

SAFETY DATA SHEETS

This SDS packet was issued with item:

071464767

N/A

REGEN Bioactive Endo Sealer

Safety Data Sheet

according to US HazCom 2012

Issue date: 31 December 2022 Revision date: 31 December 2022 Version: 1.0

SECTION 1: Identification

1.1. Identification

Product form : Mixtures
Trade name : REGEN Bioactive Endo Sealer
Product code : KIF

1.2. Recommended use and restrictions on use

Use of the substance/mixture : Root canal sealing 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)

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS US classification

Serious eye damage/eye irritation Category 2

Causes serious eye irritation

2.2. GHS Label elements, including precautionary statements

GHS US labeling

Hazard pictograms (GHS US)

:



Signal word (GHS US)

: Warning

Hazard statements (GHS US)

: Causes serious eye irritation

Precautionary statements (GHS US)

: Wash hands, face thoroughly after handling.

Wear eye protection.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

If eye irritation persists: Get medical advice/attention.

2.3. Other hazards which do not result in classification

No additional information available

2.4. Unknown acute toxicity (GHS US)

Not applicable

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SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

| Name | Product identifier | % | GHS US classification |
|--|----------------------|---------|--|
| Cement, alumina, chemicals | CAS-No.: 65997-16-2 | 10 - 70 | Eye Irrit. 2A, H319 |
| Silica, amorphous, fumed, crystalline-free | CAS-No.: 112945-52-5 | 1 - 3 | Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335 |

*Chemical name, CAS number and/or exact concentration have been withheld as confidential business information

SECTION 4: First-aid measures

4.1. Description of first aid measures

| | |
|---------------------------------------|---|
| First-aid measures general | : If you feel unwell, seek medical advice (show the label where possible). |
| First-aid measures after inhalation | : Not expected to present a significant inhalation hazard under anticipated conditions of normal use. Normal use of this product shall imply use in accordance with the instructions on the packaging. |
| First-aid measures after skin contact | : Not expected to present a significant skin hazard under anticipated conditions of normal use. Normal use of this product shall imply use in accordance with the instructions on the packaging. Get medical advice if skin irritation persists. |
| First-aid measures after eye contact | : IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. |
| First-aid measures after ingestion | : Not expected to present a significant ingestion hazard under anticipated conditions of normal use. Normal use of this product shall imply use in accordance with the instructions on the packaging. If swallowed, rinse mouth. Call a poison center or a doctor if you feel unwell. |

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

| | |
|------------------------------------|----------------------------------|
| Symptoms/effects after eye contact | : Causes serious eye irritation. |
|------------------------------------|----------------------------------|

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 | : Use extinguishing media appropriate for surrounding fire. |
| Unsuitable extinguishing media | : None known. |

5.2. Specific hazards arising from the chemical

| | |
|--|---|
| Fire hazard | : Presents no particular fire or explosion hazard. Thermal decomposition may produce : Calcium oxide. |
| Explosion hazard | : None known. |
| Hazardous decomposition products in case of fire | : Toxic fumes may be released. |

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. |
|---------------------------|--|

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Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Avoid breathing mist, spray, vapors.

6.1.1. For non-emergency personnel

Protective equipment : Wear personal protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

Emergency procedures : Avoid contact with eyes.

6.1.2. For emergency responders

Protective equipment : Wear recommended personal protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

Emergency procedures : Avoid contact with eyes

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

For containment : Collect spillage.

Methods for cleaning up : Wipe up with absorbent material (for example cloth). Take up liquid spill into inert absorbent material. Store away from other materials.

Other information : Dispose in a safe manner in accordance with local/national regulations.

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 : Avoid contact with eyes. Wear personal protection equipment.

Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product. Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep container tightly closed. Keep only in the original container in a cool well ventilated place. Keep container closed when not in use. Store locked up.

Incompatible materials : Strong acids and oxidants.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

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No additional information available

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Cement, alumina, chemicals (65997-16-2)

No additional information available

Silica, amorphous, fumed, crystalline-free (112945-52-5)

USA - OSHA - Occupational Exposure Limits

| | |
|--------------------|----------------------|
| OSHA PEL (TWA) [1] | 80 mg/m ³ |
|--------------------|----------------------|

| | |
|--------------------|--------|
| OSHA PEL (TWA) [2] | 20 ppm |
|--------------------|--------|

USA - NIOSH - Occupational Exposure Limits

| | |
|-----------------|---------------------|
| NIOSH REL (TWA) | 6 mg/m ³ |
|-----------------|---------------------|

8.2. Appropriate engineering controls

| | |
|----------------------------------|--|
| Appropriate engineering controls | : Ensure good ventilation of the work station. |
| Environmental exposure controls | : Avoid release to the environment. |

8.3. Individual protection measures/Personal protective equipment

Personal protective equipment:

Avoid all unnecessary exposure.

Hand protection:

Not required for normal conditions of use. Wear impervious gloves for prolonged contact

Eye protection:

Chemical goggles or safety glasses

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment. Where excessive dust may result, wear approved mask

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 | : Liquid |
| Appearance | : Paste. |
| Color | : White |
| Odor | : Odorless |
| Odor threshold | : No data available |
| pH | : No data available |
| Melting point | : No data available |
| Freezing point | : No data available |
| Boiling point | : No data available |
| Flash point | : No data available |
| Relative evaporation rate (butyl acetate=1) | : No data available |
| Flammability (solid, gas) | : No data available |
| 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 | : No data available |
| Decomposition temperature | : No data available |

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| | |
|----------------------|---------------------|
| Viscosity, kinematic | : No data available |
| Viscosity, dynamic | : No data available |
| Explosion limits | : No data available |
| 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).

10.5. Incompatible materials

Strong acids and oxidants.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced. Thermal decomposition may produce : Calcium oxides.

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) |

Silica, amorphous, fumed, crystalline-free (112945-52-5)

| | |
|--------------------|------------------------|
| LD50 oral rat | 3160 mg/kg |
| LD50 dermal rabbit | > 2000 mg/kg |
| ATE US (oral) | 3160 mg/kg body weight |

| | |
|-----------------------------------|---|
| Skin corrosion/irritation | : Not classified (Based on available data, the classification criteria are not met) |
| Serious eye damage/irritation | : Causes serious eye irritation. |
| 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) |

Silica, amorphous, fumed, crystalline-free (112945-52-5)

| | |
|------------|----------------------|
| IARC group | 3 - Not classifiable |
|------------|----------------------|

| | |
|-----------------------|---|
| Reproductive toxicity | : Not classified (Based on available data, the classification criteria are not met) |
|-----------------------|---|

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STOT-single exposure : Not classified (Based on available data, the classification criteria are not met)

Silica, amorphous, fumed, crystalline-free (112945-52-5)

| | |
|----------------------|-----------------------------------|
| STOT-single exposure | May cause respiratory irritation. |
|----------------------|-----------------------------------|

STOT-repeated exposure : Not classified (Based on available data, the classification criteria are not met)

Viscosity, kinematic : No data available

Symptoms/effects after eye contact : Causes serious eye irritation.

Other information : Likely routes of exposure: ingestion, inhalation, skin and eye

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

Other information : Avoid release to the environment.

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.

Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

In accordance with DOT / TDG / IMDG / IATA

| DOT | TDG | IMDG | IATA |
|---|----------------|----------------|----------------|
| 14.1. UN number | | | |
| Not regulated for transport | | | |
| 14.2. Proper Shipping Name | | | |
| Not applicable | Not applicable | Not applicable | Not applicable |
| 14.3. Transport hazard class(es) | | | |
| Not applicable | Not applicable | Not applicable | Not applicable |
| 14.4. Packing group | | | |
| Not applicable | Not applicable | Not applicable | Not applicable |

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| DOT | TDG | IMDG | IATA |
|--|----------------|----------------|----------------|
| 14.5. Environmental hazards | | | |
| Not applicable | Not applicable | Not applicable | Not applicable |
| No supplementary information available | | | |

SECTION 15: Regulatory information

15.1. US Federal regulations

No additional information available

15.2. International regulations

CANADA

No additional information available

EU-Regulations

No additional information available

National regulations

No additional information available

15.3. US State regulations

No additional information available

| Component | State or local regulations |
|--|---|
| Zirconium oxide (ZrO ₂)(1314-23-4) | U.S. - Massachusetts - Right To Know List |
| 1,2-Propanediol(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 |

SECTION 16: Other information

according to US HazCom 2012

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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.