

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

Product description: Insulator for resin.

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

Identified Use Applied on plaster model to prevent the adhesion of resin to the model.

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].

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.

The information contained herein is to be referred to the raw material which these products are manufactured with; for this purpose some instructions and indications are related to the personnel employed in the manufacturing processes and not to the final user.

2.2. Label elements

Not applicable.

2.3. Other hazards

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

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

This mixture contains no substances to be mentioned according to the criteria in Section 3.2 of Annex II of REACH.

SECTION 4: First aid measures

Never administer anything by mouth to an unconscious person. If you feel unwell, consult a doctor (if possible, show him the label).

4.1. Description of first aid measures

Inhalation Let the affected person breathe fresh air. Allow the victim to rest..

Skin contact Remove clothing and wash all exposed skin with mild soap and water, then rinse with warm water.

Eye contact Rinse immediately with plenty of water. Seek medical attention if pain, blinking or redness persists

Ingestion Rinse the mouth. DO NOT induce vomiting. Seek emergency medical attention.

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

It is not expected to pose a significant hazard under normal conditions of use.

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

No additional information is available

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

Suitable extinguishing Media Foam. Dry powder. Carbon dioxide. Water spray. Sand.

Unsuitable extinguishing Media Do not use a heavy water spray.

5.2. Special hazards arising from the substance or mixture

No additional information is available

5.3. Advice for firefighters

Fire instructions: Use water mist or spray to cool exposed containers. Use caution when fighting a chemical fire. Prevent firefighting water from entering the environment.

Fire protection: Do not enter the fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures****6.1.1. For non-emergency personnel**

Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment: Equip yourself with appropriate protection.

Emergency procedures: Ventilate the area.

6.2. Environmental precautions

Prevent entry into sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

On the ground, sweep or shovel into appropriate containers. Minimize dust generation. Store away from other materials.

6.4. Reference to other sections

Regarding personal protective equipment to be used, see Section 8. Regarding disposal after cleaning, see Section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Ensure good ventilation in the process area to prevent the formation of vapors.

7.2. Conditions for safe storage, including any incompatibilities

Storage condition: Store only in the original container in a cool, well-ventilated place. Keep the container closed when not in use.

Incompatible products: Strong bases. Strong acids.

Materiali incompatibili: Ignition sources. Direct sunlight.

Storage temperature: < 40 °C

7.3 Specific end use(s)

No additional information is available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information is available

8.2. Exposure controls

No additional information is available

8.2.1. Appropriate engineering controls

No additional information is available

8.2.2. Individual protection measures, such as personal protective equipment

Eye protection: Indossare occhiali con protezione laterale secondo la norma EN 166.

Skin and body protection: Wear appropriate protective clothing. EN 13034

Hand protection: Wear protective gloves. The protective gloves to be used must comply with the specifications of Regulation 2016/425 and the resulting EN 374 standard.

Respiratory protection: Avoid inhalation of the product. Wear an appropriate mask. Dust production: dust mask with P1 type filter.

8.2.3. Environmental exposure controls

Other information: Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Liquid.
Colour	Blue
Odour	Odorless
Melting point/freezing point	0°C
Boiling point or initial boiling point and boiling range	100°C
Flammability	Not available
Lower and upper explosion limit	Not available
Flash point	Not available
Auto-ignition temperature	Not available
Decomposition temperature	Not available
pH	Not available
Kinematic viscosity	Not available
Water solubility	Dispersible
Partition coefficient n-octanol/water (log value)	Not available
Vapour pressure	2,3 kPa 20°C
Density and/or relative density	1,1 (acqua=1) a 15°C
Relative vapour density	Not available
Particle characteristics	Not available
Particle size	Not applicable
Particle size distribution	Not applicable
Particle shape	Not applicable

Particle aspect ratio	Not applicable
Particle aggregation state	Not applicable
Particle agglomeration state	Not applicable
Particle specific surface area	Not applicable
Particle dustiness	Not applicable

9.2. Other information**9.2.1. Information with regard to physical hazard classes**

No additional information available

9.2.2. Other safety characteristics

No additional information available

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

No additional information available

10.2. Chemical stability

Not established.

10.3. Possibility of hazardous reactions

Not established.

10.4. Conditions to avoid

Keep at temperature not exceeding (°C): 200. Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

fume. Carbon monoxide. Carbon dioxide.

SECTION 11: Toxicological information**11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008**

Acute toxicity (oral)	Not classified
Acute toxicity (dermal)	Not classified
Acute toxicity (inhalation)	Not classified
Skin corrosion/irritation	Not classified
	pH: None known
Serious eye damage/irritation	Based on available data, the classification criteria are not met
Respiratory or skin sensitisation	Based on available data, the classification criteria are not met
Germ cell mutagenicity	Based on available data, the classification criteria are not met
Carcinogenicity	Based on available data, the classification criteria are not met
Reproductive toxicity	Based on available data, the classification criteria are not met
STOT-single exposure	Based on available data, the classification criteria are not met
STOT-repeated exposure	Based on available data, the classification criteria are not met
Aspiration hazard	Based on available data, the classification criteria are not met

11.2 Information on other hazards**11.2.1. Endocrine disrupting properties**

No additional information is available

11.2.2. Other information

Potential adverse human health effects and symptoms: Based on the available data, the classification criteria are not satisfactory.

SECTION 12: Ecological information**12.1. Toxicity**

Not classified

12.2. Persistence and degradability

Not established.

12.3. Bioaccumulative potential

Non stabilito.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7 Other adverse effects

Avoid release to the environment.

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

Regional legislation (waste)	Disposal must be done according to official regulations.
Product/Packaging disposal recommendations	Dispose in a safe manner in accordance with local/national regulations.
Ecology - waste materials	Avoid release to the environment.

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

Not applicable.

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

Not applicable.

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. R11/6E 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

CLP: Classification, Labeling and Packaging Regulation; Regulation (EC) No. 1272/2008.

PBT: Persistent and Bioaccumulative Toxic.

vPvB: Mole Persistent Very Bioaccumulative.

REACH: Registration, Evaluation, Authorization and Restriction of Chemicals, Regulation (EC) No. 1907/2006.

STOT: Specific target organ toxicity.

IMO: International Maritime Organization.

EN 166: Personal eye-protection – Specifications.

EN 13034: Protective clothing against liquid chemicals.

EN 374: Protective gloves against dangerous chemicals and micro-organisms.