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.Store with the syringe cap tightly sealed on the syringe and sealed in the pouch.
- S26.Store at room temperature.
- S29.Keep dry, avoid contact with moisture.
- S26.Keep dry, avoid contact with moisture.
- S29.Keep dry, avoid contact with moisture.

Risk phrases:
- R41.Risk of serious damage to eyes.

16 – Miscellaneous Information
Prepared By/Date: Brasseler USA Quality Assurance/Regulatory Affairs
June 12, 2008

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.

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

Hazardous components:

<table>
<thead>
<tr>
<th>Element</th>
<th>CAS #</th>
<th>ACGIH TLV</th>
<th>OSHA PEL</th>
<th>LD50</th>
</tr>
</thead>
<tbody>
<tr>
<td>ZrO2</td>
<td>1314-23-4</td>
<td>5 mg/m³</td>
<td>5 mg/m³ TWA</td>
<td>N/A</td>
</tr>
<tr>
<td>3CaO·SiO2</td>
<td>12168-85-3</td>
<td>10 mg/m³ total dust</td>
<td>10 mg/m³ total dust</td>
<td>N/A</td>
</tr>
<tr>
<td>2CaO·SiO2</td>
<td>10034-77-2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ca(OH)2</td>
<td>1305-62-0</td>
<td>5 mg/m³</td>
<td>5 mg/m³ TWA (respirable fraction)</td>
<td>15 mg/m³ TWA (total dust)</td>
</tr>
</tbody>
</table>

3 – Health Hazards Identification

<table>
<thead>
<tr>
<th>Routes of Entry</th>
<th>Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eyes</td>
<td>Exposure may cause irritation or inflammation in severe instances, blindness.</td>
</tr>
<tr>
<td>Skin</td>
<td>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.</td>
</tr>
<tr>
<td>Inhalation</td>
<td>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.</td>
</tr>
<tr>
<td>Ingestion</td>
<td>Exposure may cause internal discomfort or irritation to the digestive tract.</td>
</tr>
</tbody>
</table>

4 - First Aid Measures

<table>
<thead>
<tr>
<th>Routes of Entry</th>
<th>Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eyes</td>
<td>Flush eyes thoroughly with water for at least 15 minutes. Seek medical aid.</td>
</tr>
<tr>
<td>Skin</td>
<td>Wash 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.</td>
</tr>
<tr>
<td>Inhalation</td>
<td>Remove from exposure and move to fresh air immediately. Immediately seek medical aid if breathing is difficult, coughing persists or not breathing.</td>
</tr>
<tr>
<td>Ingestion</td>
<td>Do not induce vomiting. If conscious, have the victim drink plenty of water. Immediately seek medical aid.</td>
</tr>
</tbody>
</table>
**MATERIAL SAFETY DATA SHEET**

**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 bum 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**

<table>
<thead>
<tr>
<th>Conditions of Flammability</th>
<th>Not determined</th>
<th>Auto-ignition Temperature:</th>
<th>305 °C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Means of Extinction:</td>
<td>Use water spray, dry chemical, carbon dioxide, or chemical foam.</td>
<td>Hazardous Combustion Products:</td>
<td>None</td>
</tr>
<tr>
<td>Flash Point:</td>
<td>None</td>
<td>Unusual Fire and Explosion Hazards</td>
<td>None</td>
</tr>
<tr>
<td>Upper Flammable Limit:</td>
<td>None</td>
<td>Danger of Explosion:</td>
<td>None</td>
</tr>
<tr>
<td>Lower Flammable Limit:</td>
<td>None</td>
<td>Special Fire Fighting Procedures:</td>
<td>None</td>
</tr>
</tbody>
</table>

**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**
- 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**
- 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).

**Safe Handling**
- Keep dry until used.
- Protect from excessive heat and cold.
- Do not store near ammonia, ammonium nitrate, chlorine or chlorine containing items.

**Protection Against Explosions and Fires**
No special measures required.

**Storage**
- 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, ammonium nitrate, chlorine or chlorine containing items.

**8 – Exposure Controls and Personal Protection**

<table>
<thead>
<tr>
<th>Personal Protective Equipment</th>
<th>Eye Protection</th>
<th>Wear safety glasses with side shields or goggles.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Protection of Hands</td>
<td>Wear gloves to prevent skin exposure.</td>
</tr>
<tr>
<td></td>
<td>Body Protection</td>
<td>Lightweight protective clothing.</td>
</tr>
<tr>
<td></td>
<td>Respirators</td>
<td>Surgical masks are recommended.</td>
</tr>
</tbody>
</table>

**9 - Physical and Chemical Properties**

**Physical State:** Solid (paste)  
**Flashpoint:** >150°C 
**Color:** White  
**Odor:** No distinct odor.  
**Specific Gravity (H2O = 1.0):** Not determined  
**pH (in water):** >12 (Baste)  
**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, ammonium 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:**  
**Chronic 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.  

**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.