



1. Identification of the preparation and of the company

1.1 Identification of the preparation

Leocril[®] powder.

1.2 Use of the preparation

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>.

1.3 Company identification

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 (0)55.30.44.1 – Fax ++39 (0)55 374808.

1.4 Emergency telephone

++39 (0)55.30.44.1. An answering machine is on during closing time.

2. Hazards identification

- Routes of entry: methyl methacrylate is absorbed into the body by inhalation and swallowing of the powder.
- Carcinogenicity: none of the components of this product are listed by IARC¹, NTP², OSHA³ or ACGIH⁴ as carcinogens.
- Maximum concentration on workplace (MAC⁵): the accelerator has a MAC value of 5 mg/m³, however this concentration will never be reached by use according to the instructions. In case of dust formation, there is a MAC value of 10 mg/m³ for the powder.
- Short-term effects: none of the components is hazardous to health or environment. Avoid dust formation because of the mechanical irritation of the eyes and respiratory system.
- Long-term effects, repeated exposure: repeated and prolonged overexposure may cause permanent allergic skin rashes.

3. Composition/information on ingredients

Chemical product: polymer based on methyl methacrylate.

Information on hazardous ingredients⁶ and composition %

Chemical name	EC ⁷ Number	%	CAS ⁸ Number	Hazard symbols ⁹	R ⁹ Phrases
Polymethyl methacrylate	-	> 99	9011-14-7	-	-
Accelerator	202-327-6	< 1	94-36-0	O, Xi	R7-36-43
Color agents:		<< 1			
Ferro oxide	215-168-2		1309-37-1	-	-
Titan dioxide	236-675-5		13463-67-7	-	-
organic pigments	-		-	-	-

4. First aid measures

- Inhalation: remove to fresh air, rest, sit half way up. Seek for medical advice if discomfort persists.
- Skin contact: wash thoroughly with soap and water.
- Eye contact: flush thoroughly with water for 15 minutes.
- Ingestion: wash out the mouth and give water to drink.

5. Fire-fighting measures

- Suitable fire extinguishing methods: water-mist, foam, powder and carbon dioxide.
- Not suitable fire extinguishing methods: direct jet of water.
- Hazardous decomposition products: on thermal treatment, some irritating acrylic monomers, like methyl methacrylate, may be formed. Maximum concentrations at workplace for methyl methacrylate: 50 mg/m³.

¹ IARC: International Agency for Research on Cancer, France. IARC is part of the World Health Organization (WHO), Switzerland.

² NTP: National Toxicology Program, USA.

³ OSHA: Occupational Safety and Health Administration, USA.

⁴ ACGIH: American Conference of Governmental Industrial Hygienists, USA.

⁵ MAC: maximum permitted concentration value on workplace.

⁶ The occupational exposure limits (OEL), if known, are listed in section 8.

⁷ Number of European Catalogue. The EC number is made of a sequence of 7 figures, whose first group of 3 figures begins with 2 or 4 depending on which substance is included in the EINECS (European Inventory of Existing Commercial Chemical Substances) or in the ELINCS (European List of Notified Chemical Substances), or it begins with 5 if the substance is included in the list of "ex-polymers."

⁸ Numero CAS (Chemical abstract service).

⁹ Hazards related to the ingredients of the product are indicated in section 2, information to be shown on the label are indicated in section 15.

Explanation of hazardous symbols and Risk phrases is indicated in section 15 and 16.



- Hazardous reactions: polymethyl methacrylate doesn't react, so far known, with other kinds of medical products. Avoid build up of dust as there can be a risk of dust explosion.

6. Accidental release measures

- Leakage/spillage: sweep up the powder and transfer to a container for disposal or recovery. Spillage may present slipping hazard. See section 13 for disposal of the powder.
- Personal precautions: see section 8.
- Environmental precautions: see section 12.

7. Handling and storage

7.1 Handling

Work in a well ventilated place. Avoid dust formation. Keep the powder away from sources of ignition, do not use open fire.

7.2 Storage

Store fireproof in a cool dark place.

- Protection against fire and explosion: avoid dust formation. Take measures against the build-up of electrostatic charges. Keep away from sources of ignition, no open fire.

8. Exposure controls/personal protection

Respiratory protection: in case of dust protection, local exhaust ventilation or an adequate mask with a filter useful for small dust particles.

Hand protection: Polyvinyl alcohol (PVA) or latex gloves. Caution: PVA is soluble in water.

Eye protection: protecting glasses.

Other protection: none

Unusual work/hygienic practices: If dust formation is out of question, no special procedures are necessary. Just follow the standards of good industrial hygiene.

9. Physical and chemical properties

9.1. General information

Appearance: powder, clear or pink

Odour: faint ester like.

9.2. Health, safety and environmental information

Boiling point: not applicable
Melting point: >240°C decomposition
Vapour pressure: not applicable
Solubility in water: insoluble (at 20°C)
pH: not applicable
Flash point: not applicable
Explosive properties: yes, see section 5
Lower explosion limit: not determined
Upper explosion limit: not determined
Viscosity: not applicable
Decomposition temperature: > 240°C
Oxidising properties: not applicable
Density: 1.10 – 1.18 g/cm³ (a 20°C).

10. Stability and reactivity

- Stability: the product is completely stable. However the powder decomposes at a temperature higher than 240°C.
- Hazardous reactions: polymethyl methacrylate does not react, so far known, with other kinds of medical products. Avoid build up of dust as there can be a risk of dust explosion.
- Hazardous decomposition products: on thermal treatment, irritating acrylic monomers, like methyl methacrylate, may be formed. Maximum concentrations at workplace for methyl methacrylate: 50 mg/m³.

11. Toxicological information

According to literature, the powder has a very low oral toxicity. However dust may cause physical abrasion or irritation to the skin and eyes.

Chemical name: *accelerator*
Acute oral rat: LD₅₀¹⁰ => 5000 mg/kg
Acute inhalation rat: LC₅₀¹¹ => 24,3 mg/l /4 hours

¹⁰ LD₅₀ Lethal Dose, dose of substance which rel 50% of organisms used in a toxicity test.



Acute skin: not irritating
Acute eye: irritating

On thermal treatment, irritating acrylic monomers, like methyl methacrylate, may be formed.

Chemical name: methyl methacrylate

Acute oral rat: LD₅₀ = 7872 mg/kg

Acute skin rabbit: LD₅₀ = 9400 mg/kg

Acute inhalation rat: LC₅₀ = 7093 ppm/ 4 hours.

Human patch test: approx. one-third of subjects developed mild redness at site of application; 20% showed sensitivity when tested 10 days later.

12. Ecological information

The product should not be allowed to drain into sewers.

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.

14. Transport information

Not dangerous according to current transportation regulations.

15. Regulatory information

- Health, safety and environmental information shown on the label according to European Directives on hazardous materials and substances

None.

- Information related to further dispositions

This product is CE marked in accordance with the essential requirements of 93/42EEC Directive, Annex I of Directive 67/548EEC, on medical devices.

Accelerator is a substance classified under Annex I of Directive 67/548/EEC with the number 617-008-00-0.

16. Other information

The safety data sheet has been written according to relevant European provisions, on the basis of information received by the supplier of preparation.

Hazard symbols or risk phrases shown on section 3:

Hazard symbols:	O	Oxidizing agent
	Xi	Irritant
Risk phrases:	R 7	May cause fire
	R 36	Irritating to eyes
	R 43	May cause sensitization by skin contact

are specific for some ingredients and not shown on the product label.

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 drawn herein is based on our knowledge at the date of the issue.

The information is exclusively provided related to the product herewith specified 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 doesn't imply any liberty to break patent rights.

Previous safety data sheet n. R02/4E dated 17/05/2001 is to be considered cancelled. 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.

¹¹ LC₅₀ Lethal Concentration, lethal concentration of substance LC for 50% of organisms of a certain population during a certain exposure period.