

Trade Name: **Tray Adhesive**

1.0 Commercial Product Name and Supplier		
1.1	Commercial product name / designation	Tray Adhesive
1.2	Application / Use	Dental material for use by dental professionals.
1.2.2	SIC	851 Human health activity
1.2.3	Use Category	55
1.3	Manufacturer	<p>Pulpdent Corporation 80 Oakland Street, P.O. Box 780 Watertown, MA 02472 USA</p> <p>Telephone: 1 617 926-6666 / Fax: 1 617 926-6262 Email: Pulpdent@pulpdent.com</p>
1.4	Emergency Telephone Number	1-800-535-5053 (24 Hour / USA)
1.5	Authorized European Representative	<p>Advena Limited Tower Business Centre, 2nd Floor, Tower Street, Swatar, BKR 4013 Malta</p>
	UK Responsible Person	<p>Advena Limited Pure Offices, Plato Close Warwick, CV34 6WE United Kingdom</p>
	CH Authorized Representative	<p>MedEnvoy Switzerland Gotthardstrasse 28, 6302 Zug, Switzerland</p>

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
		Flammable liquid	2	H225
		Eye irritation	2	H319
		STOT SE	3	H335
		Skin irritation	2	H315
2.1.2	Classification according to Directive 67/548/EEC (See SECTION 16 for full text of risk phrases)	Flammable (F) R11		
		Irritant (Xi) R36 / 37 / 38 – 66		

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.

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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: Isopropyl alcohol preparation.

3.2 Hazardous ingredients

CAS Number	Name of the Ingredient	Concentration	Classification per 67/548/EEC	Classification per Regulation (EC) No.1272/2008 (CLP).
67-63-0	Isopropyl alcohol	60%	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.

4.0 First Aid Measures

4.1	General Information	May cause irritation of eyes or skin on contact. May cause irritation of respiratory tract if inhaled. Isopropyl alcohol may cause headache, drowsiness, lassitude, appetite loss. 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 with soap, running water. Use hand cream. Get medical attention if irritation persists.
4.4	Ingestion	Rinse mouth with water. Do not induce vomiting. Get immediate medical attention. Never give anything by mouth to an unconscious person.
4.5	Inhalation	Move to fresh air. If necessary, administer oxygen and/or artificial respiration; seek medical attention.
4.6	Precautions for first responders	Ventilate the area. Wear safety glasses and gloves.
4.7	Information for physicians	
	Symptoms	Contact with material may cause irritation or redness in eyes or on skin. Inhalation may cause irritation of respiratory tract.
	Hazards	Exposure to methanol >1000 ppm may cause headache, drowsiness, lassitude, appetite loss. Persons with chronic respiratory or skin disease are at increased risk 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.

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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	Carbon monoxide, carbon dioxide from incomplete combustion
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 and gloves.
6.2	Environmental precautions	Avoid releasing large quantities into environment.
6.3	Method for clean up	Ventilate area. Wear safety glasses, lab coat, gloves. Wipe up with absorbent material (paper or cloth towels). Rinse area of spill with water. Place all material in closed container away from heat, sparks, sun and oxidizers.
7.0	Handling and Storage	
7.1	Handling	For use by dental professionals only. Recap immediately after use. Do not use in presence of ignition sources. Take same precautions when container is emptied, as residual product is hazardous.
7.2	Storage	Store tightly capped in original container at cool room temperature in a well-ventilated area. Avoid extreme temperatures (>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 material
8.0	Exposure Controls / Personal Protection	
8.1	Exposure limit values	TWA/TLV: 200 ppm; STEL: 400 ppm
8.2	Exposure controls	
8.2.1	Occupational exposure controls	No special equipment or ventilation required under normal conditions of use. For large quantities/prolonged exposure, use enclosure, local ventilation.
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 surgical gloves.
8.2.1.3	Eye protection	No special requirements other than safety glasses.
8.2.1.4	Skin protection	No special requirements other than good hygiene and safety practices.
8.2.1.5	Other controls	Emergency eye wash fountain should be close by. Wash hands after use.
8.2.2	Environmental exposure controls	Follow all government regulations.
9.0	Physical and Chemical Properties	
9.1	Characteristics	
9.1.1	Appearance / Color / Physical state	Red, viscous liquid
9.1.2	Odor	Characteristic, alcohol odor
9.2	Important health, safety and environmental information	
9.2.1	pH	Not applicable
9.2.2	Boiling point	82°C
9.2.3	Flash point	12°C (Tag closed cup)
9.2.4	Auto-ignition temperature	425°C

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9.2.5	Explosive properties	LEL: 2; UEL: 12.7
9.2.6	Odor threshold	23.4 ppm
9.2.7	Vapor pressure	4.4 mm Hg
9.2.8	Specific gravity	Not determined
9.2.9	Solubility in water	Partial
9.2.10	Partition coefficient	Not determined
9.2.11	Viscosity	Not determined
9.2.12	Vapor density	1.59
9.2.13	Evaporation rate	Not determined
10.0 Stability and reactivity		
10.1	Conditions to avoid	Temperature >80°F/24°C, sparks, open flame, ignition source.
10.2	Materials to avoid	Oxidizing agents, acid anhydrides, aluminum, halogenated compounds, acids.
10.3	Hazardous decomposition products	Carbon oxides
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 use. LD ₅₀ Oral rat: 5000 mg/kg
11.2	Irritation and corrosiveness	May cause irritation/redness of eyes or skin on contact. May cause irritation of respiratory tract if inhaled.
11.3	Sensitization	Not applicable.
11.4	Sub-acute, sub-chronic and prolonged toxicity	No chronic health hazard under normal conditions of use.
11.5	Carcinogenicity, Mutagenicity, Reproductive Toxicity	None known
11.6	Empirical data	None available
11.7	Clinical experience	<i>Tray Adhesive</i> and similar products have been used in dentistry for decades with no reported problems.
12.0 Ecological Information		
12.1	Ecotoxicity	Follow good work practices and 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	1219
14.2	Technical name	Isopropanol
14.3	Packing group	II

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14.4	IATA class	3
15.0 Regulatory Information		
15.1	EU	Class I medical device under MDR 93/42/EEC.
15.2	US FDA	Class II medical device
15.3	Health Canada	Class I medical device
16.0 Other information		
16.1	List of relevant R phrases	R11: Highly flammable R36/37/38: Irritating to eyes, respiratory system and skin. 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.
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	Pulpdent dental materials 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.
16.6	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

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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.
