1.0 Commercial Product Name and Supplier

1.1 Commercial product name / designation
Ortho-Choice™ Orthodontic Bracket Adhesive (OBA)

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

TelephoneNumber: 1 617 926-6666 / Fax: 1 617 926-6262
Email: Pulpdent@pulpdent.com

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

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

2.0 Hazards Identification

2.1 Classification
Irritant.

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 (See SECTION 16 for full text of risk phrases)
Xi (Irritant); R 36/37/38 - 43

2.2 GHS Label Elements

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.
Pulpdent Corporation

Safety Data Sheet

Trade Name: PULPDENT Orthodontic Bracket Adhesive (OBA)

3.0 Composition

3.1 Chemical characterization of the preparation

Glass filler in light-cured aromatic / aliphatic methacrylate resins.

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>Mixture of uncured methacrylate ester monomers</td>
<td>55-65%</td>
<td>Xi (Irritant), R36/37/38; R43</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>Amorphous silica</td>
<td>5.0 %</td>
<td>Xi (Irritant), R36/37/38</td>
<td>Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315</td>
</tr>
</tbody>
</table>

4.0 First Aid Measures

4.1 General Information

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

4.2 Inhalation

Move to fresh air. If necessary, administer oxygen, artificial respiration and seek medical attention.

4.3 Skin Contact

Take off contaminated clothing. Wash skin thoroughly with soap and running water for 15 minutes.

4.4 Eye Contact

Keep eyelids apart, flush with running water for 15+ minutes. Seek medical attention.

4.5 Ingestion

Rinse mouth with water. Do not induce vomiting. Seek immediate medical attention. May be irritating to mucous membranes.

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 of fire may cause polymerization with rapid release of energy, especially in amounts greater than in this product.

5.4 Special protective equipment for firefighters

Self-contained breathing apparatus.

6.0 Accidental Release Measures

6.1 Personal precautions.

Ventilate area. Wear safety glasses, gloves, and lab coat.
6.2 Environmental precautions
Contain uncured, spilled material. Cured/set-up material is, to our knowledge, inert. Follow all government regulations.

6.3 Method for clean up
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 trained in its use. Follow good hygiene practices. Remove applicator tip from syringe and recap immediately after use. Keep light cure materials shaded from intense light sources.

7.2 Storage
Store in tightly capped original container at cool room temperature (<25°C). Avoid direct, intense light, sources of ignition, extremes of temperature (>80°F/27°C, <40°F/5°C). 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 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

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

8.2.1.2 Hand protection
Protective gloves are recommended.

8.2.1.3 Eye protection
Safety glasses are recommended

8.2.1.4 Skin protection
Good personal hygiene and safety practices; wear 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
Stiff 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

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 / 133 Pa / Id: B

9.2.8 Specific gravity
1.820

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 1
9.2.13 Evaporation rate < 0.1

10.0 Stability and reactivity

10.1 Conditions to avoid Temperature > 80°F/27°C, strong visible light.
10.2 Materials to avoid Reducing and oxidizing agents, peroxides, amines.
10.3 Hazardous decomposition products Under fire conditions and with amounts far 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 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 Not toxic. Minimal health hazard in the quantities present in this product and under normal conditions of use.
11.2 Irritation and corrosiveness May be irritating to eyes, 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) of this material may cause eye and respiratory irritation.
11.5 Carcinogenicity, Mutagenicity, Reproductive Toxicity None known
11.6 Empirical data Not available
11.7 Clinical experience OBA has been used by dental professionals for over 20 years. During that time there have been no significant complaints regarding safety or effectiveness, no recalls and no adverse events.

12.0 Ecological Information

12.1 Eco-toxicity 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.
# Safety Data Sheet

**Trade Name:** PULPDENT Orthodontic Bracket Adhesive (OBA)

## 15.0 Regulatory Information

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<th>Description</th>
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<td>15.2</td>
<td>US FDA</td>
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<td>15.3</td>
<td>Health Canada</td>
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## 16.0 Other information

<table>
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<tr>
<th>Section</th>
<th>Description</th>
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<tbody>
<tr>
<td>16.1</td>
<td>List of relevant R phrases</td>
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<tr>
<td>16.4</td>
<td>Restrictions on use</td>
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<td>16.5</td>
<td>Further information</td>
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<tr>
<td>16.7</td>
<td>Information which has been added, deleted or revised</td>
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