

# 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: 15 January 1986  
Document Number: 358  
Date Revised: 05 August 2013  
Revision Number: 7

#### 1. PRODUCT IDENTIFICATION

Trade Name (as labeled):	Trubyte® Plastic Teeth
Product Identifier (Part/Item Number):	01109, 01111, 01215, 15116, 15120, 15130, 15135, 15140, 15416, 15436, 15446, 15456, 16036, 16046, 16056, 16066, 16076, 16116, 16126, 16136, 16146, 16156, 16166, 16176, 16346, 16356, 16366, 16476, 16566, 16576, 16616, 16626, 16636, 16646, 16656, 16666, 16676, 16686, 16696, 16716, 16726, 16736, 16746, 16756, 16766, 16916, 16936, 16946, 16966, 16976, 16986, 16996, 19656
U.N. Number:	None
U.N. Dangerous Goods Classification:	Not Regulated
Recommended Use:	Plastic Teeth for Dentures
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): Not Classified

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

Labeling in accordance with 1999/45/EC: None Required

US Hazard Classification: Not Hazardous

### 3. COMPOSITION AND INFORMATION ON INGREDIENTS

Hazardous Components	C.A.S. #	EINECS #	Substance Classification	WT %
Non-Hazardous Polymers	Mixture	Mixture	Not Applicable	>99
Titanium Dioxide	13463-67-7	236-675-5	Not Applicable	<0.2





The exact concentration is being withheld as a trade secret.

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 victim's eyes with water.
Skin	Wash skin with soap and water.
Inhalation	If irritation develops, remove victim to fresh air.
Ingestion	No adverse effects expected.
Most important symptoms of exposure	This product is a non-hazardous polymer solid. Dust generated from polishing or grinding may cause eye or respiratory tract irritation.
<b>Note to Physicians (Treatment, Testing, and Monitoring):</b> Treat symptomatically. Immediate medical attention is not required.	

### 5. FIRE-FIGHTING MEASURES

<b>Suitable Extinguishing Media:</b>	These products are not classified as flammable or combustible but will burn under fire conditions. Use media appropriate for surrounding fire.		
<b>Fire Fighting Procedures:</b>	No special precautions required. Fight fire from a safe distance or protected location.		
<b>Specific Hazards Arising from the Chemical:</b>	Combustion products are toxic. Decomposition may release oxides of carbon, methyl methacrylate, and irritating smoke and fumes.		
<b>Precautions for Fire Fighters:</b>	Firefighters should wear full emergency equipment and approved positive pressure self-contained breathing apparatus. Do not enter fire area without proper protection.		
<b>Recommended Protective Equipment for Fire Fighters:</b>			
<b>EYES/FACE</b>	<b>HANDS</b>	<b>RESPIRATORY</b>	<b>THERMAL</b>
			

## 6. ACCIDENTAL RELEASE MEASURES

**Personal Precautions, PPE and Emergency Procedures:** If dust from grinding or polishing product is spilled, wear appropriate protective clothing as described in Section 8. Avoid contact with eyes. Avoid breathing dust.

**Environmental Precautions:** Report releases as required by local and national authorities.

**Methods and Materials for Containment and Clean-up:** Pick up teeth and return to container for use. For dust from grinding or polishing products: Contain spills, sweep or gather spilled material in a manner that minimizes the generation of airborne dusts, and transfer to a suitable 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 generating dust. Avoid breathing dust. Use adequate ventilation for polishing or grinding operations. Wash hands thoroughly after polishing or grinding teeth. Use good housekeeping to minimize accumulation of dust.

**Conditions for Safe Storage:** No special storage required.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Occupational Exposure Limits:**

Non-Hazardous Polymer	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
Titanium Dioxide	United States	10 mg/m <sup>3</sup> TWA ACGIH TLV 15 mg/m <sup>3</sup> TWA OSHA PEL (Total Dust)
	Germany	None Established
	United Kingdom	10 mg/m <sup>3</sup> (Inhalable), 4 mg/m <sup>3</sup> (Respirable) TWA UK WEL
	European Union	Belgium: 10 mg/m <sup>3</sup> TWA

**Biological Exposure Limits:** None Established

**Appropriate Engineering Controls:** Use with adequate local exhaust ventilation to maintain exposures below the occupational exposure limits.

**Individual Protection Measures (PPE)**

**Specific Eye/face Protection:** Follow facility requirements for operation.

**Specific Skin Protection:** None required during the normal use of this product.

**Specific Respiratory Protection:** None should be needed during normal conditions. If processing generates dust and ventilation is inadequate, use an approved particulate respirator. Respirator selection and use should be based on contaminant type, form and concentration. Use in accordance with applicable regulations and good Industrial Hygiene practice.

**Specific Thermal Hazards:** None required.

**Recommended Personal Protective Equipment**

EYES/FACE	HANDS	RESPIRATORY	SKIN

**Environmental Exposure Controls:** None required for normal use.

**General Hygiene Considerations and Work Practices:** Wash hands thoroughly after polishing or grinding teeth.

**Protective Measures During Repair and Maintenance of Contaminated Equipment:** Not applicable

**9. PHYSICAL AND CHEMICAL PROPERTIES**

<b>Appearance:</b>	White plastic solid	<b>Explosive limits:</b>	<b>LEL:</b> Not applicable <b>UEL:</b> Not applicable
<b>Odor:</b>	Not applicable	<b>Vapor pressure (mmHg):</b>	Not applicable
<b>Odor threshold:</b>	Not available	<b>Vapor density:</b>	Not applicable
<b>pH:</b>	Not applicable	<b>Relative density:</b>	Not available
<b>Melting/freezing point:</b>	Not applicable	<b>Solubility:</b>	Not applicable
<b>Initial boiling point and range:</b>	Not applicable	<b>Partition coefficient: n-octanol/water:</b>	Not applicable
<b>Flash point:</b>	Not applicable	<b>Auto-ignition temperature:</b>	Not available
<b>Evaporation rate:</b>	Not applicable	<b>Decomposition temperature:</b>	Not available

<b>Flammability:</b>	Not Flammable	<b>Viscosity:</b>	Not applicable
<b>Explosive Properties:</b>	Non-explosive	<b>Oxidizing Properties:</b>	None
<b>% Volatile by Volume:</b>	Not determined		

## 10. STABILITY AND REACTIVITY

**Reactivity:** None known.

**Chemical Stability:** Stable.

**Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.

**Conditions to Avoid:** None known

**Incompatible materials:** Oxidizing agents, reducing agents, acids, and bases.

**Hazardous Decomposition Products:** Decomposition may release oxides of carbon, methyl methacrylate, and irritating smoke and fumes.

## 11. TOXICOLOGICAL INFORMATION

### **Potential Health Effects:**

**Eyes:** No adverse effects expected. Dust may cause eye irritation if teeth are grinded or polished.

**Skin:** No adverse effects expected.

**Ingestion:** No adverse effects expected.

**Inhalation:** No adverse effects expected. Dust may cause eye irritation if teeth are grinded or polished.

**Chronic Health Effects:** None expected.

**Carcinogenicity:** This product contains a small amount of titanium dioxide, which is listed by IARC as a suspected carcinogen (Group 2B). Titanium dioxide only presents a risk of cancer by inhalation of very fine dust. None of the other components are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU Directive.

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

**Medical Conditions Aggravated by Exposure:** None known.

### **Acute Toxicity Data:**

Non-Hazardous Polymer: No toxicity data available

Titanium dioxide: Oral rat LD50 - >20000 mg/kg; Skin hamster LD50 - >10000 mg/kg

**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:**

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 adverse effects are expected.

**Results of PBT/vPvB Assessment:** Not required.

## 13. DISPOSAL CONSIDERATIONS

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

**Properties (Physical/Chemical) Affecting Disposal:** Empty containers retain product residues and can be hazardous. Follow all SDS precautions when handling empty containers.

**Waste Treatment Recommendations:** 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:** Not 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):**

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 %
Titanium Dioxide	13463-67-7	<0.2%*

\*Note: The Titanium Dioxide in this product is in a polymer solid. Regulation applies when titanium dioxide is airborne and in unbound particles of respirable size.

### International Regulations

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

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

This SDS has been prepared according to the criteria of the Controlled Products Regulation (CPR) and the SDS contains all of the information required by the CPR.

**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 – 0      Physical Hazard– 0

Full text of Classification abbreviations used in Section 2 and 3:  
None

Supersedes: 26 April 2013

Revision Summary: Added Date Issued and Revision Number to SDS.

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