



1. Identification of the preparation and of the company

1.1 Identification of the preparation

Primer for fiber glass brackets.

1.2 Use of the preparation

Preparation used for bonding fiber glass, micro-filled copolymer and Natura[®] brackets with orthodontic adhesives.

1.3 Company identification

Leone s.p.a.

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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

Human or environmental hazards

- Routes of entry: methyl methacrylate is absorbed into the body by inhalation, swallowing and through the skin. A for the health harmful concentration in the air, is quickly reached at a temperature of 20°C.
- Carcinogenic aspects: none of the components of this preparation are listed by IARC¹, NTP², OSHA³ or ACGIH⁴ as carcinogens.
- Maximum concentration at workplace (MAC⁵), methyl methacrylate: 10ppm = 40 mg/m³.
- Effects short-term: liquid or high vapour concentration can irritate eyes and respiratory system and cause skin rashes.
- Effects long-term, repeated exposure: Prolonged exposure can lead to headaches, nausea, drowsiness and unconsciousness. Repeated and prolonged overexposure may cause permanent allergic skin rashes.

3. Composition/information on ingredients

Information on hazardous ingredients⁶ and composition %

Chemical name	EC ⁷ Number	%	CAS ⁸ Number	Hazard ⁹ symbols	R ⁹ Phrases
Methyl methacrylate	201-297-1	> 95	80-62-6	Xi, F	R 11-36/37/38-43
Crosslinker	202-617-2	< 5	97-90-5	Xi	R 36/37
Accelerator	202-805-4	< 1	99-97-8	Xn	-

4. First aid measures

- Inhalation: remove to fresh air, rest, sit half way up. Get medical help if discomforts persist.
- Skin: remove contaminated clothing. Wash thoroughly with soap and water.
- Eyes: flush thoroughly with water for 15 minutes and contact a doctor.
- Ingestion: wash out the mouth and transport immediately to a hospital.

5. Fire-fighting measures

- Suitable fire extinguishing methods: powder, aqueous film forming foam (AFFF), foam and carbon dioxide.
- Not suitable fire extinguishing methods: direct jet of water.
- Hazardous decomposition preparations: none.
- Hazardous reactions: when heated above the flash point, flammable vapours are emitted which can mix with air and can burn or be explosive. Vapours are heavier than air and may travel to the source of ignition and flash back. Heat can cause polymerisation with rapid release of energy which may rupture container explosively.

6. Accidental release measures

- Leakage / spillage:

Warn bystanders. Eliminate sources of ignition. Prevent monomer from entering drains or water sources. Collect liquid in a open barrel. Absorb spilled liquid with inert material as dry earth or other absorbent material and transfer to a safe place for disposal. See section 13 for disposal of the liquid.

¹ IARC: International Agency for Research on Cancer.

² NTP: National Toxicology Program, USA.

³ OSHA: Occupational Safety and Health Administration, USA.

⁴ ACGIH: American Conference of Governmental Industrial Hygienists.

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 CAS Number (Chemical abstract service).

⁹ Hazards related to the ingredients of the preparation 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.



- Personal precautions: See section 8 for personal protection.
- Environmental precautions: See section 12 for information concerning the environment.

7. Handling and storage

7.1 Handling

Work in a well ventilated place. Material is inflammable; it must be kept away from naked flames or other sources of ignition. Keep away from food, drinks, and animal feed.

When pouring the liquid into smaller containers, use dark glass bottles or aluminium containers only. Do not use transparent containers. Also check the labelling on the new containers concerning the hazard category and the risk and safety phrases.

7.2 Storage

Store in a cool dark place, separated from oxidising agents. Container may be filled only for 80%. Keep container tightly closed to avoid evaporation of the preparation.

The preparation may at heat development, polymerise spontaneously when the expiry date and/or the storage temperature is considerable exceeded.

Protection against fire and explosion:

Keep out of direct sunlight or any source of heat, sparks or flame. Take measures against the build-up of electrostatic charges. In case of fire, keep any closed container of monomer cool by using a fine water spray if it cannot be moved away.

8. Exposure controls/personal protection

8.1. Exposure limit values

Maximum concentration at workplace (MAC), methyl methacrylate: 10ppm = 40 mg/m³.

8.2. Exposure control

Respiratory protection: local exhaust ventilation or an adequate mask with a filter useful for organic vapour (type A₂B₂)¹⁰. Possible a half-mask with active carbon may be used (FHMPE).

Hand protection: polyvinyl alcohol gloves (PVA). Warning: PVA is soluble in water!

Eye protection: protecting glasses.

Other protection: none.

Industrial hygiene: keep working clothes separately. Take off contaminated clothing immediately. Keep away from food, drinks and animal feed.

9. Physical and chemical properties

9.1. General information

Appearance: liquid, colourless

Odour: ester-like.

9.2. Health, safety and environmental information

Boiling point: 101°C

Melting point: -48°C

Vapour pressure: 47 mbar (20°C)

Specific gravity (H₂O=1) 0.94

Solubility in water: 1.5 g/100 ml (20°C)

pH: not applicable

Flash point: 10°C

Autoignition temperature: 430°C

Lower explosion limit: 2.1% volume

Upper explosion limit 12.5% volume

Viscosity: 0.6 mPa·s

Oxidising properties: not applicable.

10. Stability and reactivity

- Stability: the liquid is stabilised with hydroquinone (CAS no. 123-31-9). However polymerisation may occur when the expiry date and/or storage temperature is considerable exceeded.

- Hazardous reactions: when heated above the flash point, flammable vapours are emitted which can mix with air and can burn or be explosive. Vapours are heavier than air and may travel to the source of ignition and flash back. Heat can cause polymerisation with rapid release of energy which may rupture container explosively.

- Hazardous decomposition preparations: by use according the instructions, none.

11. Toxicological information

According to literature.

¹⁰ Filter according to EN 148-1 "Respiratory protective devices - Threads for face pieces - Standard thread connection".



Methyl methacrylate is essentially non toxic when absorbed into the body by any route, but for some few individuals is a powerful skin sensitizer. Apart from this skin allergy, human cases of ill health caused by material are of a low probability.

Long-term inhalation test on rats and hamsters with exposure concentrations ranging from 100 to 400ppm did not show any chronic toxic effects. However concentrations on excess of 100ppm volume may be irritating for some people. Handling of the preparation requires adequate ventilation to prevent accumulation of vapours in work areas.

<i>Chemical name:</i>	<i>Methyl methacrylate</i>
Acute toxicity - oral:	LD ₅₀ ¹¹ (rat): 7872 mg/kg
Acute toxicity - skin:	LD ₅₀ (rabbit): = 9400 mg/kg
Acute toxicity – inhalation:	LC ₅₀ ¹² (rat, 4 hour): = 7093ppm

Human patch test:

Approximate one-third of subjects developed mild redness at site of application. Twenty percent showed sensitivity when tested 10 days later.

<i>Chemical name:</i>	<i>Crosslinker</i>
Acute toxicity – oral:	LD ₅₀ (rat): 3300 mg/kg
Skin irritation rabbit:	not irritating
Eye irritation rabbit:	not irritating

<i>Chemical name:</i>	<i>Accelerator:</i>
Acute toxicity - oral:	LD ₅₀ (rat): = 1.88 ml/kg
Acute toxicity – inhalation:	LD ₅₀ (mouse): = 212 mg/kg
Skin irritation rabbit:	sever irritating
Eye irritation rabbit:	irritating

<i>Chemical name:</i>	<i>UV absorber</i>
Acute toxicity - oral:	LD ₅₀ (rat): => 5000 mg/kg
Skin irritation rabbit:	not irritating
Eye irritation rabbit:	not irritating.

12. Ecological information

The preparation should not be allowed to drain into sewers. There is a severe danger of explosion.

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.

The preparation can be disposed as methyl methacrylate. The preferred method for disposal of waste quantity's of methyl methacrylate is by incineration in accordance with local regulations.

14. Transport information ¹³

UN number:	1247
Land – road/railway (ADR/RID)	
Proper shipping name:	methyl methacrylate, monomer, stabilized
ADR/RID Class:	3
Packaging group:	II
Hazard identification:	339
Leone current shipping mode (ADR):	combination packaging total exemption
Inland waterways (ADNR)	
Proper shipping name:	methyl methacrylate, monomer, stabilized
ADNR Class:	3

¹¹ LD₅₀ Lethal Dose, dose of substance which results to be lethal for 50% of organisms used in a toxicity test.

¹² LC₅₀ Lethal Concentration, , lethal concentration of substance for 50% of organisms of a certain population during a certain exposure period.

¹³ UN: United Nations (ONU). ADR: Accord Dangereuses par Route. RID: Règlement concernant le transport international ferroviaire des marchandises dangereuses. ADNR: Accord pour le transport de matières dangereuses par bateau de navigation intérieure sur le Rhin. IMDG: International Maritime Dangerous Goods. IATA: International Air Transport Association. ICAO: International Civil Aviation Organization MFAG: Medical First Aid Guide. EmS: Emergency Schedules.



Sea (IMDG)
Proper shipping name: methyl methacrylate, monomer, stabilized
UN IMDG: 1247
IMDG Class: 3
Packing group: II
Medical First Aid Guide
(MFAG): 330
Emergency schedules
(EmS): 3-07

Air (IATA-ICAO)
Proper shipping name: methyl methacrylate, monomer, stabilized
UN/ID Number: 1247
IATA Class: 3
Packing group: II.

15. Regulatory information

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

Hazard symbols:



Highly flammable



Irritant

Risk phrases: R 11 Highly flammable
R 36/37/38 Irritating to eyes, respiratory system and skin.
R 43 May cause sensitisation by skin contact

Safety phrases: S 9 Keep container in well ventilated place
S 16 Keep away from ignition sources - no smoking
S 29 Do not empty into drains
S 33 Take precautionary measures against static discharges

- Information related to further dispositions

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

The preparation components are classified under Annex I of Directive 67/548/EEC with the following numbers:

Methyl methacrylate	607-035-00-6	Crosslinker	607-114-00-5
Accelerator	612-056-00-9	Hydroquinone	604-005-00-4.

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.

The preparation is intended for orthodontic and odontological use only. The use of the preparation 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 preparation 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 preparation 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. F01/4E dated 14/10/2008 has 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.



SAFETY DATA SHEET no. F01/5E
PRIMER FOR FIBER GLASS BRACKETS

Date of first issue: 10/10/95
Revision date: 29/05/09
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This safety data sheet is subject to revision.

Visit our web site www.leone.it for an updated version of the present sheet.