

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

075927108

**The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).**

075927199

## Material Safety Data Sheet according to 91/155/EEC

### 1. Product identification/preparation/company undertaking

Trade name: **R-SI-LINE® METAL-BITE®**

Manufacturer/supplier: R-dental Dentalerzeugnisse GmbH, Winterhuder Weg 88, D-22085 HAMBURG - Germany

Emergency information: Dr. A. Sprafke, Tel.: +49 40-22 75 76 17, E-mail: info@r-dental.com, www.r-dental.com

### 2. Composition/information of ingredients

Chemical characterization: Mixture of vinyl polysiloxanes/hydrogen-poly-dimethylsiloxanes/pigments/silica

Hazardous components: none

### 3. Hazards identification

Classification: Classification corresponds to present EEC guidelines, additionally information by literature

### 4. First-aid measures

General information after skin contact: Wash with plenty of water and soap

General information after eye contact: Rinse with plenty of water and consult a physician

General information after swallowing: Seek medical advice immediately

### 5. Fire fighting measures, Extinguishing media: CO<sub>2</sub>, water

### 6. Accidental release measures

Personal precautions: Not necessary

Environmental precautions: Do not let material come into contact with the environment in a not cured state

Methods for cleaning up not cured material: Pick up the material

Methods for cleaning up cured material: Treat it like plastic disposal

### 7. Handling and storage

Handling procedures: None by correct handling, for dental use only, see instructions for use

Storage: Store horizontally at dry place, at room temperature, away from food stuffs

Requirements at store rooms and containers: Store dry at room temperature

Requirements for storage with other products: Avoid contact with acids, bases, alcohols

### 8. Exposure controls/personal protection, components with limits of value to be supervised at the workplace

Additional information: There are no relevant quantities with limits of values to be supervised at the workplace

Personal protective equipment: Not necessary

General measures of protection and hygiene: Avoid contact with eyes, normal hygienic measures

Respiration: Not necessary, Hands: Carefully handling, Eyes: Protecting

### 9. Physical and chemical properties, Appearance

Form: Paste, Colour: Grey, Odour: Odourless

Information on change in the physical state (Value, unit, method)

Flash point: not applicable, Density: 1,60 g/cm<sup>3</sup> (20 °C, 68 ° F), Viscosity: Heavy viscosity, pH: Neutral

Solubility in/miscibility with: A little bit soluble in toluene and petrolether, Water solubility: Not soluble

Content of solvents: None, Water: Insoluble, Content of solids: Not applicable

### 10. Stability and reactivity

Stability and reactivity: Stable, Incompatibility with other substances: Small evaluation of hydrogen traces with acids, bases, alcohols, powdered metals and metal oxides, Hazardous decomposition products: None by right use

### 11. Toxicological information (estimated)

Acute toxicity: Non toxic, no absorption, Primary irritation skin: Irritating (species rabbit), Eye: Irritating, Inhalation: Non

volatile, Ingestion: Possible toxic when swallowed, Sensitization of product: Not observed, Additional toxicological

information: During the long period of use as impression material no health diseases are reported.

### 12. Ecological information, General information

Biodegradability: Not determined, Fish toxicity: Not determined, Classification of water endangerment: Not determined

Additional information: Do not let the not cured product come into contact with the environment

### 13. Disposal consideration

Recommendation: Not cured material use proper landfill disposal in accordance with local, state and federal regulations

### 14. Transport information

Transport information: Not classified as dangerous goods. Keep away from stuff, acids and bases

Land transport RID/ADR, GGVS/GGVE: Not necessary

Ship transport ADN/ADNR: Not necessary

Sea transport IMDG/GGVSea: Not necessary

Air transport ICAO-TI and IATA-DGR: Not necessary

### 15. Regulatory information, Classification according to EEC-guidelines

According to GEStoffV/EG: No classification necessary to actual EEC guidelines

### 16. Other informations

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 GmbH.

# Safety Data Sheet

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

This version: 2.0 replaces version of 03/2007.  
Revision: 28.06.2017  
Printing date: 28.06.2017

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

#### 1.1 Product identifier

Trade name: R-SI-LINE ® METAL-BITE ® <sup>TM</sup> GOLD

Order-No.: MBK0750

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

Dental registration material.

#### 1.3 Details of the supplier of the safety data sheet

Manufacturer: R-dental Dentalerzeugnisse GmbH  
Winterhuder Weg 88  
D-22085 Hamburg  
Germany  
Phone: +49-(0)40-30 70 70 73-0  
Fax: +49-(0)40-30 70 70 73-73  
E-mail: [info@r-dental.com](mailto:info@r-dental.com)  
Web: [www.r-dental.com](http://www.r-dental.com)

#### 1.4 Emergency telephone number

R-dental Dentalerzeugnisse GmbH,  
Phone: +49-(0)40-30 70 70 73-0

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### 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.

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### 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.

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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 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.
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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

Extinguishing media:	Water, CO <sub>2</sub> .
Unsuitable extinguishing media:	Not known.

5.2 Special hazards arising from the substance or mixture	Not known.
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5.3 Advice for firefighters	Protecting actions in use with extinguishing media, see subsection 5.1.
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#### 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.

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#### Section 7: Handling and storage

7.1 Precautions for safe handling	This product should only be used by a dentist
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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.

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## 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.

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## Section 9: Physical and chemical properties

9.1 Information on basic physical  
and chemical properties

a) Appearance:

Paste.

aa) Colour:

Gold-ochre.

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:

1,55 g/cm<sup>3</sup> (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.

r) Viscosity:

Heavy viscosity.

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 < 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, powdered metals and metal oxides.
10.5 Incompatible materials	See 10.4.
10.6 Hazardous decomposition products	None when storing at normal conditions.

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## Section 11: Toxicological information

11.1 Information on toxicological effects	
a) acute toxicity:	Not toxic.
b) irritation:	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 diseases are reported.

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## 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 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 material come in contact with the environment.

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## 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 I 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.
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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 Dentalerzeugnisse GmbH, Hamburg.

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