

1. SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Product description: Copolymer plates.

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

Identified Use Professional use: For the duplication of plaster models.

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**

According to Regulation (EC) no. 1272/2008 [CLP].

Based on the requirements of the CLP regulation, the product is not classified.

2.2. Label elements

Not applicable.

2.3. Other hazards

No PBT, vPvB or endocrine disrupting substances present at a concentration $\geq 0.1\%$

SECTION 3: Composition/information on ingredients**3.2. Mixtures**

Mixture, consisting of a copolymer and substances below applicable or non-hazardous classification limits.

SECTION 4: First aid measures

No specific measures are needed.

4.1. Description of first aid measures

No special first aid measures are provided for the product in solid form.

Inhalation Dusts or vapors emitted by thermal action: remove patient from polluted area; refer to physician's care.

Skin contact In case of contact with molten material, cool the part with cold water and call the doctor. Do not remove product that has solidified from the skin. Treat as a burn.

Eye contact Wash with running water for a few minutes while holding the eyelids wide open.

Ingestion No specific measures are required if the product is ingested as is. If necessary, call a physician.

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

No other information is available.

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

No other information is available.

SECTION 5: Firefighting measures**5.1. Extinguishing media**

Suitable extinguishing Media Water, water spray, foam, chemical powder, carbon dioxide.

Unsuitable extinguishing Media Water jets

5.2. Special hazards arising from the substance or mixture

Combustion products: carbon dioxide, carbon monoxide (as available air/oxygen decreases) and any unburned hydrocarbons.

5.3. Advice for firefighters

Use appropriate personal protective equipment (self-contained breathing apparatus, hard hat, goggles, coveralls, gloves and fireproof boots). The product is combustible. Cool containers near flames with water spray.

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

Do not walk on the granules to avoid slipping.

6.2. Environmental precautions

Prevent the product from entering sewers or waterways.

6.3. Methods and material for containment and cleaning up

Collect by mechanical means. Dispose of collected material as required by law.

6.4. Reference to other sections

For information regarding safe handling, see Section 7.

For information regarding protective equipment for personal use see Section 8.

For information regarding disposal of contaminated material see Section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Dust formation should be avoided during handling and transport, particularly during unloading; if dust formation occurs, it should be removed.

During product processing, avoid inhalation of fumes or vapors by ventilating the work environment and, if necessary, using effective extraction.

Handling:

Fire and explosion protection directions: Avoid airborne dust dispersion to reduce explosion and fire hazards.

General Work Hygiene Recommendations: Observe normal personal hygiene measures, especially do not eat, drink or smoke while handling.

7.2. Conditions for safe storage, including any incompatibilities

Storage silos should be provided with grounding to prevent the accumulation of static electricity.

Additional guidance regarding storage conditions:

In work and storage locations, avoid the presence of granules on the floor, due to the possibility of people slipping.

Carry out storage out of the sun, in well-ventilated, cool and dry places.

Storage should be carried out in such a way as to avoid risks due to instability or breakage of packed units (octabins/bags/cases on pallets). In particular, storage on overlapping rows may pose a hazard to personnel involved in warehouse activities.

7.3 Specific end use(s)

No further information available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

The product does not contain significant amounts of substances whose limit values must be kept under control in working environments.

8.2. Exposure controls

During hot processing, especially at abnormally high temperatures, traces of the monomers and other volatile substances may develop. The work environment must be provided with adequate ventilation or capture systems for dust and gases/vapors that may take place during processing.

8.2.1. Appropriate engineering controls

Accurate ventilation/suction in workplaces.

8.2.2. Individual protection measures, such as personal protective equipment

Personal protective equipment varies according to the possible exposure and hazardousness of working conditions.

Eye/face protection Protective goggles.

Hand/skin protection Protective gloves

Respiratory protection During normal handling operations, it is sufficient to have a mask with a dust filter, to be used when circumstances require it.

8.2.3. Environmental exposure controls

No information is available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Granules
Colour	White
Odour	Lightweight, distinctive
Melting point/freezing point	>58 °C
Boiling point or initial boiling point and boiling range	Not defined
Flammability	Not defined. Characteristic properties of substance groups N.A.
Lower and upper explosion limit	Non-explosive product.
Flash point	Not applicable
Auto-ignition temperature	~340 °C
Decomposition temperature	/.
pH	Not applicable
Kinematic viscosity	Not applicable
Water solubility	Insoluble
Partition coefficient n-octanol/water (log value)	/.
Vapour pressure	Not applicable
Density and/or relative density	20 °C: 0,92-0,96 g/cm ³
Apparent density	20 °C: 450-600 kg/m ³
Relative vapour density	/.

Particle characteristics

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9.2. Other information

No other information is available.

SECTION 10: Stability and reactivity

10.1. Reactivity

The product does not participate in hazardous reactions when stored and handled as prescribed/indicated.

10.2. Chemical stability

Thermal decomposition: Observe recommended processing temperatures to avoid formation of harmful gases or vapors.

Stable under normal storage conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions are known.

10.4. Conditions to avoid

No other information is available.

10.5. Incompatible materials

No other information is available.

10.6. Hazardous decomposition products

The product, if involved in a fire emits fumes composed of water, carbon dioxide, carbon monoxide (if there is a lack of air/oxygen for combustion) and other combustion products.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral)	Based on the available data, the classification criteria are not met.
Skin corrosion/irritation	Based on the available data, the classification criteria are not met.
Serious eye damage/irritation	Based on the available data, the classification criteria are not met.
Respiratory or skin sensitisation	Based on the available data, the classification criteria are not met.
Germ cell mutagenicity	Based on the available data, the classification criteria are not met.
Carcinogenicity	Based on the available data, the classification criteria are not met.
Reproductive toxicity	Based on the available data, the classification criteria are not met.
STOT-single exposure	Based on the available data, the classification criteria are not met.
STOT-repeated exposure	Based on the available data, the classification criteria are not met.
Aspiration hazard	Based on the available data, the classification criteria are not met.

11.2 Information on other hazards

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SECTION 12: Ecological information

12.1. Toxicity

Aquatic toxicity: The product is composed essentially of a high molecular weight polymer, which is not considered ecotoxic.

12.2. Persistence and degradability

The product is a non-biodegradable polymer.

12.3. Bioaccumulative potential

It does not accumulate in organisms.

12.4. Mobility in soil

No other information is available.

12.5. Results of PBT and vPvB assessment

PBT: This substance/mixture is not PBT applying the criteria of REACH Regulation, Annex XIII.

vPvB: This substance/mixture is not vPvB applying the criteria of REACH Regulation, Annex XIII.

12.6. Endocrine disrupting properties

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

12.7 Other adverse effects

No other information is available.

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

The same safety principles stated for the product as for the product as is. apply to the handling of residues.

Residues should be disposed of as required by national or local regulations.

Thermodestruction should be carried out under approved conditions, possibly with energy recovery and at facilities equipped with flue gas scrubbing prior to its release into the atmosphere.

Uncleaned packaging: Disposal in accordance with administrative regulations.

SECTION 14: Transport information

14.1. UN number or ID 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

None.

14.6. Special precautions for user

Not applicable

14.7. Maritime transport in bulk according to IMO instruments

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

Evaluation not required.

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. T06/5E dated 31/01/2023 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 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 Registry of Chemicals in Commerce.

PBT: Persistent, Bioaccumulative and Toxic: hazardous chemicals.

vPvB: very Persistent Very Bioaccumulative pier.

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

IMO: International Maritime Organization.