

# Safety Data Sheet

## According to 1907/2006/EC, Article 31

This version: 2.0 replaces version 01.03.2022.

Revision: 01.04.2024

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### Section 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1 Product identifier

Trade name:	P.U.M.A. hard ADHESIVE
REF	PUA5020 (Part of PUM5000 kit and refill)

1.2 Relevant identified uses of the substance or mixture and uses advised against	Primer for P.U.M.A. hard
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#### 1.3 Details of the supplier of the safety data sheet

Manufacturer:	R-dental Dentalmaterialien GmbH Winterhuder Weg 88 D-22085 Hamburg Germany T +49 (0)40-30 70 70 73-0 E <a href="mailto:info@r-dental.com">info@r-dental.com</a> I <a href="http://www.r-dental.com">www.r-dental.com</a>
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1.4 Emergency telephone number	R-dental Dentalmaterialien GmbH, T +49 (0)40-30 70 70 73-0
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### Section 2: Hazards identification

#### 2.1 Classification of the substance or mixture

Methyl methacrylate	Xi Irritant. F Highly flammable.  R-Sätze: R 11 Highly flammable. R 37/38 Causing irritations at respiratory organs and on skin. R 43 Sensitization possible through skin contact.
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Toluole	Xn Harmful. F Highly flammable.
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2.2 Label elements	The product is labelled according to actual EU-guidelines.
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Hazard pictograms:	No.
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Signal word:	No.
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Additional information:	No.
2.3 Other hazards	Irritating to eyes and skin. Avoid contact with skin and eyes.

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### Section 3: Composition/information on ingredients

3.1 Substances	Not applicable.
3.2 Mixtures	Solution of methyl methacrylate, dimethacrylates and toluene.
Components:	<p>EC-No.: 201-297-1, CAS-No.: [80-62-6] Name: METHYL METHACRYLATE TRGS 900 (Germany) 210 mg/m<sup>3</sup> Resp. 50 ml/m<sup>3</sup> F, Xi - R 11-37/38-43</p> <p>EC-No.. 203-625-9, CAS-No.: [108-88-3] Name: TOLUENE TRGS 900 (Germany) 190 mg/m<sup>3</sup> F, Xn - R11-38-48/20-63-65-67</p> <p>Protecting actions depends on the hazardous concentration and amount of material at working place.</p>
Additional information:	No.

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### Section 4: First-aid measures

4.1 Description of first aid measures	
General information after inhalation:	Supply fresh air; consult physician in case of complaints.
General information after skin contact:	Wash with plenty of water and soap. Remove contaminated clothes.
General information after eye contact:	Rinse with plenty of water and held the eyelid wide open and consult a physician.
General information after swallowing:	Caution if victim vomits. Keep airways free. Risk of aspiration. Immediately consult a physician.
4.2 Most important symptoms and effects, both acute and delayed	See subsection 4.1. Consult physician when in doubt.
4.3 Indication of any immediate medical attention and special treatment needed	See subsection 4.1.

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### Section 5: Fire fighting measures

5.1 Extinguishing media	
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Extinguishing media:	Powder, CO <sub>2</sub> , water or foam.
Unsuitable extinguishing media:	Not known. Suitable to surrounding conditions.
5.2 Special hazards arising from the substance or mixture	Development of hazardous combustion gases or vapours possible in the event of fire.
5.3 Advice for firefighters	Stay in dangerous area only with self-contained breathing apparatus.

## Section 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures	Avoid substance contact. Supply fresh air to working area, working clothes. Do not inhale vapours/aerosols.
6.2 Environmental precautions	Do not let liquid material come into contact with the environment.
6.3 Methods and material for containment and cleaning up	Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose contaminated material as waste according to section 13. Ventilate affected area.
6.4 Reference to other sections	See section 13.

## Section 7: Handling and storage

7.1 Precautions for safe handling	This product should only be used by a dentist and/or a licensed professional. Store away from food stuffs. When in use do not eat, drink or smoke. Always close the bottle immediately. Use only in well ventilated areas.
7.2 Conditions for safe storage, including any incompatibilities	Store tightly closed in dry place in well ventilated rooms and light protected and away from food stuffs. Always close the bottle immediately. Keep away from sources of ignition. Take measure to prevent electrostatic charge.
7.3 Special end use(s)	Store at temperatures below 25 °C and protected from light.

## Section 8: Exposure controls/personal protection

### 8.1 Control parameters

Components with workplace-related limit values that require monitoring:

EG-Nr.: 201-297-1  
CAS-Nr.: [80-62-6]  
Name: Methyl methacrylate  
Art: MAK TRGS900:  
210 mg/m<sup>3</sup> oder 50 ml/m<sup>3</sup>

EG-Nr.: 203-625-9  
CAS-Nr.: [108-88-3]  
Name: Toluole  
Art: MAK TRGS900:  
190 mg/m<sup>3</sup>

There is no need to fear a risk of fetal damage if the workplace limit value and the biological limit value (BGW) are adhered to.

## 8.2 Exposure controls

See down.

### General protective and hygienic measures

Usual hygienic measures for dental practice.  
Wash hands before breaks and at the end of work.  
Keep away from food and beverages.

Eyes:

Eye glasses are recommended.

Hands:

Wear protective gloves. Commercial gloves will not guarantee sufficient protection in every case. Quality of gloves can differ and are tested before use. Penetration times can be verified at gloves manufacturers.

Respiration:

Required if vapours/aerosols are generated. Take Filter A.

Thermal driven:

None.

Environmental exposure:

See subsection 6.2.

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## Section 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

a) Appearance:	Liquid.
aa) Colour:	Colourless.
b) Odour:	Characteristic.
c) Odour threshold:	Not applicable.
d) pH:	Not applicable.
e) Melting point/freezing point:	Not applicable.
f) Initial boiling point and boiling range:	Not applicable.
g) Flash point:	No information available.
h) Evaporation rate:	Not applicable.
i) Flammability (solid/gas):	Not applicable.
j) Upper/lower flammability or explosive limits:	No information available.
k) Vapour pressure:	No information available.
l) Vapour density:	No information available.
m) Relative density:	0,97 g/cm <sup>3</sup> (68 °F)
n) Solubility(ies):	
Water solubility:	Slightly soluble.
Soluble in/miscible with:	Organic solvents.
o) Partition coefficient:	Not applicable.
p) Auto-ignition temperature:	No information available.
q) Decomposition temperature:	Not applicable.
r) Viscosity:	No information available.
s) Explosive properties:	Not applicable.
t) Oxidising properties:	Not applicable.

### 9.2 Other information

None.

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## Section 10: Stability and reactivity

### 10.1 Reactivity

See section 2.

10.2 Chemical stability	Stable when storing cool and light protected taking into account expiration date.
10.3 Possibility of hazardous reactions	Not applicable.
10.4 Conditions to avoid	Avoid heat > 122 °F.
10.5 Incompatible materials	Avoid contact with radical starters as peroxides, reducing agents and so on. Do not use various plastics or rubber as working materials.
10.6 Hazardous decomposition products	No information available.

## Section 11: Toxicological information

11.1 Information on toxicological effects	Allergic reaction to methacrylates by chronic exposure to product are possible.
a) acute toxicity:	Small effects of toxicity.
b) irritation:	
Eye:	Irritating.
Skin:	Irritating.
Inhalation:	Mucosal irritations, in high amounts narcosis, unconsciousness.
Ingestion:	Harmful.
c) corrosivity:	Not known.
d) sensitization:	Sensitizing in case of skin contact possible.
e) repeated dose toxicity:	None.
f) carcinogenicity:	Not known.
g) mutagenicity:	Not known.
h) toxicity for reproduction	Not known.
Toxicological tests:	None.
Experience in practice:	Irritating to the skin, irritating to eyes.
Informations on ingredients:	See section 3.
Additional toxicological information: safety practice.	Handle in accordance with good industrial hygiene and

## Section 12: Ecological information

12.1 Toxicity	Do not let the undiluted material come in contact with the environment.
12.2 Persistence and degradability	No data available.
12.3 Bioaccumulative potential	No data available.
12.4 Mobility in soil	No data available.
12.5 Results of PBT and vPvB assessment	Not applicable.
12.6 Other adverse effects	Do not let the undiluted material come in contact with the environment.

### Section 13: Disposal considerations

13.1 Waste treatment methods	Use proper landfill disposal or incineration in accordance with local, state and federal regulations.
Disposal key number:	Not known.
Uncleaned packaging:	Use proper landfill disposal or incineration in accordance with local, state and federal regulations. Handle contaminated packaging in the same way as the substance itself.
Cleaned packaging:	Use proper landfill disposal or incineration in accordance with local, state and federal regulations.

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### Section 14: Transport information

14.1 UN Number	UN 1993
14.2 UN proper shipping name	Methyl methacrylate, Toluole.
14.3 Transport hazard class(es)	
Land transport ADR/RID, GGVs/GGVE:	UN 1993 FLAMMABLE LIQUID, N.A.G. (Methyl methacrylate, Toluene) 3, II.
Sea transport IMDG/GGVSea:	UN 1993 FLAMMABLE LIQUID, N.O.S. (Methyl methacrylate, Toluene) 3, II. EmS: F-E, S-D.
Air transport ICAO-TI and IATA-DGR:	UN 1993 FLAMMABLE LIQUID, N.O.S. (Methyl methacrylate, Toluene) 3, II.
14.4 Packing group	Not applicable.
14.5 Environmental hazards	See subsection 2.3.
14.6 Special precautions for user	Not applicable.
Kemler-Code:	Not applicable.
14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable.

The transport regulations are cited according to international regulations and in the form applicable in Germany. Possible national deviations in other countries are not considered.

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### Section 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture	The product is a class IIa medical device according to the MDR 2017/745.
15.2 Chemical safety assessment	No.

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### Section 16: Other informations

a) Changes to previous version: Update to MDR 2017/745.

b) Legend to abbreviations:

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 Harmonised 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 (division of the American Chemical Society)

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2

c) Literature references: Not applicable.

d) Methods of evaluation information: Not applicable.

e) Phrases, stated:

F Highly flammable.  
Xi Irritant.  
Xn Harmful.  
R 11 Highly flammable.  
R 37/38 Irritating to respiratory system and skin.  
R 43 May cause sensitization by skin contact.  
R 48/20-63-65 Harmful: danger of serious damage to health by prolonged exposure through inhalation. Possible risk of harm to unborn child. Harmful: may cause lung damage if swallowed.  
S 36/37 Wear suitable protective clothing and gloves. If swallowed do not induce vomiting: seek medical advice immediately and show bottle or label.

f) Training advices: Not applicable.

Data sheet producing area: R-dental Dentalmaterialien GmbH, Hamburg.

The above information is based on our present day knowledge and relates solely to the safety requirements of the product. The data do not signify any warranty with regards to product properties. However users of the product should satisfy themselves that the information given above is sufficient and correct for their circumstances of use.

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