SAFETY DATA SHEETS

This SDS packet was issued with item:

075914460

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

075896097 075896105 075896121 075896139 075896147 075896154 075896170 075896188 075896402 075896410 075896428

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

075896113

Trade Name: **DenTASTIC UNO-DUO**

1.0	Commercial Product Name and Supplier			
1.1	Commercial product name / designation	DenTASTIC UNO-D	UO	
1.2	Application / Use	Dental bonding ager	t for use by dentists.	
1.2.2	SIC	851 Human health a	ctivity	
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 92 Fax: 1- 617 926-626 Email: <u>Pulpdent@pu</u>	2	
1.4	Emergency Telephone Number	1-800-535-5053 (24	Hour / USA)	
1.5	Authorized European Representative	Advena Limited Tower Business Cer Tower Street, Swatar, BKR 4013 N		
	UK Responsible Person	Advena Limited Pure Offices, Plato C Warwick, CV34 6WE		
2.0	Hazards Identification			
2.1	Classification			
2.1.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Hazard Class Flammable liquid Eye irritation STOT SE Skin irritation Skin sensitization	Hazard Category 2 2 3 2	Hazard Statement H225 H319 H335 H315; EUH066 H317
2.1.2	Classification according to Directive 67/548/EEC (See SECTION 16 for full text of risk phrases)	Flammable (F), Irrita	nt (Xi). R11- 36 / 37 / 3	38; R 43; R66
2.2	CHC Label Flaments			

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.

Trade Name: DenTASTIC UNO-DUO

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.

3.0	Composition	1			
3.1	Chemical char	acterization of the prepa	aration:	Methacrylate ester monon	ners in acetone vehicle.
3.2	Hazardous ing	redients			
	CAS Number	Name of the ingredient	Concentration	Classification per 67/548/EEC	Classification per 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 Me	asures			
4.1	pr M		ppm m Methac contact.	nay cause irritation of i rylate may cause sensiti	yes or skin on contact. Exposure to >750 respiratory tract, mucous membranes. zation of skin with prolonged/repeated heet to medical personnel. Get medical
4.2				yelids apart and flush will attention.	th running water for 15+ minutes. Get
4.3	soap a			nd running water. Use hand	ng. Immediately wash skin well with mild d cream. Get medical attention if irritation
4.4	Ingestion				water to dilute, but only if person is . Get immediate medical attention.
4.5			o fresh air. If necessary, adr ek medical attention.	minister oxygen and/or artificial respiration	
4.6 4.7		for first responders or physicians	Ventilat	e the area. Wear safety gla	sses and gloves to prevent contact.
	Symptoms			n, pain or redness in eyes s system depressant.	s, throat or on skin. Headache, fatigue.

Trade Name: **DenTASTIC UNO-DUO**

	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. 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 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	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. Avoid 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	Good general ventilation is sufficient to control any airborne vapors.
8.2.1.2	Hand protection	No special requirements. Surgical gloves will limit contact.
8.2.1.3	Eye protection	Safety glasses.
8.2.1.4	Skin protection	No special requirements.
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Trade Name: **DenTASTIC UNO-DUO**

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	Appearance / Color	
9.1.1	Color	UNO: Yellow resinous liquid; DUO: Pale yellow to amber thin liquid
9.1.2	Odor	Characteristic, sweet, mint-like acetone odor
9.2	Important health, safety and environmental infor	mation
9.2.1	рН	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 UNO: 0.788; DUO: 0.795
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. 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 may cause sensitization.

Trade Name: **DenTASTIC UNO-DUO**

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
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.

Trade Name: **DenTASTIC UNO-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) 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;
16.6	Information which has been added, deleted or revised.	December 2011. European Chemicals Agency 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.

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

Revision Date: February 10, 2021

1.0	Commercial Product Name and Supplier			
1.1	Commercial product name / designation	DenTASTIC Adhesing including DASF DenTASTIC UNO DenTASTIC DUO	ve System P-A, DASP-B, DASP-C,	DASP-1 and DASP-2
1.2	Application / Use	Dental bonding ager	nt for use by dentists.	
1.2.2	SIC	851 Human health a	ctivity	
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 92 Email: <u>Pulpdent@pu</u>	26-6666 / Fax: 1- 617 92 ulpdent.com	26-6262
1.4	Emergency Telephone Number	1-800-535-5053 (24	Hour / USA)	
1.5	Authorized European Representative	Advena Limited Tower Business Centre, 2nd Floor, Tower Street, Swatar, BKR 4013 Malta		
	UK Responsible Person	Advena Limited Pure Offices, Plato 0 Warwick, CV34 6WE		
2.0	Hazards Identification			
2.1	Classification			
2.1.1	Classification according to Regulation	Hazard Class	Hazard Category	Hazard Statement
	(EC) No. 1272/2008 [CLP]	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), Irrita	ant (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.

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

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.

3.0	Composition	1			
3.1	Chemical char	Chemical characterization of the preparation:		Methacrylate ester monom	ers in acetone vehicle.
3.2	Hazardous ing	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	ppm r Methac contact		ppm ma Methacry contact.	ay cause irritation of re vlate may cause sensitiza	es or skin on contact. Exposure to >750 espiratory tract, mucous membranes. ation of skin with prolonged/repeated eet to medical personnel. Get medical
4.2	Eye Contact	Eye Contact Keep ey attention			ing water for 15+ minutes. Get medical
4.3				mediately wash skin well with mild soap eam. Get medical attention if irritation	
4.4	Ingestion			outh with water. Drink water duce vomiting. Get immedia	to dilute, but only if person is conscious. ate medical attention.
4.5	Inhalation			fresh air. If necessary, adm medical attention.	inister oxygen and/or artificial respiration
4.6 4.7		for first responders or physicians	Ventilate	the area. Wear safety glass	ses and gloves to prevent contact.
	Symptoms			pain or redness in eyes, system depressant.	, throat or on skin. Headache, fatigue.

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

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orne vapors.
oves.
Do not eat, drink or id breathing vapors.
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Trade Name: DenTASTIC DENTAL ADHESIVE SYSTEM, DenTASTIC UNO, DenTASTIC DUO

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	рН	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 / ld: 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
		4/6

Trade I	Name: DenTASTIC DENTAL ADHESI	VE SYSTEM, DenTASTIC UNO, DenTASTIC DUO
	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.

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) 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.