

Material Safety Data Sheet

Trade Name: **BioAggregate**

Innovative BioCeramix Inc. 

Material Safety Data Sheet



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June 1, 2012

15 – Regulatory Information

The product is a medical device according to the FDA, Health Canada and EC-directive 93/42.		
Safety Phases	S 7 / 8	<ul style="list-style-type: none"> Store tightly closed in the packaging provided. Store at room temperature. Keep dry, avoid contact with moisture
	S 26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
	S 29	Do not empty into drains.
	S 36 / 37 / 39	Wear suitable protective clothing, gloves and eye / face protection.
Risk Phases	R 41	Risk of serious damage to eyes.

16 - Miscellaneous Information

Prepared By / Date	Innovative BioCeramix Quality Assurance / Regulatory Affairs: June 1, 2012
<p>BioAggregate Root Canal Repair Filling Material should be used according to the manufacturer's instructions. BioAggregate Root Canal Repair Filling 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 Material Safety Data Sheet (MSDS) provides a useful summary of the hazards of BioAggregate Root Canal Repair Filling 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 BioAggregate Root Canal Repair Filling Material with other materials.</p> <p>The information provided herein is, to the best of our knowledge, believed by Innovative BioCeramix Inc. 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 Innovative BioCeramix Inc. be responsible for damages of any nature resulting from the use of or reliance upon the information contained herein.</p>	

1 - Identification

Trade Name	BioAggregate	Part Number	BioA-4605
Product Use	Root Canal Repair Filling Material		
Manufacturer	Innovative BioCeramix Inc. 1628 West 75 th Avenue Vancouver, BC V6P 6G2 Canada	Distributor	Verio Dental Co. Ltd. 1628 West 75 th Avenue Vancouver, BC V6P 6G2 Canada
	Tel: 604-221-6800	Fax: 604-677-6129	Tel: 604-688-4917
Emergency Contact	Tel: 604-221-6800		

2 - Composition

BioA Liquid			
Chemical Characterization	<ul style="list-style-type: none"> BioA Liquid is used to hydrate the BioAggregate Powder. BioA Liquid is composed of sterile deionized water. 		
Chemical Formula	Major Compounds	CAS #	Approximate Concentration (%)
H ₂ O	Deionized water	7732-18-5	100%

BioAggregate Powder	
Chemical Characterization	<ul style="list-style-type: none"> BioAggregate Powder is a fine white hydraulic cement-like material intended for dental applications. BioAggregate Powder is composed of hydraulic calcium silicates, calcium phosphate, amorphous silicon oxide and tantalum oxide, contained in a crystalline mass, not separable into individual components.

Hazardous Ingredients

Chemicals	CSA #	ACGIH	OSHA PEL	LD ₅₀
Tricalcium silicate	12168-85-3	10 mg/m ³ total dust	5 mg/m ³ respirable dust	Not available
Dicalcium silicate	10034-77-2		10 mg/m ³ total dust	
Amorphous silicon oxide	7631-86-9	10 mg/m ³ total dust	6 mg/m ³ respirable dust 6 mg/m ³ total dust	Rat (Oral): 10000 mg/kg Rabbit (Dermal): >5000 mg/kg
Tantalum pentoxide	1314-61-0	5 mg/m ³ total dust	5 mg/m ³ total dust	Oral: >4000 mg/kg Rat: 8000 mg/kg
Calcium phosphate monobasic	7758-23-8	Not listed	Not listed	Rat (Oral): 3986 – 17500 mg/kg Mouse (Oral): 15250 mg/kg Rabbit (Dermal): >2000 mg/kg

Trace Ingredients

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

3 – Health Hazards Identification

Routes of Entry	Effects
Eyes	Exposure to airborne BioAggregate Powder or splashes of moist BioAggregate material may cause immediate or delayed irritation or inflammation and in severe instances, blindness.
Skin	Exposure to the BioAggregate Powder and / or moist BioAggregate material may cause irritation, drying, cracking or fissuring of the skin. Prolonged exposure can cause severe skin damage in the form of chemical (caustic) burns.
Inhalation	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.
Ingestion	Exposure may cause internal discomfort or irritation to the digestive tract.

4 - First Aid Measures

Routes of Entry	First Aid Treatment
Eyes	Flush eyes thoroughly with water for at least 15 minutes, including under the upper and lower eyelids to remove all particles. Seek medical aid.
Skin	Flush skin thoroughly with 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.
Inhalation	Remove from exposure and move to fresh air immediately. Immediately seek medical aid if breathing is difficult, coughing persists or not breathing.
Ingestion	Do not induce vomiting. If conscious, have the victim drink plenty of water. Immediately seek medical aid.

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Emergency Information

When in contact with moisture in eyes or on skin, or when mixed with water, BioAggregate becomes highly caustic (pH >12) and will damage or burn 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 protective equipment (see Section 8).

Carcinogenic Potential

Although the components used to manufacture BioAggregate 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

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

National Fire Protection Association (NFPA) Ratings

Health	1	Reactivity	0
Flammability	0	Personal Protective Equipment	B

6 - Accidental Release Measures

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

7 – Handling and Storage

Handling	Safe Handling	<ul style="list-style-type: none"> This product is intended for use in dentistry only. Only adequately trained personnel should handle this product. Keep out of reach of children. Wear appropriate gloves to prevent skin exposure (PVC, PE, Natural Rubber or Nitrile gloves). Avoid inhaling the powder.
	Protection Against Explosions and Fires	No special measures required.
Storage	Requirements	<ul style="list-style-type: none"> Store at room temperature in a dry area. Store away from food and drinks. Store tightly closed in the packaging provided. Keep dry until used. Protect from excessive heat and cold. Do not store near ammonia, ammonia nitrate, chlorine or chlorine containing items.

8 – Exposure Controls and Personal Protection

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

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9 - Physical and Chemical Properties

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

10 - Stability and Reactivity

Chemical Stability	Product is stable. Keep dry until used.
Incompatibility	Moist BioAggregate is alkaline. It is incompatible with acids, ammonia, ammonia nitrate, ammonium salts, aluminum metal and chlorine.
Reactivity Conditions	No dangerous reactions known.
Hazardous Decomposition	None under normal conditions of storage and use.
Hazardous Polymerization	Will not occur.
Conditions to Avoid	Avoid unintentional contact with water to prevent premature setting. Contact with BioA Liquid (deionized water) or water to the BioAggregate Powder will result in hydration and produces (caustic) calcium hydroxide.

11 - Toxicological Information

Route of Entry	Skin contact, eye contact, ingestion and inhalation.	Skin Sensitization	No allergic potential after multiple uses and good tolerance by subcutaneous tissue.
Local Effects	Irritation to the skin, eyes, moist mucous membranes of the nose, throat and upper respiratory system.	Mutagenicity	Non-mutagenic
Acute Toxicity	<ul style="list-style-type: none"> Exposure to airborne BioAggregate Powder or splashes of moist BioAggregate material may cause irritation. Avoid contact with skin, mucus membranes and eyes. BioAggregate is contraindicated if a person is known to be allergic to any of the ingredients of the product. 	Chronic Toxicity	<ul style="list-style-type: none"> Exposure to airborne BioAggregate Powder or splashes of moist BioAggregate: prolonged or frequently repeated skin contact may cause allergic skin reaction in some individuals. Immediate or delayed irritation or inflammation can occur in the eyes and skin. Delayed lung injury can occur.

12 - Ecological Information

No ecological problems to be anticipated if material is properly handled and used.

13 - Waste Disposal

- Dispose of waste material according to regional and federal regulations.
- Dispose of packaging in an approved landfill or incinerator.

14 - Transportation Information

- No special precautions required.
- BioAggregate is not classified for any mode of transportation.