

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]	<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		

Safety Data Sheet

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:

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.

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.

Safety Data SheetTrade Name: **DenTASTIC DENTAL ADHESIVE SYSTEM, DenTASTIC UNO, DenTASTIC DUO**

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.1278/2008 (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 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.		

Safety Data Sheet

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

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.

Safety Data Sheet

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

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

Safety Data SheetTrade Name: **DenTASTIC DENTAL ADHESIVE SYSTEM, DenTASTIC UNO, DenTASTIC DUO**

11.1	Acute toxicity	Minimal health hazard under normal conditions of dental practice. For large quantities/prolonged exposure, acetone is a significant health hazard. LD ₅₀ in rats: 10.7 ml/kg orally. Exposure to >750 ppm may irritate respiratory tract.
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 toxicity	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.
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

Safety Data Sheet

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

15.0 Regulatory Information		
15.1	EU	DenTASTIC Dental Adhesive System, UNO and DUO are Class IIA Medical Devices under the Medical Devices Directive 93/42/EEC.
15.2	US FDA	DenTASTIC Dental Adhesive System, UNO and DUO are Class II Medical Devices.
15.3	Health Canada	DenTASTIC Dental Adhesive System, UNO and DUO are 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.
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.

Safety Data SheetTrade Name: **DenTASTIC DENTAL ADHESIVE SYSTEM, DenTASTIC UNO, DenTASTIC DUO**

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) 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
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.
