



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.

This version: 1.0

Revision: -

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

1.1 Product identifier:

Trade name: ReViCal ® RootSealer

REF: RRS1000

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

Indicated for permanent (definitive) sealing of the root canal in combination with gutta-percha.

1.3 Details of the supplier of the safety information:

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 Dentalerzeugnisse GmbH,
Phone: +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: Skin irritation, Category 2, H315 Causes skin irritation.
Eye irritation, Category 2, H319 Causes serious eye irritation.
Specific target organ toxicity - single exposure (STOT SE), Category 3, H335 May cause respiratory irritation.

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:	Warning.
Hazard pictograms:	 GHS07
Hazards statements:	H315 Causes skin irritation. H319 Causes serious eye irritation. H335 May cause respiratory irritation.
Precautionary statements:	P262 Avoid inhaling dust, smoke, gas, mist, vapors, or spray. P305 + P351 + P338 In case of eye contact – If eyelids are open, rinse thoroughly with water and consult a doctor. Remove contact lenses. Continue rinsing.
2.3 Other hazards according to CLP Regulation (EEC) No 1272/2008:	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:	
Inhaltsstoffe:	MTA, radiopaque mineral oxide. Protective measures must be selected according to the specific workplace and depending on the concentration and quantity of hazardous substances.
Hazardous components:	GHS07, H315, H317, H318.
Additional information:	None.

Section 4: First-aid measures

4.1 Description 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:	Seek medical advice immediately.

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, extinguishing powder. 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:

None known.

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 dust formation.

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. Dispose contaminated material as waste according to section 13.

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 dry, at room temperature or cool and away from food stuffs. Storage temperature < 25 °C. Store the product in its original packaging.
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 controls:	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.
Eyes:	Avoid contact with eyes.
Skin:	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 when aerosols are present.
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:	Pale pink.
b) Odour:	Odourless.
c) Odour threshold:	Not estimated.
d) pH:	pH 12.
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) Density:	1.7 g/cm ³ (20 °C)
n) Solubility(ies): Water solubility:	Slightly.
Soluble in/miscible with:	Not applicable.
o) Partition coefficient:	Not applicable.
p) Auto-ignition temperature:	Not applicable (product is not selfigniting).
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 under normal use and storage.
10.3 Possibility of hazardous reactions:	None with normal handling.
10.4 Conditions to avoid:	Heat, sunlight, peroxides, metal powder, strong oxidizing agents, radical initiators..
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:	No information available.
Primary Irritation:	
Eye:	Irritant
Skin:	Slightly irritating.
Sensitisation:	Possible through skin contact.
Additional information on toxicological effects:	Allergic reactions to the product after long-term exposure are possible. 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.
Class:	Not applicable.
Hazard number (Kemler code):	Not applicable.
Classification code:	Not applicable.
Property name:	Not applicable.
Hazard trigger:	Not applicable.
See transport IMDG/GGVSee:	Not necessary, not hazardous material.
Class:	Not applicable.
EmS-No.:	Not applicable.
Property name:	Not applicable.
Hazard trigger:	Not applicable.
Label:	Not applicable.
Air transport ICAO-TI und IATA-DGR:	Not necessary, not hazardous material.
Class:	Not applicable.
Property name:	Not applicable.
Hazard trigger:	Not applicable.
Label:	Not applicable.
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.
Kemler-Code:	Not applicable.
EMS-No.:	Not applicable.
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:	H315 Causes skin irritation. H319 Causes serious eye irritation. H335 May cause respiratory irritation. P262 Avoid inhaling dust, smoke, gas, mist, vapors, or spray. P305 + P351 + P338 In case of eye contact – If eyelids are open, rinse thoroughly with water and consult a doctor. Remove contact lenses. Continue rinsing.
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 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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