

# DENTSPLY International

## DENTSPLY PROSTHETICS

## Safety Data Sheet

Safety Data Sheet (in compliance with Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010)

Date Issued: 25 June 1997  
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### 1. PRODUCT IDENTIFICATION

Trade Name (as labeled):	Triad® TruTray Custom Tray Material
Product Identifier (Part/Item Number):	89902, 89904, 89905
U.N. Number:	None
U.N. Dangerous Goods Classification:	None
Recommended Use:	Resin used in removable dental appliances
Restrictions on Use:	For Professional Use Only
Manufacturer/Supplier Name:	Dentsply Prosthetics
Manufacturer/Supplier Address:	570 West College Ave. York, PA 17405-0872
Manufacturer/Supplier Telephone Number:	717-845-7511 (Product Information)
Emergency Contact Telephone Number:	800-424-9300 Chemtrec
Email address:	Prosthetics_MSDS@Dentsply.com

### 2. HAZARD(s) IDENTIFICATION

EU Classification (1999/45/EC): Irritant (Xi), R43, R52/53

Refer to Section 16 for the full text of the EU Classifications and R Phrases.

Labeling in accordance with 1999/45/EC

 Irritant	Contains Methacryloxypropyl trimethoxysilane. R43 May cause sensitization by skin contact. S24/25 Avoid contact with skin and eyes. S36/37 Wear suitable protective clothing and gloves.
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US Hazard Classification: Hazardous ( Sensitizer)

### 3. COMPOSITION AND INFORMATION ON INGREDIENTS

Hazardous Components	C.A.S. #	EINECS #	Substance Classification	WT %
Non-hazardous Material	Proprietary	Proprietary	Not Applicable	50-80
Urethane Dimethacrylate	72869-86-4	276-957-5	R52/53	< 25
Dichlorodimethyl silane-, reaction products with silica	68611-44-9	271-893-4	Not Applicable	1-5
Silazane Treated Silica	68909-20-6	272-697-1	Not Applicable	1-5
Methacryloxypropyl trimethoxysilane	2530-85-0	219-785-8	Xn R22, R43	1-5

Refer to Section 16 for the full text of the EU Classifications and R Phrases.

### 4. FIRST-AID MEASURES

Routes of Exposure	First Aid Instructions
<b>Eye</b>	Immediately flush victim's eyes with large quantities of water for at least 15 minutes, holding the eyelids apart. Get medical attention.
<b>Skin</b>	Remove contaminated clothing. Wash skin thoroughly with soap and water. Get medical attention if irritation develops. Launder clothing before re-use. (Discard contaminated shoes).
<b>Inhalation</b>	If irritation develops, remove to fresh air. Get medical attention if symptoms persist.
<b>Ingestion</b>	If conscious, wash mouth out with water. Do not induce vomiting. Never give anything by mouth to an unconscious or convulsing person. Get medical attention.
<b>Most important symptoms of exposure</b>	May cause eye and skin irritation. May cause allergic skin reaction (sensitization).
<b>Note to Physicians (Treatment, Testing, and Monitoring):</b> Treat symptomatically.	

### 5. FIRE-FIGHTING MEASURES

<b>Suitable Extinguishing Media:</b>	Water fog, foam, carbon dioxide, water spray or dry chemical.
<b>Fire Fighting Procedures:</b>	Cool exposed intact containers with water spray.
<b>Specific Hazards Arising from the Chemical:</b>	High temperatures and sunlight may cause a polymerizing reaction to occur. Decomposition may release acrid smoke and fumes; carbon and nitrogen oxides.
<b>Precautions for Fire Fighters:</b>	Firefighters should wear full emergency equipment and approved positive pressure self-contained breathing apparatus.

#### Recommended Protective Equipment for Fire Fighters:

EYES/FACE	HANDS	RESPIRATORY	THERMAL
			

## 6. ACCIDENTAL RELEASE MEASURES

**Personal Precautions, PPE and Emergency Procedures:** Avoid contact with skin, eyes or clothing.

**Environmental Precautions:** Spill and release reporting requirements vary. Consult local authorities regarding requirements. Prevent entry into sewers and waterways

**Methods and Materials for Containment and Clean-up:** Exposure to sunlight or artificial light will cause the paste to polymerize. Spread the paste to maximize the surface area. Once the material is hard, pick up and place into a container for disposal.

### Recommended Personal Protective Equipment for Containment and Clean-up:

EYES/FACE	HANDS	RESPIRATORY	SKIN
			

## 7. HANDLING AND STORAGE

**Precautions for Safe Handling:** Avoid contact with the eyes, skin and clothing. Wear protective clothing and equipment as described in Section 8. Use only with adequate ventilation. Wash thoroughly with soap and water after handling. Keep containers closed when not in use.

Empty containers retain product residues can be hazardous. Follow all MSDS precautions when handling empty containers.

**Conditions for Safe Storage:** Store in a tightly closed container in a cool, well ventilated location away from incompatible materials. Do not store near high temperatures or ignition sources. Prevent contact with moisture. Refrigeration prolongs shelf life. Store away from food or beverages.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Occupational Exposure Limits:

Non-hazardous Material	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established

Urethane Dimethacrylate	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
Dichlorodimethyl Silane-, reaction products with silica (as PNOC)	United States	5 mg/m <sup>3</sup> (Respirable Fraction) TWA OSHA PEL 15 mg/m <sup>3</sup> (Total Dust) TWA OSHA PEL
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
Silazane Treated Silica	United States	0.8 mg/m <sup>3</sup> TWA (manufacturer recommended)
	Germany	0.8 mg/m <sup>3</sup> TWA (manufacturer recommended)
	United Kingdom	0.8 mg/m <sup>3</sup> TWA (manufacturer recommended)
	European Union	0.8 mg/m <sup>3</sup> TWA (manufacturer recommended)
Methacryloxypropyl trimethoxysilane	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established

**Biological Exposure Limits:** None Established

**Appropriate Engineering Controls:** Use with adequate local exhaust ventilation to maintain exposures below the occupational exposure limits or when grinding polymerized (cured) materials.

**Individual Protection Measures (PPE)**

**Specific Eye/face Protection:** Chemical safety glasses or chemical splash goggles recommended.

**Specific Skin Protection:** Wear impervious gloves such as rubber to prevent skin contact. Recommended glove: Rubber. Consult glove supplier for thickness and breakthrough times.

**Specific Respiratory Protection:** None under normal use conditions. If the product is heated and ventilation is inadequate, wear an approved respirator appropriate for the exposure conditions.

**Specific Thermal Hazards:** None required.

**Recommended Personal Protective Equipment**

EYES/FACE	HANDS	RESPIRATORY	SKIN
			

<b>Environmental Exposure Controls:</b> Do not allow spills to enter sewers or waterways.
<b>General Hygiene Considerations and Work Practices:</b> Avoid contact with eyes, skin, and clothing. Wash thoroughly after handling.
<b>Protective Measures During Repair and Maintenance of Contaminated Equipment:</b> Wear appropriate protective clothing and equipment.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance:</b>	Faint yellow, translucent paste in the uncured state.	<b>Explosive limits:</b>	Not applicable
<b>Odor:</b>	Characteristic odor.	<b>Vapor pressure (mmHg):</b>	< 1
<b>Odor threshold:</b>	Not determined	<b>Vapor density:</b>	>1
<b>pH:</b>	Not determined	<b>Relative density:</b>	1.5
<b>Melting/freezing point:</b>	<-40°C(<-40°F)	<b>Solubility:</b>	Negligible
<b>Initial boiling point and range:</b>	Not applicable (polymerizes)	<b>Partition coefficient: n-octanol/water:</b>	Not available
<b>Flash point:</b>	Not applicable	<b>Auto-ignition temperature:</b>	Not applicable
<b>Evaporation rate:</b>	Not available	<b>Decomposition temperature:</b>	Not determined
<b>Flammability:</b>	Not Flammable	<b>Viscosity:</b>	Not determined
<b>Explosive Properties:</b>	None	<b>Oxidizing Properties:</b>	None
<b>% Volatile by Volume:</b>	Not determined		

## 10. STABILITY AND REACTIVITY

<b>Reactivity:</b> Polymerization can occur.
<b>Chemical Stability:</b> Unstable if heated. Polymerizes to form a hard plastic in 2 hours at 100°C(212°F) with low exotherm.
<b>Possibility of Hazardous Reactions:</b> Polymerization can occur if heated above 100°C(212°F)
<b>Conditions to Avoid:</b> Avoid heating greater than 100°C(212°F)

**Incompatible materials:** Oxidizing agents, reducing agents, inert gases, oxygen scavengers, free radical initiators. Avoid excessive heat, flames, ignition sources and direct sunlight.

**Hazardous Decomposition Products:** Thermal decomposition may release acrid smoke and fumes; carbon and nitrogen oxides.

## 11. TOXICOLOGICAL INFORMATION

**Potential Health Effects:**

Eyes: May cause irritation, redness and tearing.

Skin: May cause irritation, redness, rash and swelling. May cause allergic skin reaction (sensitization).

Ingestion: None expected under normal use conditions.

Inhalation: None expected under normal use.

**Chronic Health Effects:** None expected under normal use.

**Carcinogenicity:** None of the components at 0.1% or greater are listed as possible carcinogens by NTP, IARC, ACGIH, the EU Dangerous Substances Directive, or OSHA.

**Mutagenicity:** No data available. This product is not expected to cause mutagenic activity.

**Medical Conditions Aggravated by Exposure:** Individuals with pre-existing skin and respiratory disorders may be at increased risk from exposure.

**Acute Toxicity Data:**

Non-hazardous materials: No data available

Silazane Treated Silica: Oral Rat LD50: >5000 mg/kg

Methacryloxypropyl trimethoxysilane: Oral Rat LD50: >2000 mg/kg; Skin rat LD50: >2000 mg/kg

Urethane Dimethacrylate: Oral Rat LD50: >2000 mg/kg

Dichlorodimethyl Silane-, reaction products with silica: Oral rat LD50: >5000 mg/kg, Inhalation rat LC50: >0.477 mg/l/4 hours

**Reproductive Toxicity Data:** No data available. This product is not expected to cause adverse reproductive effects.

**Specific Target Organ Toxicity (STOT):**

Single Exposure: No data available.

Repeated Exposure: No data available.

## 12. ECOLOGICAL INFORMATION

**Toxicity:**

Non-hazardous materials: No data available

Silazane Treated Silica:

Methacryloxypropyl trimethoxysilane:

Urethane Dimethacrylate: 96h/LC50 zebra fish: 10.1 mg/l,

Dichlorodimethyl Silane-, reaction products with silica: 96 hr LC50 Zebrafish >10,000 mg/L,  
48 hr EC50 dapnia magna >10,000 mg/l

<b>Persistence and Degradability:</b> Urethane Dimethacrylate is not readily biodegradable
<b>Bio-accumulative Potential:</b> No data is currently available
<b>Mobility in Soil:</b> No data is currently available
<b>Other Adverse Effects:</b> Some components are toxic to aquatic organisms, and may cause long-term adverse effects in the aquatic environment.
<b>Results of PBT/vPvB Assessment:</b> Not applicable.

### 13. DISPOSAL CONSIDERATIONS

<b>Regulations:</b> Dispose in accordance with all national and local regulations.
<b>Properties (Physical/Chemical) Affecting Disposal:</b> Exposure to sunlight or artificial light will cause the material to polymerize into a hard plastic. Empty containers retain product residues can be hazardous. Follow all MSDS precautions when handling empty containers.
<b>Waste Treatment Recommendations:</b> Dispose in accordance with national and local regulations.

### 14. TRANSPORT INFORMATION

<b>UN Number:</b>	ADR/RID: None	IMDG: None	IATA: None	DOT: None
<b>UN proper shipping name:</b>	ADR/RID: Not Regulated IMDG: Not Regulated IATA: Not Regulated DOT: Not Regulated			
<b>Transport hazard class(es):</b>	ADR/RID: None	IMDG: None	IATA: None	DOT: None
<b>Packaging group:</b>	ADR/RID: None	IMDG: None	IATA: None	DOT: None
<b>Environmental hazards:</b>	ADR/RID: No	IMDG Marine pollutant: No	IATA: No	DOT: No
<b>Special precautions for user:</b>	Not applicable			

### 15. REGULATORY INFORMATION

#### U.S. Federal Regulations

**US OSHA Hazard Classification:** Sensitizer

**Comprehensive Environmental Response and Liability Act of 1980 (CERCLA):** This product is not subject to CERCLA reporting requirements. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations.

**Toxic Substances Control Act (TSCA):** This product is a medical device and not subject to chemical notification

**Clean Water Act (CWA):** This material is not regulated under the Clean Water Act

**Clean Air Act (CAA):** This material is not regulated under the Clean Air Act

**Superfund Amendments and Reauthorization Act (SARA) Title III Information:**

**SARA Section 311/312 (40 CFR 370) Hazard Categories:**

<b>Immediate Hazard:</b>	Yes	<b>Pressure Hazard:</b>	No
<b>Delayed Hazard:</b>	No	<b>Reactivity Hazard:</b>	No
<b>Fire Hazard:</b>	No		

**This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):**

Components	C.A.S. #	WT %
None		

**State Regulations**

**California:** This product contains the following substances known to the state of California to cause cancer and/or reproductive toxicity: None

Components	C.A.S. #	WT %
None		

**International Regulations**

**Canadian Workplace Hazardous Materials Information System (WHMIS):** Class D Division 2B (Toxic material causing other toxic effects).

**European Inventory of Existing Chemicals (EINECS):** This product is a medical device and not subject to chemical notification requirements.

**EU REACH:** All components requiring registration have been pre-registered.

**Australian Inventory of Chemical Substances:** This product is a medical device and not subject to chemical notification requirements.

**China Inventory of Existing Chemicals and Chemical Substances:** This product is a medical device and not subject to chemical notification requirements.

**Japanese Existing and New Chemical Substances:** This product is a medical device and not subject to chemical notification requirements.

**Korean Existing Chemicals List:** This product is a medical device and not subject to chemical notification requirements.

**Philippine Inventory of Chemicals and Chemical Substances:** This product is a medical device and not subject to chemical notification requirements.

## 16. OTHER INFORMATION

**HMIS Hazard Rating:**

Health – 1      Flammability – 1      Physical Hazard– 1

Full text of Classification abbreviations used in Section 2 and 3:

Xi Irritant

Xn Harmful

N Dangerous for the environment.

R22 Harmful if swallowed

R43 May cause sensitization by skin contact.

R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Supersedes: 05 June 2009

Revision Summary: Change in format. Comprehensive review. Changes to all sections.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, IUCLID Dataset EU Chemical Bureau, EESIS, Country websites for occupational exposure limits.