Revision Date: July 1, 2015

Safety Data Sheet

Trade Name: DenTASTIC UNO

1.0	Commercial Product Name and Supplier			
1.1	Commercial product name / designation	DenTASTIC UNO		
1.2	Application / Use	Dental bonding agent 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	1-800-535-5053 (24 Hour / USA)	
1.5	Authorized European Representative	Advena Ltd. Pure Offices, Plato C 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> Flammable liquid	<u>Hazard Category</u> 2	<u>Hazard Statement</u> 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	nt (Xi). R11- 36 / 37 / 3	38; R 43; R66
2.2	GUS I shal 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.

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.

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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.

	P370+P378: In case of fire, use dry chemical, alcohol foam, or carbon dioxide for extinction.				
3.0	Composition				
3.1	Chemical chara	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	First Aid Measures			
4.1	ppm Metha conta		ppm m Methaci contact.	cetone may cause irritation of eyes or skin on contact. Exposure to >750 cm may cause irritation of respiratory tract, mucous membranes. Lethacrylate may cause sensitization of skin with prolonged/repeated contact. Show this safety data sheet to medical personnel. Get medical tention in case of uncertainty.	
4.2	Eye Contact			yelids apart and flush wi attention.	th running water for 15+ minutes. Get
4.3	soap		soap ar	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			e mouth with water. Drink water to dilute, but only if person is cious. Do not induce vomiting. Get immediate medical attention.	
4.5	Inhalation			e to fresh air. If necessary, administer oxygen and/or artificial respiration seek medical attention.	
4.6	Precautions f	for first responders	Ventilate the area. Wear safety glasses and gloves to prevent conta		sses and gloves to prevent contact.
4.7	Information for	or physicians			
			n, pain or redness in eyes s system depressant.	s, throat or on skin. Headache, fatigue.	

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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. 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.

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2.1.3 Eye protection 2.1.4 Skin protection 2.1.5 Other controls Emergency eye wash fountain should be close by. Do not eat, drink smoke. Avoid contact with eyes, skin or clothing. Avoid breathing vapors. Wash hands after use. 2.2 Environmental exposure controls Physical and Chemical Properties Appearance / Color Color Yellow resinous liquid Characteristic, sweet, mint-like acetone odor Important health, safety and environmental information PH Not applicable Boiling point Boiling point Boiling Point: 56.5°C -18°C (Tag closed cup) Not determined Lower 2.5 Upper 12.8 Odor threshold 159 ppm The Dorn the survey of the service of carbon. Safety glasses. No special requirements. Emergency eye wash fountain should be close by. Do not eat, drink smoke. Avoid contact with eyes, skin or clothing. Avoid breathin vapors. Wash of clothing. Avoid breathing. 1.2 Boiling point 1.3 Flash point 1.4 Boiling Point: 56.5°C 1.5 Explosive properties 1.6 Depth 1.6 Explosive properties 1.7 Vapor pressure 1.8 Depth 1.7 Vapor pressure 1.8 D			
2.1.4 Skin protection No special requirements. 2.1.5 Other controls Emergency eye wash fountain should be close by. Do not eat, drink smoke. Avoid contact with eyes, skin or clothing. Avoid breathing vapors. Wash hands after use. 2.2 Environmental exposure controls Follow all government regulations. 3 Physical and Chemical Properties 4 Appearance / Color 5 Color Yellow resinous liquid 6 Characteristic, sweet, mint-like acetone odor 1 Important health, safety and environmental information 1.1 pH Not applicable 1.1 PH Not applicable 1.1 PH Not applicable 1.1 PH Not determined 1.1 PH Not determined 1.2 Disprison 1.2 Dispr	8.2.1.2	Hand protection	No special requirements. Surgical gloves will limit contact.
Emergency eye wash fountain should be close by. Do not eat, drink smoke. Avoid contact with eyes, skin or clothing. Avoid breath vapors. Wash hands after use. Physical and Chemical Properties Appearance / Color Color Yellow resinous liquid Codor Characteristic, sweet, mint-like acetone odor Important health, safety and environmental information PH Not applicable Boiling point Boiling point Boiling Point: 56.5°C Ighition temperature Not determined Lower 2.5 Upper 12.8 Codor threshold Toyor pressure 180 mm Hg / 239.98 mbar / Id: E Specific gravity O.788 Solubility in water Acetone: Very soluble. Resins: Insoluble Not determined Viscosity Not determined Not determined Codor breathod Toyor pressure Resins: Insoluble Not determined Codor breathod Toyor pressure Resins: Insoluble The artition coefficient Not determined Toyor pressure Resins: Insoluble Toyor pressive Resins: Insoluble The artition coefficient Not determined Toyor pressive Resins: Insoluble The artition coefficient Not determined The artition coefficient The artition coefficient The artition coefficient The artition coefficient The artition coefficient counter coun	8.2.1.3	Eye protection	Safety glasses.
smoke. Avoid contact, with eyes, skin or clothing. Avoid breath vapors. Wash hands after use. Physical and Chemical Properties Appearance / Color Yellow resinous liquid Color Yellow resinous liquid Characteristic, sweet, mint-like acetone odor Important health, safety and environmental information PH Not applicable Boiling point Boiling Point: 56.5°C 18ah point 18°C (Tag closed cup) Apper 12.8 Codor threshold 159 ppm Apor pressure 180 mm Hg / 239.98 mbar / Id: E Specific gravity 0.788 Specific gravity 0.788 Solubility in water Acetone: Very soluble. Resins: Insoluble Not determined Vapor determined Codor threshold 159 ppm Acetone: Very soluble. Resins: Insoluble Resins: Insoluble Codor threshold Acetone: Very soluble, Resins: Insoluble Acetone: Very soluble, Resins: Insoluble Acetone: Very soluble, Resins: Insoluble Codor threshold Acetone: Very soluble, Resins: Insoluble Acetone: Very soluble, Resins: I	8.2.1.4	Skin protection	No special requirements.
Physical and Chemical Properties Appearance / Color Yellow resinous liquid Color Characteristic, sweet, mint-like acetone odor Important health, safety and environmental information PH Not applicable Boiling point Boiling Point: 56.5°C Boiling point Solibing Point: 56.5°C Ignition temperature Not determined Lower 2.5 Upper 12.8 Odor threshold 159 ppm Tyapor pressure Boiling Point: 56.5°C Upper 12.8 Odor threshold 159 ppm Tyapor pressure Boiling Point: 56.5°C Upper 12.8 Odor threshold 159 ppm Tyapor pressure Boiling Point: 56.5°C Upper 12.8 Diper 12.8 Paper 12.8 Diper	8.2.1.5	Other controls	smoke. Avoid contact with eyes, skin or clothing. Avoid breath
Appearance / Color Yellow resinous liquid Color Yellow resinous liquid Characteristic, sweet, mint-like acetone odor Important health, safety and environmental information PH Not applicable Boiling point Boiling Point: 56.5°C Plash point -18°C (Tag closed cup) Indition temperature Not determined Sepolation temperature Lower 2.5 Upper 12.8 Codor threshold 159 ppm To Vapor pressure 180 mm Hg / 239.98 mbar / Id: E Specific gravity 0.788 Solubility in water Acetone: Very soluble. Resins: Insoluble Partition coefficient Not determined Vapor density 2 To Stability and reactivity Conditions to avoid Heat, sparks, open flame, cross-contamination. Acetyl chloride, acids, bases, amines, bromines, chloroform, hydrogen peroxide, strong oxidizers, plastics, rayon, ketones and acetaldehyde. Thermal decomposition may produce toxic oxides of carbon. Further information Stable if stored and used as directed. Toxicological information 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 mil/kg orally.	8.2.2	Environmental exposure controls	Follow all government regulations.
Color Yellow resinous liquid Characteristic, sweet, mint-like acetone odor Important health, safety and environmental information PH Not applicable Boiling point Boiling Point: 56.5°C Boiling point Boiling Point: 56.5°C Boiling point Plash	9.0	Physical and Chemical Properties	
Characteristic, sweet, mint-like acetone odor Important health, safety and environmental information PH	9.1	Appearance / Color	
Important health, safety and environmental information pH Not applicable Boiling Point: 56.5°C Plash point -18°C (Tag closed cup) Injury (Tag closed c	9.1.1	Color	Yellow resinous liquid
Not applicable	9.1.2	Odor	Characteristic, sweet, mint-like acetone odor
Boiling point Boiling Point: 56.5°C 2.3 Flash point -18°C (Tag closed cup) 2.4 Ignition temperature Not determined 2.5 Explosive properties Lower 2.5 Upper 12.8 2.6 Odor threshold 159 ppm 2.7 Vapor pressure 180 mm Hg / 239.98 mbar / Id: E 2.8 Specific gravity 0.788 2.9 Solubility in water 2.10 Partition coefficient Not determined 2.11 Viscosity Not determined 2.12 Vapor density 2 2 2.13 Evaporation rate 6 Stability and reactivity 1 Conditions to avoid Heat, sparks, open flame, cross-contamination. Acetyl chloride, acids, bases, amines, bromines, chloroform, hydrogen peroxide, strong oxidizers, plastics, rayon, ketones and acetaldehyde. Acetyl chloride, acids, bases, amines, bromines, chloroform, hydrogen peroxide, strong oxidizers, plastics, rayon, ketones and acetaldehyde. Acetyl chloride, acids, bases, amines, bromines, chloroform, hydrogen peroxide, strong oxidizers, plastics, rayon, ketones and acetaldehyde. Thermal decomposition may produce toxic oxides of carbon. 4 Further information Stable if stored and used as directed. 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.	9.2	Important health, safety and environmental inform	mation
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2.6 Odor threshold 2.7 Vapor pressure 2.8 Specific gravity 2.8 Specific gravity 3.7 Vapor pressure 3.8 Specific gravity 4.9 Solubility in water 5.10 Partition coefficient 5.11 Viscosity 7.12 Vapor density 7.12 Vapor density 7.13 Evaporation rate 7.16 Stability and reactivity 7.1 Conditions to avoid 7.1 Conditions to avoid 8.1 Heat, sparks, open flame, cross-contamination. 8.2 Materials to avoid 8.3 Hazardous decomposition products 8.4 Further information 8.5 Thermal decomposition may produce toxic oxides of carbon. 8.6 Toxicological information 9. Minimal health hazard under normal conditions of dental practice. For large quantities/prolonged exposure, acetone is a significant health hazard. LD₂₀ in rats: 10.7 ml/kg orally.	9.2.4	Ignition temperature	Not determined
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2.9 Solubility in water 2.10 Partition coefficient Not determined 2.11 Viscosity Not determined 2.12 Vapor density 2 2.13 Evaporation rate 6 3.0 Stability and reactivity 1.1 Conditions to avoid Materials to avoid Acetyl chloride, acids, bases, amines, bromines, chloroform, hydrogen peroxide, strong oxidizers, plastics, rayon, ketones and acetaldehyde. 3. Hazardous decomposition products Thermal decomposition may produce toxic oxides of carbon. 4. Further information Stable if stored and used as directed. 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.	9.2.7	Vapor pressure	180 mm Hg / 239.98 mbar / Id: E
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2.12 Vapor density 2 2.13 Evaporation rate 6 3.0 Stability and reactivity 3.1 Conditions to avoid 4.1 Heat, sparks, open flame, cross-contamination. 4.2 Materials to avoid 5.3 Hazardous decomposition products 5.4 Further information 6 5.6 Toxicological information 6 6 6 6 7 7 8 8 8 8 8 9 9 9 9 9 9 9 9 9 9 9 9 9	9.2.10	Partition coefficient	Not determined
Evaporation rate 5.0 Stability and reactivity 1.1 Conditions to avoid Heat, sparks, open flame, cross-contamination. 1.2 Materials to avoid Acetyl chloride, acids, bases, amines, bromines, chloroform, hydrogen peroxide, strong oxidizers, plastics, rayon, ketones and acetaldehyde. 1.3 Hazardous decomposition products Thermal decomposition may produce toxic oxides of carbon. 1.4 Further information Stable if stored and used as directed. 1.5 Toxicological information 1.6 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.	9.2.11	Viscosity	Not determined
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Conditions to avoid Heat, sparks, open flame, cross-contamination. Acetyl chloride, acids, bases, amines, bromines, chloroform, hydrogen peroxide, strong oxidizers, plastics, rayon, ketones and acetaldehyde. Hazardous decomposition products Thermal decomposition may produce toxic oxides of carbon. Stable if stored and used as directed. Toxicological information 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.	9.2.13	Evaporation rate	6
Acetyl chloride, acids, bases, amines, bromines, chloroform, hydrogen peroxide, strong oxidizers, plastics, rayon, ketones and acetaldehyde. Thermal decomposition may produce toxic oxides of carbon. Stable if stored and used as directed. Toxicological information 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.	10.0	Stability and reactivity	
peroxide, strong oxidizers, plastics, rayon, ketones and acetaldehyde. Thermal decomposition may produce toxic oxides of carbon. Stable if stored and used as directed. Toxicological information 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.	10.1	Conditions to avoid	Heat, sparks, open flame, cross-contamination.
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.0 Toxicological information .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.	10.3	Hazardous decomposition products	Thermal decomposition may produce toxic oxides of carbon.
.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.	10.4	Further information	Stable if stored and used as directed.
practice. For large quantities/prolonged exposure, acetone is a significant health hazard. LD $_{50}$ in rats: 10.7 ml/kg orally.	11.0	Toxicological information	
	11.1	Acute toxicity	practice. For large quantities/prolonged exposure, acetone is a significant health hazard. LD $_{50}$ in rats: 10.7 ml/kg orally.

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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
15.0	Regulatory Information	
15.1	EU	Class IIa medical device under MDD 93/42/EEC.
15.2	US FDA	Class II medical device
15.3	Health Canada	Class III medical device
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.

Revision Date: July 1, 2015

Trade Name: **DenTASTIC UNO**

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 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.