critical hazards
Teratogenicity	No known significant effects or critical hazards
Developmental effects	No known significant effects or critical hazards
Fertility effects	No known significant effects or critical hazards.

Numerical measures of toxicity:

Acute toxicity estimates: not available.

SECTION 12: Ecological information

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 generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste



disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

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

Transport within user's premises: always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

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

Not available.

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.

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.: Chemical Abstract Service Registry number.

IBC: Intermediate Bulk Container

MARPOL: International Convention for the Prevention of Pollution From Ships, 1973

PBT: Persistent, Bioaccumulative And Toxic Substances.

vPvB: Very Persistent And Very Bioaccumulative Substances.