Safety Data Sheet

Trade Name: ACTIVA BioACTIVE-CEMENT

1.0 Commercial Product Name and Supplier

1.1 Commercial product name
ACTIVA BioACTIVE-CEMENT

1.2 Application / Use
Dental material for use by dental professional only.

1.2.2 SIC
851 Human health activity

1.3 Manufacturer
Pulpdent Corporation
80 Oakland Street, P.O. Box 780
Watertown, MA 02472 USA
Telephone: 1 617 926-6666 / Fax: 1 617 926-6262
Email: Pulpdent@pulpdent.com

1.4 Emergency Telephone Number
1-800-535-5053 (24 Hour / USA)

1.5 Authorized European Representative
Advena Ltd.
Pure Offices, Plato Close
Warwick, CV34 6WE
United Kingdom

2.0 Hazards Identification

2.1 Classification

2.1.1 Classification according to Regulation (EC) No 1272/2008 [CLP]

<table>
<thead>
<tr>
<th>Hazard Class</th>
<th>Hazard Category</th>
<th>Hazard Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye irritation</td>
<td>2</td>
<td>H319</td>
</tr>
<tr>
<td>STOT SE</td>
<td>3</td>
<td>H335</td>
</tr>
<tr>
<td>Skin irritation</td>
<td>2</td>
<td>H315</td>
</tr>
<tr>
<td>Skin sensitization</td>
<td>1</td>
<td>H317</td>
</tr>
</tbody>
</table>

2.1.2 Classification according to Directive 67/548/EEC
Irritant; Xi; R 36/37/38 – 43 (See SECTION 16 for full text of risk phrases)

2.2 GHS Label Elements

Hazard Pictograms

Signal Word: WARNING

Restricted to use by dental professional only.

Hazard Statements

H319: Eye irritation. 2. May cause eye irritation.
H335: STOT SE. 3. May cause respiratory irritation.
H315: Skin irritation. 2. May cause skin irritation.
H317: Sensitization. 1. May cause an allergic skin reaction.

Precautionary Statements

P261: Avoid breathing vapor.
P280: Wear protective gloves and eye protection
P305+P351: If in eyes, rinse cautiously with water for several minutes.
P337+P313: If eye irritation persists, get medical advice/attention.
P302+P352: If on skin, wash with plenty of soap and water.
P333+P313: If irritation or rash occurs, get medical advice/attention.
P410+P411: Protect from sunlight. Store at temperature not exceeding 27°C / 80°F.
3.0 Composition

3.1 Chemical characterization of the preparation: Bioactive ionic resin with reactive glass filler

3.2 Hazardous ingredients

<table>
<thead>
<tr>
<th>CAS Number</th>
<th>Name of the Ingredient</th>
<th>Concentration</th>
<th>Classification per 67/548/EEC</th>
<th>Classification per Regulation (EC) No.1272/2008 (CLP)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proprietary</td>
<td>Blend of diurethane and other methacrylates with modified polyacrylic acid</td>
<td>52.9%</td>
<td>Irritant; Xi R 3637//38 - 43</td>
<td>Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315 Skin sensitization, 1, H317</td>
</tr>
<tr>
<td>112945-52-5</td>
<td>Silica, amorphous</td>
<td>5.1%</td>
<td>Irritant; Xi, R 36/37/38</td>
<td>Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315</td>
</tr>
<tr>
<td>7681-49-4</td>
<td>Sodium fluoride</td>
<td>0.90%</td>
<td>Harmful (Xn); R22-36/38</td>
<td>Acute toxicity, 4, H302 Skin irritation, 2, H315 Eye irritation, 2, H319</td>
</tr>
</tbody>
</table>

4.0 First Aid Measures

4.1 General Information
May be irritating to eyes, respiratory system and skin. Avoid contact with eyes and skin. Do not inhale vapors. May cause sensitization by skin contact. Show this safety data sheet to medical personnel. Get medical attention in case of uncertainty.

4.2 Inhalation
Move to fresh air. If necessary, administer oxygen and/or artificial respiration. Seek medical attention.

4.3 Skin Contact
Take off contaminated clothing. Wash skin thoroughly with soap and water.

4.4 Eye Contact
Keep eyelids apart; flush with running water for 15+ minutes. Get medical attention.

4.5 Ingestion
Rinse mouth with water. Do not induce vomiting. Get immediate medical attention. May be irritating to mucous membranes. Never give anything by mouth to an unconscious person.

4.6 Precautions for first responders
Ventilate the area. Wear eye and skin protection.

4.7 Information for physicians
Symptoms: Irritation or redness in eyes, throat or on skin.
Hazards: May be irritating to eyes, respiratory system and skin. May cause sensitization by skin contact.
Treatment: As above under First Aid.

5.0 Fire Fighting Measures

5.1 Suitable extinguishing media
Carbon dioxide, dry chemical, alcohol foam, or water fog. Water spray may be used to keep fire exposed containers cool.

5.2 Extinguishing media to avoid
Do not use direct water stream

5.3 Special exposure hazards in a fire
Heat may cause polymerization with rapid release of energy.

5.4 Special protective equipment for fire-fighters
Self-contained breathing apparatus

6.0 Accidental Release Measures

6.1 Personal precautions.
Wear safety glasses, gloves and lab coat.
6.2 Environmental precautions
Avoid releasing large amounts of uncured material into the environment. Cured / set-up material is, to our knowledge, inert.

6.3 Method for clean up
Contain spilled material. Absorb or wipe up spill with suitable material (paper towels or cloths). Collect for disposal in a covered container. Wash area of spill with alcohol or soap and water.

7.0 Handling and Storage

7.1 Handling
For use only by dental professionals. Follow good hygiene practices. Avoid direct / strong light sources, temperature extremes (>27°C/80°F, <5°C/40°F), contamination, cross-contamination. Recap immediately after use.

7.2 Storage
Store product tightly capped in original container at cool room temperature (<25°C). Avoid direct, strong light, sources of ignition and extremes of temperature. Shelf life for unopened product is two years from date of manufacture, provided that the material has been stored properly.

7.3 Specific uses
Dental cement

8.0 Exposure Controls / Personal Protection

8.1 Exposure limit values
PEL: Not established. TLV: Not established.

8.2 Exposure controls

8.2.1 Occupational exposure controls
No special equipment required under normal conditions of use

8.2.1.1 Respiratory protection
Good general ventilation is sufficient to control any airborne vapors.

8.2.1.2 Hand protection
No special requirements other than the usual surgical gloves worn by dental staff.

8.2.1.3 Eye protection
No special requirements other than the usual safety glasses worn by dental staff.

8.2.1.4 Skin protection
Good personal hygiene and safety practices; wearing a lab coat.

8.2.1.5 Other controls
Emergency eye wash fountain should be available. Wash hands after use.

8.2.2 Environmental exposure controls
Cure material before disposing.

9.0 Physical and Chemical Properties

9.1 Characteristics

9.1.1 Appearance / Color / Physical state
Two pastes: Part A is yellowish; Part B is off-white

9.1.2 Odor
Faint, characteristic

9.2 Important health, safety and environmental information

9.2.1 pH
Not determined

9.2.2 Boiling point
Not determined

9.2.3 Flash point
Not determined

9.2.4 Flammability (solid, gas)
Not applicable

9.2.5 Explosive properties
Not applicable

9.2.6 Oxidizing properties
Not determined

9.2.7 Vapor pressure
< 1 mm Hg

9.2.8 Specific gravity
Part A: 1.460 ± 0.02 g/mL; Part B: 1.380 ± 0.02 g/mL

9.2.9 Solubility in water
Nil
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9.2.10 Partition coefficient Not determined
9.2.11 Viscosity Not determined
9.2.12 Vapor density Not determined
9.2.13 Evaporation rate Not determined

10.0 Stability and reactivity

10.1 Conditions to avoid Temperature > 38°C, intense light, cross-contamination.
10.2 Materials to avoid Reducing and oxidizing agents, peroxides, amines.
10.3 Hazardous decomposition products Under fire conditions and with amounts greater than that supplied in this product, hazardous polymerization may occur with heat build-up and release of carbon monoxide, carbon dioxide, and oxides of nitrogen.
10.4 Further information Stable material if stored and used as directed. Polymerization will occur when light-cured material is exposed to direct light.

11.0 Toxicological information

11.1 Acute toxicity Finished product in paste form presents a minimal health hazard under normal conditions of use and in the quantities necessary for dental restoration. Sodium fluoride: Oral rat LD$_{50}$: 180 mg/kg
Silica, amorphous: Oral rat LD$_{50}$: 3160 mg/kg
11.2 Irritation and corrosiveness May be irritating to eyes, respiratory tract, mucous membranes or skin on contact or with prolonged exposure.
11.3 Sensitization May be sensitizing. Prolonged or frequent skin contact may cause allergic skin reactions in some susceptible individuals.
11.4 Sub-acute, sub-chronic and prolonged toxicity Prolonged and/or frequent skin contact may cause allergic skin reactions in susceptible individuals. Prolonged exposure to large amounts (more than in this product) may cause eye and respiratory irritation.
11.5 Carcinogenicity, Mutagenicity, Reproductive Toxicity None known
11.6 Empirical data Biocompatibility has been tested and found to be acceptable.
11.7 Clinical experience ACTIVA Bio-ACTIVE-CEMENT is a new product that has been evaluated by dentist consultants. There have been no reports of adverse events. ACTIVA Bio-ACTIVE-BASE/LINER, a similar material, has been on the market for about 18 months with positive reviews and no complaints or adverse events.

12.0 Ecological Information

12.1 Ecotoxicity Avoid release of uncured material into the environment. To the best of our knowledge, polymerized material is inert. No other information is available. Follow all government regulations.

13.0 Disposal Considerations

13.1 Regulations Follow all local and national government regulations in disposing material or contaminated packaging.

14.0 Transport Information

14.1 Restrictions None. Not regulated.
## 15.0 Regulatory Information

<table>
<thead>
<tr>
<th>15.1</th>
<th>EU Regulations</th>
<th>Class Ila medical device under MDD 93/42/EEC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>15.2</td>
<td>US FDA</td>
<td>Class II Medical Device</td>
</tr>
<tr>
<td>15.3</td>
<td>Health Canada</td>
<td>Class III medical device</td>
</tr>
</tbody>
</table>

## 16.0 Other information

| 16.1 | List of relevant R phrases | R36/37/38: Irritating to eyes, respiratory system and skin.  
|      |                              | R43: Sensitizing by skin contact. |
|      |                              | H335: Specific Target Organ Toxicity - Single exposure; hazard category. 3.  
|      |                              | Respiratory tract irritation.  
|      |                              | H315: Skin irritation. Hazard category 2.  
|      |                              | H317: Skin Sensitization. Hazard category 1. |
| 16.3 | Precautionary Statements  | P261: Avoid breathing vapor. |
|      |                              | P280: Wear protective gloves and eye protection |
|      |                              | P305 + P351: If in eyes, rinse cautiously with water for several minutes.  
|      |                              | P337 + P313: If eye irritation persists, get medical advice/attention. |
|      |                              | P302 + P352: If on skin, wash with plenty of soap and water.  
|      |                              | P333 + P313: If irritation or rash occurs, get medical advice / attention. |
|      |                              | P410 + P411: Protect from sunlight. Store at temperature ≤ 27°C / 80°F. |
| 16.4 | Restrictions on use       | ACTIVA Bio-ACTIVE-CEMENT is to be sold to and used by dental professionals only. |
| 16.5 | Further information       | The information presented herein is believed to be factual as it has been derived from the works of persons believed to be qualified experts. However, nothing contained in this information is to be taken as a warranty or representation for which Pulpdent Corporation bears legal responsibility. The user should review any recommendations in the specific context of the intended use to determine whether they are appropriate. |
| 16.6 | Sources of key data       | National Institute for Occupational Safety (NIOSH)  
|      |                              | US Occupational Safety and Health Administration (OSHA)  
| 16.7 | Information which has been added, deleted or revised. | This Safety Data Sheet has been revised to meet the requirements of the GHS SDS format, Regulations (EC) No. 1272/2008 (CLP) and (EC) No. 1907/2006 (REACH). Specifically, Sections 2.1, 2.2, 3.2, 16.2, 16.3 have been modified. |