Bite to Perfection

Safety Information sheet for Medical Devices according 1907/2006/EG, Article 31

This product is a medical device according to Directive 93/42/EEC and Regulation (EU) 2017/745 (MDR), used invasively or involving contact with the body. A safety data sheet is not legally required for this product. Providing this document is voluntary.

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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 ®
REF:	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 information:	
Manufacturer:	R-dental Dentalmaterialien GmbH Winterhuder Weg 88 D-22085 Hamburg - Germany T +49-(0)40-30 70 70 73-0 E info@r-dental.com I www.r-dental.com
1.4 Emergency telephone number:	R-dental Dentalerzeugnisse GmbH, T +49-(0)40-30 70 70 73-0

Section 2: Hazards identification

2.1 Classification of the substance or mixture (EG) Nr. 1272/2008:	Medical devices according to Directive 93/42/EEC and Regulation (EU) 2017/745 (MDR) that are used invasively or through contact with the body are exempt from the labeling requirements of Regulation (EU) 1272/2008 (CLP/GHS). Although classification and labeling are not required, they are provided here.
Classification:	STOT RE 1 H372 Causes lung damage through prolonged or repeated exposure. Route of exposure: Inhalation.

2.2 Label elements according to CLP Regulation (EEC) No. 1272/2008:	The product is classified and labelled in accordance with the CLP Regulation.
Signal word:	-
Hazard pictograms:	No.
2.3 Other hazards according to CLP Regulation (EEC) No 1272/2008:	No. The product is classified and labelled in accordance with the CLP Regulation.
Results of PBT- and vPvB-assessment:	
PBT:	Not applicable.
vPvB:	Not applicable.

Section 3: Composition/information on ingredients

3.1 Substances:	Not applicable.
3.2 Mixtures:	Mixture of vinylmethylpolymethylsiloxane, polydimethylpolymethylhydrogensiloxane, silicon dioxide, paraffin, silicon dioxide and pigments.
Additional information:	None.

Section 4: First-aid measures

4.1 Decription of first aid measures:

General information:	Call a doctor if symptoms occur that could be caused by the product.
After inhalation:	Supply fresh air.
After skin contact:	Wash with plenty of water and soap. Remove contaminated clothes.
After eye contact:	Rinse with the eyelid held wide open with plenty of water and consult a physician.
After swallowing:	If symptoms persist consult a doctor.
4.2 Most important acute or delayed symptoms and effects:	See subsection 4.1. If in doubt, consult a doctor.
4.3 Information on immediate medical assistance or special treatment:	See subsection 4.1.

Section 5: Fire fighting measures

5.1 Extinguishing media:	
Extinguishing media:	CO_2, water spray. In case of a fire in the surrounding area, vote.
Unsuitable extinguishing media:	None known.
5.2 Special hazards arising from the substance or mixture:	No information available.
5.3 Instructions for fire fighting:	Appropriate protective measures when handling “suitable extinguishing agents”, see subsection 5.1.

Section 6: Accidental release measures

6.1 Personal precautions, protective equipment and procedures to be used in emergencies:	Avoid contact with skin and eyes.
6.2 Environmental precautions:	Do not allow uncured material to come into contact with the environment. Do not allow it to enter the sewer system or groundwater.
6.3 Methods and materials for containment and cleaning:	Pick-up the material and clean.
6.4 Reference to other sections:	See sections 7, 8 and 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 in a dry place, at room temperature or cool below 25°C and away from food.
7.3 Specific end use(s):	See section 7.2.

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 limitation and monitoring:	None.
General protective and hygienic measures:	Observe standard hygiene practices. Wash hands after working with the product. Keep away from food and drinks. Protective measures must be selected according to the specific workplace and depending on the concentration and quantity of the hazardous substance.
Eye and face protection:	Safety glasses are recommended.
Skin protection:	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.
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:	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:	Not applicable.
l) Vapour density:	Not applicable.
m) Densitiy:	1,55 g/cm³ (20 °C)
n) Solubilitiy(ies):	
Water solubility:	Insoluble.
Soluble in/miscible with:	Slightly soluble in toluene and petroleum ether.

o) Partition coefficient:	Not applicable.
p) Auto-ignition temperature:	Not applicable.
q) Decomposition temperature:	Not applicable.
r) Viscosity:	Not applicable.
s) Explosive properties:	Not applicable.
t) Oxidising properties.	Not applicable.
9.2 Other information:	None.

Section 10: Stability and reactivity

10.1 Reactivity:	The product is not reactive under normal use.
10.2 Chemical stability:	Stable when stored below 25 °C, observing the expiration date.
10.3 Possibility of hazardous reactions:	None under normal handling.
10.4 Conditions to avoid:	Slight hydrogen evolution in connection with bases, acids, alcohols, powdered metals or – metal oxides.
10.5 Incompatible materials:	See subsection 10.4.
10.6 Hazardous decomposition products:	None when storing at normal conditions.

Section 11: Toxicological information

11.1 Information on toxicological effects:

Acute toxicity:	None-toxic.
Primary Irritation:	
Eye:	Irritating.
Skin:	No.
Sensitisation:	No.
Toxicological tests:	None.
Practical experience:	No known dangers.
For information on ingredients:	See section 3.
Additional information on toxicological effects:	Experience has shown that proper handling by authorized personnel poses no health risks. No adverse health effects have been observed to date when using this material.

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 Bioaccumulation 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:	No environmental problems are to be expected if handled and used properly.
Water hazard class:	WGK 1 (self-classification): Slightly hazardous to water.

Section 13: Disposal considerations

13.1 Waste treatment methods:	Use proper landfill disposal or incineration in accordance with local, state and federal regulations.
Waste code according to the Waste Catalogue Ordinance (AVV):	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):	Not applicable.
Land transport ADR/RID GGVSE:	Not necessary, not hazardous material.
See transport IMDG/GGVSee:	Not necessary, not hazardous material.
Air transport ICAO-TI und IATA-DGR:	Not necessary, not hazardous material.
14.4 Packing group:	Not applicable.
14.5 Environmental hazards:	See subsection 2.3.
14.6 Special precautions for user:	Not necessary, not hazardous material.
14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:	Not applicable The transport regulations are specified in accordance with international regulations and in the form in which they are applied in Germany. Deviations in other countries are not taken into account.

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 Annex IX, Chapters I and III of Regulation (EU) 2017/745 (MDR).
15.2 Chemical safety assessment:	It was not carried out.
EU regulations:	Not applicable.
Water hazard class:	WGK 1 (self-classification): Slightly hazardous to water.

Section 16: Other informations

a) Changes to previous version:	Preparation of the safety information sheet in accordance with 1907/2006/EC, Article 31.
b) Legend to abbreviations:	
c) Literature references:	Not applicable.
d) Methods of evaluation information:	Not applicable.
e) Hazards statements:	STOT RE 1 H372 Causes lung damage through prolonged or repeated exposure. Route of exposure: Inhalation.
f) Training instructions:	Not applicable.
Data sheet producing area:	R-dental Dentalmaterialien GmbH, Hamburg, Germany.

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 regard 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 Dentalerzeugnisse GmbH.