

## Safety Data Sheet

Date Issued:  
Document Number: 169  
Date Revised: 03/17/2011  
Revision Number: 3

### 1. PRODUCT IDENTIFICATION

**Trade Name (as labeled):** Lucitone® Characterized Denture Base Resin

**Product Identifier (Part/Item Number):** 686001, 686004, 686031, 686034, 686042-046, 686054, 686056, 686120, 686123-124, 686130, 686133-134

**U.N. Number:** Not applicable

**U.N. Dangerous Goods Classification:** Not applicable

**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):** Toxic (T) R36/37/38, R61, R62

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

Labeling in accordance with 1999/45/EC



Toxic

Contains: Dibutyl Phthalate  
R36/37/38 Irritating to respiratory system and skin.  
R61 May cause harm to the unborn child.  
R62 Possible risk of impaired fertility.  
S9 Keep container in a well ventilated place.  
S36/37 Wear suitable protective clothing and gloves.  
S46 If swallowed, seek medical advice immediately and show this container or label.  
S53 Avoid exposure - obtain special instructions before use.

US Hazard Classification: Hazardous.

### 3. COMPOSITION AND INFORMATION ON INGREDIENTS

Hazardous Components	C.A.S. #	EINECS #	Substance Classification	WT %
Polymethyl Methacrylate and Acrylic Copolymers	Mixture	Mixture	Xi R36/37/38	85-100
Dibutyl Phthalate	84-74-2	201-557-4	T, N R50, R61, R62	0-15

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





### 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 develops.
Skin	Wash skin with soap and water. Remove contaminated clothing and shoes. Get medical attention if irritation develops. Launder clothing before re-use.
Inhalation	Remove victim to fresh air. If breathing is difficult have qualified personnel administer oxygen. Get medical attention if symptoms persist.
Ingestion	Do not induce vomiting. If conscious, give 8 ounces of water to dilute. Never give anything by mouth to an unconscious or convulsing person. Get medical attention.
Most important symptoms of exposure	Dust may be irritating to eyes and respiratory system. Prolonged skin contact may cause irritation. Individuals with sensitivity to methacrylates may develop an allergic reaction when exposed to this product.
<b>Note to Physicians (Treatment, Testing, and Monitoring)</b>	
Treat symptomatically.	

### 5. FIRE-FIGHTING MEASURES

<b>Suitable Extinguishing Media:</b>	Water fog, carbon dioxide, dry chemical.
<b>Fire Fighting Procedures:</b>	Do not use a water stream. Water stream can disperse dust in air producing a fire hazard and possible explosion hazard if exposed to ignition source. Use water to cool fire-exposed containers.
<b>Specific Hazards Arising from the Chemical:</b>	High concentrations of dust in air may be explosive.
<b>Precautions for Fire Fighters:</b>	Do not enter fire area without proper protection. 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:** Remove all sources of ignition. Wear appropriate protective clothing as described in Section 8. Avoid contact with skin, eyes or clothing. Spilled powder can be a slip hazard.

**Environmental Precautions:** Prevent entry into sewers and waterways. Do not allow into lakes, streams, ponds, groundwater or soil. Report releases as required by local, state, and national authorities.

**Methods and Materials for Containment and Clean-up:** Do not generate airborne dust. Carefully collect 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. Do not breathe dust. Wash thoroughly after handling. Wear protective clothing and equipment as described in Section 8. Use with adequate ventilation. Use good housekeeping to minimize accumulation of dust on equipment and surfaces. Keep away from sources of heat or ignition sources. Empty containers retain product residues can be hazardous. Follow all MSDS precautions when handling empty containers.

**Conditions for Safe Storage:** Store in a cool, dry, well ventilated area. Keep container tightly closed when not in use. Keep away from oxidizers and other incompatible materials.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION



### Occupational Exposure Limits:

Polymethyl Methacrylate and Acrylic Copolymers:

- 15 mg/m<sup>3</sup> TWA OSHA PEL (Total Dust)
- 5 mg/m<sup>3</sup> TWA OSHA PEL (Respirable)
- 10 mg/m<sup>3</sup> TWA WEL (Inhalable)
- 4 mg/m<sup>3</sup> TWA WEL (Respirable)
- 4 mg/m<sup>3</sup> TWA MAK (Inhalable)
- 1.5 mg/m<sup>3</sup> TWA MAK (Respirable)

Dibutyl Phthalate:

- 5 mg/m<sup>3</sup> TWA OSHA PEL
- 5 mg/m<sup>3</sup> TWA ACGIH TLV
- 5 mg/m<sup>3</sup> TWA UK WEL
- 10 mg/m<sup>3</sup> STEL UK WEL

<b>Biological Exposure Limits:</b> None established.			
<b>Appropriate Engineering Controls:</b> Use ventilation that is adequate to keep employee exposure to airborne concentrations below exposure limits.			
<b>Individual Protection Measures (PPE)</b> <b>Specific Eye/face Protection:</b> Chemical safety glasses with side shields or chemical goggles. <b>Specific Skin Protection:</b> Wear impervious gloves such as butyl or nitrile rubber to avoid skin contact. <b>Specific Respiratory Protection:</b> None should be needed for normal use. If the exposure levels are excessive an approved particulate/organic vapor respirator appropriate for the form and concentration of the contaminants should be used. Selection and use of respiratory equipment must be in accordance with good industrial hygiene practice. <b>Specific Thermal Hazards:</b> None			
Recommended Personal Protective Equipment			
EYES/FACE	HANDS	RESPIRATORY	THERMAL
			
<b>Environmental Exposure Controls:</b> Prevent entry into sewers and waterways. Do not allow into lakes, streams, ponds, groundwater or soil.			
<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>	<b>Pink free flowing powder</b>	<b>Explosive limits:</b>	<b>LEL: 20 g/m<sup>3</sup> UEL: Not applicable</b>
<b>Odor:</b>	<b>Faint methacrylate odor</b>	<b>Vapor pressure:</b>	<b>Not applicable</b>
<b>Odor threshold:</b>	<b>Not available</b>	<b>Vapor density:</b>	<b>Not applicable</b>
<b>pH:</b>	<b>Not applicable</b>	<b>Relative density:</b>	<b>Not available</b>
<b>Melting/freezing point:</b>	<b>Not applicable</b>	<b>Solubility:</b>	<b>Insoluble</b>
<b>Initial boiling point and range:</b>	<b>Not applicable</b>	<b>Partition coefficient: n-octanol/water:</b>	<b>Not available</b>
<b>Flash point:</b>	<b>572°F (300°C) TCC</b>	<b>Auto-ignition temperature:</b>	<b>Not available</b>

<b>Evaporation rate:</b>	<b>Not applicable</b>	<b>Decomposition temperature:</b>	<b>392°F (200°C)</b>
<b>Flammability:</b>	<b>Not flammable</b>	<b>Viscosity:</b>	<b>Not applicable</b>
<b>Explosive Properties:</b>	<b>High concentrations of dust in air may be explosive.</b>	<b>Oxidizing Properties:</b>	<b>None</b>

## 10. STABILITY AND REACTIVITY

**Reactivity:** Non reactive under normal conditions

**Chemical Stability:** Stable

**Possibility of Hazardous Reactions:** Non reactive under normal conditions

**Conditions to Avoid:** Excessive heat (temperatures greater than 572°F (300°C). Keep away heat, sparks or ignition sources.

**Incompatible materials:** Avoid oxidizing agents.

**Hazardous Decomposition Products:** Thermal decomposition may release carbon oxides and methacrylate monomers.

## 11. TOXICOLOGICAL INFORMATION

**Potential Health Effects:**

Eyes: Dust may cause irritation with redness, itching and tearing.

Skin: Prolonged exposure may cause irritation. Individuals with sensitivity to methacrylates may develop an allergic reaction.

Ingestion: Swallowing large amounts may cause nausea, vomiting and diarrhea.

Inhalation: Inhalation of dust may cause irritation of the nose, throat and upper respiratory tract.

**Chronic Health Effects:** Prolonged or repeated overexposure may cause skin irritation or sensitization in some individuals.

**Carcinogenicity:** None of the components of this product are listed as carcinogens by OSHA, IARC or NTP or the EU directive.

**Mutagenicity:** No data available.

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

**Acute Toxicity Data:**

Polymethyl Methacrylate and Acrylic Copolymers: No data available

Dibutyl Phthalate: Oral Rat LD50 - 7499 mg/kg Inhalation Mouse LC50 - 25 gm/m3/2 hours Skin Rabbit LD50 - >20 mL/kg
<b>Reproductive Toxicity Data:</b> Contains butyl phthalate which may cause adverse reproductive effects based on studies with laboratory animals.
<b>Specific Target Organ Toxicity (STOT):</b> <u>Single Exposure:</u> No data available <u>Repeated Exposure:</u> Prolonged or repeated overexposure may cause skin irritation or rash in some individuals.

## 12. ECOLOGICAL INFORMATION

<b>Toxicity:</b> Polymethyl Methacrylate and Acrylic Copolymers: No data available Dibutyl Phthalate: 96 hr/LC50 fathead minnow: 0.92 mg/l 96 hr/LC50 rainbow trout: 1.6 mg/l 48 hr/EC50 daphnia: 3.0 mg/l
<b>Persistence and Degradability:</b> Dibutyl phthalate: had an average aerobic and anaerobic biodegradation half-lives of 2.9 and 14.4 days, respectively.
<b>Bio-accumulative Potential:</b> No data available.
<b>Mobility in Soil:</b> Dibutyl phthalate: expected to have low mobility
<b>Other Adverse Effects:</b> No data available.
<b>Results of PBT/vPvB Assessment:</b> No data available.

## 13. DISPOSAL CONSIDERATIONS

<b>Regulations:</b> Dispose in accordance with all national and local regulations.
<b>Properties (Physical/Chemical) Affecting Disposal:</b> 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 Identification Number:</b> Not Regulated
<b>UN Proper Shipping Name:</b> Not Regulated
<b>Transport hazard class(es):</b> Not Regulated
<b>Packing Group:</b> Not Regulated

Special precautions for user: Not Regulated

## 15. REGULATORY INFORMATION

### U.S. Federal Regulations

**US OSHA Hazard Classification:** Irritant, Target organ effects.

**Comprehensive Environmental Response and Liability Act of 1980 (CERCLA):** This product has a Reportable Quantity (RQ) of 66.6 lbs. based on the RQ for Dibutyl Phthalate of 10 lbs. Releases above the RQ must be reported to the National Response Center. 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>	Yes	<b>Pressure Hazard:</b>	No
<b>Delayed Hazard:</b>	Yes	<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):**

<b>Components</b>	<b>C.A.S. #</b>	<b>WT %</b>
Dibutyl Phthalate	84-74-2	0-15

### State Regulations

**California:** This product contains the following chemical(s) known to the State of California to cause cancer, birth defects or reproductive harm:

<b>Components</b>	<b>C.A.S. #</b>	<b>WT %</b>
Dibutyl Phthalate	84-74-2	0-15

### International Regulations

**Canadian Environmental Protection Act:** This product is a medical device and not subject to chemical notification requirements.

**Canadian Workplace Hazardous Materials Information System (WHMIS):** Medical devices are not covered by WHMIS.

**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.

**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– 0

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

T Toxic

Xi Irritant

N Dangerous for the Environment

R36/37/38 Irritating to eyes, respiratory system and skin

R50 Very toxic to aquatic organisms.

R61 May cause harm to the unborn child.

R62 Possible risk of impaired fertility.

Supersedes: January 7, 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.