Safety Data Sheet

Trade Name: ACTIVA BioACTIVE-RESTORATIVE

1.0 Commercial Product Name and Supplier

1.1 Commercial product name
ACTIVA BioACTIVE-RESTORATIVE

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

1.2.2 SIC
851 Human health activity

1.2.3 Use Category
55

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 Limited
Tower Business Centre, 2nd Floor, Tower Street, Swatar, BKR 4013 Malta

UK Responsible Person
Advena Limited
Pure Offices, Plato Close
Warwick, CV34 6WE United Kingdom

CH Authorized Representative
MedEnvoy Switzerland
Gotthardstrasse 28, 6302 Zug, Switzerland

2.0 Hazards Identification

2.1 Classification

2.1.1 Classification according to Regulation (EC) No 1272/2008 [CLP]
Eye irritation
STOT SE
Skin irritation
Skin sensitization

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
Pulpdent Corporation

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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 methacylates with modified polyacrylic acid</td>
<td>44.6%</td>
<td>Irritant; Xi, R 3637/38 - 43</td>
<td>Eye irritation, 2 STOT SE 3 Skin irritation, 2 Skin sensitization, 1</td>
</tr>
<tr>
<td>112945-52-5</td>
<td>Silica, amorphous</td>
<td>6.7%</td>
<td>Irritant; Xi, R 36/37/38</td>
<td>Eye irritation, 2 STOT SE 3 Skin irritation, 2</td>
</tr>
<tr>
<td>7681-49-4</td>
<td>Sodium fluoride</td>
<td>0.75%</td>
<td>Harmful (Xn); R22-36/38</td>
<td>Acute toxicity, 4 Skin irritation, 2 Eye irritation, 2</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

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Hazards</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Irritation or redness in eyes, throat or on skin.</td>
<td>May be irritating to eyes, respiratory system and skin. May cause sensitization by skin contact.</td>
<td>As above under First Aid.</td>
</tr>
</tbody>
</table>

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
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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/wipe up spill with 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 in tightly capped 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 restorative material

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 of this product in the quantity provided.

8.2.1.1 Respiratory protection
None required. Good general ventilation is sufficient to control any airborne vapors from uncured material.

8.2.1.2 Hand protection
No special requirements. The usual surgical gloves worn by dental staff will limit contact with uncured material.

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
No special requirements. Good personal hygiene, safety practices and wearing a lab coat should protect dental staff from unnecessary exposure to uncured material.

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
Part A: Thick, tooth-colored paste.
Part B: Thick, off-white paste.

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
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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: 1.580 ± 0.02 g/mL; Part B: 1.620 ± 0.02 g/mL
9.2.9 Solubility in water Nil
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 LD₅₀: 180 mg/kg
- Silica, amorphous: Oral rat LD₅₀: 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 Restorative is a new product that has been evaluated by dentist consultants. There have been no reports of adverse events.

### 12.0 Ecological Information
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Trade Name: **ACTIVA BioACTIVE-RESTORATIVE**

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>12.1</td>
<td>Ecotoxicity</td>
</tr>
<tr>
<td></td>
<td>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.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>13.0</th>
<th>Disposal Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>13.1</td>
<td>Regulations</td>
</tr>
<tr>
<td></td>
<td>Follow all local and national government regulations in disposing material or contaminated packaging.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>14.0</th>
<th>Transport Information</th>
</tr>
</thead>
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<tr>
<td>14.1</td>
<td>Restrictions</td>
</tr>
<tr>
<td></td>
<td>None. Not regulated.</td>
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</table>

<table>
<thead>
<tr>
<th>15.0</th>
<th>Regulatory Information</th>
</tr>
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<tr>
<td>15.1</td>
<td>EU Regulations</td>
</tr>
<tr>
<td></td>
<td>Class IIa medical device under MDD 93/42/EEC.</td>
</tr>
<tr>
<td>15.2</td>
<td>US FDA</td>
</tr>
<tr>
<td></td>
<td>Class II medical device</td>
</tr>
<tr>
<td>15.3</td>
<td>Health Canada</td>
</tr>
<tr>
<td></td>
<td>Class III medical device</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>16.0</th>
<th>Other information</th>
</tr>
</thead>
<tbody>
<tr>
<td>16.1</td>
<td>List of relevant R phrases</td>
</tr>
<tr>
<td></td>
<td>R36/37/38: Irritating to eyes, respiratory system and skin.</td>
</tr>
<tr>
<td></td>
<td>R43: Sensitizing by skin contact.</td>
</tr>
<tr>
<td>16.2</td>
<td>Hazard Statements</td>
</tr>
<tr>
<td></td>
<td>H319: Eye irritation. Hazard category 2.</td>
</tr>
<tr>
<td></td>
<td>H335: Specific Target Organ Toxicity - Single exposure; hazard category 3. Respiratory tract irritation.</td>
</tr>
<tr>
<td></td>
<td>H315: Skin irritation. Hazard category 2.</td>
</tr>
<tr>
<td></td>
<td>H317: Skin Sensitization. Hazard category 1.</td>
</tr>
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<td>16.3</td>
<td>Precautionary Statements</td>
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<td>P261: Avoid breathing vapor.</td>
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</tr>
<tr>
<td>16.4</td>
<td>Restrictions on use</td>
</tr>
<tr>
<td></td>
<td>To be sold to and used by dental professionals only.</td>
</tr>
<tr>
<td>16.5</td>
<td>Further information</td>
</tr>
<tr>
<td></td>
<td>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.</td>
</tr>
<tr>
<td>16.6</td>
<td>Sources of key data</td>
</tr>
<tr>
<td></td>
<td>National Institute for Occupational Safety (NIOSH)</td>
</tr>
<tr>
<td></td>
<td>US Occupational Safety and Health Administration (OSHA)</td>
</tr>
<tr>
<td>16.7</td>
<td>Information which has been added, deleted or revised.</td>
</tr>
<tr>
<td></td>
<td>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.</td>
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1907/2006 (REACH). Specifically, Sections 2.1, 2.2, 3.2, 16.2, 16.3 have been modified.