Material Safety Data Sheet:
RADIOPAQUE BONE CEMENT

Section 1: Identification

Trade/Common Names  AVAtex® and AVAmax® Radiopaque Bone Cement
Product Code(s) BCPM003, BCT00CT, BCTXLCT, VMX00CT, VMXXLCT
Description Methyl Methacrylate Copolymer with Barium Sulfate Opacifier
Product Use Bone cement with radiopacifier for cement injection

Section 2: Composition and Information on Ingredients

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS Number</th>
<th>%</th>
<th>Exposure Limits</th>
<th>NOTES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methyl Methacrylate Copolymer</td>
<td>25034-86-0</td>
<td>65-75%</td>
<td>ACGIH TLV – TWA: 10 mg/m³</td>
<td>NONE</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>ACGIH TLV – STEL: NE</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>OSHA PEL – TWA: 15 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>OSHA PEL – CEILING: NE</td>
<td></td>
</tr>
<tr>
<td>Barium Sulfate</td>
<td>7727-43-7</td>
<td>25-35%</td>
<td>ACGIH TLV – TWA: 10 mg/m³</td>
<td>NONE</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>OSHA PEL – Total dust: 15 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>OSHA PEL – Respirable dust: 5 mg/m³</td>
<td></td>
</tr>
</tbody>
</table>

KEY
NE = Not Established
NA = Not Applicable
TLV = Threshold Limit Value
TWA = Time Weighed Average
STEL = Short Term Exposure Limit
PEL = Permissible Exposure Limit
OSHA = Occupational Safety and Health Administration
ACGIH = American Conference of Governmental Industrial Hygienist

Section 3: Hazard Identification

EMERGENCY OVERVIEW
WARNING: For Polymer: May irritate eyes, skin and respiratory tract. OSHA classifies this material as Particulates, Not Otherwise Classified.

Eyes
May be irritating to the eyes by gross overexposure, no matter how generated. Symptoms of overexposure may include redness, itching, irritation and watering. Keep dust out of eyes.

Skin
May be irritating to skin in some sensitive individuals, especially after prolonged and/or repeated contact.

Inhalation
May be irritated by gross overexposure, no matter how generated.
Ingestion

Not expected to cause any harmful effects. May be irritating if product is swallowed, may cause nausea, headache, vomiting and/or diarrhea.

Chronic Exposure

Long term inhalation of dust may lead to deposition in lungs in sufficient quantities to produce baritosis – a benign pneumoconiosis. This produces a radiological picture even though symptoms and abnormal signs may not be present.

Aggravation of Pre-existing Conditions

No information found.

Section 4: First Aid Measures

Eyes

If product gets in the eyes, flush with copious amounts of lukewarm water for at least 15 minutes. If irritation occurs, contact a physician.

Skin

If irritation occurs and product is on the skin, rinse thoroughly with lukewarm water, followed by a thorough washing of the effected area with soap and water. If irritation, redness or swelling persists, contact a physician immediately.

Inhalation

Remove to fresh air. Seek immediate medical attention.

Ingestion

If ingested, do not induce vomiting. If product has been swallowed, drink plenty of water or milk IMMEDIATELY. If the patient is vomiting, continue to offer water or milk. Never give water or milk to an unconscious person. Provide an estimate of the time at which the material was ingested and the amount of the substance that was swallowed. Get medical attention immediately.

Section 5: Fire-Fighting Measures

Extinguishing Media

Water, carbon dioxide, dry chemical.

Fire-Fighting Procedures

Avoid extinguishing methods which may generate dust clouds. Water stream can disperse dust into air, producing a fire hazard and possible explosion hazard if exposed to ignition source.

Unusual Fire/Explosion Hazards

Polymer dust is combustible. The explosive limits of the polymer particles suspended in air are approximately those of coal dust. Firefighters should wear self-contained breathing apparatus.

Hazardous Decomposition Products

Methyl Methacrylate Monomer and Oxides of Carbon and Sulfur when burned.

Flash Point

304 °C (580 °F)

Method

NA

Section 6: Accidental Release Measures

Personal Precautions

Ventilate area of leak or spill. Before cleaning any spill or leak, individuals involved in spill cleanup must wear appropriate Personal Protective Equipment. Wear appropriate personal protective equipment (e.g., goggles, gloves). Remove any contaminated clothing and wash thoroughly before reuse.

Environmental Precautions and Clean-up Methods

Sweep up to avoid slipping hazard. Keep airborne particulates at a minimum when cleaning up spills. Dispose of properly in accordance with local, state and federal regulations. Wash all affected areas with plenty of warm water and soap.

Section 7: Handling and Storage

Handling

Use in well ventilated areas. Avoid contact with skin, eyes and clothing. Avoid breathing dust. Use good personal hygiene and housekeeping.
**Material Safety Data Sheet:**
**RADIOPAQUE BONE CEMENT**

### Storage
Store in a cool, dry location, away from direct sunlight, other light sources, or sources of intense heat. Material should be stored in secondary containers as appropriate. Keep container closed to prevent water absorption and contamination.

### Industrial Hygiene Practices
Avoid prolonged contact with the product. Use in a well-ventilated location (e.g., local exhaust ventilation, fans). After use, wash hands and exposed skin with soap and water. Do not eat, drink or smoke while handling product.

### Section 8: Exposure Controls and Personal Protection

#### Occupational Exposure Limits
See Section 2.

#### Engineering controls
When working with large quantities of product, provide adequate ventilation (e.g., local exhaust ventilation, fans). Ensure that an eyewash station, sink or washbasin is available in case of exposure to eyes. Use good, local exhaust at processing equipment, including buffers, sanders, grinders and polishers.

#### Personal Protective Equipment

##### Respiratory Protection
No special respiratory protection is required under typical circumstances of use or handling. If necessary, use only respiratory protection authorized per U.S. OSHA's requirement in 29 CFR §1910.134, or applicable U.S. state regulations, or the appropriate standards of Canada, its provinces, E.C. member states, or Australia.

##### Skin
If anticipated that prolonged & repeated skin contact will occur during use of this product, wear latex or rubber gloves for routine industrial use. If necessary, refer to U.S. OSHA 29 CFR §1910.138, the appropriate standards of Canada, of the E.C. member states.

##### Eyes
Depending on the use of this product, splash or safety glasses may be worn. If necessary, refer to U.S. OSHA 29 CFR §1910.133, Canadian standards, or the European Standard EN166. Ensure that an eyewash station, sink or washbasin is available in case of exposure to eyes.

### Section 9: Physical and Chemical Properties

**Appearance**
Fine clear to pigmented powder.

**Odor**
Faint odor in bulk.

**pH**
Not determined.

**Boiling Point**
NA

**Melting Point**
NA

**Vapor Density (air = 1)**
NA

**Vapor Pressure**
NA

**Solubility in Water**
Insoluble.

**Specific Gravity (H₂O = 1)**
1.25 for Methyl Methacrylate copolymer and 4.5 for Barium Sulfate

**Evaporation Rate**
(BuAc = 1)
NA

### Section 10: Stability and Reactivity

**Stability**
Stable under ordinary conditions of use and storage.

**Incompatibility**
Strong oxidizing agents, Aluminum, and phosphorus.

**Conditions to Avoid**
Heating above 240°C (464°F)

**Hazardous Decomposition Products**
Methacrylate Monomer and Oxides of Carbon when burned.
Material Safety Data Sheet:  
RADIOPAQUE BONE CEMENT

Hazardous Polymerization Will not occur.

Section 11: Toxicological Information

Acute Effects

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Eyes</td>
<td>NA</td>
</tr>
<tr>
<td>Skin</td>
<td>NA</td>
</tr>
<tr>
<td>Mucous Membrane</td>
<td>NA</td>
</tr>
<tr>
<td>Ingestion</td>
<td>NA</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>None</td>
</tr>
<tr>
<td>Mutagenicity</td>
<td>This product is not reported to produce mutagenic effects in humans.</td>
</tr>
<tr>
<td>Teratogenicity</td>
<td>This product is not reported to cause teratogenic effects in humans.</td>
</tr>
<tr>
<td>Embryotoxicity</td>
<td>This product is not reported to produce embryotoxic effects in humans.</td>
</tr>
<tr>
<td>Reproductive Toxicity</td>
<td>This product is not reported to cause reproductive effects in humans.</td>
</tr>
</tbody>
</table>

Section 12: Ecological Information

Ecotoxicity Data

For polymer: There is no specific data available for this product; however, very large releases of this product may be harmful or fatal to overexposed aquatic life.

Environmental Hazards

There is no specific data available for this product.

Section 13: Disposal Considerations

Waste Disposal Method

Dispose in a landfill or incinerate according to Federal, State, and Local regulations.

Section 14: Transportation Information

DOT Designation

SYNTHETIC GUM RESIN GRANULAR, NOIBN

Section 15: Regulatory Information

US Regulations

Hazard Communication  This product is hazardous under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200.
TSCA Status  This compound is on the EPA Toxix Substance Control Act (TSCA) inventory list.
California Proposition 65  NA
WHMIS  This MSDS has been prepared according to the hazard criteria of the controlled products regulations (CPR) and the MSDS contains all of the information required by the CPR.

Section 16: Other Information

NFPA Ratings: Health: 1 Flammability: 1 Reactivity: 0
HMIS Ratings: Health: 1 Flammability: 1 Reactivity: 0 Personal Protective Equipment: Gloves and Safety Glasses or Chemical Splash Goggles.

Neither Cardinal Health nor any of its affiliates or subsidiaries assumes any legal responsibility for use or reliance upon this information. Final determination of suitability of any material for a particular use is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards which exist. It is
the user’s responsibility to determine the appropriate handling, disposal or open disposition for the material or emergency response actions in light of the condition of the material, applicable regulations and other circumstances.

1  NEW
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