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 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 F +49-(0)40-30 70 70 73-73 E <u>info@r-dental.com</u> I <u>www.r-dental.com</u>

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:



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:

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.

None.

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: 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

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: 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) Appearence: Liquid.

aa) Colour: Slightly yellow.b) Odour: Sweetish.c) Odour threshold: Not applicable.

d) pH: Neutral.

e) Melting point/freezing point:
f) Initial boiling point and boiling range:
g) Flash point:
h) Evaporation rate:
Not applicable.
l) 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/cm³ (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:
r) Viscosity:
s) Explosive properties:
t) Oxidising properties.
Not applicable.
Not applicable.
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 vormitting.

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 deseases 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 Bioaccumulatice 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 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.

Prepared by: Dr. Andreas Sprafke, R-dental Dentalmaterialien GmbH.

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

This version: 3.0 replaces version of 06/2017.

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 Gingiva (A-Silicone)

Order-No.: PUK4010

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 <u>info@r-dental.com</u>
I <u>www.r-dental.com</u>

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

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

4.1 Decription 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 swollowing: 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: 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

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

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

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

a) Appearence: Paste.

aa) Colour:

b) Odour:

c) Odour threshold:
d) pH:
e) Melting point/freezing point:
f) Initial boiling point and boiling range:
Not estimated.
Not estimated.
Not estimated.
Not estimated.
Not estimated.
Not estimated.
Not applicable.

g) Flash point:

h) Evaporation rate:
i) Flammability (solid/gas):
j) Upper/lower flammability or explosive limits:
k) Vapour pressure:
l) Vapour density:
m) Relative density:
Not applicable.
Not applicable.
Not applicable.
Not applicable.
1,40 g/cm³ (68 °F).

n) Solubility(ies):

Water solubility: Unsoluble.

Soluble in/miscible with: Slightly in toluene and petrolether.

r) Viscosity: Syringable.
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 < 77 °F, taking into account expiration

date.

10.3 Possibility of hazardous reactions

None with normal handling.

10.4 Conditions to avoid Small evaluation of hydrogen traces with acids, bases,

alcohols, powered metals and metal oxides.

10.5 Incompatible materials See 10.4.

10.6 Hazardous decomposition products

None when storing at normal conditions.

Section 11: Toxicological information

11.1 Information on toxicological effects

a) acute toxicity:
b) irritation:
Not toxic.
Irritating to eyes.

c) corrosivity:
 d) sensitisation:
 e) repeated dose toxicity:
 f) carcinogenicity:
 not known.
 g) mutagenicity:
 Not known.
h) toxicity for reproduction

Toxicological tests: None.

Experience in practice: No hazards known. Informations on ingredients: See section 3.

Additional toxicological information: During the long period of use no health deseases are

reported.

Section 12: Ecological information

12.1 Toxicity Do not let the material come in contact with the

environment.

12.2 Persistence and degradability No data available.

12.3 Bioaccumulatice 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 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 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

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.

Prepared by: Dr. Andreas Sprafke, R-dental Dentalmaterialien GmbH.

Safety Data Sheet

According to 1907/2006/EC, Article 31

This version: 3.0 replaces version of 06/2017.

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 SEAL A+B (A-Silicone)

Order-No.: PSA403132

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 <u>info@r-dental.com</u> I <u>www.r-dental.com</u>

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

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

4.1 Decription 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 swollowing: 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: Water, CO₂. 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

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

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

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

a) Appearence: Paste.

aa) Colour:
Gingiva coloured.
b) Odour:
Odourless.
c) Odour threshold:
Not estimated.
d) pH:
Neutral.
e) Melting point/freezing point:
f) Initial boiling point and boiling range:
Not estimated.
g) Flash point:
Not applicable.

g) Flash point:

h) Evaporation rate:
i) Flammability (solid/gas):
j) Upper/lower flammability or explosive limits:
k) Vapour pressure:
l) Vapour density:
m) Relative density:
Not applicable.
Not applicable.
Not applicable.
Not applicable.
1,40 g/cm³ (68 °F).

n) Solubility(ies):

Water solubility: Unsoluble.

Soluble in/miscible with: Slightly in toluene and petrolether.

r) Viscosity: Syringable. 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 < 77 °F, taking into account expiration

date.

10.3 Possibility of hazardous reactions

None with normal handling.

10.4 Conditions to avoid Small evaluation of hydrogen traces with acids, bases,

alcohols, powered metals and metal oxides.

10.5 Incompatible materials See 10.4.

10.6 Hazardous decomposition products

None when storing at normal conditions.

Section 11: Toxicological information

11.1 Information on toxicological effects

a) acute toxicity:b) irritation:Not toxic.Irritating to eyes.

c) corrosivity: None.
d) sensitisation: None.
e) repeated dose toxicity: Not known.
f) carcinogenicity: Not known.
g) mutagenicity: Not known.
h) toxicity for reproduction Not known.

Toxicological tests: None.

Experience in practice: No hazards known. Informations on ingredients: See section 3.

Additional toxicological information: During the long period of use no health deseases are

reported.

Section 12: Ecological information

12.1 Toxicity Do not let the material come in contact with the

environment.

12.2 Persistence and degradability No data available.

12.3 Bioaccumulatice 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 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 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

15.1 Safety, health and environmental regulations/legislation specific

for the substance of a sisteman

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.

Prepared by: Dr. Andreas Sprafke, R-dental Dentalmaterialien GmbH.