

**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), US 29CFR1910.1200, Canada Hazardous Products Regulation

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**1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING**

**1.1 Product Identifier:**

**Trade Name (as labeled):** Thermoflex™ Acetal Resin  
**Part/Item Number:** N406131 – N406149, N406160

**1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against:**

**Recommended Use:** Used in construction of artificial dentures  
**Restrictions on Use:** For Professional Use Only

**1.3 Details of the Supplier of the Safety Data Sheet:**

**Manufacturer/Supplier Name:** DENTSPLY Prosthetics  
**Manufacturer/Supplier Address:** 570 West College Ave.  
York, PA 17401  
**Manufacturer/Supplier Telephone Number:** 717-845-7511 (Product Information)  
**Email address:** Prosthetics\_MSDS@Dentsply.com

**1.4 Emergency Telephone Number:**

**Emergency Contact Telephone Number:** 800-424-9300 Chemtrec

**2. HAZARDS IDENTIFICATION**

**2.1 Classification of the Substance or Mixture:**

<b>GHS Classification:</b>		
<b>Health</b>	<b>Environmental</b>	<b>Physical</b>
Not Hazardous	Not Hazardous	Not Hazardous

**OSHA Specific Hazards:** Combustible Dust

**2.2 Label Elements:**

**Signal Word:** Warning

<b>Hazard Phrases</b>	<b>Precautionary Phrases</b>
May form combustible dust concentrations in air.	None Required

2.3 Other Hazards: None known.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

**3.2 Mixture:**

Hazardous Components	C.A.S. #	EINECS # / REACH Registration #	Classification	WT %
Polyoxymethylene Copolymer (Acetal Copolymer)	24969-26-4	607-470-1/	Not Applicable	99-100
Pigments	Mixture	Mixture/	Not Applicable	<1.0

The exact concentration is being withheld as a trade secret.

Refer to Section 16 for the full text of the GHS Classifications.

### 4. FIRST AID MEASURES

**4.1 Description of First Aid Measures:**

<b>Eye</b>	Flush eyes with water, while holding the eyelids apart. Get medical attention if irritation persists. If product is hot, immediately flush eyes with water, while holding the eyelids apart. Get immediate medical attention.
<b>Skin</b>	Wash skin with soap and water. If product is molten, cool skin with large amounts of water. Do not remove material bonded to the skin. Do not apply saves or ointment. Get immediate medical attention. Launder contaminated clothing before re-use. (Discard contaminated shoes).
<b>Inhalation</b>	In solid form, no adverse effects are expected. If dust or fumes from molten material are inhaled and irritation or systems occur, remove victim to fresh air. If breathing is difficult have qualified personnel administer oxygen. If breathing has stopped, administer artificial respiration. Get medical attention if irritation or symptoms occur.
<b>Ingestion</b>	If small quantities are swallowed, rinse out mouth with water. Do not induce vomiting. If large amounts are swallowed or if irritation or discomfort occurs, get medical attention.

**4.2 Most Important Symptoms and Effects, Both Acute and Delayed:**

Dust generated from grinding or polishing, or fumes from molten material may cause eye and respiratory tract irritation. Contact with molten product may cause thermal burns.

**4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:**

Immediate medical attention is required when in contact with molten material.

### 5. FIRE-FIGHTING MEASURES

**5.1 Extinguishing Media:**

Water fog, carbon dioxide dry chemical. 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.

**5.2 Special Hazards Arising from the Substance or Mixture:**

This product is not flammable or combustible; however, consideration must be given to the potential fire/explosion

hazards from the material being processed. Dust generated during polishing or grinding may present a potential fire and explosion hazard if suspended in air at high concentrations. Settled dust presents a fire hazard. Re-suspension of the dust into the air by vibration, traffic, material handling, etc. in high concentrations in the presence of an ignition source could result in a dust explosion. Minimize the generation and accumulation of dust. During fire conditions, material may release carbon monoxide, carbon dioxide, formaldehyde, trioxane, paraformaldehyde, and formic acid.

### 5.3 Advice for Fire-Fighters:

#### Fire Fighting Procedures/Precautions for Fire Fighters:

Cool fire exposed containers and structures with water. Do not use solid water jet as that may create a dust cloud that can present an explosion hazard. Firefighters should wear full emergency equipment and approved positive pressure self-contained breathing apparatus. Do not enter fire area without proper protection.

## 6. ACCIDENTAL RELEASE MEASURES

### 6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

Avoid prolonged contact with eyes, skin or clothing. Wear appropriate protective clothing as described in Section 8. If dust is generated or spilled, avoid breathing dust. Powders that become wet may cause surfaces to be extremely slippery and present a slip hazard.

### 6.2 Environmental Precautions:

Report releases as required by local, state, and national authorities.

### 6.3 Methods and Material for Containment and Cleaning up:

At ambient temperatures, pick up material and place into a container for disposal. If molten, allow material to solidify and cool. Pick up or scrape up and place into a containers for disposal. If dust is generated, collect in a manner that minimizes the generation of airborne dust. If vacuum is used, explosion-proof equipment is required.

### 6.4 Reference to Other Sections:

Refer to Section 8 for Personal Protective Equipment and Section 13 for Disposal information.

## 7. HANDLING AND STORAGE

### 7.1 Precautions for Safe Handling:

Avoid contact with molten material. Avoid generating dust. Avoid breathing dust or fumes from thermal processing. Use with adequate ventilation. Wear protective clothing and equipment as described in Section 8. Follow good housekeeping practices to keep surfaces, including areas overhead such as piping, drop ceilings, ductwork, etc. free from settled dust. Dry powders can build static electricity charges when subjected to friction of transfer and in mixing operations. Provide adequate precautions, such as electrical grounding and bonding. Wash thoroughly with soap and water after handling. Keep dust away from open flames, hot surfaces and sources of ignition.

Do not reuse containers. Empty containers retain product residues and can be hazardous. Follow all SDS precautions when handling empty containers.

**7.2 Conditions for Safe Storage, Including Any Incompatibilities:** Store in a dry, well ventilated area away from heat, direct sunlight and all sources of ignition. Keep container tightly closed when not in use. Keep away from oxidizing agents and other incompatible materials.

7.3 Specific End Use (s): For Professional Use.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control Parameters:

#### Occupational Exposure Limits:

Polyoxymethylene Copolymer (as Particulates Not Otherwise Specified)	5 mg/m <sup>3</sup> (Respirable fraction), 15 mg/m <sup>3</sup> (Total dust) TWA OSHA PEL
	4 mg/m <sup>3</sup> TWA DFG MAK (Inhalable)
Pigments (as Particulates Not Otherwise Specified)	5 mg/m <sup>3</sup> (Respirable fraction), 15 mg/m <sup>3</sup> (Total dust) TWA OSHA PEL
	4 mg/m <sup>3</sup> TWA DFG MAK (Inhalable)

**Biological Exposure Limits:** None Established.

### 8.2 Exposure Controls:

**Appropriate Engineering Controls:** Use adequate general or local exhaust ventilation to maintain exposures below the occupational exposure limits. Provide local exhaust ventilation where product is processed in a manner that generates dust. It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in handling this product contain explosion relief vents or an explosion suppression system or an oxygen deficient environment. Ensure that dust handling systems (such as exhaust ducts, dust collectors, vessels and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e. there is no leakage from the equipment). Use only appropriately classified electrical equipment.

#### Individual Protection Measures (PPE):

**Specific Eye/face Protection:** Wear chemical safety glasses or tight fitted goggles during polishing or grinding. In Europe follow EN 166.

**Specific Skin Protection:** For dusty conditions, wear gloves. In Europe follow EN 374 and EN 13034.

**Specific Respiratory Protection:** None should be needed for normal use. If the exposure limits are exceeded, 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 applicable regulations and good industrial hygiene practice.

**Specific Thermal Hazards:** Wear safety goggles and insulated gloves when handling hot material.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on Basic Physical and Chemical Properties:

<b>Appearance:</b>	Opaque cylindrical pellets	<b>Explosive limits:</b>	<b>LEL:</b> Not applicable <b>UEL:</b> Not applicable
<b>Odor:</b>	Odorless	<b>Vapor pressure (mmHg):</b>	Not applicable
<b>Odor threshold:</b>	Not applicable	<b>Vapor density:</b>	Not applicable
<b>pH:</b>	Not applicable	<b>Relative density:</b>	1.41

<b>Melting/freezing point:</b>	Not determined	<b>Solubility(ies):</b>	Insoluble
<b>Initial boiling point and boiling range:</b>	Not determined	<b>Partition coefficient: n-octanol/water:</b>	Not applicable
<b>Flash point:</b>	Not applicable	<b>Auto-ignition temperature:</b>	Not applicable
<b>Evaporation rate:</b>	Not applicable	<b>Decomposition temperature:</b>	Not determined
<b>Flammability (solid, gas):</b>	Combustible dust	<b>Viscosity:</b>	Not applicable
<b>Explosive Properties:</b>	High concentrations of dust in the presence of an ignition source could result in a dust explosion.	<b>Oxidizing Properties:</b>	Not an oxidizer

## 9.2 Other Information:

# 10. STABILITY AND REACTIVITY

<b>10.1 Reactivity:</b> Not reactive
<b>10.2 Chemical Stability:</b> Stable under normal storage and handling conditions.
<b>10.3 Possibility of Hazardous Reactions:</b> Hazardous polymerization will not occur.
<b>10.4 Conditions to Avoid:</b> Avoid extreme heat (460°F/238°C), flames, and other ignition sources.
<b>10.5 Incompatible materials:</b> Strong oxidizing agents, acid, bases, halogenated polymers such as PVC and PVDC at processing temperatures.
<b>10.6 Hazardous Decomposition Products:</b> Thermal decomposition may release carbon monoxide, carbon dioxide, formaldehyde, trioxane, paraformaldehyde, and formic acid.

# 11. TOXICOLOGICAL INFORMATION

## 11.1 Information on Toxicological Effects:

<p><b>Potential Health Effects:</b></p> <p><b>Eyes:</b> Dust generated during polishing and grinding may cause mechanical irritation. Fumes from molten product may cause eye irritation with redness and tearing. Contact with molten product may cause thermal burns.</p> <p><b>Skin:</b> Contact with molten product may cause thermal burns.</p> <p><b>Ingestion:</b> Small amounts are not anticipated to cause adverse effects. Large quantities may cause obstruction of the bowel.</p> <p><b>Inhalation:</b> Inhalation of dusts may cause irritation of the eyes, nose and upper respiratory tract. Inhalation of fumes from molten material may cause irritation of the eyes, nose and upper respiratory tract. Symptoms include coughing, sneezing and difficulty in breathing.</p>
<p><b>Chronic Health Effects:</b> None currently known.</p>
<p><b>Irritation:</b> No data available. This product may cause mechanical irritation.</p>
<p><b>Corrosivity:</b> This product is not classified as corrosive.</p>

<b>Sensitization:</b> No data available.
<b>Carcinogenicity:</b> None of the other components are listed as a carcinogen or potential carcinogen by IARC, NTP, OSHA or the EU CLP.
<b>Mutagenicity:</b> No data available.
<b>Acute Toxicity Data:</b> No toxicity data available
<b>Reproductive Toxicity Data:</b> No data available.
<b>Specific Target Organ Toxicity Single Exposure (STOT-SE):</b> No data available.
<b>Specific Target Organ Toxicity Repeated Exposure (STOT-RE):</b> No data available.

## 12. ECOLOGICAL INFORMATION

<b>12.1 Toxicity:</b> No data available
<b>12.2 Persistence and Degradability:</b> No data available
<b>12.3 Bio-accumulative Potential:</b> No data available
<b>12.4 Mobility in Soil:</b> No data available
<b>12.5 Results of PBT and vPvB Assessment:</b> No data available
<b>12.6 Other Adverse Effects:</b> No data available

## 13. DISPOSAL CONSIDERATIONS

<b>13.1 Waste Treatment Methods:</b>
<b>Waste Treatment Recommendations:</b> Dispose in accordance with all national and local regulations.

## 14. TRANSPORT INFORMATION

	14.1 UN Number	14.2 UN Proper Shipping Name	14.3 Hazard Class(s)	14.4 Packing Group	14.5 Environmental Hazards
<b>DOT</b>	None	Not Regulated	None	None	None
<b>ADR/RID</b>	None	Not Regulated	None	None	None
<b>IMDG</b>	None	Not Regulated	None	None	None
<b>IATA/ICAO</b>	None	Not Regulated	None	None	None

**14.6 Special Precautions for User:** Not applicable

**14.7 Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code:** Not applicable – product is transported only in packaged form.

## 15. REGULATORY INFORMATION

**15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture:**

### U.S. Federal Regulations

**Comprehensive Environmental Response and Liability Act of 1980 (CERCLA):** This product is not subject to CERCLA reporting requirements as it is sold. 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:** Fire Hazard

**This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):** None

### State Regulations

**California:** This product contains the following chemicals that are known to the State of California to cause cancer, birth defects or other reproductive harm: None known

### International Regulations

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

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

**EU REACH:** This product is a medical device and not subject to chemical notification requirements.

**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.

**Philippines Inventory of 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.

**15.2 Chemical Safety Assessment:** None required.

## 16. OTHER INFORMATION

HMIS Hazard Rating:

Health: 1          Flammability: 2          Physical Hazard: 0

Full Text of Hazard Statements and Abbreviations used In Section 3:

None

Supersedes: 6 February 2015

Date Updated: 28 September 2015

Revision Summary: Updated format to comply with REACH.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, ECHA Registered Substances, C&L Inventory, Country websites for occupational exposure limits.