

14 - Transportation Information

No special precautions required. EndoSequence BC Sealer is not classified for any mode of transportation.

15 - Regulatory Information

The product is a medical device according to the FDA, Health Canada and EC-directive 93/42.

Safety phrases:	S7/8	<ul style="list-style-type: none"> • Store with the syringe cap tightly sealed on the syringe and sealed in the pouch. • Store at room temperature. • Keep dry, avoid contact with moisture.
	S26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
	S29	Do not empty into drains.
	S36/37/39	Wear suitable protective clothing, gloves and eye/face protection.
Risk phrases:	R41	Risk of serious damage to eyes.

16 - Miscellaneous Information

Prepared By/Date	Brasseler USA Quality Assurance/Regulatory Affairs June 12, 2008
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EndoSequence BC Sealer should be used according to manufacturer's instructions. EndoSequence BC Sealer reacts chemically with 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 moist EndoSequence BC Sealer paste.

This MSDS provides a useful summary of the hazards of EndoSequence BC Sealer 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. As with all medical devices 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 EndoSequence BC Sealer with other materials.

The information provided herein is, to the best of our knowledge, believed by Brasseler USA 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 BrasselerUSA be responsible for damages of any nature resulting from the use of or reliance upon the information contained herein.

1 - Identification

Product Name: EndoSequence® BC Sealer
BioCeramic Root Canal Sealer

Company Identification: Brasseler USA
One Brasseler Boulevard
Savannah, Georgia 31419

Order No: 5017560U0

Figure No: ESBCS

Date of Issue: 06.12.08

Telephone: 1-800-841-4522

2 - Composition

Chemical characteristics: The paste is composed of zirconium oxide, calcium silicates, calcium phosphate monobasic, calcium hydroxide, filler and thickening agents.

Hazardous components:

Element		CAS #	ACGIH TLV	OSHA PEL	LD50
ZrO2	Zirconium oxide	1314-23-4	5 mg/m ³	5 mg/m ³ TWA	N/A
3CaO-SiO2	Tricalcium silicate	12168-85-3	10 mg/m ³ total dust	5 mg/m ³ respirable dust 10 mg/m ³ total dust	N/A
2CaO-SiO2	Dicalcium silicate	10034-77-2			
Ca(OH)2	Calcium hydroxide	1305-62-0	5 mg/m ³	5 mg/m ³ TWA (respirable fraction) 15 mg/m ³ TWA (total dust)	7300 mg/kg

3 - Health Hazards Identification

Routes of Entry	Effects
Eyes	Exposure may cause irritation or inflammation and in severe instances, blindness.
Skin	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.
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	Effects
Eyes	Flush eyes thoroughly with water for at least 15 minutes. 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.

Emergency Information

When in contact with moisture in eyes or on skin, or when mixed with water, EndoSequence BC Sealer 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. See Section 8.

Carcinogenic Potential

Although the components used to manufacture EndoSequence BC Sealer 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:	305 °C
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

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 personal protective equipment. Avoid contacting the paste (see Section 8). Use dry clean-up methods (moist paper towel) that do not disperse the paste into surface water or wash large amounts down drains, and dispose of in a suitable container.
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).
	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	Wear safety glasses with side shields or goggles. Contact lenses should not be worn.
	Protection of Hands	Wear gloves to prevent skin exposure.
	Body Protection	Lightweight protective clothing.
	Respirators	Surgical masks are recommended.

9 - Physical and Chemical Properties

Physical State:	Solid (paste)	Flashpoint:	>150° C
Color:	White	Evaporation Rate:	Not applicable
Odor:	No distinct odor.	Vapor Pressure (at 20°C) (68°F):	Not applicable
Specific Gravity (H2O = 1.0):	Not determined	Vapor Density:	Not applicable
pH (in water):	>12 (Base)	Density:	Not determined
Boiling/Melting Point:	Not determined	Solubility in / Miscibility w/ Water:	Slightly soluble

10 - Stability and Reactivity

Chemical Stability:	Product is stable. Keep dry until used.	Hazardous Decomposition Products:	None under normal conditions of storage and use.
Incompatibility:	EndoSequence BC Sealer is alkaline. It is incompatible with acids, ammonia, ammonia nitrate, ammonium salts, aluminum metal and chlorine.	Hazardous Polymerization:	Will not occur.
Reactivity Conditions:	No dangerous reactions known.	Conditions to Avoid:	Avoid unintentional contact with water to prevent premature setting; contact 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.
Local Effects:	Irritation to the skin, eyes, moist mucous membranes of the nose, throat and upper respiratory system.	Mutagenicity:	Non-mutagenic.
Acute Toxicity:	Uncured material may cause irritation. Avoid contact with skin, mucous membranes and eyes. The material 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"> Uncured material: prolonged or frequently repeated skin contact may cause allergic skin reactions 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.