DENTSPLY International

Safety Data Sheet

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

1.1 Product Identifier:
   - Trade Name (as labeled): Eclipse® Prosthetic Resin Materials (Baseplate, Set-Up and Contour Resin)
   - Part/Item Number: 905001-905003, 905005-905009, 905011-905013, 905018-905020, 905022, 905075-905077, 905080-905083, 905086-905087, 905092-905094

1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against:
   - Recommended Use: Resin used in removable dental appliances.
   - 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: 800-424-9300 Chemtrec

2. HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture:

<table>
<thead>
<tr>
<th>GHS Classification</th>
<th>Health</th>
<th>Environmental</th>
<th>Physical</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Eye Irritant Category 2A (H319)</td>
<td>Aquatic Chronic Toxicity Category 3 (H412)</td>
<td>Not Hazardous</td>
</tr>
<tr>
<td></td>
<td>Reproductive Toxicity Category 2 (H361f)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Skin Irritant Category 2 (H315)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Skin Sensitization Category 1 (H317)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2.2 Label Elements:
Signal Word: Warning

Contains: Urethane Methacrylate, Stearyl Acrylate, and Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

<table>
<thead>
<tr>
<th>Hazard Phrases</th>
<th>Precautionary Phrases</th>
</tr>
</thead>
<tbody>
<tr>
<td>H315 Causes skin irritation.</td>
<td>P201 Obtain special instructions before use.</td>
</tr>
<tr>
<td>H317 May cause an allergic skin reaction.</td>
<td>P202 Do not handle until all safety precautions have been read and understood.</td>
</tr>
<tr>
<td>H319 Causes serious eye irritation.</td>
<td>P261 Avoid breathing dust or fume.</td>
</tr>
<tr>
<td>H361f Suspected of damaging fertility.</td>
<td>P264 Wash thoroughly after handling.</td>
</tr>
<tr>
<td>H412 Harmful to aquatic life with long lasting effects.</td>
<td>P272 Contaminated work clothing must not be allowed out of the workplace.</td>
</tr>
<tr>
<td></td>
<td>P273 Avoid release to the environment.</td>
</tr>
<tr>
<td></td>
<td>P280 Wear protective gloves, protective clothing, eye protection and face protection.</td>
</tr>
<tr>
<td></td>
<td>P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</td>
</tr>
<tr>
<td></td>
<td>P337+P313 If eye irritation persists: Get medical attention.</td>
</tr>
<tr>
<td></td>
<td>P302+P352 IF ON SKIN: Wash with plenty of soap and water.</td>
</tr>
<tr>
<td></td>
<td>P333+P313 If skin irritation or rash occurs: Get medical attention.</td>
</tr>
<tr>
<td></td>
<td>P362+P364 Take off contaminated clothing and wash it before reuse.</td>
</tr>
<tr>
<td></td>
<td>P308+P313 IF exposed or concerned: Get medical attention.</td>
</tr>
<tr>
<td></td>
<td>P405 Store locked up.</td>
</tr>
<tr>
<td></td>
<td>P501 Dispose of contents and container in accordance with local and national regulations.</td>
</tr>
</tbody>
</table>

2.3 Other Hazards: None known.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.2 Mixture:

<table>
<thead>
<tr>
<th>Hazardous Components</th>
<th>C.A.S. #</th>
<th>EINECS # / REACH Registration #</th>
<th>Classification</th>
<th>WT %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urethane Methacrylate</td>
<td>Proprietary</td>
<td>Proprietary</td>
<td>Eye Irrit. 2A, H319 Skin Irrit. 2, H315 Skin Sens. 1, H317</td>
<td>40-100</td>
</tr>
<tr>
<td>Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide</td>
<td>75980-60-8</td>
<td>278-355-8 /</td>
<td>Skin Sens. 1B, H317 Repr. 2, H361</td>
<td>&lt;0.5</td>
</tr>
</tbody>
</table>
4. FIRST AID MEASURES

4.1 Description of First Aid Measures:

<table>
<thead>
<tr>
<th>Condition</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye</td>
<td>Immediately flush eyes with large quantities of water for at least 15 minutes, while holding the eyelids apart. Get medical attention if irritation persists.</td>
</tr>
<tr>
<td>Skin</td>
<td>Remove clothing. Wash skin thoroughly with soap and water. Get medical attention if irritation or rash develops. Launder contaminated clothing before re-use.</td>
</tr>
<tr>
<td>Inhalation</td>
<td>If irritation develops, remove to fresh air. Get medical attention if symptoms persist.</td>
</tr>
<tr>
<td>Ingestion</td>
<td>Do not induce vomiting. If conscious, wash mouth out with water. Never give anything by mouth to an unconscious or convulsing person. Get medical attention if you feel unwell.</td>
</tr>
</tbody>
</table>

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

- May cause eye and skin irritation.
- Prolonged or repeated contact may cause allergic skin reaction.
- Individuals with sensitivity to methacrylates may develop an allergic reaction when exposed to this product. This product contains a component that is suspected of damaging fertility based on animal studies.

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

Immediate medical attention should not be required.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media:

Use water fog, foam, carbon dioxide, water spray or dry chemical.

5.2 Special Hazards Arising from the Substance or Mixture:

High temperatures and sunlight may cause a polymerizing reaction to occur. Decomposition may release acrid smoke or fumes, carbon and nitrogen oxides.

5.3 Advice for Fire-Fighters:

<table>
<thead>
<tr>
<th>Fire Fighting Procedures/Precautions for Fire Fighters:</th>
</tr>
</thead>
<tbody>
<tr>
<td>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. Contain water used in firefighting from entering sewers or natural waterways.</td>
</tr>
</tbody>
</table>

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

Avoid contact with skin, eyes or clothing. Avoid breathing dust or fumes. Wear appropriate protective clothing as described in Section 8.

6.2 Environmental Precautions:

Avoid releases to the environment. Report releases as required by local and national authorities.
6.3 Methods and Material for Containment and Cleaning up:
Exposure to sunlight or artificial light will cause the resin to polymerize. Spread the paste to maximize the surface area. Once the material is hard, pick up and place into a container for disposal.

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 dust or fumes. 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.

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 tightly closed container in a cool (29-90°F/-1.7-32.2°C), well-ventilated location away from incompatible materials. Do not store near high temperatures or ignition sources. Do not store in an oxygen-free environment. Avoid freezing the material.

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:

**Occupational Exposure Limits:**

<table>
<thead>
<tr>
<th>Substance</th>
<th>Exposure Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urethane Methacrylate</td>
<td>None Established</td>
</tr>
<tr>
<td>Stearyl Acrylate</td>
<td>None Established</td>
</tr>
<tr>
<td>Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide</td>
<td>None Established</td>
</tr>
</tbody>
</table>

**Biological Exposure Limits:** None Established

8.2 Exposure Controls:

**Appropriate Engineering Controls:** Use with adequate local exhaust ventilation to minimize exposure levels or when grinding polymerized (cured) materials.

**Individual Protection Measures (PPE):**
- **Specific Eye/face Protection:** Chemical safety goggles recommended.
- **Specific Skin Protection:** Wear impervious gloves such as rubber to prevent skin contact.
- **Specific Respiratory Protection:** None should be 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 applicable regulations and good industrial hygiene practice.
9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

<table>
<thead>
<tr>
<th>Property</th>
<th>Baseplate resin</th>
<th>Setup resin</th>
<th>Contour resin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Moldable, translucent pink or clear resin.</td>
<td>Firm, opaque pink resin.</td>
<td>Wax-like opaque pink resin.</td>
</tr>
<tr>
<td>Explosive limits:</td>
<td>LEL: Not applicable</td>
<td>UEL: Not applicable</td>
<td></td>
</tr>
<tr>
<td>Odor:</td>
<td>Not available</td>
<td>Vapor pressure (mmHg):</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Odor threshold:</td>
<td>Not applicable</td>
<td>Vapor density:</td>
<td>&gt;1</td>
</tr>
<tr>
<td>pH:</td>
<td>Not available</td>
<td>Relative density:</td>
<td>1.1</td>
</tr>
<tr>
<td>Melting/freezing point:</td>
<td>&lt;40°F (&lt;-48°C)</td>
<td>Solubility(ies):</td>
<td>Negligible</td>
</tr>
<tr>
<td>Initial boiling point and boiling range:</td>
<td>Not applicable</td>
<td>Partition coefficient: n-octanol/water:</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flash point:</td>
<td>&gt;356°F (&gt;180°C)</td>
<td>Auto-ignition temperature:</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Evaporation rate:</td>
<td>Not available</td>
<td>Decomposition temperature:</td>
<td>Not available</td>
</tr>
<tr>
<td>Flammability (solid, gas):</td>
<td>Not applicable</td>
<td>Viscosity:</td>
<td>Not available</td>
</tr>
<tr>
<td>Explosive Properties:</td>
<td>Non-Explosive</td>
<td>Oxidizing Properties:</td>
<td>None</td>
</tr>
<tr>
<td>Oxidizing Properties:</td>
<td>None</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

9.2 Other Information: None available

10. STABILITY AND REACTIVITY

10.1 Reactivity: None known.

10.2 Chemical Stability: Stable under normal handling and storage conditions.

10.3 Possibility of Hazardous Reactions: Material can polymerize if exposed to high temperatures or to direct sunlight.

10.4 Conditions to Avoid: Avoid excessive heat, flames, ignition sources and direct sunlight.

10.5 Incompatible materials: Avoid oxidizing agents, reducers, free radical initiators and oxygen-free environments.

10.6 Hazardous Decomposition Products: Thermal decomposition may release acrid smoke or fumes, carbon and nitrogen oxides.
11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

**Potential Health Effects:**
- Eyes: May cause irritation with redness and tearing.
- Skin: May cause irritation. Prolonged contact may cause dermatitis. May cause allergic skin reaction (sensitization).
- Ingestion: May cause gastrointestinal irritation and nausea.
- Inhalation: None expected under normal use. Inhalation of dust from grinding resin may cause respiratory irritation.

**Chronic Health Effects:** None expected under normal use.

**Irritation:** Urethane Methacrylate and Stearyl Acrylate are classified as an eye and skin irritant. Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide: Not irritating in rabbit skin and eyes.

**Corrosivity:** This product is not classified as corrosive.

**Sensitization:** Diphenyl (2,4,6-trimethylbenzoyl)phosphine oxide: Sensitizing in Mouse local lymphnode assay. Individuals with sensitivity to methacrylates may develop an allergic reaction.

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

**Mutagenicity:** No data available.

**Aspiration Hazard:** Not an aspiration hazard.

**Acute Toxicity Data:**
- Urethane Methacrylate: No toxicity data available
- Stearyl Acrylate: Oral rat LD50- >2000 mg/kg; Skin rat LD50 - >5000 mg/kg
- Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide: Oral rat LD50 - >5000 mg/kg; Skin rat LD50=>2000 mg/kg

**Reproductive Toxicity Data:** Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide: Animal studies suggest a fertility impairing effect. Testicular atrophy was seen in all male rats dosed at 750 mg/kg/day.

**Specific Target Organ Toxicity Single Exposure (STOT-SE):** No data available.

**Specific Target Organ Toxicity Repeated Exposure (STOT-RE):** Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide: May cause damage to the testes after repeated ingestion of high doses, in animal studies.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:
- Stearyl Acrylate: 48 hr. EC50 Daphnia magna- 0.6-2.1 mg/L
- Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide: 48 hr. LC50 Oryzias latipes- 6.53 mg/L; 48 hr. EC50 Daphnia magna- 3.53 mg/L

This product is classified as harmful to the aquatic environment with long-term adverse effects. Releases to the environment should be avoided.

**12.2 Persistence and Degradability:** Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide: Not readily biodegradable- <20% in 28 days.

**12.3 Bio-accumulative Potential:** No data is currently available
12.4 Mobility in Soil: No data is currently available

12.5 Results of PBT and vPvB Assessment: Not required

12.6 Other Adverse Effects: None known

### 13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:

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

### 14. TRANSPORT INFORMATION

<table>
<thead>
<tr>
<th>DOT</th>
<th>14.1 UN Number</th>
<th>14.2 UN Proper Shipping Name</th>
<th>14.3 Hazard Class(s)</th>
<th>14.4 Packing Group</th>
<th>14.5 Environmental Hazards</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>None</td>
<td>Not Regulated</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>IMDG</td>
<td>None</td>
<td>Not Regulated</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>IATA/ICAO</td>
<td>None</td>
<td>Not Regulated</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

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):** 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:** Acute Health, Chronic Health.

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: Titanium Dioxide (0-0.1%).
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.

Philippine 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

<table>
<thead>
<tr>
<th>HMIS Hazard Rating:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health – 2* Flammability – 1 Physical Hazard– 1</td>
</tr>
<tr>
<td>*Chronic Health Hazard</td>
</tr>
</tbody>
</table>

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

- Repr. Cat 3 Reproductive Toxicity Category 3
- Aq. Acute 2 Aquatic Acute Toxicity Category 2
- Aq. Chronic 2 Aquatic Chronic Toxicity Category 2
- Aq. Chronic 3 Aquatic Chronic Toxicity Category 3
- Eye Irrit. 2 Eye Irritant Category 2
- Repr. 2 Reproductive Toxicity Category 2
- Skin Irrit. 2 Skin Irritant Category 2
- Skin Sens. 1 Skin Sensitizer Category 1
- STOT SE 3 Specific Target Organ Toxicity Single Exposure Category 3
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.
- H335 May cause respiratory irritation.
- H361 Suspected of damaging fertility or the unborn child.
- H401 Toxic to aquatic life.
- H411 Toxic to aquatic life with long lasting effects.
- H412 Harmful to aquatic life with long lasting effects.

Supersedes: 25 February 2014
Date Updated: 27 March 2017
Revision Summary: 3 Year update. Changes to Sections 1, 3, 11, & 16.
Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, ECHA REACH Registration Website, Country websites for occupational exposure limits.