

Safety Data Sheet

According to 1907/2006/EC, Article 31

This version: 3.0 replaces version of 06/2017.
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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 Transparent (A-Silicone)

Order-No.: PUK4015

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

Dental impression material.

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
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

STOT RE 1 H372 Causes damage to organs through prolonged or repeated exposure.

See section 15.

2.2 Label elements

Not applicable.

Hazard pictograms:

None.

Signal word:

Not applicable.

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.

Section 3: Composition/information on ingredients

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| 3.1 Substances | Not applicable. |
| 3.2 Mixtures | Mixture of vinyl methyl polymethylsiloxanes, polydimethyl polymethyl hydrogen siloxane, paraffin, silica and pigments. |
| Additional information: | None. |

Section 4: First-aid measures

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| 4.1 Description of first aid measures | |
| General information after inhalation: | Supply fresh air. Consult physician when in doubt. |
| 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: | 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

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|---|---|
| 5.1 Extinguishing media | |
| Extinguishing media: | Water, CO ₂ . |
| Unsuitable extinguishing media: | Not known. |
| 5.2 Special hazards arising from the substance or mixture | Not known. |
| 5.3 Advice for firefighters | Protecting actions in use with extinguishing media, see subsection 5.1. |

Section 6: Accidental release measures

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|---|---|
| 6.1 Personal precautions, protective equipment and emergency procedures | See subsection 4.1. |
| 6.2 Environmental precautions | Do not let unpolymerized material come into contact with the environment. |
| 6.3 Methods and material for containment and cleaning up | Pick-up the material. Dispose contaminated material as waste according to section 13. |
| 6.4 Reference to other sections | See section 13. |

Section 7: Handling and storage

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| 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 dry, at room temperature or cool and away from food stuffs. |
| 7.3 Special end use(s) | Store < 77 °F. |

Section 8: Exposure controls/personal protection

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| 8.1 Control parameters | The mixture does not contain any relevant quantities of substances with workplace-related, monitored limits. |
| 8.2 Exposure controls | None. |
| 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: | Avoid contact with eyes. |
| 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: | Not applicable. |
| Pregnancy: | None. |
| Thermal driven: | None. |
| Environmental exposure: | See subsection 6.2. |

Section 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

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| a) Appearance: | Paste. |
| aa) Colour: | Transparent. |
| b) Odour: | Odourless. |
| c) Odour threshold: | Not estimated. |
| d) pH: | Neutral. |
| e) Melting point/freezing point: | Not estimated. |
| f) Initial boiling point and boiling range: | Not estimated. |
| g) Flash point: | Not applicable. |
| h) Evaporation rate: | Not applicable. |
| i) Flammability (solid/gas): | Not applicable. |
| j) Upper/lower flammability or explosive limits: | Not applicable. |
| k) Vapour pressure: | Negligible. |
| l) Vapour density: | Not applicable. |
| m) Relative density: | 1,30 g/cm ³ (68 °F). |
| n) Solubility(ies): | |
| Water solubility: | Unsoluble. |
| Soluble in/miscible with: | Slightly in toluene and petrolether. |
| o) Partition coefficient: | Not applicable. |
| p) Auto-ignition temperature: | Not applicable. |
| q) Decomposition temperature: | Not applicable. |

Section 13: Disposal considerations

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| 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

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| 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 | 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. |

Section 15: Regulatory information

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| 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: Revision of 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:

H372 Causes damage to organs through prolonged or repeated exposure

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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