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

1.1. Product identifier

Product description: Primer for fiber glass and Natura® brackets.

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

Identified Use: Professional: Preparation used for bonding fiber glass and Natura® (siliceous copolymer) brackets with orthodontic adhesives.

Uses advised against: Mixtures containing unreacted liquid monomer intended to come into contact with skin 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.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Flammable Liquid Category 2	H225
Skin corrosion / Irritation Category 2	H315
Skin sensitization Category 1	H317
STOT-single exposure Category 3	H335

For full text of H phrases see Section 16.

2.2. Label elements

Signal word	Danger	
Hazard statement(s)	H225	Highly flammable liquid and vapour.
	H315	Causes skin irritation.
	H317	May cause an allergic skin reaction.
	H335	May cause respiratory irritation.
Precautionary statement(s)	P210	Keep away from heat sparks, open flame, hot surfaces – No smoking.
	P261	Avoid breathing vapours.
	P280	Wear protective gloves/protective clothing/eye protection/face protection.
	P302+P352	IF ON SKIN: Wash with plenty of soap and water.
	P501	Dispose of contents/container to hazardous waste in accordance with local, State or national legislation. Incinerate under approved controlled conditions, using incinerators suitable for the disposal of flammable organics.

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

Substances in the product which may present a health or environmental hazard, or which have been assigned occupational exposure limits, are detailed below.

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

Hazardous ingredient(s)	%W/W	EC no.	CAS no.	Hazard Class and Category	Hazard statement

				Code(s)	Code(s)
Methyl methacrylate (MMA)	>95	201-297-1	80-62-6	Flammable Liquid 2 Skin Irritation 2 Skin Sensitisation 1 STOT SE 3	H225 H315 H317 H335
Ethylenglycol dimethacrylate	<5	202-617-2	97-90-5	Skin Sens.1 STOT SE 3	H317 H335
N,N-Dimethyl-p-toluidine (DMPT)	<1	202-805-4	99-97-8	Acute Toxicity, oral 3 Acute Toxicity, dermal 3 Acute Toxicity., inhal. 3 STOT RE 2 Aquatic Chronic 3	H301 H311 H331 H373 H412

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. Call a poison centre or doctor if you feel unwell.

Skin contact: IF ON SKIN (or hair): wash with plenty of soap and water. If skin irritation or rash occurs: Get medical attention. Take off contaminated clothing and wash before reuse.

Eye contact: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get immediate medical attention.

Ingestion: Do not induce vomiting. Rinse mouth. Get immediate medical attention.

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

Causes skin irritation. May cause respiratory irritation. May cause an allergic skin reaction.

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

None necessary.

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. Keep containers cool by spraying with water if exposed to fire.

Unsuitable extinguishing Media: Do not use water jet.

5.2. Special hazards arising from the substance or mixture

Highly flammable liquid and vapour. May polymerise on heating. Sealed containers may rupture explosively if hot.

5.3. Advice for firefighters

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

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Eliminate sources of ignition. Wear protective gloves and eye/face protection. Avoid breathing vapours. See section: 8.

6.2. Environmental precautions

Avoid release to the environment. Spillages or uncontrolled discharges into watercourses must be alerted to the appropriate regulatory body.

6.3. Methods and material for containment and cleaning up

Collect spillage. Do not adsorb onto sawdust or other combustible materials. Transfer to a lidded container for disposal or recovery. Use only non-sparking tools.

6.4. Reference to other sections

See Sections 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Do not eat, drink or smoke at the work place. Wash thoroughly after handling. Avoid breathing vapours. Use only outdoors or in a well-ventilated area. The vapour is heavier than air; beware of pits and confined spaces.

Ground container and receiving equipment. Use explosion proof electrical equipment. Use only non-sparking tools. Take precautionary measures against static discharge.

7.2. Conditions for safe storage, including any incompatibilities

Keep container tightly closed. Store in a well-ventilated place. Keep cool. Store locked up. Keep away from heat, sparks, open flame, hot surfaces – No smoking. Protect from sunlight.

IMPORTANT: Methacrylates stored in bulk must be kept in contact with air (oxygen). Monomer vapours are uninhibited and may form polymers in vent or flame arresters, resulting in blockage of vents.

Storage temperature preferably not exceeding 25°C.

7.3. Specific end use(s)

None.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Substance	EC no.	CAS no.	LTEL ppm (8 hr TWA)	LTEL mg/m^3 (8hr TWA)	STEL ppm	STEL mg/m^3	Notes
Methyl Methacrylate	201-297-1	80-62-6	50.	208.	100.	416.	WEL, IOELV.

DNEL	Oral	Inhalation	Dermal
Worker - Long Term – Local effects	1.	210 mg/m^3.	1.5 mg/cm^2.
Worker - Long Term – Systemic effects	1.	210 mg/m^3.	13.67 mg/kg body weight/day.
Worker - Short Term – Local effects	1.	2.	1.5 mg/cm^2.
Worker - Short Term – Systemic effects	1.	2.	3.
Consumer - Long Term – Local effects	1.	105 mg/m^3.	1.5 mg/m^2.
Consumer - Long Term – Systemic effects	1.	74.3 mg/m^3.	8.2 mg/kg body weight/day.
Consumer - Short Term – Local effects	1.	2.	1.5 mg/cm^2.
Consumer - Short Term – Systemic effects	1.	2.	3.

	PNEC
Aquatic Compartment	0.94 mg/l (Fresh water). 0.094 mg/l (Sea water). 5.74 mg/kg dry weight (sediment).
Terrestrial Compartment	1.47 mg/kg dry weight.

1 Oral toxicity: DNEL not established.
2 Long term DNEL is protective of effects resulting from short exposure.
3 Dermal toxicity: DNEL not established.

Substance	EC no.	CAS no.
N,N-Dimethyl-p-toluidine	202-805-4	99-97-8

DNEL	Oral	Inhalation	Dermal
Worker – Long Term – Systemic effects	1.	1.35 mg/m^3.	1.19 mg/kg.
Consumer – Long Term – Systemic effects	2.37 mg/kg.	0.34 mg/m^3.	0.29 mg/kg.

	PNEC
Aquatic Compartment	0.153 mg/l (Fresh water). 0.0152 mg/l (Sea water). 45.38 mg/kg dry weight (sediment).
Terrestrial Compartment	18.68 mg (kg dry weight).

1 Oral toxicity: DNEL not established.

8.2. Exposure controls

Appropriate engineering controls

Do not eat, drink or smoke place. Provide adequate ventilation, including appropriate local extraction, to ensure that the defined occupational exposure limit is not exceeded. Consideration 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.

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

Eye/face protection: Wear eye/face protection.
Safety spectacles/goggles/full face shield.

Skin protection: Wear suitable gloves.
The most appropriate glove depends on consideration of a number of factors.
Including the physical strength of the glove, the degree of manual dexterity required, the amount of permeation through the glove material and the duration of wear. There are a wide variety of elastomeric and laminate gloves available. Common elastomeric glove material include latex (natural rubber), neoprene (poly isoprene), nitrile rubber (ABS rubber), butyl rubber, polyvinyl alcohol (PVA), polyvinyl chloride (PVC) and fluoroelastomers. Laminate gloves are made from heat sealed sheets of PVA between layers of polyethylene. In permeations tests PVA/Polyethylene laminate and supported PVA gloves performed best (note that PVA can be rendered ineffective by contact with water if the laminate layer is breached). Butyl and nitrile rubber gloves offer short-term protection. Later surgical offer little protection. Later surgical gloves offer little

	protection. Gloves should be stored correctly and changed regularly, especially if excessive exposure has occurred.
Respiratory protection	Wear suitable respiratory protective equipment if engineering controls are insufficient, or not present, and exposure to levels above the DNEL is likely. A suitable mask with filter type A (EN141 or EN405) may be appropriate.
Other	Keep working clothes separately. Take off contaminated clothing immediately. Keep away from food, drinks and animal feed.

Environmental exposure controls
Ensure effective control measures when working within the boundaries as specified in Section 6.2 of each GES.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Liquid.
Colour	Clear/colourless.
Odour	Ester like, characteristic strong and acrid.
pH:	Not applicable.
Melting point:	-48°C.
Boiling point	100.5°C.
Flash point	10°C.
Flammable limits (Lower)	2.1% v/v.
Flammable limits (Upper)	12.5% v/v.
Vapour pressure	3600 Pa at 20°C.
Solubility (Water)	Slightly soluble. 1.6% at 20°C.
Solubility (Other)	Miscible with most organic solvents.
Auto ignition temperature	421°C.
Explosive properties	Not applicable.
Oxidizing properties	Not applicable.
Relative density	0.94(Water = 1) at 15.5°C.

9.2. Other information

Minimum Ignition Energy (mJ): 0.89 – 0.97 at 23°C.

SECTION 10: Stability and reactivity

10.1. Reactivity

Will exothermically polymerise in the presence of initiators.

10.2. Chemical stability

Stable in the presence of inhibitor.

10.3. Possibility of hazardous reactions

Susceptible to polymerisation initiated by prolonged storage or the presence of catalyst.

10.4. Conditions to avoid

Heat and direct sunlight.

10.5. Incompatible materials

Polymerisation catalysts, such as peroxy or azo compounds, strong acids, alkalis and oxidising agents. Oxides and salts of transition metals. Organic Nitrogen containing compounds. Cyclohexanone/Cyclohexenol tautomer.

10.6. Hazardous decomposition product(s)

Does not decompose up to auto-ignition temperature.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

(Based on MMA).

Acute toxicity

Ingestion	Low oral toxicity, but ingestion may cause irritation of gastrointestinal tract.
Ingestion toxicity data	LD50 (Oral)>5000mg/kg. N, N-Dimethyl-p-toluidine (100%) LD50 (oral)=1767 mg/kg.
Ingestion STOT-single exposure	Not applicable.
Inhalation	May cause respiratory irritation. May cause drowsiness or dizziness.
Inhalation toxicity data	LC50 (vapour) 7093pp, (29.8 mg/l)(4 hr). N, N-Dimethyl-p-toluidine (100%) LC50 (vapour)=1.4 mg/l.
Inhalation STOT-single exposure	Exposure to high concentrations may produce adverse effects on the nasal epithelium.

Skin contact	May cause an allergic reaction. Cause skin irritation. Repeated or prolonged contact may cause dermatitis.
Skin contact toxicity data	LD50(dermal)>5000 mg/kg. N, N-Dimethyl-p-toluidine (100%)>2000mg/kg.
Skin contact STOT-single exposure	Not applicable.
Eye contact	High vapour concentration will cause irritation.
Eye contact toxicity data	Slight irritant to rabbit eyes (OECD 405).
Eye contact STOT-single exposure	Not applicable.
Aspiration hazard data	Not an aspiration hazard.

Sensitization

Skin sensitization data	Skin sensitization data has been reported is studies with guinea pigs (OECD 406). Evidence of contact sensitization in man.
Respiratory sensitization data	Not a respiratory sensitizer. Irritant to the respiratory system and high concentrations may aggravate pre-existing conditions.

CMR effects (carcinogenicity, mutagenicity and toxicity for reporoduction)

Carcinogenicity data	No evidence of carcinogenicity. (OECD 451).
Germ cell mutagenicity	Salmonella typhimurium (TA1535, 153, 97, 98, 100) negative (OECD 71).
	Teratogenic and fetotoxic effects only observed in presence of maternal toxicity. NOAEC (mouse)=9000 ppm. NOAEC (rat)>2028 ppm.

Repeated exposure toxicity

Chronic exposure	Repeated exposure to high levels produces adverse effects on the heart, lungs, liver and kidneys. Repeated exposure of animals by inhalation to levels at or above the occupational exposure level produces adverse effects on the nasal epithelium (levels 100 and 400 ppm). There is no reason to believe that Methyl Methacrylate represents a carcinogenic or mutagenic hazard to man based upon evidence from well conducted animal studies, relevant mutagenicity studies and adequate epidemiology studies in relevant cohorts. Recent studies in animals have shown that high exposure do not produce embryo or fetotoxic nor teratogenic effects in the presence of maternal toxicity.
STOT- repeated exposure data	NOEL (oral)(rat)(104 weeks)>2000 pm. NOAEC (inhalation)(rat)(104 weeks) 100 ppm (OECD 453). NOAEC (inhalation)(mouse)(14 weeks) 1000 ppm (OECD 412).

SECTION 12: Ecological information

12.1. Toxicity

Low toxicity to fish.
MMA (100%) LC50 (fish)(typically)>100 mg/l.
MMA (100%) LC50 (fathead minnow)(96 hours)(static) 130 mg/l.
DMPT (100%) LC50 (fish) (96 hours) 46-52 mg/l.
Harmful to aquatic invertebrates.
MMA (100%) EC50 (Daphnia magna) (48 hours) 69 mg/l.
Low toxicity to algae.
MMA (100%) EC50 (Selenastrum capricornutum) (96 hours) 170 mg/l.
MMA (100%) NOEC (zebra fish) (35 days) (flow through) 8.4 mg/l.
The product is substantially removed in biological treatment processes.

12.2. Persistence and degradability

Readily biodegradable:
MMA (100%) Chemical Oxygen Demand (COD): 88% (28 days).
Inherent Biodegradation:
Dissolved organic Carbon Removal (DOC removal): >95% (28 days).

12.3. Bioaccumulative potential

The product has low potential for bioaccumulation.

12.4. Mobility in soil

The product is predicted to have high mobility in soil.

12.5. Results of PBT and vPvB assessment

Not classified as PBT or vPvB.

12.6. Other adverse effects

Not subject to international restrictions.

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.
Avoid release to the environment. Decontaminate empty drums before recycling.

13.1. Waste treatment methods

Dispose of contents/container to hazardous waste in accordance with local, state or national legislation. Incinerate under approved controlled conditions, using suitable for disposal of flammable organics.

SECTION 14: Transport information

14.1. UN-number

UN 1247.

14.2. UN proper shipping name

Methyl methacrylate monomer, stabilized.

14.3. Transport hazard class(es)

Class	3
IMDG-Class	3
IMDG EMS	F-E, S-D
IATA	3
ADR-Classification code	F1
ADR HIN	339
ADR-Transport category	2
Tunnel Restriction Code	D/E
RID	3
AND	3
UK CDG Road: Emergency Action Code	3YE

Leone current shipping mode (ADR): combination packaging total exemption.

14.4. Packing group

II.

14.5. Environmental hazards

Not classified as a Marine pollutant.

14.6. Special precautions for user

No special requirements.

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).
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 been carried out for Methyl Methacrylate.

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. F01/6E dated 16/01/2017 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.
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

H301 Toxic if swallowed.
H311 Toxic in contact with skin.
H331 Toxic if inhaled.
H373 May cause damage to organs through prolonged or repeated exposure.
H412 Harmful to aquatic life with long-lasting effects.

Legend:

ADR HIN: accordo europeo relativo ai trasporti internazionali di merci pericolose su strada -Identification Number.
AND: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways.
CAS No.: Chemical Abstract Service Registry number.
CDG: Carriage Of Dangerous Good.
DNEL: Derived No-Effect Levels.
EC50: Half maximal Effective Concentration: Refers to the concentration of toxicant which induces a response halfway between the baseline and maximum after a specified exposure time.
EC No.: European Inventory of Existing Commercial Chemical Substances.
EN141: Specification for Gas Filters & Combined Filters Used in Respiratory Protective Equipment.
EN405: Respiratory protective devices. Valved filtering half masks to protect against gases or gases and particles. Requirements, testing, marking.
GES: Generic Exposure Scenario.
IATA: International Air Transport Association.
IBC Code: International Bulk Chemicals Code.
IMDG EMS: International Maritime Dangerous Goods-Emergency Response Procedures for Ships Carrying Dangerous Goods.
IMDG: International Maritime Dangerous Goods.
IOELV: Indicative Occupational Exposure Limit Value.
LC50: Lethal Concentration 50: lethal concentration of substance for 50% of organisms of a certain population during a certain exposure period.
LD50 Lethal Dose 50: the dose required to kill half the members of a tested population after a specified test duration.
LTEL: Long Term Exposure Limit.
NOAEC: No Observed Effect Concentration.
NOAEL: No Observed Adverse Effect Level.
OECD 405: Organization for Economic Co-operation and Development, Acute Eye Irritation/Corrosion.
OECD 406: Organization for Economic Co-operation and Development, Skin Sensitisation.
OECD 412: Organization for Economic Co-operation and Development, Subacute Inhalation Toxicity: 28-Day Study.
OECD 451: Organization for Economic Co-operation and Development, Carcinogenicity Studies.
OECD 453: Organization for Economic Co-operation and Development, Combined Chronic Toxicity/Carcinogenicity Studies.
PBT: Persistent, Bioaccumulative And Toxic Substances.
PNEC: Predicted No Effect Concentration.
RID: Regulations concerning the International rail trasport of goods Dangerous.
STEL: Short Term Exposure Limit.
STOT RE: Specific Target Organ Toxicity-Repeated Exposure.
STOT SE: Specific Target Organ Toxicity-Single Exposure.
TA: Ames Test.
TWA: Time Weighted Average.
vPvB: Very Persistent And Very Bioaccumulative Substances.
WEL: Work Place Exposure Limits.