



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

1.1. Product identifier

Product name Leocryl[®] powder.
Product Description Polymer powder based on Poly Methyl Methacrylate.

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

Identified Use Professional: End use of mixtures containing for manufacturing of dental prosthesis, expanding or repairing dental prosthesis, manufacturing of dental regulators and individually formed impression trays. Polymer for self-curing orthodontic acrylic, either for spray-on or doughing technique. For further information on the utilization, visit our web site: <http://www.leone.it>

Uses advised against Mixtures containing unreacted liquid monomer intended to come into contact with skins or nails.

Refer to Exposure scenario Annex for further details.

1.3. Details of the supplier of the safety data sheet

Leone s.p.a.
I – 50019 Sesto Fiorentino – Firenze - Via P. a Quaracchi, 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.

2. 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.

2.2. Label elements

Not applicable.

2.3. Other hazards

Not classified as PBT or vPvB. Combustible but not readily ignited. May form explosible dust clouds in air. Low toxicity under normal conditions of handling use.

3. SECTION 3: Composition/information on ingredients

3.1. Substances

This product is a mixture.

3.2. Mixtures

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. Substances in the product which may present a health or environmental hazard, or which have been assigned occupational exposure limits, are detailed below. Note that the concentration of hazardous goods in the mixture are too low to give the mixture some of their specific hazard.

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

Hazardous ingredient(s)	%W/W	EC no.	CAS no.	Hazard Class and Category Codes(s)	Hazard statement Code(s)
Dibenzoyl peroxide	<1	202-327-6	94-36-0	Org. Perox. B Skin Sens. 1 Eye Irrit. 2 Aquatic Acute. 1	H241 H317 H319 H400
Barbituric acid	<1	276-940-2	72846-00-5	Skin Irrit. 2 Eye Irrit. 2 STOT SE. 3	H315 H319 H335
Methyl Metacrylate	<1	201-297-1	80-62-6	Flam. Liq. 2 Skin Irrit. 2 Skin Sens. 1 STOT SE. 3	H225 H315 H317 H335

4. SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation IF INHALED: Remove person to fresh air and keep comfortable for breathing.

Skin contact IF ON SKIN (or hair): Wash with plenty of water. If skin irritation or rash occurs: Get medical attention.

Eye contact IF IN EYES: Rinse cautiously with plenty of water for several minutes. Remove contact lenses, if



present and easy to do. Continue rinsing.

Ingestion Do not induce vomiting. Rinse mouth. Obtain medical attention if ill effect occurs.

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

Not applicable.

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

None necessary.

5. SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing Media In case of fire, use water spray, foam, dry powder or CO₂ for extinction.

Unsuitable extinguishing Media Do not use water.

5.2. Special hazards arising from the substance or mixture

Combustible but not readily ignited. Combustion or thermal decomposition will evolve toxic, irritant and flammable vapours. This product can form flammable dust clouds at elevated temperatures. The minimum ignition temperature of a dust cloud of a similar polymer has been measured at approximately 480°C (IEC 21241-2-1).

5.3. Advice for firefighters

A self-contained breathing apparatus and suitable protective clothing should be worn in fire conditions.

6. SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Caution-spillage may be slippery.

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Collect containers for disposal using approved dust respirator.

6.4. Reference to other sections

See Sections 8 and 13.

7. SECTION 7: Handling and storage

7.1. Precautions for safe handling

Do not eat, drink or smoke at the work place. Product as supplied: avoid contact with eyes. Avoid prolonged skin contact. Unlikely to present a dust hazard under normal handling conditions. Dental resins are usually processed in conjunction with reactive monomers and this may require the use of a higher level of PPE than necessary for the polymer itself. Please also see the advice in Section 8 and Section 11.

7.2. Conditions for safe storage, including any incompatibilities

Acrylic polymers are supplied in either bags or bulk containers. Keep containers in a clean, cool and dry area away from heat sources. Natural ventilation is adequate.

Storage temperature: Ambient.

Incompatible materials: Polymer contains residual Benzoyl peroxide. This may react with oxidizing agents, reducing agents, acids, bases and amine leading to decomposition.

7.3. Specific end use(s)

Not intended for thermal processing.

8. SECTION 8: Exposure controls/personal protection

8.1. Control parameters

In each case, the currently valid national exposure limit values for Dibenzoyl Peroxide, Methyl Methacrylate and dust must be observed.

Substance	EC no.	CAS no.	LTEL mg/m ³ (8h TWA)	Notes
Dibenzoyl Peroxide	202-327-6	94-36-0	5	WEL
Methyl Methacrylate	201-297-1	80-62-6	208	WEL
Dust (inhalable dust)			10	WEL
Dust (respirable dust)			4	WEL

8.2. Exposure controls

Appropriate engineering controls

Do not eat, drink or smoke at the work place. Provide adequate ventilation, including appropriate local extraction, to ensure that the occupational exposure limit is not exceeded. Considerations should be given to the work procedures involved and the potential extent of exposure as they may determine whether a higher level of protection is required. The following information is given as general guidance.



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

Eye/face protection	Wear eye/face protection.
Skin protection	Wear suitable gloves. Butyl and nitrile rubber gloves are suitable. Latex surgical gloves offer little protection.
Respiratory protection	A suitable dust mask or dust respirator with filter type P3 or FFP3 (EN143 or EN 149) may be appropriate. In the unlikely event of formation of particularly high levels of dust a self-contained breathing apparatus may be appropriate.

9. SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Fine beads.
Colour	Coloured.
Odour	Typically Methacrylate.
pH:	Not applicable.
Melting point	150-230°C.
Boiling point	Not applicable.
Flash point	390°C ca.
Flammable limits (Lower)	Not applicable.
Flammable limits (Upper)	Not applicable.
Vapour pressure	Not applicable.
Solubility (Water)	Negligible.
Solubility (Other)	Not applicable.
Auto ignition temperature	465°C.
Explosive properties	Weakly to moderately explosive.
Oxidizing properties	Not applicable.
Relative density	1.1-1.18 g/cm ³ .
Bulk density	0.60-0.70 g/ml.

9.2. Other information

None.

10. SECTION 10: Stability and reactivity

10.1. Reactivity

Non-reactive material.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

None know.

10.4. Conditions to avoid

Avoid dust generation.

10.5. Incompatible materials

Polymer contains residual Benzoyl peroxide. This may react with oxidizing agents, reducing agents, acids, bases and amines leading to decomposition.

10.6. Hazardous decomposition product(s)

Methyl methacrylate, Dibenzoyl peroxide, Carbon dioxide, Carbon monoxide.

11. SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

Ingestion	Low oral toxicity.
Inhalation	Unlikely to be hazardous by inhalation.
Skin contact	Contains less than 1.0% residual (Methyl Methacrylate, Dibenzoyl peroxide, Barbituric Acid). During normal handlings this will not constitute a hazard. If the polymer matrix is destroyed e.g. when the product is dissolved in organic solvent, chemical residues will be released from the polymer matrix. Under these conditions, they may produce an allergic reaction in persons already sensitized.
Eye contact	Dust may cause irritation.

12. SECTION 12: Ecological information

12.1. Toxicity

The product is predicted to have low toxicity aquatic organisms.

12.2. Persistence and degradability

The product is non-biodegradable in soil. There is no evidence of degradation in soil and water.



12.3. Bioaccumulative potential

The product has low potential for bioaccumulation.

12.4. Mobility in soil

The product is predicted to have low Mobility in soil.

12.5. Results of PBT and vPvB assessment

No classified as PBT or vPvB.

12.6. Other adverse effects

None know.

13. SECTION 13: Disposal considerations

The waste is considered to be non hazardous. Clean scrap may be processed. Certain package are returnable. Ensure that all packaging are returnable. 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

May be disposed of by landfill in accordance with local regulations. Incineration may be used to recover energy value. Allocation of a waste code number, according to the European Waste Catalogue, should be carried out in agreement with regional waste disposal company.

14. 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.

15. 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

A chemical safety assessment has not been carried out for this mixture. Not applicable.

16. 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. R02/5E 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.

Hazard statements

- H225 Highly flammable liquid and vapour.
- H241 Heating may cause a fire or explosion.
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.
- H335 May cause respiratory irritation.
- H400 Very toxic to aquatic life.

Legend

CAS No.: Chemical Abstract Service Registry number.

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

EN143: Respiratory protective devices - Particle filter - Requirements, testing, marking.

EN149: Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking.

IBC Code: International Bulk Chemicals Code.

LTEL: Long Term Exposure Limit.

PBT: Persistent, Bioaccumulative And Toxic Substances.

STOT SE: Specific Target Organ Toxicity-Single Exposure.

TWA: Time Weighted Average.

vPvB: Very Persistent And Very Bioaccumulative Substances.

WEL: Work Place Exposure Limits.