This SDS packet was issued with item:
071859230

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

071851518 071858612 071858638 071858646 071858653 071858661 071858679 071858687 071858695 071858703
071858711 071858729 071858737 071858745 071858752 071858760 071858778 071858836 071858844 071858851
071858877 071858885 071859107 071859248 071859255 071859438 078319725 078319727 078319728 078319731
078319734 078319735 078319737 078319740 078319745 078319746 078319747 078319770 078319773 078319776
078319779 078319782 078319785 078319788 078319791 078319794 078319797 078319824 078319825 078319827
078319830 078319833 078319835 078319836 078319839 078319842 078319843 078319845 078319847 078319848
078319860 078319863 078319866 078319869 078319872 078319875 078319878

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

071858604 071858869 071858893 071858901 071858919 071858927 071858935 071858943 071858950 071858968
071858976 071858984 071858992 071859008 071859016 071859024 071859115 071859123 071859131 071859149
071859156 071859164 071859172 071859180 071859198 071859206 071859214 071859222 071859263 071859271
071859289 071859297 071859305 071859321 071859339 071859347 071859354 071859362 071859370 071859388
071859396 071859412 071859420
1. Identification

<table>
<thead>
<tr>
<th>Product Name</th>
<th>SDS Code Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>TPH Spectra®</td>
<td>542699</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substance Identity</th>
<th>Date of Last Revision</th>
</tr>
</thead>
<tbody>
<tr>
<td>TPH Spectra® Universal Composite Restorative</td>
<td>11/13/15</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>DENTSPLY Caulk</td>
<td>38 West Clarke Avenue Milford DE 19963-1805</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Information Telephone Number</th>
<th>Emergency Telephone Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)</td>
<td>(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)</td>
</tr>
</tbody>
</table>

2. Hazard(s) Identification

**WARNING**

MAY CAUSE AN ALLERGIC SKIN REACTION

Wash hands thoroughly after handling.

Wear protective gloves.

3. Composition/Information on Ingredients

<table>
<thead>
<tr>
<th>Hazardous Components</th>
<th>C.A.S. Number</th>
<th>Exposure Limits</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Titanium Dioxide</td>
<td>13463-67-7</td>
<td>10 mg/m³</td>
<td>&lt; than 1</td>
</tr>
<tr>
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<td>67762-90-7</td>
<td>3 mg/m³</td>
<td>&lt; than 5</td>
</tr>
<tr>
<td>Barium boron fluoro alumino silicate glass</td>
<td>65997-18-4</td>
<td>10 mg/m³</td>
<td>&lt; than 30</td>
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<tr>
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<td>65997-17-3</td>
<td>10 mg/m³</td>
<td>&lt; than 50</td>
</tr>
<tr>
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<td>126646-17-1</td>
<td>Not Established</td>
<td>&lt; than 10</td>
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<tr>
<td>Polymerizable dimethacrylate resin</td>
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<td>109-16-0</td>
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</tr>
</tbody>
</table>

Other Information: Colorants are inorganic iron oxides and titanium dioxide.

4. First Aid Measures

<table>
<thead>
<tr>
<th>Routes of Exposure</th>
<th>First Aid Instructions</th>
<th>Immediate Medical Attention</th>
<th>Delayed Effects</th>
</tr>
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<tbody>
<tr>
<td>Eye</td>
<td>Rinse opened eye for several minutes under running water.</td>
<td>Not Applicable</td>
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</tr>
<tr>
<td></td>
<td>If symptoms persist consult physician</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skin</td>
<td>Immediately wash with soap and water and rinse thoroughly</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Inhalation</td>
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<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Ingestion</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Mucosa</td>
<td>Rinse tissue for several minutes under running water.</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
<tr>
<td></td>
<td>If symptoms persist consult physician</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note to Physicians (Treating, Testing and Monitoring): Treat symptomatically.

5. Fire Fighting Measures

<table>
<thead>
<tr>
<th>Flame Propagation or Burning Rate (for Solids)</th>
<th>Properties Contributing to Fire Intensity</th>
<th>Flammability Classification</th>
<th>Other: Not Applicable</th>
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<tbody>
<tr>
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<td>Not Applicable</td>
<td>Not Applicable</td>
<td></td>
</tr>
</tbody>
</table>

Extinguishing Media: CO₂, extinguishing powder, foam carbon dioxide or water spray. Fight larger fires with water spray or alcohol resistant foam.

Extinguishing Media to Avoid: Water with full jet.

Protection and Procedures for Firefighters: Firefighters should wear self-contained respiratory protective devices.

Unusual Fire and Explosion Hazards: Formation of toxic, irritating gases is possible from the decomposition of the dimethacrylate resins. Product does not present an explosion hazard.
6. Accidental Release Measures

Containment Techniques: Material is a paste and as such will not flow.

Spill/Leak Clean-up Procedures and Equipment: Wear protective clothing and scoop up bulk material and place in a labeled plastic or metal container. Avoid gross skin contact to minimize the possibility of contact dermatitis to susceptible persons. Ensure adequate ventilation.

Evacuation Procedures: Not Applicable  Special Instructions: Not Applicable  Reporting Requirements: Not Applicable

7. Handling and Storage

Handling Practices and Warnings: Product is intended for dental use only. Handling of this product should be by trained dental healthcare professionals only. Observe normal care for working with chemicals.

Storage Practices and Warnings: Store only in the original package. Keep package tightly sealed. Store in a dry area. Protect from exposure to direct light. Store away from food and beverages.

8. Exposure Control / Personal Protection


Eye/Face  Safety Glasses  Not Applicable  Skin  The glove material has to be impermeable and resistant to the product.  Not Applicable  Inhalation  Not Required  Not Applicable  Body Protection  Protective work clothing  Not Applicable

9. Physical and Chemical Characteristics


10. Stability and Reactivity Data

Incompatibility (Materials to Avoid): Strong Oxidizing materials.

Hazardous Products Produced During Decomposition: No dangerous decomposition products known if used according to Directions for Use.

Hazardous Polymerization: ☑ May Occur ☑ May Not Occur  Conditions to Avoid: None known  Stability? ☑ Stable ☐ Unstable  Conditions to Avoid: None known

11. Toxicological Information

Toxicity Data, Epidemiology Studies, Carcinogenicity, Neurological Effects, Genetic Effects, Reproductive Effects, or Structure Activity Data: Product is an irritant to the skin and mucous membranes. The unpolymerized product may be an irritant to the skin in susceptible persons. On the eye the product has an irritating effect. Sensitization: Repeated or prolonged contact with the unpolymerized material may cause sensitization for persons allergic to acrylates and methacrylates. This product shows the following dangers according to internally approved calculation methods for composite materials: Irritant.

Emergency Overview Material is irritating to eyes, respiratory system and skin.

Routes of Exposure  Signs and Symptoms  Single, Repeated, or Lifetime Exposure  Severity (Mild, Moderate, Severe)  Acute and Chronic Health Effect(s)  Target Organ(s)

Eye  Material can cause irritation.  Single  Moderate  Irritation and possible corneal damage  Not Applicable

Skin  Material may be an irritant  Single & Repeated  Moderate  Irritation or possible allergic response. Severe allergic response may result in breathing difficulties.  Not Applicable

Inhalation  Not Applicable  Not Applicable  Not Applicable  Not Applicable  Not Applicable

Ingestion  Material is not harmful if swallowed using clinically relevant quantities  Not Applicable  Mild  Not Applicable  Not Applicable

Mucosa  Material can cause irritation.  Single  Mild  Inflammation of the mucosa  Not Applicable

Medical Conditions Aggravated by Exposure: Open sores and wounds of the skin. Individuals with known sensitivity to methacrylates, acrylates, or urethane dimethacrylate resin used in Dental restorative products.

Carcinogenicity  NTP?: Not listed  IARC monographs?: Not listed  OSHA regulated?: No All components of this product are in compliance with the inventory listing Requirements of the U. S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory.

Potential Environmental Effects: Do not allow to enter sewers/ surface or ground water.

NFPA Hazard Classification Ratings (Scale 0-4): Health = 1, Fire = 1, Reactivity = 0
12. Ecological Information
Toxicity Data, Environmental Fate, Physical/Chemical Data, or other Data Supporting Environmental Hazard Statements: Water Hazard class 1 (Self-assessment): slightly hazardous for water. Do not allow undiluted product or large quantities of it to reach ground water, water streams or sewage system.

13. Disposal Considerations
Regulations: Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
Dispose of material as solid waste in a closed container. Dispose of in accordance with Federal, State and Local regulations
Properties (Physical/Chemical) Affecting Disposal: Dispose of material as solid waste in a closed container.

14. Transport Information
<table>
<thead>
<tr>
<th>Regulated for Shipping:</th>
<th>DOT Shipping Name:</th>
<th>Packing Group:</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. Not Regulated</td>
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<tr>
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<th>UN Number:</th>
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15. Regulatory Information
This product has been classified in accordance with the hazard criteria of the Globally Harmonized System of Classification and Labeling of Chemicals and the SDS contains all of the information required by the Canadian Controlled Products Regulations.

U.S. Federal Regulations:
- CERCLA 103 Reportable Quantity: 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.
- Section 313 Toxic Chemicals: This product contains the following chemicals subject to Annual Release Reporting Requirements Under SARA Title III, Section 313 (40 CFR 372): None
- Section 302 Extremely Hazardous Substances (TPQ): None
- EPA Toxic Substances Control Act (TSCA) Status: All of the components of this product are listed on the TSCA inventory.
- U.S. State Regulations California Proposition 65: This product does not contain any chemicals, which are on the California Proposition 65 list.
- International Regulations: Canadian Environmental Protection Act:
  This product is a medical device and not subject to chemical notification requirements.
- European Community Labeling: Not a dangerous preparation.
- European Inventory of New and Existing Chemicals Substances (EINECS):
  This product is a medical device and not subject to chemical notification requirements.
- Other: Not Applicable

16. Other Information
To the best of our knowledge this product does not contain gluten, wheat grains, flaxseed, natural rubber, or natural latex.
All components are synthetically produced; none are derived from animal products.
This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific products features and shall not establish a legally valid contractual relationship.
The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer. For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.
1. Identification

Product Name: TPH Spectra®
SDS Code Number: 542699

Substance Identity: TPH Spectra® Universal Composite Restorative
Date of Last Revision: 11/13/15

Manufacturer: DENTSPLY Caulk
Address: 38 West Clarke Avenue
Milford DE 19963-1805

Grades or Minor Variant Identities: Not Applicable

Information Telephone Number:
(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)

Emergency Telephone Number:
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2. Hazard(s) Identification

WARNING
MAY CAUSE AN ALLERGIC SKIN REACTION
Wash hands thoroughly after handling.
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Other Information: Colorants are inorganic iron oxides and titanium dioxide.

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Note to Physicians (Treating, Testing and Monitoring): Treat symptomatically.

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Extinguishing Media: CO₂, extinguishing powder, foam carbon dioxide or water spray. Fight larger fires with water spray or alcohol resistant foam.
Extinguishing Media to Avoid: Water with full jet.

Protection and Procedures for Firefighters: Firefighters should wear self-contained respiratory protective devices.

Unusual Fire and Explosion Hazards: Formation of toxic, irritating gases is possible from the decomposition of the dimethacrylate resins. Product does not present an explosion hazard.
6. Accidental Release Measures

Containment Techniques: Material is a paste and as such will not flow.

Spill/Leak Clean-up Procedures and Equipment: Wear protective clothing and scoop up bulk material and place in a labeled plastic or metal container. Avoid gross skin contact to minimize the possibility of contact dermatitis to susceptible persons. Ensure adequate ventilation.

Evacuation Procedures: Not Applicable
Special Instructions: Not Applicable
Reporting Requirements: Not Applicable

7. Handling and Storage

Handling Practices and Warnings: Product is intended for dental use only. Handling of this product should be by trained dental healthcare professionals only. Avoid normal care for working with chemicals.

Storage Practices and Warnings: Store only in the original package. Keep package tightly sealed. Store in a dry area. Protect from exposure to direct light. Store away from food and beverages.

8. Exposure Control / Personal Protection

Occupational Exposure Limits: Not Applicable
Engineering Controls: Not Applicable
Individual Protection Measures
Eye/Face
Safety Glasses
Not Applicable

Skin
The glove material has to be impermeable and resistant to the product.
Not Applicable

Inhalation
Not Required
Not Applicable

Body Protection
Protective work clothing
Not Applicable

9. Physical and Chemical Characteristics

Appearance: Various shades of viscous paste.

Normal Physical State: Very High Viscosity Liquid (Paste)

Solubility in Water: Not soluble

Melting Point: Not Applicable

Odor: Characteristic sweet acrylic ester odor.

Specific Gravity: 2.1 g/cm³

Vapor Pressure (mm Hg): Not Applicable

Flashpoint Method: Not Applicable

Autoignition Temperature: Not Applicable, Product will not autoignite.

10. Stability and Reactivity Data

Incompatibility (Materials to Avoid): Strong oxidizing materials.

Hazardous Products Produced During Decomposition: No dangerous decomposition products known if used according to Directions for Use.

Hazardous Polymerization: Not Applicable

Conditions to Avoid: None known

Conditions to Avoid: None known

11. Toxicological Information

Toxicity Data, Epidemiology Studies, Carcinogenicity, Neurological Effects, Genetic Effects, Reproductive Effects, or Structure Activity Data: Product is an irritant to the skin and mucous membranes. The unpolymerized product may be an irritant to the skin in susceptible persons. On the eye the product has an irritating effect. Sensitization: Repeated or prolonged contact with the unpolymerized material may cause sensitization for persons allergic to acrylics and methacrylates. This product shows the following dangers according to internally approved calculation methods for composite materials: Irritant.

Emergency Overview Material is irritating to eyes, respiratory system and skin.

Routes of Exposure
Eye
Material can cause irritation.

Skin
Material may be an irritant

Inhalation
Not Applicable

Ingestion
Material is not harmful if swallowed using clinically relevant quantities

Mucosa
Material can cause irritation.

Signs and Symptoms
Single, Repeated, or Lifetime Exposure

Severity (Mild, Moderate, Severe)

Acute and Chronic Health Effect(s)

Target Organ(s)

Eye
Single
Moderate
Irritation and possible corneal damage
Not Applicable

Skin
Single & Repeated
Moderate
Irritation or possible allergic response. Severe allergic response may result in breathing difficulties.
Not Applicable

Inhalation
Not Applicable

Ingestion
Not Applicable

Mucosa
Single
Mild
Inflammation of the mucosa
Not Applicable

Medical Conditions Aggravated by Exposure
Open sores and wounds of the skin. Individuals with known sensitivity to methacrylates, acrylics, or urethane dimethacrylate resin used in Dental restorative products.

Carcinogenicity
NTP?: Not listed
IARC monographs?: Not listed
OSHA regulated?: No All components of this product are in compliance with the inventory listing Requirements of the U. S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory.

Potential Environmental Effects
Do not allow to enter sewers/ surface or ground water.

NFPA Hazard Classification Ratings (Scale 0-4), Health = 1, Fire = 1, Reactivity = 0

Obtained by Global Safety Management www.globalsafetynet.com (877) 683-7460
12. Ecological Information

Toxicity Data, Environmental Fate, Physical/Chemical Data, or other Data Supporting Environmental Hazard Statements: Water Hazard class I (Self-assessment): slightly hazardous for water. Do not allow undiluted product or large quantities of it to reach ground water, water streams or sewage system.

13. Disposal Considerations

Regulations: Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Dispose of material as solid waste in a closed container. Dispose of in accordance with Federal, State and Local regulations
Properties (Physical/Chemical) Affecting Disposal: Dispose of material as solid waste in a closed container.

14. Transport Information

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15. Regulatory Information

This product has been classified in accordance with the hazard criteria of the Globally Harmonized System of Classification and Labeling of Chemicals and the SDS contains all of the information required by the Canadian Controlled Products Regulations.

U.S. Federal Regulations: CERCLA 103 Reportable Quantity: 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
Section 313 Toxic Chemicals: This product contains the following chemicals subject to Annual Release Reporting Requirements Under SARA Title III, Section 313 (40 CFR 372): None
Section 302 Extremely Hazardous Substances (TPQ): None
EPA Toxic Substances Control Act (TSCA) Status: All of the components of this product are listed on the TSCA inventory.
U.S. State Regulations California Proposition 65: This product does not contain any chemicals, which are on the California Proposition 65 list.
International Regulations: Canadian Environmental Protection Act: This product is a medical device and not subject to chemical notification requirements.
European Community Labeling: Not a dangerous preparation.
European Inventory of New and Existing Chemicals Substances (EINECS): This product is a medical device and not subject to chemical notification requirements.
Other: Not Applicable

16. Other Information

To the best of our knowledge this product does not contain gluten, wheat grains, flaxseed, natural rubber, or natural latex. All components are synthetically produced; none are derived from animal products.
This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific products features and shall not establish a legally valid contractual relationship.
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