1. Identification

Product Name: Esthet•X® HD

SDS Code Number: 530699

Substance Identity: Esthet•X® HD High Definition Micro Matrix Restorative

Date of Last Revision: 05/16/13

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)

Product Use (for Canada): Light Curing Composite/Dental Filling Material

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

2. Hazard(s) Identification

WARNING

CAUSES SKIN IRRITATION

Wash hands thoroughly after handling.

Wear protective gloves.

IF ON SKIN: Wash with plenty of soap and water.

If skin irritation occurs: Get Medical Advice/attention.

Take off contaminated clothing and wash before reuse.

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>Hydrophobic Amorphous Fumed Silica</td>
<td>68611-44-9</td>
<td>10 mg/m³</td>
<td>&lt; than 5</td>
</tr>
<tr>
<td>Silica (Amorphous)</td>
<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>
</tr>
<tr>
<td>Barium boron alumino silicate glass</td>
<td>65997-17-3</td>
<td>10 mg/m³</td>
<td>&lt; than 50</td>
</tr>
<tr>
<td>Urethane modified Bis-GMA dimethacrylate</td>
<td>126646-17-1</td>
<td>Not Established</td>
<td>&lt; than 10</td>
</tr>
<tr>
<td>Polymerizable dimethacrylate resins</td>
<td>24448-20-2/109-16-0</td>
<td>Not Established</td>
<td>&lt; than 20</td>
</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>
</thead>
<tbody>
<tr>
<td>Eye</td>
<td>Rinse opened eye 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>
<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>
<td>Not Applicable</td>
<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

| Flame Propagation or Burning Rate (for Solids) | Not Applicable |
| Properties Contributing to Fire Intensity      | Not Applicable |
| Flammability Classification: Not Applicable    | Other: Not Applicable |
| Extinguishing Media: CO₂, extinguishing powder, foam carbon dioxide or water spray. | 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

| Occupational Exposure Limits: Not Applicable |
| Engineer Controls: Not Applicable |
| Individual Protection Measures | Personal Protective Equipment for Normal Use | Personal Protective Equipment for Emergencies |
| 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.

Odor: Characteristic sweet acrylic ester odor.

Normal Physical State: Very High Viscosity Liquid (Paste)

Specific Gravity: 2.1 g/cm³

Solubility in Water: Not soluble

Melting Point: Not Applicable

pH: Not Applicable

Vapor Pressure (mm Hg): Not Applicable

Vapor Density (AIR=1): Not Applicable

Evaporation Rate (Butyl Acetate =1): Not Applicable

Flashpoint Method: Not Applicable

Flammable (Explosive) Limits in Air

LEL: Not Applicable

UEL: 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: 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) |
<table>
<thead>
<tr>
<th></th>
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<th></th>
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<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Eye</td>
<td>Material can cause irritation.</td>
<td>Single</td>
<td>Moderate</td>
<td>Irritation and possible corneal damage</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Skin</td>
<td>Material may be an irritant</td>
<td>Single &amp; Repeated</td>
<td>Moderate</td>
<td>Irritation or possible allergic response. Severe allergic response may result in breathing difficulties.</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Inhalation</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Ingestion</td>
<td>Material is not harmful if swallowed using clinically relevant quantities</td>
<td>Not Applicable</td>
<td>Mild</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Mucosa</td>
<td>Material can cause irritation.</td>
<td>Single</td>
<td>Mild</td>
<td>Inflammation of the mucosa</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

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 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
| Regulated for Shipping: No. Not Regulated | DOT Shipping Name: Not Regulated | Packing Group: Not Applicable |
| Do Changes in Quantities, packaging, or shipment method change product classification? No | DOT Hazard Class: Not Applicable | UN Number: Not Applicable |

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.