

# DENTSPLY International

## Prosthetics

### Safety Data Sheet

Safety Data Sheet conforms to Regulation (EC) 1907/2006,  
Regulation (EC) 1272/2008 and Regulation (EC) 2015/830,  
US 29CFR1910.1200, Canada Hazardous Products  
Regulation

Date Issued: 22 February 2005  
Document Number: 315  
Date Revised: 22 May 2018  
Revision Number: 7

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

##### 1.1 Product Identifier:

**Trade Name (as labeled):** Polyflex® Duplicating Material  
**Part/Item Number:** N021855, N021955

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

**Recommended Use:** Model Duplicating Material  
**Restrictions on Use:** For Professional Use Only

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

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

##### 1.4 Emergency Telephone Number:

**Emergency Contact Telephone Number:** 800-243-1942

#### 2. HAZARDS IDENTIFICATION

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

GHS Classification:		
Health	Environmental	Physical
Not Hazardous	Not Hazardous	Not Hazardous

##### 2.2 Label Elements:

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 %
Non-Hazardous Ingredients	Proprietary	Proprietary	Not Applicable	60-80
Glycerin	56-81-5	200-289-5 /	Not Applicable	20-40
Potassium Aluminum Sulfate	7784-24-9	233-141-3 /	Not Applicable	1-5

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, holding the eyelids apart. Get medical attention if irritation persists.
<b>Skin</b>	Wash skin with soap and water. Get medical attention if irritation develops. Launder clothing before re-use.
<b>Inhalation</b>	Remove victim to fresh air. Get medical attention if irritation develops.
<b>Ingestion</b>	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.

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

May cause eye irritation. Prolonged skin contact may cause irritation. Inhalation of mist may cause mucous membrane and respiratory irritation.

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

Immediate medical attention is not required.

## 5. FIRE-FIGHTING MEASURES

**5.1 Extinguishing Media:** Use media appropriate for surrounding fire.

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

Decomposition may release oxides of carbon and sulfur, aldehydes and acrolein.

### 5.3 Advice for Fire-Fighters:

<b>Fire Fighting Procedures/Precautions for Fire Fighters:</b>	Cool fire exposed containers and structures with water. Firefighters should wear full emergency equipment and approved positive pressure self-contained breathing apparatus. Do not enter fire area without proper protection.
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## 6. ACCIDENTAL RELEASE MEASURES

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

Evacuate spill area and keep unprotected personnel away. Ventilate area. Wear appropriate protective clothing as described in Section 8. Avoid contact with skin, eyes or clothing.

**6.2 Environmental Precautions:**

Prevent entry into sewers and waterways. Consult local authorities regarding requirements.

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

Contain and collect using an inert absorbent material and place in appropriate containers for disposal. Rinse spill area with water.

**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 the eyes, skin and clothing. Avoid breathing mists. Wear protective clothing and equipment as described in Section 8. Use with adequate ventilation. Wash thoroughly with soap and water after handling. Keep containers closed when not in use.

Empty containers retain product residues. Follow all SDS precautions when handling empty containers.

**7.2 Conditions for Safe Storage, Including Any Incompatibilities:** Store in a container in a cool, dry, well-ventilated location away from incompatible materials.

**7.3 Specific End Use (s):** For professional use only.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**8.1 Control Parameters:****Occupational Exposure Limits:**

Glycerin	5 mg/m <sup>3</sup> TWA US OSHA PEL (Respirable fraction), 15 mg/m <sup>3</sup> TWA (Total dust)
	200 mg/m <sup>3</sup> TWA DFG MAK (Inhalable aerosol), 400 mg/m <sup>3</sup> STEL (Inhalable aerosol)
	10 mg/m <sup>3</sup> TWA WEL Belgium
	10 mg/m <sup>3</sup> TWA UK WEL
Potassium Aluminum Sulfate (As Aluminum, Al)	1 mg/m <sup>3</sup> TWA ACGIH TLV (Respirable fraction) 5 mg/m <sup>3</sup> (Respirable fraction) TWA OSHA PEL 15 mg/m <sup>3</sup> (Total dust) TWA OSHA PEL
	4 mg/m <sup>3</sup> (Inhalable aerosol) TWA DFG MAK, 1.5 mg/m <sup>3</sup> (Respirable fraction) TWA
	10 mg/m <sup>3</sup> TWA UK WEL (inhalable aerosol), 4 mg/m <sup>3</sup> TWA (respirable aerosol)

**Biological Exposure Limits:** None established.

**8.2 Exposure Controls:**

**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:** Chemical safety glasses or goggles recommended if eye contact is possible.

**Specific Skin Protection:** Wear impervious gloves such as rubber if needed to avoid prolonged skin contact.

**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:** None required.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

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

<b>Appearance:</b>	Blue or light brown semi-solid gel	<b>Explosive limits:</b>	<b>LEL:</b> Not applicable <b>UEL:</b> Not applicable
<b>Odor:</b>	Not available	<b>Vapor pressure (mmHg):</b>	Not available
<b>Odor threshold:</b>	Not available	<b>Vapor density: (Air = 1)</b>	Not available
<b>pH:</b>	Not available	<b>Relative density:</b>	1.10 @ 25°C (77°F)
<b>Melting/freezing point:</b>	96°C (205°F)	<b>Solubility:</b>	Soluble in water
<b>Initial boiling point and range:</b>	Not available	<b>Partition coefficient: n-octanol/water:</b>	Not available
<b>Flash point:</b>	Not flammable	<b>Auto-ignition temperature:</b>	370°C (698°F) (Glycerin)
<b>Evaporation rate: (n-BuAc = 1)</b>	Slight	<b>Decomposition temperature:</b>	Not determined
<b>Flammability:</b>	Not flammable	<b>Viscosity:</b>	Not applicable
<b>Explosive Properties:</b>	Not determined	<b>Oxidizing Properties:</b>	None

**9.2 Other Information:** None available.

## 10. STABILITY AND REACTIVITY

**10.1 Reactivity:** None known.

**10.2 Chemical Stability:** Stable under normal conditions.

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

**10.4 Conditions to Avoid:** None known

**10.5 Incompatible materials:** Avoid oxidizing agents.

**10.6 Hazardous Decomposition Products:** Decomposition may release oxides of carbon and sulfur, aldehydes and acrolein.

## 11. TOXICOLOGICAL INFORMATION

### 11.1 Information on Toxicological Effects:

**Potential Health Effects:**

**Eyes:** Direct contact may cause mild irritation with redness and tearing.

**Skin:** Prolonged contact may cause irritation with redness and itching of the skin.

**Ingestion:** Accidental ingestion of large amounts may cause gastrointestinal irritation, nausea, vomiting and diarrhea. Excessive exposure to glycerin may cause central nervous system effects and increased blood sugar levels.

**Inhalation:** Inhalation of mists may cause irritation to the nose, throat and upper respiratory tract with coughing and shortness of breath.

**Chronic Health Effects:** No adverse effects expected under normal use. Repeated excessive exposures to glycerin may cause increased fat levels in the blood and damage to the kidney and liver.

**Irritation:** May cause slight irritation.

**Corrosivity:** No data available. This product is not expected to be corrosive.

**Sensitisation:** No data available. This product is not expected to cause sensitization.

**Carcinogenicity:** Glycerin: No increase in tumor incidence was found in a 2 year oral feeding study with rats at doses of 5 and 10 g/kg. None of the components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU CLP.

**Mutagenicity:** Glycerin: Negative in AMES, in vitro sister chromatid exchange and unscheduled DNA synthesis.

**Aspiration Hazard:** Not an aspiration hazard

**Acute Toxicity Data:**

Glycerin: Oral rabbit LD50- >12,600 mg/kg ; Skin rabbit LD50 - >10,000 mg/kg; Inhalation rat LC50 - >570 mg/m<sup>3</sup>/1hr  
Potassium Aluminum Sulfate: No toxicity data available.

**Reproductive Toxicity Data:** Glycerin: No effects were observed in a 2 generation study at doses of 0.2 mg/kg/day. No developmental effects were observed in rabbits administered up to 1180 mg/kg or in rats or mice administered up to 1310 mg/kg. This product is not expected to cause adverse reproductive effects.

**Specific Target Organ Toxicity Single Exposure (STOT-SE):** Glycerin: When placed into the eye of a rabbit, glycerin will cause an inflammatory reaction, edema of the cornea and damage of the endothelial cells.

**Specific Target Organ Toxicity Repeated Exposure (STOT-RE):** Glycerin: In a 13 week sub-chronic inhalation study with rats, glycerin was found to cause mild irritation of mucous membranes. In a 2 year study in rats, no adverse effects were found in animals with 20% glycerin in their feed.

## 12. ECOLOGICAL INFORMATION

**12.1 Toxicity:**

Glycerin: 24 hr LC50 Goldfish - >5000 mg/L; 48 hr EC50 Daphnia magna -10,000 mg/L

<b>12.2 Persistence and Degradability:</b> Glycerin is readily biodegradable (63% after 14 days).
<b>12.3 Bio-accumulative Potential:</b> Glycerin is not expected to bioconcentrate in fish and aquatic organisms.
<b>12.4 Mobility in Soil:</b> Glycerin: Very high mobility in soil.
<b>12.5 Results of PBT and vPvB Assessment:</b> Not required
<b>12.6 Other Adverse Effects:</b> None

### 13. DISPOSAL CONSIDERATIONS

**13.1 Waste Treatment Methods:**

**Waste Treatment Recommendations:** Dispose in accordance with national and local regulations.

### 14. TRANSPORT INFORMATION

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

**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.

### 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):** Releases above the RQ of 100,000 Lbs. (based on the RQ for Potassium Hydroxide of 1,000 lbs present at <0.1%) 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:** See OSHA Hazard Classification in Section 2.

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

### **International Regulations**

**Canadian Environmental Protection Act:** All of the components in this product are listed on the Domestic Substances List (DSL).

**European Inventory of Existing Chemicals (EINECS):** All of the components in this product are listed on the EINECS inventory.

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

**Australian Inventory of Chemical Substances:** All of the components in this product are listed on the AICS for Australia.

**China Inventory of Existing Chemicals and Chemical Substances:** All of the components in this product are listed on the IECSC for China.

**Korean Existing Chemicals List:** All of the components in this product are listed on the KECL for Korea.

**Philippine Inventory of Chemicals and Chemical Substances:** All of the components in this product are listed on the PICCS.

## **16. OTHER INFORMATION**

### **HMIS Hazard Rating:**

Health – 1      Flammability – 0      Physical Hazard – 0

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

None

Supersedes: 30 April 2015

Date Updated: 22 May 2018

Revision Summary: 3 Year update. Changes to Section 11 & 15.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, ECHA REACH Registration Website, Country websites for occupational exposure limits.