

Safety Data Sheet

According to 1907/2006/EC, Article 31

This version: 3.0 replaces version 28.06.2017.
Revision: 15.01.2024
Printing date: 15.01.2024

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

1.1 Product identifier

Trade name: R-SI-LINE ® METAL-BITE ® ™
Order-No.: MBK1074

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 Dentalmaterialien GmbH
Winterhuder Weg 88
D-22085 Hamburg
Germany
Phone: +49 (0)40-30 70 70 73-0
E-mail: info@r-dental.com
Web: www.r-dental.com

1.4 Emergency telephone number

R-dental Dentalmaterialien GmbH,
Phone: +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 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

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) Appearance:	Paste.
aa) Colour:	Grey.
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 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.
r) Viscosity:	Heavy viscosity.

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, powdered 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:	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.

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.

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 MDR 2017/745.
15.2 Chemical safety assessment	No.

Section 16: Other informations

- a) Changes to previous version: Update.
- 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.