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

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]

Hazard Class | Hazard Category | Hazard Statement
--- | --- | ---
Flammable liquid | 2 | H225
Eye irritation | 2 | H319
STOT SE | 3 | H335
Skin irritation | 2 | H315; EUH066
Skin sensitization | 1 | H317

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; R 43; R66

2.2 GHS Label Elements

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+P351+P338: 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+P338: 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.

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.1272/2008 (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; flush with running water for 15+ minutes. Get medical attention.

4.3 Skin Contact
Remove 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.

5.0 Fire Fighting Measures

5.1 Suitable extinguishing media

Use dry chemical, alcohol foam, or carbon dioxide.

5.2 Extinguishing media to avoid

Water may be ineffective, but will 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 firefighters

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

Wear gloves and safety glasses. Wipe up with paper towels or cloths. 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

Avoid cross-contamination. Avoid heat, ignition sources, and intense light. Empty containers may retain residual product; handle appropriately.

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 adhesives

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

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.

8.2.1.3 Eye protection

Safety glasses.

8.2.1.4 Skin protection

No special requirements.

8.2.1.5 Other controls

Emergency eye wash fountain should be close by. 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 Characteristics

9.1.1 Appearance / Color / Physical state
- 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

11.1 Acute toxicity
Minimal health hazard under normal conditions of dental practice. Large quantities/prolonged exposure: acetone is a significant health hazard. LD₅₀ in rats: 10.7 ml/kg orally. Respiratory irritant at >750 ppm.

11.2 Irritation and corrosiveness
May cause irritation of eyes or skin on contact. May cause irritation of respiratory tract if inhaled.

11.3 Sensitization
Prolonged or repeated exposure to methacrylates may cause sensitization.

11.4 Sub-acute, sub-chronic and prolonged
No chronic health hazard under normal conditions of use. Prolonged
## Trade Name: DenTASTIC DENTAL ADHESIVE SYSTEM, DenTASTIC UNO, DenTASTIC DUO

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>11.5</td>
<td>Carcinogenicity, Mutagenicity, Reproductive Toxicity</td>
</tr>
<tr>
<td>11.6</td>
<td>Empirical data</td>
</tr>
<tr>
<td>11.7</td>
<td>Clinical experience</td>
</tr>
</tbody>
</table>

### 12.0 Ecological Information

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

### 13.0 Disposal Considerations

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>13.1</td>
<td>Regulations</td>
</tr>
</tbody>
</table>

### 14.0 Transport Information

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>14.1</td>
<td>UN Number</td>
</tr>
<tr>
<td>14.2</td>
<td>Technical name</td>
</tr>
<tr>
<td>14.3</td>
<td>Packing group</td>
</tr>
<tr>
<td>14.4</td>
<td>IATA class</td>
</tr>
</tbody>
</table>

### 15.0 Regulatory Information

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>15.1</td>
<td>EU</td>
</tr>
<tr>
<td>15.2</td>
<td>US FDA</td>
</tr>
<tr>
<td>15.3</td>
<td>Health Canada</td>
</tr>
</tbody>
</table>

### 16.0 Other information

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
</table>
| 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.  
EUH066: Repeated exposure may cause skin dryness or cracking.  
H317: May cause an allergic skin reaction. Category 2. |
Safety Data Sheet

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

16.3 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.

16.4 Restrictions on use

DenTASTIC dental adhesives are 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.

16.5 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.