# Safety Data Sheet

Trade Name: **DenTASTIC DENTAL ADHESIVE SYSTEM, DenTASTIC UNO, DenTASTIC DUO**

## 1.0 Commercial Product Name and Supplier

### 1.1 Commercial product name / designation

**DenTASTIC Adhesive System**
- including DASP-A, DASP-B, DASP-C, DASP-1 and DASP-2

**DenTASTIC UNO**

**DenTASTIC DUO**

### 1.2 Application / Use

Dental bonding agent for use by dentists.

### 1.2.2 SIC

851 Human health activity

### 1.2.3 Use Category

55

### 1.3 Manufacturer, Importer

#### 1.3.1 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

**International Business Solutions Ltd.**
- 54 Mayfield Ridge, Hatch Warren, Basingstoke, RG22 4RS UK
- Tel: 07989 407479 / Fax: 01256 350330
- Email: s.williams5@btconnect.co.uk

## 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>Flammable liquid</td>
<td>2</td>
<td>H225</td>
</tr>
<tr>
<td>Eye irritation</td>
<td>2</td>
<td>H319</td>
</tr>
<tr>
<td>STOT SE</td>
<td>3</td>
<td>H35</td>
</tr>
<tr>
<td>Skin irritation</td>
<td>2</td>
<td>H315; EUH066</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)

Flammable (F), Irritant (Xi).
- R11-36 / 37 / 38 / R43 / R66
Trade Name: DenTASTIC DENTAL ADHESIVE SYSTEM, DenTASTIC UNO, DenTASTIC DUO

2.2 Label Elements
Labeling according to Regulation (EC) No 1272/2008 [CLP]

Hazard Pictograms

Signal Word: DANGER
Restricted to use by dental professional only

Hazard Statements:
H319: Causes serious eye irritation. Category 2.
H335: Specific Target Organ Toxicity (STOT), single exposure, respiratory tract, Category 3: May cause respiratory irritation.
H315: Causes skin irritation. Category 2.
EUH066: Repeated exposure may cause skin dryness or cracking.
H317: May cause an allergic skin reaction. Category 2.

Precautionary Statements:
P210: Keep away from heat, sparks, open flame, hot surfaces. No smoking.
P403+P233: Store in a well-ventilated place. Keep container tightly closed.
P261: Avoid breathing fumes.
P280: Wear protective gloves/ clothing and eye protection.
P304+P340: If inhaled, remove victim to fresh air and keep at rest in a position comfortable for breathing.
P305+P351+P338: If in eyes, rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P303+P361+P353: If on skin or hair, remove contaminated clothing. Rinse skin with water.
P370+P378: In case of fire, use dry chemical, alcohol foam, or carbon dioxide for extinction.
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3.0 Composition

3.1 Chemical characterization of the preparation: Methacrylate ester monomers in acetone vehicle.

3.2 Hazardous ingredients

<table>
<thead>
<tr>
<th>CAS Number</th>
<th>Name of the ingredient</th>
<th>Concentration</th>
<th>Classification according to 67/548/EEC</th>
<th>Classification according to Regulation (EC) No.1278/2008 (CLP).</th>
</tr>
</thead>
<tbody>
<tr>
<td>67-64-1</td>
<td>Acetone</td>
<td>50% to 80%</td>
<td>Flammable (F); Irritant (Xi). R11-36/37/38-66</td>
<td>Flammable liquid; Category 2 Eye irritation; Category 2 STOT SE; Category 3 Skin irritation; Category 2</td>
</tr>
<tr>
<td>----</td>
<td>Methacrylate ester monomers</td>
<td>5% to 50%</td>
<td>Irritant (Xi). R 43</td>
<td>Skin sensitization; Category 1</td>
</tr>
</tbody>
</table>

4.0 First Aid Measures

4.1 General Information
Acetone may cause irritation of eyes or skin on contact. Exposure to >750 ppm may cause irritation of respiratory tract, mucous membranes. Methacrylate may cause sensitization of skin with prolonged/repeated contact. Show this safety data sheet to medical personnel. Get medical attention in case of uncertainty.

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

4.3 Skin Contact
Remove any contaminated clothing. Immediately wash skin well with mild soap and running water. Use hand cream. Get medical attention if irritation persists.

4.4 Ingestion
Rinse mouth with water. Drink water to dilute, but only if person is conscious. Do not induce vomiting. Get immediate medical attention.

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

4.6 Precautions for first responders
Ventilate the area. Wear safety glasses and gloves to prevent contact.

4.7 Information for physicians
Symptoms
Irritation, pain or redness in eyes, throat or on skin. Headache, fatigue. Nervous system depressant.

Hazards
Acetone may cause irritation of eyes or skin on contact. Exposure to >750 ppm may cause irritation of respiratory tract and mucous membranes. Persons with chronic respiratory or skin disease are at increased risk with prolonged exposure to acetone.

Methacrylate may cause sensitization of skin with prolonged and/or repeated contact.

Treatment
Same as above under First Aid.
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5.0 Fire Fighting Measures

5.1 Suitable extinguishing media
Use dry chemical, alcohol foam, or carbon dioxide. Water may be ineffective, but should be used to keep fire-exposed containers cool.

5.2 Extinguishing media to avoid
Water may be ineffective, but should be used to keep fire-exposed containers cool.

5.3 Special exposure hazards in a fire
Thermal decomposition may produce toxic oxides of carbon.

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

6.0 Accidental Release Measures

6.1 Personal precautions.
Wear chemical splash goggles, gloves and lab coat.

6.2 Environmental precautions
Avoid releasing large quantities into environment.

6.3 Method for clean up
For small quantities (as in this product): Wear gloves and safety glasses. Wipe up with absorbent material, such as paper or cloth. Rinse area of spill with soap and water. Place all absorbent material in closed container away from heat, sparks, sun and oxidizers.

7.0 Handling and Storage

7.1 Handling
For professional use only. Avoid cross-contamination between parts. Avoid heat, sparks, flame, sources of ignition, intense light. Empty containers may retain residual product; handle appropriately. Keep tightly capped in original container.

7.2 Storage
Replace cap over applicator tip immediately after use. Keep tightly capped in original container. Store at cool room temperature in a well-ventilated area. Avoid extremes of temperature (>27°C/80°F, <5°C/40°F), sparks, direct sunlight, oxidizing agents. Vapor may form flammable mixtures with air.

7.3 Specific uses
Dental adhesive

8.0 Exposure Controls / Personal Protection

8.1 Exposure limit values
Acetone: 750 ppm

8.2 Exposure controls

8.2.1 Occupational exposure controls
Wear chemical splash goggles, gloves, lab coat. No other special equipment or ventilation required under normal conditions of use. For large quantities/prolonged exposure, use enclosure, local ventilation and dilution to reduce concentration below TLV.

8.2.1.1 Respiratory protection
No special requirements under normal conditions of use. Good general ventilation is sufficient to control any airborne vapors.

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

8.2.1.3 Eye protection
Safety glasses.
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8.2.1.4 Skin protection
No special requirements.

8.2.1.5 Other controls
Emergency eye wash fountain should be close by and maintained. Do not eat, drink or smoke. Avoid contact with eyes, skin or clothing. Avoid breathing vapors. Wash hands after use.

8.2.2 Environmental exposure controls
Follow all government regulations.

9.0 Physical and Chemical Properties

9.1 Appearance / Color

9.1.1 Color
Part A and DUO: Pale yellow to amber thin liquid
Part B and UNO: Yellow resinous liquid
Part C: Amber-colored thin liquid

9.1.2 Odor
Characteristic, sweet, mint-like acetone odor

9.2 Important health, safety and environmental information

9.2.1 pH
Not applicable

9.2.2 Boiling point
Boiling Point: 56.5°C

9.2.3 Flash point
-18°C (Tag closed cup)

9.2.4 Ignition temperature
Not determined

9.2.5 Explosive properties
Lower 2.5 Upper 12.8

9.2.6 Odor threshold
159 ppm

9.2.7 Vapor pressure
180 mm Hg / 239.98 mbar / Id: E

9.2.8 Specific gravity
DenTASTIC A, B, C, DUO: 0.795
DenTASTIC 1, 2: 1.100
DenTASTIC UNO: 0.788

9.2.9 Solubility in water
Acetone: Very soluble. Resins: Insoluble

9.2.10 Partition coefficient
Not determined

9.2.11 Viscosity
Not determined

9.2.12 Vapor density
2

9.2.13 Evaporation rate
6

10.0 Stability and reactivity

10.1 Conditions to avoid
Heat, sparks, open flame, cross-contamination.

10.2 Materials to avoid
Acetyl chloride, acids, bases, amines, bromines, chloroform, hydrogen peroxide, strong oxidizers, plastics, rayon, ketones and acetaldehyde.

10.3 Hazardous decomposition products
Thermal decomposition may produce toxic oxides of carbon.

10.4 Further information
Stable if stored and used as directed.

11.0 Toxicological information
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<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>11.1</td>
<td>Acute toxicity</td>
<td>Minimal health hazard under normal conditions of dental practice. For large quantities/prolonged exposure, acetone is a significant health hazard. LD₅₀ in rats: 10.7 ml/kg orally. Exposure to &gt;750 ppm may irritate respiratory tract.</td>
</tr>
<tr>
<td>11.2</td>
<td>Irritation and corrosiveness</td>
<td>May cause irritation of eyes or skin on contact. May cause irritation of respiratory tract if inhaled.</td>
</tr>
<tr>
<td>11.3</td>
<td>Sensitization</td>
<td>Prolonged or repeated exposure to methacrylates may cause sensitization.</td>
</tr>
<tr>
<td>11.4</td>
<td>Sub-acute, sub-chronic and prolonged toxicity</td>
<td>No chronic health hazard under normal conditions of use. Prolonged and/or repeated exposure to methacrylates may cause sensitization. Prolonged and/or repeated exposure to acetone may cause skin to dry and crack.</td>
</tr>
<tr>
<td>11.5</td>
<td>Carcinogenicity, Mutagenicity, Reproductive Toxicity</td>
<td>None known</td>
</tr>
<tr>
<td>11.6</td>
<td>Empirical data</td>
<td>None available</td>
</tr>
<tr>
<td>11.7</td>
<td>Clinical experience</td>
<td>Dental adhesives with an acetone base have been used for decades with a high benefit-to-risk ratio. There is no evidence of short-term or long-term risk or any problems after thousands of procedures.</td>
</tr>
</tbody>
</table>

### 12.0 Ecological Information

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>12.1</td>
<td>Ecotoxicity</td>
<td>Follow good working practices and all government regulations. Avoid release into environment.</td>
</tr>
</tbody>
</table>

### 13.0 Disposal Considerations

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

### 14.0 Transport Information

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>14.1</td>
<td>UN Number</td>
<td>1090</td>
</tr>
<tr>
<td>14.2</td>
<td>Technical name</td>
<td>Acetone</td>
</tr>
<tr>
<td>14.3</td>
<td>Packing group</td>
<td>Packing Group II</td>
</tr>
<tr>
<td>14.4</td>
<td>IATA class</td>
<td>3</td>
</tr>
</tbody>
</table>
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## 15.0 Regulatory Information

<table>
<thead>
<tr>
<th>15.1</th>
<th>EU</th>
<th>DenTASTIC Dental Adhesive System, UNO and DUO are Class IIa Medical Devices under the Medical Devices Directive 93/42/EEC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>15.2</td>
<td>US FDA</td>
<td>DenTASTIC Dental Adhesive System, UNO and DUO are Class II Medical Devices.</td>
</tr>
<tr>
<td>15.3</td>
<td>Health Canada</td>
<td>DenTASTIC Dental Adhesive System, UNO and DUO are Class III Medical Devices</td>
</tr>
</tbody>
</table>

## 16.0 Other information

| 16.1 | List of relevant R phrases | R11: Highly flammable  
R 36 / 37 / 38: Irritating to eyes, respiratory system and skin.  
R43: May cause sensitization by skin contact  
R66: Repeated exposure may cause skin dryness or cracking. |
|------|-----------------------------|----------------------------------------------------------------------------------------------------------------------------------|
H319: Causes serious eye irritation. Category 2.  
H335: Specific Target Organ Toxicity (STOT), single exposure, respiratory tract, Category 3: May cause respiratory irritation.  
H315: Causes skin irritation. Category 2.  
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| 16.3 | Precautionary Statements | P210: Keep away from heat, sparks, open flame, hot surfaces. No smoking.  
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P303+P361+P353: If on skin or hair, remove contaminated clothing. Rinse skin with water.  
P370+P378: In case of fire, use dry chemical, alcohol foam, or carbon dioxide for extinction. |
| 16.4 | Restrictions on use | DenTASTIC dental adhesives are to be sold to and used by dental professionals only. |
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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.

16.5 Sources of key data

- National Institute for Occupational Safety (NIOSH)
- US Occupational Safety and Health Administration (OSHA)


16.6 Information which has been added, deleted or revised.

This Safety Data Sheet has been revised to meet the requirements of the GHS SDS format and 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.