

SAFETY DATA SHEETS

This SDS packet was issued with item:

075896105

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).

075896097 075896113 075896121 075896139 075896147 075896154 075896170 075896188 075896402 075896410

075896428 075914460

MATERIAL SAFETY DATA SHEET: DenTASTIC A, B, C

IDENTITY: Trade Name: DenTASTIC DENTAL ADHESIVE
Code: DAS, DAS-C1, DASP-A, DASP-B, DASP-C

Chemical Description:

Part A: Mg NTG-GMA in acetone base (magnesium salt of the reaction product of N-toluene glycine and glycidil methacrylate) and inhibitors.

Part B: PMGDM in acetone base (the reaction product of pyromellitic dianhydride with glycerol dimethacrylate), di- and tri-functional monomers and activators.

Part C: Activators, mono- and di-functional monomers and oligomers in acetone base.

Product Use: Dental adhesive system

SECTION I

Pulpdent Corporation

80 Oakland Street

Watertown, MA 02472 USA

Date Prepared: September 1, 2008

Phone Numbers:

24 Hour Emergency: 1-800-535-5053

Customer Service: 1-800-343-4342/1-617-926-6666

SECTION II - HAZARDOUS INGREDIENTS

| Ingredients | CAS RN | PEL/TLV | UN Number |
|-------------|-------------|-------------------------------|-----------|
| Mg NTG GMA | 83418-59-1 | Not established | ---- |
| PMGDM | 148019-46-9 | Not established | ---- |
| Acetone | 67-64-1 | TWA: 750 ppm / STEL: 1000 ppm | UN 1090 |

DOT HAZARD CLASSIFICATION: Class 3, PG II, Flammable Liquid

WHMIS CLASSIFICATION: B-2, Flammable Liquid / D-2, Possible Irritant or Sensitizer

NFPA HMIS RATING: HEALTH: 1 FLAMMABILITY: 3 REACTIVITY: 2

SECTION III - PHYSICAL / CHEMICAL CHARACTERISTICS

Boiling Point: 56.5°C Specific Gravity: 0.788 Vapor Pressure: 180 mm Hg

Melting Point: -94°C Vapor Density: 2.0 Evaporation Rate: 6

Solubility in water: Very soluble Odor Threshold: 20 ppm

Odor: Characteristic, sweet mint-like acetone odor

Appearance: Part A: Pale yellow to amber thin liquid; Part B: Yellow liquid; Part C: Amber colored thin liquid;

SECTION IV - FIRE AND EXPLOSION HAZARD DATA

Flash Point: - 18°C Flammable limits: LEL 2.5% UEL 12.8%

Extinguishing Media: Use dry chemical, CO₂, alcohol resistant foam, water spray.

Special Fire Fighting Procedures: Use water to keep fire exposed containers cool. Firefighters should wear self-contained breathing apparatus in the positive pressure mode with a full face piece, when there is the possibility of exposure to smoke, fumes, or hazardous decomposition products.

Hazardous Combustion Products / Unusual Fire and Explosion Hazards: Heat, aging or contamination can lead to explosive polymerization.

SECTION V - REACTIVITY DATA

Stability: Stable under normal conditions of use and storage.

Conditions to avoid: Heat, sparks and flame, ungrounded metal containers, contamination. Use promptly.

Incompatibility: 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.

Hazardous Polymerization: Possible

Conditions to avoid: Heat, sparks and flame, contamination, storage for prolonged periods.

SECTION VI - HEALTH HAZARD DATA

Summary of Acute Hazards: Minimal health hazard under normal conditions of use and storage and in the quantities present in this product. May be irritating to eyes, skin, or respiratory tract. In large quantities and with prolonged exposure, acetone presents a significant health hazard.

| <i>Route of Exposure</i> | <i>Signs & Symptoms</i> |
|--------------------------|---|
| Inhalation | May irritate nose, throat. Headache/fatigue with prolonged/repeated exposure. |
| Eye Contact | May irritate eyes. |
| Skin Absorption | Slightly toxic. |
| Skin Contact | May cause dry or red skin or allergic reaction. |
| Ingestion | Harmful if swallowed; nervous system depressant. LD ₅₀ (rat): 10.7 ml/kg |

Summary of Chronic Hazards: Prolonged exposure to acetone, over TLV, may cause mucous membrane irritation, fatigue, weakness, headache, hematological and central nervous system changes, conjunctivitis. Methacrylates may cause sensitization in susceptible individuals.

| | |
|------------------------|--|
| Carcinogenicity | Not known to be a carcinogen. |
| Teratogenicity | None known |
| Mutagenicity | None known |
| Reproductive Toxicity | None known |
| Special Health Effects | Persons with chronic respiratory or skin disease are at increased risk with prolonged exposure to acetone. |

Emergency First Aid Procedures:

| | |
|--------------|--|
| Inhalation | Move to fresh air. Give oxygen; get medical care for difficult breathing. |
| Eye contact | Flush the contaminated eye with flowing water for 15+ minutes. If irritation persists, obtain medical care. |
| Ingestion | For large quantities, dilute with water, but only if person is conscious. Give activated charcoal. Get emergency medical care. |
| Skin contact | Wash affected area thoroughly with mild soap and water. If irritation develops or persists, seek medical advice. |

SECTION VII - PRECAUTIONS FOR SAFE HANDLING & USE

Handling and Storage Precautions: Store tightly capped in original container at cool room temperature. Avoid cross-contamination between parts. Avoid heat, sparks, flames moisture and incompatible materials. Ground metal containers. Empty containers may retain residual product and should be handled appropriately.

Steps to Be Taken if Material is Released or Spilled: For small quantities, as in this product: Wear gloves and splash goggles. Absorb spill with inert material, such as paper towels. Place all absorbent material in closed container away from heat, sparks, and flame. Wash area of spill with soap and water.

Waste Disposal Method: Follow all government regulations. Keep spills out of sewers, open bodies of water.

Other Precautions: Avoid contact with eyes, skin or clothing. Avoid breathing vapors. Wash hands after use.

SECTION VIII - CONTROL MEASURES

Respiratory Protection: Surgical mask is usually adequate. For exposure >TLV, use a NIOSH-approved respirator.

Ventilation: No special ventilation is usually required. Large quantities of acetone require local exhaust.

Protective Gloves: Recommended.

Eye Protection: Safety glasses or splash goggles are recommended.

Other Protective Clothing or Equipment: Emergency eye wash fountain. Dental staff should wear lab coats.

Work/Hygienic Practices: Wash hands after use.

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.

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 Limited Tower Business Centre, 2nd Floor, Tower Street, Swatar, BKR 4013 Malta |
| | UK Responsible Person Advena Limited 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.

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

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. |

Trade Name: **DenTASTIC DENTAL ADHESIVE SYSTEM, DenTASTIC UNO, DenTASTIC 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. |
| 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. |

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 | 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 |

Trade Name: **DenTASTIC DENTAL ADHESIVE 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 | <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> |
