

# Safety Data Sheet

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

This version: 1.0  
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### Section 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1 Product identifier

Trade name: ReViCal ® RootSealer

Order-No. (REF): RRS1000

1.2 Relevant identified uses of the substance or mixture and uses advised against  
Bioactive MTA Root canal filling 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 [info@r-dental.com](mailto:info@r-dental.com)  
I [www.r-dental.com](http://www.r-dental.com)

1.4 Emergency telephone number  
R-dental Dentalerzeugnisse GmbH  
T +49-(0)40-30 70 70 73-0

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### Section 2: Hazards identification

#### 2.1 Classification of the substance or mixture according to Regulation EC No. 1272/2008

Skin Irr. 2 H315 Causes skin irritation.  
Skin Sens. 1 H317 May cause an allergic skin reaction.  
H318 Causes serious eye damage.  
Eye Irr. 2 H319 Causes serious eye irritation.

The product is classified according to actual EU-guidelines.  
See Section 15.

#### 2.2 Label elements according to Regulation EC No. 1272/2008

The product is classified and labelled according to the CLP regulation.

#### Hazard pictograms:



GHS07

Signal word: Attention, Danger

Precautionary statements:	P280 Wear protective gloves/protective clothing/eye protection/face protection  P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to go. Continue rinsing.  P302 + P352 IF ON SKIN: Wash with plenty of soap and water
Additional information:	-
2.3 Other hazards	Irritating for eyes and skin. Avoid contact with skin and eyes.

### Section 3: Composition/information on ingredients

3.1 Substances	Not applicable.
3.2 Mixtures	Solution of mineral oxides and methacrylates.
Components:	Mineral oxide GHS05, GHS07, H315, H317, H318. Methacrylate GHS07, H315, H319, H335, H317.  Protecting actions depends on the hazardous concentration and amount of material at working place.
Additional information:	None.

### Section 4: First-aid measures

4.1 Description of first aid measures	
General informations:	Consult a physician if symptoms occur that may be caused By the product.
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.
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. Caution if victim vomits. Risk of aspiration.
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:	CO <sub>2</sub> , water, powder. No restrictions to surrounding conditions.
Unsuitable extinguishing media:	Not known.
5.2 Special hazards arising from the substance or mixture	Not known.
5.3 Advice for firefighters	Practically non combustible. 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. Do not allow to enter drains or groundwater.
6.3 Methods and material for containment and cleaning up	Absorb with binding material.
6.4 Reference to other sections	See section 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	Sealed, unopened pack: Store dry and unopened between 36 - 46 °F and light protected and away from food stuffs.  Opened pack after first use: Store dry between 66 - 77 °F and light protected and away from food stuffs.
7.3 Special end use(s)	See subsection 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 limit values that require monitoring. Good ventilation is sufficient.
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. Protective measures are to be selected specifically for the workplace depending on the concentration and quantity of hazardous substances.
Eyes:	Wear tightly fitting safety eye glasses.
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.  
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:	White.
b) Odour:	Odourless.
c) Odour threshold:	Not applicable.
d) pH:	10-12.
e) Melting point/freezing point:	About 1022-1112 °F (decomposition).
f) Initial boiling point and boiling range:	Not applicable.
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) Relative density:	1,88 g/cm <sup>3</sup> (68 °F)
n) Solubility(ies): Water solubility:	Not soluble.
Soluble in/miscible with:	Not applicable.
o) Partition coefficient:	Not applicable.
p) Auto-ignition temperature:	Not applicable.
q) Decomposition temperature:	Not applicable.
r) Viscosity:	Pasty, creamy.
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	Sealed, unopened pack: Store dry and unopened between 36 - 46 °F and light protected.  Opened pack after first use: Store dry between 66 - 77 °F and light protected.
10.3 Possibility of hazardous reactions	Not applicable.
10.4 Conditions to avoid	Not applicable.
10.5 Incompatible materials	See subsection 10.4.
10.6 Hazardous decomposition products	None under normal storage and handling conditions.

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## Section 11: Toxicological information

### 11.1 Information on toxicological effects

a) acute toxicity:	No informations available.
b) irritation:	
Eye:	Strong corrosive effect. Severe irritating.
Skin:	Irritating. Sensitization possible.
Inhalation:	Slight irritation of the mucous membranes. Causes nausea and intoxication in high concentrations.
Ingestion:	Poisonous.
c) corrosivity:	Not applicable.
d) sensitization:	See b).
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:	Experience has shown that there are no health hazards when used properly by authorized personnel. During the long period of use no health diseases are reported.

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## Section 12: Ecological information

12.1 Toxicity	Do not allow to enter waterways, sewage or soil.
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	If handled and used properly, no environmental problems are to be expected.  WGK 1 slightly hazardous to water (self-assessment).

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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.

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## 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, 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 section 2.3.
14.6 Special precautions for user	Not classified as dangerous goods.
Kemler-Code:	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 given according to the international regulations and in the form as 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	ReViCal ® RootSealer is a class IIa Medical Device according to annex IX, chapter I and III of Regulation (EU) 2017/745 (MDR).
15.2 Chemical safety assessment	No.
Water hazard class:	WGK 1 slightly hazardous to water (self-assessment).

### 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:
- H315 Causes skin irritation.
  - H317 May cause an allergic skin reaction.
  - H318 Causes serious eye damage.
  - H319 Causes serious eye irritation.
  - Xi Irritating
  - R 41 Danger of serious eye damage.
  - S 24 Avoid skin contact.
  - S 26 In case of contact with eyes, rinse thoroughly with water and consult a physician.
  - S 39 Wear safety glasses/face protector.
- f) Training advices: Not applicable.
- Data sheet producing area: R-dental Dentalerzeugnisse 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.

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