SAFETY DATA SHEETS

This SDS packet was issued with item:

075912423

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

075912415 075912431 075912449 075912456 075912464 075912472 075912514 075912522 075912530 075912548 075912555 075912563 075912571

Pulpdent Corporation

Material Safety Data Sheet: *Tuff-Temp* Temporary Crown and Bridge Material

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IDENTITY *Tuff-Temp Temporary Crown and Bridge Material*

Chemical Description: Glass-filled resin in two parts, base and catalyst, with photo-initiator and self-cure chemistry.

Product Use: Temporary crown and bridge material

SECTION I

Pulpdent Corporation
80 Oakland Street
Watertown, MA 02472 USA

Phone Numbers
24 Hour Emergency: 1-800-535-5053
Customer Service: 1-800-343-4342/1-617-926-6666

Date prepared: December 1, 2008

SECTION II - HAZARDOUS INGREDIENTS

Ingredients	*CAS Number*	*PEL / TLV*
Uncured methacrylate resins	-------	Not established
Silica, amorphous	112945-52-5	6 mg/m^3 / 10 mg/m^3

DOT HAZARD CLASSIFICATION: None required

WHMIS CLASSIFICATION: D-2, Possible irritant

NFPA HMIS RATING: HEALTH: 1 FLAMMABILITY: 0 REACTIVITY: 1

SECTION II - PHYSICAL / CHEMICAL CHARACTERISTICS

Light cure set time	20 seconds
Self-cure set time	7 minutes
Appearance	Two tooth-colored pastes, base and catalyst
Odor	Slight, characteristic

SECTION IV - FIRE AND EXPLOSION HAZARD

Flash point: Not established Auto-ignition temperature: Not established

Flammable limits: Not established

Hazardous Combustion Products: Under fire conditions and with amounts greater than that supplied in this product, hazardous polymerization may occur with heat build up and release of carbon monoxide, carbon dioxide, and oxides of nitrogen.

Extinguishing Media: Carbon dioxide, dry chemical, alcohol foam or water fog. Water spray may be used to keep exposed containers cool.

Special Fire Fighting Procedures: A self-contained breathing apparatus should be worn by fire-fighting personnel. Cool exposed containers with water spray to prevent polymerization under fire conditions.

SECTION V - REACTIVITY DATA

Stability: Stable

Conditions to avoid: Intense light, temperature >100°F / 38°C, cross-contamination.

Incompatibility: Reducing and oxidizing agents.

Hazardous Decomposition Products: Carbon monoxide, carbon dioxide, oxides of nitrogen

Hazardous Polymerization: None under normal conditions of use.

Conditions to avoid: Strong light, temperature >100°F / 38°C, cross-contamination.

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SECTION VI - HEALTH HAZARD DATA

Summary of Acute Hazards: Minimal health hazard in the small quantities present in this product and under normal conditions of use. Material may be irritating to eyes, mucous membranes or skin on contact.

Route of Exposure	*Signs and Symptoms*
Inhalation	May be irritating to mucous membranes.
Eye Contact	May be irritating.
Skin Absorption	Not applicable
Skin Contact	Primary route of exposure, possibly irritating or sensitizing.
Ingestion	None expected with this product in normal conditions of use. May be irritating to mucous membranes.

Summary of Chronic Hazards: May be sensitizing, especially with prolonged and/or repeated exposure.

Carcinogenicity	Not known to be a carcinogen.

Teratogenicity, Mutagenicity, Reproductive Toxicity: None known

Emergency First Aid Procedures	
Inhalation	Move exposed person to fresh air. Seek medical care.
Eye contact	Flush eyes with running water for 15+ minutes. Seek medical attention.
Ingestion	Rinse mouth. Consult physician.
Skin contact	Wash skin with soap and running water. Seek medical attention if irritation persists.

SECTION VII - PRECAUTIONS FOR SAFE HANDLING AND USE

Handling/Storage Precautions: Avoid temperature extremes, strong light, cross-contamination, moisture.

Release or Spill: Wear gloves, safety glasses. Pick up with absorbent material (paper or cloth) and collect for suitable disposal.

Waste Disposal Method: Follow all government regulations.

Other Precautions: Wash hands after use.

SECTION VIII - CONTROL MEASURES

Respiratory Protection: Not necessary under normal conditions of use of this product.

Ventilation: No special ventilation required under normal conditions of use of this product.

Protective Gloves: Recommended

Eye Protection: Safety glasses are recommended when normal conditions of use are anticipated. Chemical splash goggles should be worn whenever there is a possibility of splashing or contact.

Other Protective Clothing or Equipment: Emergency eye wash fountain should be close-by and maintained.

Work / Hygienic Practices: Wash hands after use

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Safety Data Sheet

Trade Name: ***Tuff-Temp™ Plus Provisional Veneer, Crown & Bridge Resin***

1.0 Commercial Product Name and Supplier

1.1	Commercial product name / designation	Tuff-Temp™ Plus Provisional Veneer, Crown & Bridge Resin Tuff-Temp™ Provisional Add-On Tuff-Temp™ Provisional Glaze
1.2	Application / Use	Dental material for use by dental professional only.
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]

Hazard Class	Hazard Category	Hazard Statement
Eye irritation	2	H319
STOT SE	3	H335
Skin irritation	2	H315
Skin sensitization	1	H317

2.1.2 Classification according to Directive 67/548/EEC Irritant; Xi; R 36/37/38 – 43 *(See SECTION 16 for full text of risk phrases)*

2.2 GHS Label Elements

Hazard Pictograms



Signal Word: WARNING

Restricted to use by dental professional only.

Hazard Statements

H319: Eye irritation. 2. May cause eye irritation.
H335: STOT SE. 3. May cause respiratory irritation.
H315: Skin irritation. 2. May cause skin irritation.
H317: Sensitization. 1. May cause an allergic skin reaction.

Precautionary Statements

P261: Avoid breathing vapor.
P280: Wear protective gloves and eye protection
P305+P351: If in eyes, rinse cautiously with water for several minutes.
P337+P313: If eye irritation persists, get medical advice/attention.
P302+P352: If on skin, wash with plenty of soap and water.
P333+P313: If irritation or rash occurs, get medical advice/attention.
P410+P411: Protect from sunlight. Store at temperature not exceeding 27°C / 80°F.

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Safety Data Sheet

Trade Name: ***Tuff-Temp™ Plus Provisional Veneer, Crown & Bridge Resin***

3.0 Composition

3.1 Chemical characterization of the preparation: Glass-filled methacrylate resins in a two-part, dual-cure paste.

3.2 Hazardous ingredients

CAS Number	Name of the Ingredient	Concentration	Classification per 67/548/EEC	Classification per Regulation (EC) No.1272/2008 (CLP).
Proprietary	Uncured methacrylate resins	55-60%	Xi (Irritant), R 36/37/38 - 43	Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315 Skin sensitization, 1, H317
112945-52-5	Silica, amorphous	5 %	Xi (Irritant), R 36/37/38	Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315

4.0 First Aid Measures

4.1	General Information	May be irritating to eyes, mucous membranes or skin on contact. Avoid contact with eyes and skin. May cause sensitization by skin contact. Show this safety data sheet to medical personnel. Get medical attention in case of uncertainty.
4.2	Inhalation	Move to fresh air. If necessary, administer oxygen and/or artificial respiration. Seek medical attention.
4.3	Skin Contact	Take off contaminated clothing. Wash skin thoroughly with soap and water.
4.4	Eye Contact	Keep eyelids apart and flush with running water for 15+ minutes. Get medical attention.
4.5	Ingestion	Rinse mouth with water. Do not induce vomiting. Get immediate medical attention. May be irritating to mucous membranes. Never give anything by mouth to an unconscious person.
4.6	Precautions for first responders	Ventilate the area. Wear eye and skin protection.
4.7	Information for physicians	
	Symptoms	Irritation or redness in eyes, throat or on skin.
	Hazards	May be irritating to eyes, mucous membranes and skin. May cause sensitization by skin contact.
	Treatment	As above under First Aid.

5.0 Fire Fighting Measures

5.1	Suitable extinguishing media	Carbon dioxide, dry chemical, alcohol foam, or water fog. Water spray may be used to keep fire exposed containers cool.
5.2	Extinguishing media to avoid	Do not use direct water stream
5.3	Special exposure hazards in a fire	Heat may cause polymerization with rapid release of energy.
5.4	Special protective equipment for fire-fighters	Self-contained breathing apparatus

6.0 Accidental Release Measures

6.1	Personal precautions.	Wear safety glasses, gloves and lab coat.

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6.2	Environmental precautions	Avoid releasing large amounts of uncured material into the environment Cured / set-up material is, to our knowledge, inert.
6.3	Method for clean up	Contain spilled material. Absorb or wipe up spill paper towels or cloths. Collect for disposal in a covered container. Wash area of spill with alcohol or soap and water.
7.0	Handling and Storage	
7.1	Handling	For use only by dental professionals. Follow good hygiene practices. Avoid direct, strong light sources, temperature extremes (>27°C/80°F, <5°C/40°F), contamination, cross contamination. Recap immediately after use.
7.2	Storage	Store tightly capped in original container at cool room temperature (<25°C). Avoid direct, strong light, sources of ignition, extremes of temperature. Shelf life for unopened product is two years from date of manufacture, provided that the material has been stored properly.
7.3	Specific uses	Provisional dental material
8.0	Exposure Controls / Personal Protection	
8.1	Exposure limit values	PEL: Not established. TLV: Not established.
8.2	Exposure controls	
8.2.1	Occupational exposure controls	No special equipment required under normal conditions of use of this product in the quantity provided.
8.2.1.1	Respiratory protection	Good general ventilation is sufficient to control any airborne.
8.2.1.2	Hand protection	Surgical gloves
8.2.1.3	Eye protection	Safety glasses
8.2.1.4	Skin protection	Good personal hygiene and safety practices; wear a lab coat.
8.2.1.5	Other controls	Emergency eye wash fountain. Wash hands after use.
8.2.2	Environmental exposure controls	Cure material before disposing.
9.0	Physical and Chemical Properties	
9.1	Characteristics	
9.1.1	Appearance / Color / Physical state	Two pastes: tooth-colored base; off-white catalyst
9.1.2	Odor	Faint, characteristic
9.2	Important health, safety and environmental information	
9.2.1	pH	Not determined
9.2.2	Boiling point	Not determined
9.2.3	Flash point	Not determined
9.2.4	Flammability (solid, gas)	Not applicable
9.2.5	Explosive properties	Not applicable
9.2.6	Oxidizing properties	Not determined
9.2.7	Vapor pressure	< 1 mm Hg

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9.2.8	Specific gravity	1.520
9.2.9	Solubility in water	Nil
9.2.10	Partition coefficient	Not determined
9.2.11	Viscosity	Not determined
9.2.12	Vapor density	Not determined
9.2.13	Evaporation rate	Not determined
10.0	Stability and reactivity	
10.1	Conditions to avoid	Temperature > 27°C / 80°F, light, cross-contamination of parts.
10.2	Materials to avoid	Reducing and oxidizing agents, peroxides, amines.
10.3	Hazardous decomposition products	Under fire conditions and with amounts greater than that supplied in this product, hazardous polymerization may occur with heat build-up and release of carbon monoxide, carbon dioxide, and oxides of nitrogen.
10.4	Further information	Stable material if stored and used as directed. Polymerization will occur when light-sensitive material is exposed to direct light.
11.0	Toxicological information	
11.1	Acute toxicity	Not toxic. Minimal health hazard in the quantities present in this product and under normal conditions of use.
11.2	Irritation and corrosiveness	May be irritating to eyes, mucous membranes or skin on contact or with prolonged exposure.
11.3	Sensitization	May be sensitizing. Prolonged or frequent skin contact may cause allergic skin reactions in some susceptible individuals.
11.4	Sub-acute, sub-chronic and prolonged toxicity	Prolonged and/or frequent skin contact may cause allergic skin reactions in susceptible individuals. Prolonged exposure to large amounts (more than in this product) may cause eye and respiratory irritation.
11.5	Carcinogenicity, Mutagenicity, Reproductive Toxicity	None known
11.6	Empirical data	Testing confirmed biocompatibility of Tuff-Temp Plus.
11.7	Clinical experience	Tuff-Temp Plus has been on the market for more than four years with no reports of adverse events.
12.0	Ecological Information	
12.1	Ecotoxicity	Avoid release of uncured material into the environment. To the best of our knowledge, polymerized material is inert. No other information is available. Follow all government regulations.
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	Restrictions	None. Not regulated.

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Safety Data Sheet

Trade Name: ***Tuff-Temp™ Plus Provisional Veneer, Crown & Bridge Resin***

15.0	Regulatory Information	
15.1	EU Regulations	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	R36/37/38: Irritating to eyes, respiratory system and skin. R43: Sensitizing by skin contact.
16.2	Hazard Statements	H319: Eye irritation. Hazard category 2. H335: Specific Target Organ Toxicity - Single exposure; hazard category. 3. Respiratory tract irritation. H315: Skin irritation. Hazard category 2. H317: Skin Sensitization. Hazard category 1.
16.3	Precautionary Statements	P261: Avoid breathing vapor. P280: Wear protective gloves and eye protection P305 + P351: If in eyes, rinse cautiously with water for several minutes. P337 + P313: If eye irritation persists, get medical advice/attention. P302 + P352: If on skin, wash with plenty of soap and water. P333 + P313: If irritation or rash occurs, get medical advice / attention. P410 + P411: Protect from sunlight. Store at temperature not exceeding 27°C / 80°F.
16.4	Restrictions on use	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.
16.6	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
16.7	Information which has been added, deleted or revised.	This Safety Data Sheet has been revised to meet the requirements of the GHS SDS format, 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.

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