



# RE-GEN™ Bioactive EndoPutty

## Safety Data Sheet

according to US HazCom 2012

Issue date: 21 November 2024 Revision date: 21 November 2024 Version: 1.0

### SECTION 1: Identification

#### 1.1. Identification

Product form : Mixtures  
Trade name : RE-GEN™ Bioactive EndoPutty

#### 1.2. Recommended use and restrictions on use

Recommended use : Root canal repair and filling material

#### 1.3. Supplier

Manufacturer:  
Inter-Med, Inc. / Vista Dental Products  
2200 South Street  
Racine, WI 53404  
T: (877)-418-4782

info@vista-dental.com

#### 1.4. Emergency telephone number

Emergency number : 800-424-9300 (North America) / +1 (703) 527-3887 (International)

### SECTION 2: Hazard(s) identification

#### 2.1. Classification of the substance or mixture

##### GHS US classification

Not classified

#### 2.2. GHS Label elements, including precautionary statements

##### GHS US labeling

No labeling applicable

#### 2.3. Other hazards which do not result in classification

No additional information available

#### 2.4. Unknown acute toxicity (GHS US)

No additional information available

### SECTION 3: Composition/Information on ingredients

#### 3.1. Substances

Not applicable

#### 3.2. Mixtures

This mixture does not contain any substances to be mentioned according to the criteria for section 3.2 of HCS

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### SECTION 4: First-aid measures

#### 4.1. Description of first aid measures

First-aid measures general	: Not expected to present a significant hazard under anticipated conditions of normal use. If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation	: Not expected to present a significant hazard under anticipated conditions of normal use. Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact	: Not expected to present a significant hazard under anticipated conditions of normal use. Seek medical attention if ill effect or irritation develops.
First-aid measures after eye contact	: Not expected to present a significant hazard under anticipated conditions of normal use. Seek medical attention if ill effect or irritation develops.
First-aid measures after ingestion	: Not expected to present a significant hazard under anticipated conditions of normal use. If you feel unwell, seek medical advice.

#### 4.2. Most important symptoms and effects (acute and delayed)

Symptoms/effects	: Not expected to present a significant hazard under anticipated conditions of normal use.
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#### 4.3. Immediate medical attention and special treatment, if necessary

Treat symptomatically.

### SECTION 5: Fire-fighting measures

#### 5.1. Suitable (and unsuitable) extinguishing media

Suitable extinguishing media	: Foam. Dry powder. Carbon dioxide. Water spray. Sand.
Unsuitable extinguishing media	: Do not use a heavy water stream.

#### 5.2. Specific hazards arising from the chemical

Fire hazard	: Not expected under normal conditions of use.
Explosion hazard	: None known.
Hazardous decomposition products in case of fire	: Toxic fumes may be released. Thermal decomposition can lead to the release of irritating gases and vapors.

#### 5.3. Special protective equipment and precautions for fire-fighters

Firefighting instructions	: Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.
Protection during firefighting	: Do not attempt to take action without suitable protective equipment.

### SECTION 6: Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures

General measures	: No special requirements.
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##### 6.1.1. For non-emergency personnel

Protective equipment	: No special protection required.
Emergency procedures	: No additional risk management measures required.

##### 6.1.2. For emergency responders

Protective equipment	: No special protection required.
Emergency procedures	: No additional risk management measures required.

#### 6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

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### 6.3. Methods and material for containment and cleaning up

For containment	: Collect spillage. Wipe up with absorbent material (for example cloth).
Methods for cleaning up	: Mechanically recover the product. On land, sweep or shovel into suitable containers.
Other information	: Dispose of materials or solid residues at an authorized site.

### 6.4. Reference to other sections

For further information refer to section 8: "Exposure controls/personal protection". For disposal of residues refer to section 13 : "Disposal considerations".

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Precautions for safe handling	: None reasonably foreseeable.
Hygiene measures	: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Handle in accordance with good industrial hygiene and safety procedures.

### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Keep only in the original container in a cool well ventilated place. Keep container closed when not in use.
Incompatible materials	: Strong acids. Strong bases.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

Zirconium oxide (ZrO <sub>2</sub> ) (1314-23-4)	
USA - ACGIH - Occupational Exposure Limits	
Local name	Zirconium and compounds, as Zr
ACGIH OEL TWA	5 mg/m <sup>3</sup>
ACGIH OEL STEL	10 mg/m <sup>3</sup>
Remark (ACGIH)	TLV® Basis: Resp irr. Notations: A4 (Not classifiable as a Human Carcinogen)
Regulatory reference	ACGIH 2024
Sulfuric acid, calcium salt (1:1) (7778-18-9)	
USA - ACGIH - Occupational Exposure Limits	
Local name	Calcium sulfate, the anhydrate
ACGIH OEL TWA	10 mg/m <sup>3</sup> (inhalable particulate matter)
Remark (ACGIH)	TLV® Basis: Nasal symptoms
Regulatory reference	ACGIH 2024

### 8.2. Appropriate engineering controls

Appropriate engineering controls	: None in normal use conditions. Normal use of this product shall imply use in accordance with the instructions on the packaging.
Environmental exposure controls	: Avoid release to the environment.

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### 8.3. Individual protection measures/Personal protective equipment

#### Personal protective equipment:

None in normal use conditions. Normal use of this product shall imply use in accordance with the instructions on the packaging.

#### Other information:

Do not eat, drink or smoke during use.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Paste.
Color	: White
Odor	: Not available
Odor threshold	: No data available
pH	: > 11
Melting point	: No data available
Freezing point	: Not applicable
Boiling point	: No data available
Flash point	: Not applicable
Relative evaporation rate (butyl acetate=1)	: No data available
Flammability (solid, gas)	: Non flammable.
Vapor pressure	: No data available
Relative vapor density at 20°C	: No data available
Relative density	: No data available
Solubility	: No data available
Partition coefficient n-octanol/water (Log Pow)	: No data available
Auto-ignition temperature	: Not applicable
Decomposition temperature	: No data available
Viscosity, kinematic	: Not applicable
Viscosity, dynamic	: No data available
Explosion limits	: Not applicable
Explosive properties	: No data available
Oxidizing properties	: No data available

### 9.2. Other information

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

### 10.2. Chemical stability

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

### 10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

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### 10.5. Incompatible materials

Strong acids. Strong bases.

### 10.6. Hazardous decomposition products

No hazardous decomposition products known at room temperature.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity (oral)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation)	: Not classified (Based on available data, the classification criteria are not met)
Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: > 11
Serious eye damage/irritation	: Not classified pH: > 11
Respiratory or skin sensitization	: Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity	: Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure	: Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)
Viscosity, kinematic	: Not applicable
Symptoms/effects	: Not expected to present a significant hazard under anticipated conditions of normal use.
Other information	: Likely routes of exposure: ingestion, inhalation, skin and eye.

## SECTION 12: Ecological information

### 12.1. Toxicity

Ecology - general : This material has not been tested for environmental effects.

### 12.2. Persistence and degradability

#### RE-GEN™ Bioactive EndoPutty

Persistence and degradability	Not established.
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### 12.3. Bioaccumulative potential

#### RE-GEN™ Bioactive EndoPutty

Bioaccumulative potential	Not established.
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### 12.4. Mobility in soil

No additional information available

### 12.5. Other adverse effects

Effect on the ozone layer	: No additional information available
Other information	: Avoid release to the environment.

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### SECTION 13: Disposal considerations

#### 13.1. Disposal methods

Waste treatment methods	: Dispose of contents/container in accordance with licensed collector's sorting instructions.
Product/Packaging disposal recommendations	: Dispose in a safe manner in accordance with local/national regulations.
Ecological waste information	: Avoid release to the environment.

### SECTION 14: Transport information

In accordance with DOT / TDG / IMDG / IATA

DOT	TDG	IMDG	IATA
<b>14.1. UN number</b>			
Not regulated for transport			
<b>14.2. Proper Shipping Name</b>			
Not regulated	Not regulated	Not regulated	Not regulated
<b>14.3. Transport hazard class(es)</b>			
Not regulated	Not regulated	Not regulated	Not regulated
<b>14.4. Packing group</b>			
Not regulated	Not regulated	Not regulated	Not regulated
<b>14.5. Environmental hazards</b>			
Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information available			

#### 14.6. Special precautions for user

##### DOT

Not regulated

##### TDG

Not regulated

##### IMDG

Not regulated

##### IATA

Not regulated

#### 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. US Federal regulations

All components of this product are present and listed as Active on the United States Environmental Protection Agency Toxic Substances Control Act (TSCA) inventory, except for:

Silica, amorphous, fumed, crystalline-free	CAS-No. 112945-52-5	> 0 – 5%
Calcium aluminate	CAS-No. 65997-16-2	9.8 – 24.5%

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Chemical(s) subject to the reporting requirements of Section 313 or Title III of the Superfund Amendments and Reauthorization Act (SARA) of 1986 and 40 CFR Part 372.

Aluminum oxide (Al <sub>2</sub> O <sub>3</sub> )	CAS-No. 1344-28-1	> 0 - 15%
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### 15.2. International regulations

No additional information available

### 15.3. US State regulations

California Proposition 65 - This product does not contain any substances known to the state of California to cause cancer, developmental and/or reproductive harm

Component	State or local regulations
Propane-1,2-diol(57-55-6)	U.S. - New Jersey - Right to Know Hazardous Substance List; U.S. - Pennsylvania - RTK (Right to Know) List; U.S. - Minnesota - Hazardous Substance List
Zirconium oxide (ZrO <sub>2</sub> )(1314-23-4)	U.S. - Massachusetts - Right To Know List
Sulfuric acid, calcium salt (1:1)(7778-18-9)	U.S. - New Jersey - Right to Know Hazardous Substance List; U.S. - Pennsylvania - RTK (Right to Know) List; U.S. - Minnesota - Hazardous Substance List; U.S. - Massachusetts - Right To Know List
Aluminum oxide (Al <sub>2</sub> O <sub>3</sub> )(1344-28-1)	U.S. - New Jersey - Right to Know Hazardous Substance List; U.S. - Pennsylvania - RTK (Right to Know) List; U.S. - Minnesota - Hazardous Substance List; U.S. - Massachusetts - Right To Know List; U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List

## SECTION 16: Other information

according to US HazCom 2012

Revision date : 21 November 2024

Other information : None.

Safety Data Sheet (SDS), USA

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.