

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 <i>DenTASTIC Adhesive System</i> including DASP-A, DASP-B, DASP-C, DASP-1 and DASP-2 <i>DenTASTIC UNO</i> <i>DenTASTIC DUO</i>
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]																		
	<table border="1"> <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>H335</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>	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
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:

H225: Highly flammable liquid and vapor. Category 2.

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.

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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.

3.0 Composition

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

3.2 Hazardous ingredients

CAS Number	Name of the ingredient	Concentration	Classification according to 67/548/EEC	Classification according to Regulation (EC) No.1272/2008 (CLP).
67-64-1	Acetone	50% to 80%	Flammable (F); Irritant (Xi). R11- 36/37/38-66	Flammable liquid; Category 2 Eye irritation; Category 2 STOT SE; Category 3 Skin irritation; Category 2
----	Methacrylate ester monomers	5% to 50%	Irritant (Xi). R 43	Skin sensitization; Category 1

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.

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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 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 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.

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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 information11.1 Acute toxicity Minimal health hazard under normal conditions of dental practice. Large quantities/prolonged exposure: acetone is a significant health hazard. LD₅₀ in rats: 10.7ml/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.

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11.3	Sensitization	Prolonged or repeated exposure to methacrylates may cause sensitization.
11.4	Sub-acute, sub-chronic and prolonged toxicity	No chronic health hazard under normal conditions of use. Prolonged or repeated exposure to methacrylates may cause sensitization. Prolonged/repeated exposure to acetone may cause skin to dry and crack.
11.5	Carcinogenicity, Mutagenicity, Reproductive Toxicity	None known
11.6	Empirical data	None available
11.7	Clinical experience	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.
12.0	Ecological Information	
12.1	Ecotoxicity	Follow good working practices and all government regulations. Avoid release into environment.
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	UN Number	1090
14.2	Technical name	Acetone
14.3	Packing group	Packing Group II
14.4	IATA class	3
15.0	Regulatory Information	
15.1	EU	Class IIa Medical Devices under MDD 93/42/EEC.
15.2	US FDA	Class II Medical Devices.
15.3	Health Canada	Class III Medical Devices
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.
16.2	Hazard Statements	H225: Highly flammable liquid and vapor. Category 2. 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.

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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	<p>National Institute for Occupational Safety (NIOSH)</p> <p>US Occupational Safety and Health Administration (OSHA)</p> <p>Eur-Lex European Union Law: Regulation (EC) No. 1272/2008 (CLP) and Regulation (EC) No. 1907/2006 (REACH).</p> <p>Guidance on the compilation of safety data sheets. Version 1.1; December 2011. European Chemicals Agency</p>
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.
