Safety Data Sheet

according to regulation (EU) No. 1907/2006

1. Identification of the substance/preparation and of the company/undertaking

1.1. Information on the product
Trade name: Majesthetik-Laseal

1.2. Relevant identified uses of the substance/preparation and uses that are inadvisable
dental use

1.3. Details about the supplier of the safety data sheet
Manufacturer/Supplier:
Company name: picodent Dental Produktions- und Vertriebs-GmbH
Street: Lüdenscheider Str. 24-26
City: D-51688 Wipperfürth
Telephone: +49 2267 6580-0
E-Mail: picodent@picodent.de
Internet: www.picodent.de
Department for information: picodent Dental Produktions- und Vertriebs-GmbH
Telephone-No. +49 2267 6580-0

1.4. Emergency contact number:
Medical Emergency information in case of poisoning: -24 h – Phone: +49 6131 19240
advisory service in German or English language
Poison Information Center Mainz

2. Hazards identification *

2.1. Classification of the substance or mixture
Regulation (EC) No 1272/2008
Flam. Liq. 2; H225
Skin Irrit. 2; H315
Eye Dam. 1; H318
Skin Sens. 1; H317
STOT SE 3; H335
Aquatic Chronic 3; H412

Full text of hazard statements: see SECTION 16.

2.2. Label elements
Regulation (EC) No 1272/2008
Hazard components for labelling
methyl methacrylate
2-Propenoic acid, reaction products with pentaerythritol (PETIA / PETTA)
Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO)

Signal word: Danger

Pictograms:

Hazard pictograms:

H225	Highly flammable liquid and vapour.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H335	May cause respiratory irritation.
H412	Harmful to aquatic life with long lasting effects.

Precautionary statements

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P261	Avoid breathing dust/vapours/spray.
P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection.
P302+P352	IF ON SKIN: Wash with plenty of soap and water.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P501	Dispose of contents/container in accordance with local regulation.

2.3. Other hazards

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.
Polymerization with heat evolution may occur in the presence of radical forming substances (e.g. peroxides), reducing substances, and/or heavy metal ions.

3. Composition/information on ingredients *

3.2. Mixture

Chemical characterization Mixture of acrylic resins and initiators.

Hazardous components

CAS No	Chemical name	Quantity
	EC No / Index No / REACH No	
	Classification (Regulation (EC) No 1272/2008)	
80-62-6	methyl methacrylate	20 - 60 %
	201-297-1 / 607-035-00-6	
	Flam. Liq. 2, Skin Irrit. 2, Skin Sens. 1, STOT SE 3; H225 H315 H317 H335	
	acrylic resin	< 25 %
	Skin Irrit. 2, Eye Irrit. 2; H315 H319	
1245638-61-2	2-Propenoic acid, reaction products with pentaerythritol (PETIA / PETTA)	< 20 %
	629-850-6	
	Acute Tox. 4, Skin Irrit. 2, Eye Dam. 1, Skin Sens. 1, Aquatic Chronic 2; H302 H315 H318 H317 H411	
75980-60-8	Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO)	< 3 %
	278-355-8 / 015-203-00-X	
	Repr. 2, Skin Sens. 1B, Aquatic Chronic 2; H361f H317 H411	

Full text of H and EUH statements: see section 16.

Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
	Specific Conc. Limits, M-factors and ATE		
80-62-6	201-297-1	methyl methacrylate	20 - 60 %
	inhalation: LC50 = 78 mg/l (vapours); dermal: LD50 = > 5000 mg/kg; oral: LD50 = > 5000 mg/kg		
1245638-61-2	629-850-6	2-Propenoic acid, reaction products with pentaerythritol (PETIA / PETTA)	< 20 %
	inhalation: LC50 = > 5 mg/l (dusts or mists); oral: ATE = 500 mg/kg		
75980-60-8	278-355-8	Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO)	< 3 %
	dermal: LD50 = >2000 mg/kg; oral: LD50 = > 5000 mg/kg		

4. First aid measures

4.1. Description of first aid measures

General information
Medical treatment is necessary if symptoms occur which are obviously caused by skin or eye contact with the product or by inhalation of its vapours. Take off all contaminated clothing immediately.

After inhalation
Provide fresh air. When in doubt or if symptoms are observed, get medical advice.

After contact with skin
After contact with skin, wash immediately with plenty of water and soap. Take off immediately all contaminated clothing and wash it before reuse. Medical treatment necessary.

After contact with eyes
After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately.

After ingestion
If swallowed, do not induce vomiting: seek medical advice immediately and show this container or label. Rinse mouth immediately and drink plenty of water.

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

No information available.

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

Treat symptomatically.

5. Fire-fighting measures

5.1. Extinguishing media

Suitable extinguishing agents:
Carbon dioxide (CO2), Foam, Extinguishing powder.

Unsuitable extinguishing media:
Water, Full water jet.

5.2. Special hazards arising from the substance or mixture:

Flammable. Vapours can form explosive mixtures with air. In case of fire may be liberated: Hazardous decomposition products

5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing. Full protection suit.

Additional information

Use water spray jet to protect personnel and to cool endangered containers. Suppress gases/vapours/mists with water spray jet. Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures:

General advice
Remove all sources of ignition. Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and clothes. Use personal protection equipment.

6.2. Environmental precautions:
Do not allow uncontrolled discharge of product into the environment.

6.3. Methods and material for containment and cleaning up:

Other information
Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

6.4. Reference to other sections:
Safe handling: see section 7
Personal protection equipment: see section 8
Disposal: see section 13

7. Handling and storage *

7.1. Precautions for safe handling:

Advice on safe handl
Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray.

Advice on protection against fire and explosion
Keep away from sources of ignition - No smoking. Take precautionary measures against static discharges.
Vapours can form explosive mixtures with air.

Advice on general occupational hygiene
Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme.
Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat or drink.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels
Keep container tightly closed. Keep in a cool, well-ventilated place. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Hints on joint storage
Do not store together with: Oxidising agent.

Further information about storage conditions:
Protect from the action of light. Keep only in the original container at a temperature between 4 -25 °C. Can polymerize with intense heat release.

7.3. Specific end use(s):
dental use

8. Exposure controls/personal protection *

8.1. Control parameters

Occupational exposure limit values

CAS No	Name of agent	ppm	mg/m³	fib/cm³	Category	Origin
80-62-6	Methyl methacrylate	50	-		TWA (8 h)	
		100	-		STEL (15 min)	

DNEL/DMEL values

CAS No	Name of agent			
DNEL type		Exposure route	Effect	Value
75980-60-8	Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO)			
Worker DNEL, long-term		dermal	systemic	0,233 mg/kg bw/day
Consumer DNEL, long-term		inhalation	systemic	0,145 mg/m³
Consumer DNEL, long-term		oral	systemic	0,0833 mg/kg bw/day

PNEC values

CAS No	Name of agent	
Environmental compartment		Value
75980-60-8	Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO)	
Marine water		0,00014 mg/l
Freshwater sediment		0,115 mg/kg
Marine sediment		0,0115 mg/kg
Soil		0,0222 mg/kg

8.2. Exposure controls

Appropriate engineering controls: Do not breathe gas/fumes/vapour/spray.

Individual protection measures, such as personal protective equipment

Eye/face protection tightly fitting goggles

Hand protection Gloves should be replaced regularly, especially after extended contact with the product. For each work-place a suitable glove type has to be selected.

Skin protection Wear suitable protective clothing.

Respiratory protection In case of inadequate ventilation wear respiratory protection.

9. Physical and chemical properties *

9.1. Information on basic physical and chemical properties

Physical state:	Liquid	
Colour:	colourless	
Odour:	stinging	
		Test method
Melting point/freezing point:	not determined	
Boiling point or initial boiling point and boiling range:	100 °C	
Flammability:	Flammable	
Lower explosion limits:	2,1	
Upper explosion limits:	12,5	
Flash point:	10 °C	DIN 51755
Auto-ignition temperature:	430 °C	DIN 51794
Decomposition temperature:	not determined	
pH-Value:	not determined	
Viscosity / kinematic:	not determined	
Water solubility:	not determined	
not determined		
Solubility in other solvents		
Partition coefficient n-octanol/water:	not determined	
Relative vapour density:	not determined	
Particle characteristics:	not applicable	

9.2. Other information

Important information on protection of health	Self-ignition temperature
Solid:	not applicable
Gas:	not applicable
Other safety characteristics	
Evaporation rate:	not determined
Solid content:	not determined

Further Information Product has not been tested. The statement is derived from the properties of the components.

10. Stability and reactivity

10.1. Reactivity. Flammable, Ignition hazard.

10.2. Chemical stability The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions: Polymerization with heat evolution may occur in the presence of radical forming substances (e.g. peroxides), reducing substances, and/or heavy metal ions.

10.4. Conditions to avoid: Protect from the action of light. Keep only in the original container at a temperature between 4 -25 °C. Can polymerize with intense heat release.

10.5. Incompatible materials: Oxidising agent, Reducing agent, Heavy metals, Peroxides.

10.6. Hazardous decomposition products: No known hazardous decomposition products.

11. Toxicological information *

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity Based on available data, the classification criteria are not met.

ATEmix calculated ATE (oral) 3226 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

CAS No	Chemical name Exposure route	Dose	Species	Source	Method
80-62-6	**methyl methacrylate**				
	oral	LD50 > 5000 mg/kg	Rat		
	dermal	LD50 > 5000 mg/kg	Rat		
	inhalation (4 h) vapour	LC50 78 mg/l	RTECS		
1245638-61-2	**2-Propenoic acid, reaction products with pentaerythritol (PETIA / PETTA)**				
	oral	ATE mg/kg	500		
	inhalation (4 h) dust/mist	LC50 > 5 mg/l	Rat		
75980-60-8	**Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO)**				
	oral	LD50 > 5000 mg/kg	Rat	ECHA	OECD 401
	dermal	LD50 >2000 mg/kg	Rat	ECHA	

Irritation and corrosivity Causes skin irritation.
Causes serious eye damage.

Sensitising effects May cause an allergic skin reaction. (methyl methacrylate; 2-Propenoic acid, reaction products with pentaerythritol (PETIA / PETTA); Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO))

Carcinogenic/mutagenic/toxic effects for reproduction Based on available data, the classification criteria are not met.

STOT-single exposure May cause respiratory irritation. (methyl methacrylate)

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.

Additional information on tests The mixture is classified as hazardous according to Directive 1999/45/EC.

12. Ecological information *

12.1. Toxicity Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] | [d]	Species	Source	Method
80-62-6	methyl methacrylate					
	Acute fish toxicity	LC50 > 79 mg/l	96 h	Oncorhynchus mykiss (Rainbow trout)		
	Acute crustacea toxicity	EC50 69 mg/l	48 h	Daphnia magna (Big water flea)		
75980-60-8	**Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO)**					
	Acute fish toxicity	LC50 1,4 mg/l	96 h	Cyprinus carpio (Common Carp)	ECHA	OECD 203
	Acute algae toxicity	ErC50 >2,01 mg/l	72 h	Daphnia magna (Biwater flea)	ECHA	OECD 201
	Acute crustacea toxicity	EC50 3,53 mg/l	48 h	Daphnia magna (Big water flea)	ECHA	OECD 202
	Acute bacteria toxicity	(EC50 >1000 mg/l)	3 h	Activated sludge	ECHA	OECD 209

12.2. Persistence and degradability The product has not been tested.

CAS No	Chemical name			
	Method	Value	d	Source
	Evaluation			
75980-60-8	**Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO)**			
	OECD 301 F	0-10 %	28	
	Not readily biodegradable (according to OECD criteria)			

12.3. Bioaccumulative potential The product has not been tested.

BCF

CAS No	Chemical name	BCF	Species	Source
75980-60-8	Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO)	47-55		

12.4. Mobility in soil The product has not been tested.

12.5. Results of PBT and vPvB assessment The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.
The product has not been tested.

12.6. Endocrine disrupting properties This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7. Other adverse effects No information available.

Further information Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

13. Disposal considerations

13.1. Waste treatment methods

Disposal recommendations Small quantities can be polymerized by light and the cured solid material can be disposed of with the regular garbage. Larger quantities must be disposed of following the regulations of the local authorities. Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil. Dispose of waste according to applicable legislation.

Contaminated packaging Non-contaminated packages may be recycled. Handle contaminated packages in the same way as the substance itself.

14. Transport information

Land transport (ADR/RID)

14.1. UN number or ID number:	UN 1247
14.2. UN proper shipping name:	METHYL METHACRYLATE MONOMER, STABILIZED
14.3. Transport hazard class(es):	3
14.4. Packing group:	II
Hazard label:	3
Classification code:	F1
Limited quantity:	1 L
Transport category:	2
Hazard No:	339
Tunnel restriction code:	D/E

Other applicable information (land transport)

E2

Inland waterways transport (ADN)

14.1. UN number or ID number:	UN 1247
14.2. UN proper shipping name:	METHYL METHACRYLATE MONOMER, STABILIZED
14.3. Transport hazard class(es):	3
14.4. Packing group:	II
Hazard label:	3
Classification code:	F1
Limited quantity:	1 L

Other applicable information (inland waterways transport)

E2

Marine transport (IMDG)

14.1. UN number or ID number:	UN 1247
14.2. UN proper shipping name:	METHYL METHACRYLATE MONOMER, STABILIZED
14.3. Transport hazard class(es):	3
14.4. Packing group:	II
Hazard label:	3
Special Provisions:	-
Limited quantity:	1 L
EmS:	F-E, S-D

Other applicable information (marine transport)

E2

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number or ID number:	UN 1247
14.2. UN proper shipping name:	METHYL METHACRYLATE MONOMER, STABILIZED
14.3. Transport hazard class(es):	3
14.4. Packing group:	II
Hazard label:	3
Limited quantity Passenger:	1 L
IATA-packing instructions - Passenger:	353
IATA-max. quantity - Passenger:	5 L
IATA-packing instructions - Cargo:	364
IATA-max. quantity - Cargo:	60 L

Other applicable information (air transport)

Passenger-LQ: Y341

E2

14.6. Special precautions for user	No information available.
14.7. Maritime transport in bulk according to IMO instruments	not applicable

15. Regulatory information *

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulatory information

Authorisations (REACH, annex XIV):	Substances of very high concern, SVHC (REACH, article 59): Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO)
Restrictions on use (REACH, annex XVII):	Entry 40, Entry 75
Additional information	Observe employment restrictions for young people. Observe employment restrictions for child bearing mothers and nursing (Directive 92/85/EEC).

National regulatory information

Water hazard class (D):	2 - obviously hazardous to water
15.2. Chemical safety assessment	Chemical safety assessments for substances in this mixture were not carried out.

16. Other information *

Abbreviations and acronyms:
ADR: Accord européen sur le transport des marchandises dangereuses par Route
(European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonized System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service
LC50: Lethal concentration, 50%
LD50: Lethal dose, 50%
Flam. Liq: Flammable liquid
Acute Tox: Acute toxicity
Skin Irrit: Skin irritation
Eye Dam: Eye damage
Eye Irrit: Eye irritation
Skin Sens: Skin sensitisation
Repr: Reproductive toxicity
STOT SE: Specific target organ toxicity - single exposure
Aquatic Chronic: Chronic aquatic hazard

Classification for mixtures and used evaluation method according to Regulation (EC) No 1272/2008 [CLP]

Classification	Classification procedure
Flam. Liq. 2; H225	On basis of test data
Skin Irrit. 2; H315	Calculation method
Eye Dam. 1; H318	Calculation method
Skin Sens. 1; H317	Calculation method
STOT SE 3; H335	Calculation method
Aquatic Chronic 3; H412	Calculation method

Relevant H and EUH statements (number and full text)

H225	Highly flammable liquid and vapour.
H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H361f	Suspected of damaging fertility.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

Further Information
The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

* Data compared to the previous version Rev.-No. 1.5 altered.