

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

### 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.

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

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

Labeling according to Regulation (EC) No. 1272/2008

### 2.3. Other hazards

No particular hazards to report.

The substance does not meet the criteria for being identified as persistent, bioaccumulative, and toxic (PBT). The substance does not meet the criteria for being identified as very persistent and very bioaccumulative (vPvB). This substance has no endocrine-disrupting properties in humans. This substance has no endocrine-disrupting properties in non-target organisms.

## SECTION 3: Composition/information on ingredients

### 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

To date, no symptoms are known.

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

Notes to Physician/Risks: In the case of ingestion with subsequent vomiting, aspiration may reach the lungs, which may result in chemical pneumonia or lead to asphyxiation.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing Media Recommended: alcohol-resistant foam, CO<sub>2</sub>, powder, water mist, Adapt fire extinguishing measures to the specific environment

Unsuitable extinguishing Media /.

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

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### 5.3. Advice for firefighters

In case of fire, wear an appropriate protective mask.

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

In case of fire, wear an appropriate protective mask.

**6.2. Environmental precautions**

Do not enter sewers or surface waters.

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

Pick up with mechanical equipment. Thoroughly clean contaminated objects and floors in accordance with relevant regulations.

**6.4. Reference to other sections**

Refer to the precautionary measures given in Sections 7 and 8.

**SECTION 7: Handling and storage****7.1. Precautions for safe handling**

Take the usual precautions expected when handling chemicals.

**7.2. Conditions for safe storage, including any incompatibilities****Storage and container requirements**

The product should be stored in closed containers.

**Directions for storage together with other products**

Do not store with food.

**Additional information for storage conditions**

Keep container tightly closed and protected from moisture

**7.3 Specific end use(s)**

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**SECTION 8: Exposure controls/personal protection****8.1. Control parameters**

Contains no substances with occupational exposure limit value.

**8.2. Exposure controls**

Eye/face protection	Protective goggles.
Hand protection	Heat-resistant protective gloves for use.
Body Protection	Customary work clothes for the chemical industry.
Respiratory protection	Avoid inhalation of vapors.
General safety and hygiene	Take the usual precautions expected when handling chemicals.

**SECTION 9: Physical and chemical properties****9.1. Information on basic physical and chemical properties**

Physical state	Thermoforming sheet
Colour	colorless, transparent
Odour	characteristic
Melting point/freezing point	> 100 °C/ not determined
Boiling point or initial boiling point and boiling range	not determined
Flammability	not determined
Lower and upper explosion limit	not determined
Flash point	Not applicable
Auto-ignition temperature	not determined
Decomposition temperature	not determined
pH	not determined
Kinematic viscosity	not determined
Water solubility	not determined
Partition coefficient n-octanol/water (log value)	not determined
Vapour pressure	not determined
Density and/or relative density	Value 1.2 g/cm <sup>3</sup> Temperature 20 °C
Relative vapour density	not determined
Particle characteristics	/.

**9.2. Other information**

Water solubility: practically insoluble

**SECTION 10: Stability and reactivity****10.1. Reactivity**

No hazardous reaction if stored and used properly.

**10.2. Chemical stability**

No dangerous reactions are known.

### 10.3. Possibility of hazardous reactions

No dangerous reactions are known.

### 10.4. Conditions to avoid

Protect from heat and direct sunlight

### 10.5. Incompatible materials

None known

### 10.6. Hazardous decomposition products

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## SECTION 11: Toxicological information

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

Acute toxicity (oral)	Based on the available data, it is not possible to meet the classification criteria
Acute toxicity (dermal)	Based on the available data, it is not possible to meet the classification criteria
Acute toxicity (inhalation)	Based on the available data, it is not possible to meet the classification criteria
Skin corrosion/irritation	Based on the available data, it is not possible to meet the classification criteria
Serious eye damage/irritation	Based on the available data, it is not possible to meet the classification criteria
Respiratory or skin sensitisation	Based on the available data, it is not possible to meet the classification criteria
Germ cell mutagenicity	Based on the available data, it is not possible to meet the classification criteria
Carcinogenicity	Based on the available data, it is not possible to meet the classification criteria
Reproductive toxicity	Based on the available data, it is not possible to meet the classification criteria
STOT-single exposure	Based on the available data, it is not possible to meet the classification criteria
STOT-repeated exposure	Based on the available data, it is not possible to meet the classification criteria
Aspiration hazard	Based on the available data, it is not possible to meet the classification criteria

### 11.2 Information on other hazards

#### 11.2.1. Endocrine disrupting properties

This substance has no endocrine-disrupting properties in humans.

## SECTION 12: Ecological information

### 12.1. Toxicity

#### Fish toxicity (Components)

##### Vinyl acetate

Species	Cadavedano (Pimephales promelas)
NOEC	0,551 mg/l
Exposure duration	34 d
Method	OCSE 210

#### Toxicity to Daphnia (Components)

##### vinyl acetate.

Species	Daphnia magna
CE50	12,6 mg/l
Exposure duration	48 h
Method	OECD 202

#### Toxicity to algae (Components)

##### vinyl acetate.

Species	Pseudokirchneriella subcapitata
ErC50	12,7 mg/l
Exposure duration	72 h
Method	OECD 201

### 12.2. Persistence and degradability

Readily biodegradable (according to criteria-OECD)

### 12.3. Bioaccumulative potential

Not determined

### 12.4. Mobility in soil

Not determined

### 12.5. Results of PBT and vPvB assessment

The substance does not meet the criteria to be identified as persistent, bioaccumulative and toxic (PBT).

The substance does not meet the criteria to be identified as very persistent and very bioaccumulative (vPvB).

### 12.6. Endocrine disrupting properties

This substance has no endocrine-disrupting properties in nontarget organisms.

### 12.7 Other adverse effects

The product should not be released into the environment in an uncontrolled manner.

**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**

Waste from discarded product

Do not dispose of the product with household waste.

Dispose of in accordance with local authority regulations.

Contaminated containers

Non-washable packaging should be disposed of in accordance with the disposer having regional jurisdiction.

**SECTION 14: Transport information****14.1. UN number or ID number**

The product is not a hazard commodity for land transport.

The product is not an air transport hazard commodity.

**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**

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**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**

No chemical safety assessment has been carried out for this preparation.

**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. R21/1E dated 09/03/2021 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.

**H-phrases**

H225: Highly flammable liquid and vapour

H332: Harmful if inhaled.

H335: May cause respiratory irritation.

H351: Suspected of causing cancer.

**Legend**

CAS No.: A numerical identifier that uniquely identifies a chemical, assigned by the Chemical Abstract Service.

IMO: International Maritime Organization.

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

PBT: Persistent, Bioaccumulative and Toxic: hazardous chemicals.

vPvB: Persistent Very Bioaccumulative dock.

NOEC: No-Observed Effect Concentration.