

**DiaDent**<sup>®</sup>**Material Safety Data Sheet****DiaRoot<sup>®</sup> BioAggregate**

January 1, 2007

**1 - Identification**

<b>Trade Name</b>	DiaRoot <sup>®</sup> BioAggregate		
<b>Synonyms</b>	BioAggregate Root Canal Repair Filling Material		
<b>Product Use</b>	Root Canal Repair Material		
<b>Manufacturer</b>	Innovative BioCeramix Inc. 3650 Wesbrook Mall Vancouver, BC V6S 2L2 Canada	<b>Distributor</b>	DiaDent Group International 11-3871 North Fraser Way Burnaby, BC V5J 5G6 Canada
	Tel: 604-221-6800 Fax: 604-677-6129		Tel: 604-451-8851
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**2 - Composition****BioAggregate Powder**

<b>Description</b>	DiaRoot BioAggregate Root Canal Repair Material is a fine white hydraulic powder cement-like material intended for dental applications. This material is essentially hydraulic calcium silicates, calcium phosphate, amorphous silicon oxide and tantalum oxide, contained in a crystalline mass, not separable into individual components.		
<b>Chemical Formula</b>	<b>Major Compounds</b>	<b>CAS #</b>	<b>Approximate Concentration (%)</b>
3CaO·SiO <sub>2</sub>	Tricalcium silicate	12168-85-3	41
2CaO·SiO <sub>2</sub>	Dicalcium silicate	10034-77-2	24
Ta <sub>2</sub> O <sub>5</sub>	Tantalum pentoxide	1314-61-0	25
Ca(H <sub>2</sub> PO <sub>4</sub> ) <sub>2</sub>	Calcium phosphate monobasic	7758-23-8	6
SiO <sub>2</sub>	Amorphous silicon oxide	7631-86-9	4

**BioA Liquid**

<b>Chemical Formula</b>	<b>Major Compounds</b>	<b>CAS #</b>	<b>Approximate Concentration (%)</b>
H <sub>2</sub> O	Deionized water	7732-18-5	100%

**Hazardous Ingredients**

<b>Chemicals</b>	<b>CSA #</b>	<b>ACGIH TLV-TWA (1995-1996)</b>	<b>OSHA PEL (8-hour TWA)</b>	<b>OSHA PEL (8-hour TWA)</b>
Tricalcium silicate Dicalcium silicate	12168-85-3 10034-77-2	10mg/m <sup>3</sup> total dust	10mg/m <sup>3</sup> total dust	5 mg/m <sup>3</sup> respirable dust
Amorphous silicon oxide	7631-86-9	10mg/m <sup>3</sup> total dust	6mg/m <sup>3</sup> total dust	6 mg/m <sup>3</sup> respirable dust
Tantalum pentoxide	1314-61-0	5mg/m <sup>3</sup> total dust	5mg/m <sup>3</sup> total dust	5mg/m <sup>3</sup> total dust
Calcium phosphate monobasic	7758-23-8	Not listed	Not listed	Not listed

**Trace Ingredients**

Trace amounts of naturally occurring potentially harmful constituents may be detected during chemical analysis.

**3 – Health Hazards Identification**

Routes of Entry	Effects
<b>Eyes</b>	Exposure to airborne dry powder or splashes of moist DiaRoot BioAggregate material may cause immediate or delayed effects ranging from eye irritation or inflammation to chemical burns and in severe instances, blindness.
<b>Skin</b>	<ul style="list-style-type: none"> <li>Exposure to the dry powder and /or moist DiaRoot BioAggregate material may cause discomfort or pain and may cause a delayed response, and therefore cannot be relied upon to alert a person to a hazardous skin exposure.</li> <li>Exposure may cause irritation, drying, cracking or fissuring of the skin. Prolonged exposure can cause severe skin damage in the form of chemical (caustic) burns.</li> </ul>
<b>Inhalation</b>	Exposure may cause irritation to the moist mucus membranes of the nose, throat and upper respiratory system. Pre-existing upper respiratory and lung diseases may be aggravated. The effects may cause delayed lung injury.
<b>Ingestion</b>	Exposure may cause internal discomfort or irritation to the digestive tract.

**4 - First Aid Measures**

Routes of Entry	First Aid Treatment
<b>Eyes</b>	Immediately flush eyes thoroughly with running water for at least 15 minutes, including under the upper and lower eyelids to remove all particles. Seek medical aid.
<b>Skin</b>	Flush skin thoroughly with running water and pH-neutral skin soap or a mild detergent for at least 15 minutes. Remove any contaminated clothes and shoes. Seek medical aid if irritation or inflammation develops or persists. Seek immediate medical aid in the event of burns.
<b>Inhalation</b>	Remove from exposure and move to fresh air immediately. Immediately seek medical aid if breathing is difficult, coughing persists or not breathing.
<b>Ingestion</b>	Do not induce vomiting. If conscious, have the victim drink plenty of water. Immediately seek medical aid.

**Emergency Information**

DiaRoot BioAggregate Root Canal Repair Material is a white powder and when it is in contact with moisture in eyes or on skin, or when mixed with water, DiaRoot BioAggregate becomes highly caustic (pH >12) and will damage or burn (as severely as third-degree) the eyes or skin. Inhalation may cause irritation to the moist mucous membranes of the nose, throat and upper respiratory system or may cause or aggravate certain lung diseases or conditions. Use personal protection methods described in Section 8.

**Carcinogenic Potential**

Although the components used to manufacture DiaRoot BioAggregate Root Canal Repair Material are not listed as carcinogens by NTP, OSHA or IARC; it may, however contain trace amounts of substances recognized as carcinogens by these organizations.

**5 - Fire Fighting Measures**

<b>Conditions of Flammability:</b> None	<b>Auto-ignition Temperature:</b> Not combustible.
<b>Means of Extinction:</b> Use water spray, dry chemical, carbon dioxide, or chemical foam.	<b>Hazardous Combustion Products:</b> None
<b>Flash Point:</b> None	<b>Unusual Fire and Explosion Hazards:</b> None
<b>Upper Flammable Limit:</b> None	<b>Danger of Explosion:</b> None
<b>Lower Flammable Limit:</b> None	<b>Special Fire Fighting Procedures:</b> None

**National Fire Protection Association (NFPA) Ratings**

<b>Health:</b> 1	<b>Reactivity:</b> 0
<b>Flammability:</b> 0	<b>Personal Protective Equipment:</b> B

**6 - Accidental Release Measures**

<b>Person-Related Safety Precautions</b>	Not required.
<b>Measures for Environmental Protection</b>	No special measures required.
<b>Measures for Cleaning of Accidental Release and Spills</b>	<ul style="list-style-type: none"> <li>Wear appropriate person protective equipment (see Section 8).</li> <li>Use dry clean-up methods that do not disperse the powder into the air or entry into surface water and dispose of in a suitable container. Avoid inhaling or contacting the powder.</li> <li>Wipe or scrape up moist material with a moist paper towel and dispose of in a suitable container.</li> <li>Do Not wash large amounts of powder or moist material down drains.</li> </ul>
<b>Additional Information</b>	No dangerous substances are released

**7 – Handling and Storage**

<b>Handling</b>	<b>Information for Safe Handling</b>	<ul style="list-style-type: none"> <li>Wear appropriate gloves to prevent skin exposure (PVC, PE, Natural Rubber or Nitrile gloves).</li> <li>Avoid inhaling the powder.</li> </ul>
	<b>Information About Protection Against Explosions and Fires</b>	No special measures required.
<b>Storage</b>	<b>Requirements</b>	<ul style="list-style-type: none"> <li>Keep dry until used.</li> <li>Store at room temperature in a dry area.</li> <li>Store in a tightly closed container.</li> <li>Store away from food and drinks.</li> <li>Do Not store near ammonia, ammonia nitrate, chlorine or chlorine containing items.</li> </ul>

**8 – Exposure Controls and Personal Protection**

<b>Personal Protective Equipment</b>	<b>Eye Protection</b>	<ul style="list-style-type: none"> <li>Wear safety glasses with side shields or goggles.</li> <li>Contact lenses should not be worn when working with DiaRoot BioAggregate Root Canal Repair Material.</li> </ul>
	<b>Protection of Hands</b>	Wear appropriate gloves to prevent skin exposure (PVC, PE, Natural Rubber or Nitrile gloves).
	<b>Body Protection</b>	Light-weight protective clothing.
	<b>Respirators</b>	Surgical masks are recommended.

**9 - Physical and Chemical Properties**

<b>Physical State:</b>	Solid (powder)	<b>Vapor Pressure</b> (at 20°C) (68°F):	Not applicable.
<b>Color:</b>	White	<b>Vapor Density:</b>	Not applicable.
<b>Odor:</b>	No distinct odor.	<b>Evaporation Rate:</b>	Not applicable.
<b>Specific Gravity</b> (H <sub>2</sub> O = 1.0):	3 to 4	<b>Boiling/Melting Point:</b>	>1000°C (1800°F)
<b>pH (in water):</b>	12 to 13	<b>Solubility in / Miscibility with Water:</b>	Slightly soluble

**10 - Stability and Reactivity**

<b>Chemical Stability</b>	Product is stable. Keep dry until used.
<b>Incompatibility</b>	Moist DiaRoot BioAggregate Root Canal Repair Material is alkaline. It is incompatible with acids, ammonia, ammonia nitrate, ammonium salts, aluminum metal and chlorine.
<b>Reactivity Conditions</b>	No dangerous reactions known.
<b>Hazardous Decomposition</b>	Decomposition will not spontaneously occur.
<b>Hazardous Polymerization</b>	Will not occur.
<b>Conditions to Avoid</b>	Avoid unintentional contact with water to prevent premature setting. Contact with BioA Liquid (deionized water) or water to the powder will result in hydration and produces (caustic) calcium hydroxide.

**11 - Toxicological Information**

Cytotoxicity, mutagenicity and skin sensitization tests have been performed to ensure that DiaRoot BioAggregate Root Canal Repair Material is safe for the indications for use described on the instructions for use.			
<b>Route of Entry:</b>	Skin contact, eye contact, ingestion and inhalation.	<b>Mutagenicity:</b>	Non-mutagenic
<b>Cytotoxicity:</b>	Non-cytotoxic	<b>Skin Sensitization:</b>	No allergic potential after multiple uses.

**12 - Ecological Information**

No known toxicity to plants or animals.
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**13 - Waste Disposal**

<ul style="list-style-type: none"> <li>Dispose of waste material according to regional and federal regulations.</li> <li>Dispose of packaging in an approved landfill or incinerator.</li> </ul>
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**14 - Transportation Information**

No special precautions required. DiaRoot BioAggregate Root Canal Repair Material is not hazardous under the Canada or U.S. Department of Transportation regulations.
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**15 – Regulatory Information**

<b>Status under Canadian Environmental Protection Act</b>	Not listed.
<b>Status under Canadian DSL List</b>	The major compounds of DiaRoot BioAggregate Root Canal Repair Material are on the Canadian DSL List.
<b>Status under WHMIS</b>	DiaRoot BioAggregate Root Canal Repair Material (major compounds) is considered to contain hazardous materials under the hazardous Products Act as defined by the Controlled Products Regulations (Class E – Corrosive Material) and subject to the requirements of WHMIS.
<b>Status under US OSHA Hazard Communication Rule 29 CFR 1910.1200</b>	DiaRoot BioAggregate Root Canal Repair Material (major compounds) is considered to be “hazardous chemicals” under this regulation and should be included in the employer’s hazard communication program.
<b>Status under US CERCLA/Superfund, 40 CFR 117 and 302</b>	Not listed.
<b>Hazard Category under US SARA (Title III), Section 311 and 312</b>	DiaRoot BioAggregate Root Canal Repair Material (major compounds) qualifies as a “hazardous substances” with delayed health effects.
<b>Status under US SARA (Title III), Section 313</b>	Not subject to reporting requirements under Section 313.
<b>Status under US TSCA (as of May 1997)</b>	Some substances in DiaRoot BioAggregate Root Canal Repair Material are on the TSCA inventory list.
<b>Status under the US Federal Hazardous Substances Act</b>	DiaRoot BioAggregate Root Canal Repair Material (major compounds) is considered a hazardous substance subject to statutes promulgated under the subject act.
<b>Status under California Proposition 65</b>	This product may contain chemicals and heavy metals (trace), a substance known to the State of California to cause cancer, birth defects or other reproductive harm. California law requires the manufacturer to give the above warning in the absence of definitive testing to prove that the defined risk does not exist.

**16 - Miscellaneous Information**

<b>Prepared By/Date</b>	DiaDent Group International January 1, 2007
<b>Date of Previous MSDS</b>	Not applicable
<p>DiaRoot BioAggregate Root Canal Repair Material should be used according to the manufacturer’s instructions. DiaRoot BioAggregate Root Canal Repair Material reacts chemically with BioA Liquid or water, and that specific intermediate products of this reaction (i.e. calcium hydroxide, a common material used in dental procedures) is present only while the product is setting or curing,) can produce a more severe hazard than does the dry BioAggregate powder.</p> <p>This MSDS provides a useful summary of the hazards of DiaRoot BioAggregate Root Canal Repair Material as it is to be used for the indications for use described in the instructions for use. Health and safety precautions in this MSDS may not be adequate for all individuals or situations. Inexperienced product users or handlers should obtain proper training before using or packaging this product. Users have the responsibility to comply with all laws and procedures applicable to the products’ safe handling and use, determine the suitability of the product for its intended use, and understand possible hazards associated with mixing DiaRoot BioAggregate Root Canal Repair Material with other materials.</p> <p>The information provided herein is, to the best of our knowledge, believed by DiaDent Group International. to be accurate at the time of preparation. However, the data is provided without any warranty, expressed or implied, regarding its correctness or accuracy. In no event will DiaDent Group International. be responsible for damages of any nature resulting from the use of or reliance upon the information contained herein.</p>	