Safety Data Sheet According to 1907/2006/EC, Article 31

This version: 4.0 replaces version 05/2017. Revision: 01.05.2022 Printing date: 01.05.2022

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 against1.3 Details of the supplier of the safety data sheet	Primer for P.U.M.A. soft ®
Manufacturer:	R-dental Dentalmaterialien GmbH Winterhuder Weg 88 D-22085 Hamburg Germany T +49-(0)40-30 70 70 73-0 F +49-(0)40-30 70 70 73-73 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

Hazard pictograms:

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



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/m ³ or 350 mg/m ³
Additional information:	Protecting actions depends on the hazardous concentration and amount of material at working place. None.

Section 4: First-aid measures

4.1 Decription 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 swollowing:	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 spezial treatment needed	See subsection 4.1.

Section 5: Fire fighting measures

5.1 Extinguishing media

Extinguishing media: Unsuitable extinguishing media:

5.2 Special hazards arising from the substance or mixture

5.3 Advice for firefighters

Powder or CO_2 or foam. Not known. Suitable to surrounding conditions.

Development of hazardous combustion gases or vapours possible in the event of fire.

Practically non combustible. Protecting actions in use with

Section 6: Accidental release measures	
6.1 Personal precautions, protective equipment and emergency procedures	Supply fresh air to working area, working clothes. Do not inhalate 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: Hands:	Eye glasses are recommended. 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: Thermal driven: Environmental exposure:	Required if vapours/aerosols are generated. Take Filter A. None. See subsection 6.2.

Section 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

a) Appearence:

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.
1) Vapour density:	Not applicable.
m) Relative density:	$1,30 \text{ g/cm}^3 (68 ^\circ\text{F})$
n) Solubilitiy(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:b) irritation:	Small effects of toxicity.
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 vormitting.
c) corrosivity:	Not known.
d) sensitisation:	Not known.

e) repeated dose toxicity:f) carcinogenicity:g) mutagenicity:h) toxicity for reproduction

Toxicological tests: Experience in practice: Informations on ingredients: Additional toxicological information:

None. Not known. Not known. Not known.

None. Irritating to the skin, irritating to eyes. See section 3. During the long period of use no health deseases are reported.

Section 12: Ecological information

12.1 Toxicity

12.2 Persistence and degradability

12.3 Bioaccumulatice potential

12.4 Mobility in soil

12.5 Results of PBT and vPvB assessment

12.6 Other adverse effects

Do not let the undiluted material come in contact with the environment.

No data available.

No data available.

No data available.

Not applicable.

Do not let the undiluted material come in contact with the environment.

Section 13: Disposal considerations

13.1 Waste treatment methods

Disposal key number: Uncleaned packaging:

Cleaned packaging:

Use proper landfill disposal or incineration in accordance with local, state and federal regulations. Not known. Use proper landfill disposal or incineration in accordance with local, state and federal regulations. 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 breave 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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