

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]	<u>Hazard Class</u>	<u>Hazard Category</u>	<u>Hazard Statement</u>
		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.
8.2.2	Environmental exposure controls	Follow all government regulations.

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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. LD ₅₀ 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.
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

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	toxicity	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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16.3	Precautionary Statements	<p>P210: Keep away from heat, sparks, open flame, hot surfaces. No smoking.</p> <p>P403+P233: Store in a well-ventilated place. Keep container tightly closed.</p> <p>P261: Avoid breathing fumes.</p> <p>P280: Wear protective gloves/ clothing and eye protection.</p> <p>P304+P340: If inhaled, remove victim to fresh air and keep at rest in a position comfortable for breathing.</p> <p>P305+P351+P338: If in eyes, rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>P303+P361+P353: If on skin or hair, remove contaminated clothing. Rinse skin with water.</p> <p>P370+P378: In case of fire, use dry chemical, alcohol foam, or carbon dioxide for extinction.</p>
16.4	Restrictions on use	<p>DenTASTIC dental adhesives are to be sold to and used by dental professionals only.</p>
16.5	Further information	<p>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.</p>
16.5	Sources of key data	<p>National Institute for Occupational Safety (NIOSH) US Occupational Safety and Health Administration (OSHA) Eur-Lex European Union Law: Regulation (EC) No. 1272/2008 (CLP) and Regulation (EC) No. 1907/2006 (REACH). 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.	<p>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.</p>
