

Safety Data Sheet

According to 1907/2006/EC, Article 31

This version: 4.0 replaces version 05/2017.
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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. soft ® Adhesive

Order-No.: PUA4020

1.2 Relevant identified uses of the substance or mixture and uses advised against
Primer for P.U.M.A. soft ®

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
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E info@r-dental.com
I www.r-dental.com

1.4 Emergency telephone number
R-dental Dentalmaterialien GmbH,
T +49-(0)40-30 70 70 73-0

Section 2: Hazards identification

2.1 Classification of the substance or mixture
Xn Harmfull
R 40 Possible risks of irreversible effects

See Section 15.

2.2 Label elements
The product is classified and labelled according to the CLP regulation.

Hazard pictograms:



GHS07

Signal word: Attention, Danger

Additional information: Medical Devices as defined in MDD 93/42/EEC and which

are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

2.3 Other hazards

PBT, vPvB not applicable.
Avoid contact with skin and eyes.

Section 3: Composition/information on ingredients

3.1 Substances

Not applicable.

3.2 Mixtures

Solution of polyacrylates in dichloromethane.

Components:

CAS-No.: [75-09-2]
Name: DICHLOROMETHANE
MAK: 100 ml/m³ or 350 mg/m³

Protecting actions depends on the hazardous concentration and amount of material at working place.

Additional information:

None.

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 the eyelid held wide open with plenty of water and consult a physician.

General information after swallowing:

Rinse out mouth and then drink plenty of water, but no milk, castor oil or alcohol. Caution if victim vomits. 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.

Section 5: Fire fighting measures

5.1 Extinguishing media

Extinguishing media:

Powder or CO₂ 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

Practically non combustible. Protecting actions in use with

extinguishing media, see subsection 5.1.

Section 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures	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.
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.
7.2 Conditions for safe storage, including any incompatibilities	Store tightly closed in dry place in well ventilated rooms at temperature at 59 - 77 °F and light protected and away from food stuffs. Always close the bottle immediately.
7.3 Special end use(s)	Store at 59 - 77 °F, dry and light protected.

Section 8: Exposure controls/personal protection

8.1 Control parameters	See subsection 3.2.
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.

Section 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties	
a) Appearance:	Liquid.

aa) Colour:	Slightly yellow.
b) Odour:	Sweetish.
c) Odour threshold:	Not applicable.
d) pH:	Neutral.
e) Melting point/freezing point:	About - 139 °F.
f) Initial boiling point and boiling range:	About 104 °F.
g) Flash point:	Not applicable.
h) Evaporation rate:	Not applicable.
i) Flammability (solid/gas):	Not applicable.
j) Upper/lower flammability or explosive limits:	Lower: 13 Vol.-%, upper 22 Vol.-% (Kühn-Birett).
k) Vapour pressure:	About 475 mbar.
l) Vapour density:	Not applicable.
m) Relative density:	1,30 g/cm ³ (68 °F)
n) Solubility(ies):	
Water solubility:	Not soluble.
Soluble in/miscible with:	Soluble in Toluene and THF, slightly in Petrolether.
o) Partition coefficient:	Not applicable.
p) Auto-ignition temperature:	> 1121 °F according to DIN 51794.
q) Decomposition temperature:	Not applicable.
r) Viscosity:	Slightly viscous.
s) Explosive properties:	Not applicable.
t) Oxidising properties:	Not applicable.
9.2 Other information	None.

Section 10: Stability and reactivity

10.1 Reactivity	See section 2.
10.2 Chemical stability	Stable when storing cool and light protected under 77 °F taking into account expiration date.
10.3 Possibility of hazardous reactions	Not applicable.
10.4 Conditions to avoid	Avoid heat > 122 °F. Thermal decomposition occurs > 248 °F.
10.5 Incompatible materials	Avoid contact with alkali metals, alkaline earth metals and metals in powder form.
10.6 Hazardous decomposition products	HCl and phosgene.

Section 11: Toxicological information

11.1 Information on toxicological effects	
a) acute toxicity:	Small effects of toxicity.
b) irritation:	
Eye:	Severe irritating. Risk of corneal clouding.
Skin:	Irritating (Xi), degreasing effects of the skin; possibly followed by secondary inflammation; resorption possible.
Inhalation:	Mucosal irritations, in high amounts narcosis, unconsciousness.
Ingestion:	Nausea and vomiting.
c) corrosivity:	Not known.
d) sensitisation:	Not known.

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:	During the long period of use no health diseases are reported.

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.
Cleaned packaging:	Use proper landfill disposal or incineration in accordance with local, state and federal regulations.

Section 14: Transport information

14.1 UN Number	Not applicable.
14.2 UN proper shipping name	Not applicable.
14.3 Transport hazard class(es)	
Land transport ADR/RID, GGVS/GGVE:	Not classified as dangerous goods.
Sea transport IMDG/GGVSea:	Not classified as dangerous goods.
Air transport ICAO-TI and IATA-DGR:	Not classified as dangerous goods.
14.4 Packing group	Not applicable.
14.5 Environmental hazards	Not applicable.

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.

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 MDD 93/42/EEC.
15.2 Chemical safety assessment	No.

Section 16: Other informations

a) Changes to previous version: Preparing the Material Safety Data Sheet according to 1907/2006/EC, Article 31.

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:

Xn Harmful
R 40 Possible risks of irreversible effects
S 23 Do not breathe vapours
S 24/25 Avoid contact with skin and eyes
S 36/37 Wear suitable protective clothing and gloves

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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