

Date of first issue: 17/10/96 Revision date: 16/01/2017 Page 1 of 4

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

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.

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e-mail: <u>research@leone.it</u> - <u>http://www.leone.it</u> 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.

The product does not present risks to human health in the form in which it is placed on the market and under the normal and recommended conditions of storage and processing. The product is not hazardous according to the criteria set by the European Union. See also Sections 4 and Section 11. The product is stable and inert under normal handling and storage. It does not present significant risks for the environment.

Information given by this safety data sheet refers to the raw material used to manufacture all or part of Leone products, for this reason some instructions concern the personnel involved in the manufacturing process and not the final user.

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

Ethylene vinyl acetate copolymer (EC no. 607-457-0, CAS no. 24937-78-8).

SECTION 4: First aid measures

4.1. Description of first aid measures

No special measures are required.

Inhalation Dust or vapors emitted by thermal action: remove the patient from the polluted area; entrust the medical

attention.

Skin contact If melted polymer gets in contact with skin, wash immediately with cool water and contact a doctor. Do

not remove the solidified product from the skin. Burns have to be treated clinically.

Eye contact Rinse opened eye for several minutes under running water.

Ingestion No specific measures in case of ingestion of the product as it is. If necessary, seek medical advice.

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

No specific data.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing Media Water, CO2, foam or dry extinguishers.

Unsuitable extinguishing Media None.

5.2. Special hazards arising from the substance or mixture

Carbon dioxide, water. In case of incomplete combustion, carbon monoxide, hydrocarbons, aldehydes, ketones and acetic acid may be developed.

5.3. Advice for firefighters

Use appropriate safety equipment (self breathing apparatus, helmet, safety glasses, working clothes, fireproof gloves and boots).

The product is combustible. Cool containers close to the flame with water spray.



Date of first issue: 17/10/96 Revision date: 16/01/2017 Page 2 of 4

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Do not walk on granules to avoid slipping.

6.2. Environmental precautions

Do not allow product to reach sewage system or waterways.

6.3. Methods and material for containment and cleaning up

Gather with the available mechanical means. Reuse if possible, or dispose of in compliance with current regulations (see Section 13).

6.4. Reference to other sections

For disposal information see Section 13. No dangerous materials are released.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

The formation of dust must be avoided during handling and transportation, in particular during unloading; if there is the formation of dust, it must be eliminated. During the processing of the product, avoid inhalation of fumes or vapours, aerating the environment work and, if necessary, using an suction apparatus.

Protection against explosions and fires

Avoid dispersal of dust in the air to reduce the risks of explosion and fire.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage in rooms and containers The storage bins are to be provided with a ground connection to

avoid the accumulation of static electricity.

Joint storage Not necessary.

Additional details regarding storage In the workplace and storage sites, avoid the presence of granules

on the floor, to reduce the possibility of sliding of the people. In order to preserve the performance of the product, store away from direct sunlight, in well ventilated, cool and dry places.

The storage must be done in order to avoid hazards due to instability or rupture of the packaging units (octabins/bags/boxes on pallets). In particular, the overlapping storage of the product can be a danger for operating and maintenance personnel involved

in warehouse operations.

7.3 Specific end use(s)

No further relevant information available.

SECTION 8: Exposure controls/personal protection

Additional information about design of technical systems: No further data; see Section 7.

8.1. Control parameters

Not necessary.

8.2. Exposure controls

General protective and hygienic measures

During the hot working, especially at abnormally high temperatures, you can develop traces of monomers and other volatile substances. The working environment must be provided with adequate ventilation or dedusting apparatus.

<u>Individual protection measures, such as personal protective equipment (PPE)</u>

Eye/face protection Safety glasses.

Hand protection Chemical resistant gloves.

Breakthrough time of glove's material: see the manufacturer's specifications. Material of gloves: the selection of suitable gloves not only depends on the material, but also on other quality and changes from one manufacturer to

another.

Penetration time of glove material: to be asked the glove's supplier. The

exact break trough time has to be observed.

Respiratory protection During normal handling, use mask with dust filter.

Body protection Standard working clothes.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance Granulate.

Colour White.

Odour Odourless.

pH Not applicable.

Melting point/range >60°C.

Boiling point/range Not defined.



Date of first issue: 17/10/96 Revision date: 16/01/2017 Page 3 of 4

Flammability point Not applicable. Flash point ~340°C.

Risk of explosion Product is not explosive.

Not defined. Upper flammability limit Lower flammability limit Not defined. Not applicable. Vapour pressure Density at 20°C $0.92 - 0.96 \text{ g/cm}^3$. Bulk Density at 20°C $450 - 600 \text{ kg/m}^3$. Solubility in water Insoluble. Dynamic Viscosity Not applicable. Not applicable. Cinematic Viscosity

9.2. Other information

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

SECTION 10: Stability and reactivity

10.1. Reactivity

No further information available.

10.2. Chemical stability

No further information available.

10.3. Possibility of hazardous reactions

Not known.

10.4. Conditions to avoid

Observe the recommended processing temperatures to avoid the formation of gas or harmful vapours.

10.5. Incompatible materials

None

10.6. Hazardous decomposition product(s)

Not known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Potential Acute Health Effects Skin corrosion/irritation: not available.

Ocular damage/irritation: the dust released by the

product may cause ocular irritation.

Skin and respiratory system sensitization: not available.

Signs and Symptoms of Exposure
Medical Conditions Generally Aggravated by Exposure
Carcinogenic or Potential Carcinogenic, mutagenic and
Not available.

toxic for reproduction effects

Other Potential Health Effects

Not known.

Potential Chronic Health Effects

Not known.

SECTION 12: Ecological information

12.1. Toxicity

No further information available.

12.2. Persistence and degradability

The product consists essentially of a high molecular weight polymer, not considered ecotoxic.

12.3. Bioaccumulative potential

It does not accumulate in organisms.

12.4. Mobility in soil

Not available.

12.5. Results of PBT and vPvB assessment

Not applicable.

12.6. Other adverse effects

The product is a non-biodegradable polymer.

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

For what concerns the handling of the residues, use the same principles given for the product.

Waste must be disposed of as required by national or local regulations.



Date of first issue: 17/10/96 Revision date: 16/01/2017 Page 4 of 4

The product, as a result of appropriate treatment (eg. Cleaning, granulating etc), if eligible, may be reused in appropriate application fields, as it is or mixed with virgin material.

The thermal destruction must be carried out in the approved conditions, possibly with energy recover, and at plants equipped with flue gas cleaning before their emission into the atmosphere.

Uncleaned packaging

Disposal according to official regulations.

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).

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. T06/3E dated 29/05/2009 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 sheet.

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.

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

IBC Code: International Bulk Chemicals Code.

PBT: Persistent, Bioaccumulative And Toxic Substances.

vPvB: Very Persistent And Very Bioaccumulative Substances.