

**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: 2 June 2006  
Document Number: 324  
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### 1. PRODUCT IDENTIFICATION

**Trade Name (as labeled):** Radica® Provisional & Diagnostic Resin Enamel, Dentin, Effect Dentin

**Product Identifier (Part/Item Number):** 908028, 908033, 908100-110, 908118, 908119, 908120-908130, 908200, 908300, 908305, 908310, 908315, 908320, 908325, 908330, 908335, 908340, 908345, 908350, 908355, 908360.

**U.N. Number:** None

**U.N. Dangerous Goods Classification:** None

**Recommended Use:** Used in fabrication of provisional crowns and bridges.

**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](mailto:Prosthetics_MSDS@Dentsply.com)

### 2. HAZARD(s) IDENTIFICATION

**EU Classification (1999/45/EC as amended):** Not Classified as Hazardous

**Labeling in accordance with 1999/45/EC as amended:** None required

**US Hazard Classification:** Hazardous

### 3. COMPOSITION AND INFORMATION ON INGREDIENTS





Hazardous Components	C.A.S. #	EINECS #	Substance Classification	WT %
Barium Fluoroaluminato Borosilicate Glass	Proprietary	Proprietary	Not applicable	50-70
Urethane Methacrylate	Proprietary	Proprietary	Not applicable	10-20
Aliphatic Urethane Diacrylate	Proprietary	Proprietary	Xi, R43	1-5
Aliphatic Urethane Acrylate	Proprietary	Proprietary	Xi, R36/38, R43	5-10
Methacrylate Ester	Proprietary	Proprietary	Xi R36/38, R43	5-10

#### 4. FIRST-AID MEASURES

Routes of Exposure	First Aid Instructions
Eye	Flush eyes with water for at least 15 minutes, holding the eyelids apart. Get medical attention if irritation persists.
Skin	Wash skin with soap and water. Get medical attention if irritation develops. Launder contaminated clothing before re-use.
Inhalation	Remove victim to fresh air. Get medical attention if irritation develops.
Ingestion	If small quantities are swallowed, rinse out mouth with water. Do not induce vomiting. Never give anything by mouth to an unconscious or drowsy person. If irritation or discomfort occurs, get immediate medical attention.
Most important symptoms of exposure	May cause eye irritation. Dust from grinding or polishing may cause mechanical eye irritation. Uncured product may cause slight skin irritation in susceptible individuals.
<b>Note to Physicians (Treatment, Testing, and Monitoring):</b> Treat symptomatically.	

#### 5. FIRE-FIGHTING MEASURES

<b>Suitable Extinguishing Media:</b>	Use carbon dioxide, foam or dry chemical.
<b>Fire Fighting Procedures:</b>	Cool fire exposed containers with water.
<b>Specific Hazards Arising from the Chemical:</b>	None known.
<b>Precautions for Fire Fighters:</b>	Firefighters should wear full emergency equipment and approved positive pressure self-containing 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 eyes, skin and clothing.

**Environmental Precautions:** None known.

**Methods and Materials for Containment and Clean-up:** Wear appropriate protective clothing as described in Section 8. Scoop or pick up and place into a container for disposal.

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

EYES/FACE	HANDS	RESPIRATORY	THERMAL
			

## 7. HANDLING AND STORAGE

**Precautions for Safe Handling:** Avoid contact with eyes and skin. Avoid breathing dust. Wash thoroughly after handling. Wear protective clothing and equipment as described in Section 8. Use with adequate ventilation.

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

**Conditions for Safe Storage:** Store in a dry, well ventilated area. Keep container closed when not in use. Material is light sensitive. Light will cause uncured product to polymerize. Do not store in direct sunlight. Protect from physical damage. Keep away from oxidizers and other incompatible materials.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Occupational Exposure Limits:

Barium Fluoroaluminoborosilicate Glass	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
Urethane Methacrylate	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
Aliphatic Urethane Diacrylate	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
Aliphatic Urethane Acrylate	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
Methacrylate Ester	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established

**Biological Exposure Limits:** None established.

**Appropriate Engineering Controls:** When grinding or polishing, use with adequate general or local exhaust ventilation to minimize exposures levels.



### Individual Protection Measures (PPE)

**Specific Eye/face Protection:** None needed under normal use conditions. Wear safety glasses when grinding or polishing.

**Specific Skin Protection:** Wear latex, PVC or other impervious gloves to minimize skin contact. Recommended glove: Latex or PVC. Consult glove supplier for thickness and breakthrough times.

**Specific Respiratory Protection:** None needed for normal use. When grinding, polishing or where exposure levels are excessive, an approved respirator with dust/mist cartridges or supplied air respirator appropriate for the form and concentration of the contaminants should be used. Selection and use of respiratory equipment must be in accordance with OSHA 1910.134 and good industrial hygiene practice.

**Specific Thermal Hazards:** None

Recommended Personal Protective Equipment			
EYES/FACE	HANDS	RESPIRATORY	THERMAL
			
<b>Environmental Exposure Controls:</b> None required for normal use.			
<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>	Tooth colored solid.	<b>Explosive limits:</b>	<b>LEL: Not applicable</b> <b>UEL: Not applicable</b>
<b>Odor:</b>	Characteristic acrylate odor.	<b>Vapor pressure:</b>	Negligible
<b>Odor threshold:</b>	Not determined	<b>Vapor density:</b>	Not applicable
<b>pH:</b>	Not available	<b>Relative density:</b>	approx. 1.6
<b>Melting/freezing point:</b>	approx. 60°C (140°F)	<b>Solubility:</b>	Not miscible
<b>Initial boiling point and range:</b>	Not applicable	<b>Partition coefficient: n-octanol/water:</b>	Not applicable
<b>Flash point:</b>	> 180°C (356°F)	<b>Auto-ignition temperature:</b>	Not available
<b>Evaporation rate:</b>	Not applicable	<b>Decomposition temperature:</b>	Not available
<b>Flammability:</b>	Non flammable	<b>Viscosity:</b>	Not applicable
<b>Explosive Properties:</b>	Not explosive	<b>Oxidizing Properties:</b>	None

## 10. STABILITY AND REACTIVITY

**Reactivity::** Not reactive

**Chemical Stability:** Stable.

**Possibility of Hazardous Reactions:** This product will polymerize when exposed to sunlight.

**Conditions to Avoid:** Elevated temperatures and direct sunlight.

**Incompatible materials:** Avoid contact with strong oxidizers, amines, halogens, and bases.

**Hazardous Decomposition Products:** Carbon monoxide, carbon dioxide, silicone dioxide, barium oxide, hydrogen fluoride.

## 11. TOXICOLOGICAL INFORMATION

### **Potential Health Effects:**

**Eyes:** Direct contact may cause irritation with redness, burning and tearing. Dust from grinding or polishing may cause mechanical irritation. Dust from grinding or polishing cured material may cause mechanical irritation.

**Skin:** Uncured product may cause mild skin irritation or cause contact dermatitis on prolonged contact. Not irritating in primary skin irritation studies. Non-sensitizing in Kligman Maximization Test.

**Inhalation:** Not expected to cause respiratory tract irritation. Dust from grinding or polishing may cause sneezing, coughing and other signs of mechanical irritation. Dust from grinding or polishing cured material may cause mechanical irritation with coughing or sneezing.

**Ingestion:** No adverse effects are expected from swallowing small amounts. This product was found to be non-toxic in tests with laboratory animals. This product was found to be non-irritating to mucous membranes in studies with laboratory animals.

**Chronic Health Effects:** Prolonged or repeated skin contact with uncured material may cause skin irritation or sensitization in some individuals.

**Carcinogenicity:** None of the components of this product are listed as a carcinogen by OSHA, IARC or NTP or the EU Substances Directive.

**Mutagenicity:** This product tested negative in the Ames Test.

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

### **Acute Toxicity Data:**

Barium Fluoroaluminato Borosilicate Glass: No toxicity data available

Urethane Methacrylate: No toxicity data available

Aliphatic Urethane Diacrylate: No toxicity data available

Aliphatic Urethane Acrylate: No toxicity data available

Methacrylate Ester: No toxicity data available

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

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

**Single Exposure:** The cured and uncured product tested negative in the Kligman Maximization test for sensitization. The cured and uncured product was negative in a primary skin irritation study.

**Repeated Exposure:** No data available

## 12. ECOLOGICAL INFORMATION

**Toxicity:**

Barium Fluoroalumino Borosilicate Glass: No data available  
 Urethane Methacrylate: No data available  
 Aliphatic Urethane Diacrylate: No data available  
 Aliphatic Urethane Acrylate: No data available  
 Methacrylate Ester: No data available

**Persistence and Degradability:** No data available

**Bio-accumulative Potential:** No data available

**Mobility in Soil:** No data available

**Other Adverse Effects:** No data available

**Results of PBT/vPvB Assessment:** No data available

## 13. DISPOSAL CONSIDERATIONS

**Regulations:** Dispose in accordance with all national and local regulations.

**Properties (Physical/Chemical) Affecting Disposal:** This product will polymerize when exposed to sunlight. Small amounts (gram quantity) can be allowed to polymerize in sunlight to a hard solid then disposed of normally.

**Waste Treatment Recommendations:** None known.

## 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:** Non-hazardous.

**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 requirements.

**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>	No	<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):** None

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:

Components	C.A.S. #	WT %
Toluene	108-88-3	<70 ppm

### International Regulations

**Canadian Workplace Hazardous Materials Information System (WHMIS):** Not a controlled product.

**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 –0      Flammability – 1      Reactivity – 0

Full text of Classification abbreviations used in Section 2 and 3

Xi Irritant

R36/38 Irritating to eyes and skin.

R43 May cause sensitization by skin contact.

Supersedes: 7 February 2008

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, ESIS, Country websites for occupational exposure limits.