

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

071709187

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

071708908 071708916

**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).**

071707587 071707595 071707603 071707611 071707629 071707637 071707645 071707652 071707660 071707678  
071708221 071708239 071708247 071708254 071708262 071708270 071708288 071708296 071708304 071708312  
071708320 071708338 071708346 071708353 071708361 071708379 071708387 071708395 071708403 071708411  
071708429 071708437 071708445 071708452 071708460 071708478 071708486 071708494 071708502 071708510  
071708528 071708536 071708924 071708932 071708940 071708957 071708965 071708973 071708981 071708999  
071709005 071709013 071709021 071709153 071709161 071709179 071709195 071709203 071709211 071709229  
071709245 071709252 071709260 071709278 071709286 071709294 071709302 071709310 071709328 071709336  
071709344 071709351 071709369 071709377 071709534 071709542 071709559 071709567 071709575 071709583  
071709591 071709609 071709617 071709625 071709633 071709641 071709658 071709666 071709674 071709682  
071709690 071709708 071709716 071709724 071709732 071709740 071709757 071709765 071709773 071709781  
071709799 071709807 071709815 071709823 071709831 071709849



# DentsplySirona Safety Data Sheet

530699

## 1. Identification

|  |  |
|--|--|
| Product Name<br><b>Esthet•X® HD</b>  | SDS Code Number<br><b>530699</b>   |
| Substance Identity<br><b>Esthet•X® HD High Definition Micro Matrix Restorative</b> | Date of Last Revision<br><b>02/28/19</b>   |
| Manufacturer:<br>DENTSPLY Caulk  | Address<br>38 West Clarke Avenue<br>Milford DE 19963-1805<br><a href="http://www.dentsplysirona.com">http://www.dentsplysirona.com</a> |
| Grades or Minor Variant Identities<br>Not Applicable                               | Company Telephone Number (Product Inquiries)<br>(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)  |
| Product Use (for Canada)<br>Light Curing Composite/Dental Filling Material         | Emergency Telephone Number<br>CHEMTREC: 1-800-424-9300 (24 hours)<br>(Outside U.S. +1-703-527-3887) CCN6510                            |

## 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

| Hazardous Components                       | C.A.S. Number       | Exposure Limits      | %         |
|--|---------------------|----------------------|-----------|
| Hydrophobic Amorphous Fumed Silica         | 68611-44-9          | 10 mg/m <sup>3</sup> | < than 5  |
| Silica (Amorphous)                         | 67762-90-7          | 3 mg/m <sup>3</sup>  | < than 5  |
| Barium boron fluoro alumino silicate glass | 65997-18-4          | 10 mg/m <sup>3</sup> | < than 30 |
| Barium boron alumino silicate glass        | 65997-17-3          | 10 mg/m <sup>3</sup> | < than 50 |
| Urethane modified Bis-GMA dimethacrylate   | 126646-17-1         | Not Established      | < than 10 |
| Polymerizable dimethacrylate resins        | 24448-20-2/109-16-0 | Not Established      | < than 20 |

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

\* The titanium dioxide in this product is inextricably bound in a manner that no airborne exposure occurs during normal use and handling. Therefore, this product is not classified as a carcinogen.

## 4. First Aid Measures

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

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<br>Not Applicable | Flammability Classification: Not Applicable        | Other: Not Applicable |
| Extinguishing Media: CO <sub>2</sub> , 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.<br>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 |  |   |
|--|--|---|
| Engineering 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) |  | Melting Point: Not Applicable   |  |
| Specific Gravity: 2.1 g/cm <sup>3</sup>                   | Solubility in Water: Not soluble   | 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<br>LEL: Not Applicable UEL: Not Applicable | Autoignition Temperature: Not Applicable,<br>Product will not autoignite. |  |
| Other: Not Applicable                                     |  |   |  |

## 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: <input type="checkbox"/> May Occur <input checked="" type="checkbox"/> May Not Occur                       | Conditions to Avoid: None known |  |
| Stability? <input checked="" type="checkbox"/> Stable <input type="checkbox"/> Unstable  | Conditions to Avoid: None known |  |

## 11. Toxicological Information

| Toxicity Data, Epidemiology Studies, Carcinogenicity, Neurological Effects, Genetic Effects, Reproductive Effects, or Structure Activity Data:<br>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 class1 (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.

ACTIO MSDS ID: 956705

View Section : 12345678910111213141516

SECTION 1: CHEMICAL PRODUCT and COMPANY IDENTIFICATION 530699

Product Name: EsthetX HD

Synonyms: EsthetX« HD  
High Definition Micro Matrix Restorative  
CAS Number: Not Applicable  
Manufacturer MSDS.: 530699

Manufacturer Name: Dentsply/Caulk

Address: 38 West Clarke Avenue  
Milford DE 19963-1805

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

<http://www.caulk.com>

General Use: (For Canada): Light Curing Composite/Dental Filling Material

Business Phone: (302) 422-4511  
Hours Of Operation: (8:00 AM - 4:30 PM Eastern Time)  
Revision Date: 06/03/08  
Trade Names: EsthetX« HD  
High Definition Micro Matrix Restorative  
NFPA Hazard Classification Ratings (Scale 0-4)

DENTSPLY/International

Chemical Name: Dimethacrylate Resins

Grades or Minor Variant Identities:  
Compules« and EasyoTwist Syringe  
NFPA

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SECTION 2 : COMPOSITION, INFORMATION ON INGREDIENTS530699

Ingredient NameCAS#Ingredient Percent

Hydrophobic Amorphous Fumed Silica 68611-44-9< than 5%

Hazardous:Yes

EC Index Number:1

Other Exposure Guidelines:10 mg/m3

Silica (Amorphous) 67762-90-7< than 5%

Hazardous:Yes

EC Index Number:1

Other Exposure Guidelines:3 mg/m3

Barium boron fluoro alumino silicate glass 65997-18-4< than 30%

Hazardous:Yes

EC Index Number:1

Other Exposure Guidelines:10 mg/m3

Barium boron alumino silicate glass 65997-17-3< than 50%

Hazardous:Yes

EC Index Number:1

Other Exposure Guidelines:10 mg/m3

Urethane modified Bis-GMA dimethacrylate 126646-17-1< than 10%

Hazardous:Yes

EC Index Number:1

Other Exposure Guidelines:Not Established

Polymerizable dimethacrylate resins 109-16-0

Hazardous:Yes

EC Index Number:1

Polymerizable dimethacrylate resins 24448-20-2

Hazardous:Yes

EC Index Number:1

Composition/Information:Hazardous Components: Polymerizable dimethacrylate resins  
C.A.S. Number: 24448-20-2/109-16-0  
Exposure Limits: Not Established  
Total % : < than 20  
Other Information: Colorants are inorganic iron oxides and titanium dioxide.

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### SECTION 3 : HAZARDS IDENTIFICATION530699

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

Applies to All Ingredients :

Route of Exposure:Eye, Skin, Inhalation, Ingestion

Potential Health Effects:Acute:

Other: Not Applicable

Eye Contact:Acute: Irritation and possible corneal damage

Skin Contact:Acute: Irritation or possible allergic response. Severe allergic response may result in breathing difficulties.

Inhalation:Acute: Not Applicable

Ingestion:Acute: Not Applicable

Chronic Health Effects:Other: Not Applicable

Chronic Eye Contact:Irritation and possible corneal damage

Chronic Skin Contact:Irritation or possible allergic response.

Severe allergic response may result in breathing difficulties.

Chronic Inhalation:Not Applicable

Chronic Ingestion:Not Applicable

Carcinogenicity: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.

NTP Designation:Not listed

IARC Designation:Monographs: Not listed

Target Organs:Eye: Not Applicable

Skin: Not Applicable

Inhalation: Not Applicable

Ingestion: Not Applicable

Other: Not Applicable

Signs/Symptoms:Eye: Material can cause irritation.

Skin: Material may be an irritant

Inhalation: Not Applicable

Ingestion: Material is probably not harmful if swallowed

Other: Not Applicable

Aggravation of Pre-Existing Conditions:Open sores and wounds of the

skin. Individuals with known sensitivity to methacrylates, acrylates, or urethane dimethacrylate resin used in Dental restorative products.

Single, Repeated, or Lifetime Exposure:

Eye: Single

Skin: Single & Repeated

Inhalation: Not Applicable

Ingestion: Not Applicable

Other: Not Applicable

Severity (Mild, Moderate, Severe):

Eye: Moderate

Skin: Moderate

Inhalation: Not Applicable

Ingestion: Not Applicable

Other: Not Applicable

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

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#### SECTION 4 : FIRST AID MEASURES530699

Eye Contact:First Aid Instructions: Rinse opened eye for several minutes under running water. If symptoms persist consult physician

Immediate Medical Attention: Not Applicable

Delayed Effects: Not Applicable

Skin Contact:First Aid Instructions: Immediately wash with soap and water and rinse thoroughly

Immediate Medical Attention: Not Applicable

Delayed Effects: Not Applicable

Inhalation:First Aid Instructions: Supply fresh air, consult physician if symptoms persist

Immediate Medical Attention: Not Applicable

Delayed Effects: Not Applicable

Ingestion:First Aid Instructions: If symptoms persist consult physician

Immediate Medical Attention: Not Applicable

Delayed Effects: Not Applicable

Note to Physicians:(Treating, Testing and Monitoring): Not Applicable

Other First Aid:First Aid Instructions: Not Applicable

Immediate Medical Attention: Not Applicable

Delayed Effects: Not Applicable

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#### SECTION 5 : FIRE FIGHTING MEASURES530699

Flash Point Method:Not Applicable



Upper Flammable or Explosive Limit:In Air: Not Applicable  
Lower Flammable or Explosive Limit:In Air: Not Applicable  
Auto Ignition Temperature:Not Applicable Product will not autoignite.  
Flammability Class:Not Applicable  
Extinguishing Media:CO2, extinguishing powder, foam carbon dioxide or water spray. Fight larger fires with water spray or alcohol resistant foam.  
Unsuitable Media:Water with full jet.  
Flame Propagation in Air:Flame Propagation or Burning Rate (for Solids): Not Applicable  
Fire Fighting Instructions:For Firefighters: Firefighters should wear self-contained respiratory protective devices.  
Unusual Fire Hazards:Formation of toxic, irritating gases is possible from the decomposition of the dimethacrylate resins. Product does not present an explosion hazard.  
Other: Not Applicable

Properties Contributing to Fire Intensity: Not Applicable

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#### SECTION 6 : ACCIDENTAL RELEASE MEASURES530699

Spill Cleanup 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

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#### SECTION 7 : HANDLING and STORAGE530699

Handling: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: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.

Hygiene Practices:Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing. Wash hands before breaks and at end of work. Avoid contact with the eyes and skin.

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SECTION 8 : EXPOSURE CONTROLS, PERSONAL PROTECTION530699

Ventilation System:None required during normal intended use of this product  
Skin Protection Description:The glove material has to be impermeable and resistant to the product.  
Eye/Face Protection:Safety Glasses  
Protective Clothing/Body Protection:Body Protection:  
Protective work clothing  
Respiratory Protection:Inhalation: Not Required  
Other Protective:Equipment: Not Applicable  
Emergency Skin Protection:Not Applicable  
Emergency Eye/Face Protection:Not Applicable  
Emergency Clothing/Body Protection:Body Protection: Not Applicable  
Emergency Respiratory Protection:Inhalation: Not Applicable  
General Hygiene Considerations and Work Practices: Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing. Wash hands before breaks and at end of work. Avoid contact with the eyes and skin.

Protective Measures During Repair and Maintenance of Contaminated Equipment: Not Applicable

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SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES530699

Physical State/Appearance:Various shades of viscous paste.  
Odor:Characteristic sweet acrylic ester odor.  
Physical State:Normal Physical State: Very High Viscosity Liquid (Paste)  
pH:Not Applicable  
Vapor Pressure:(mm Hg): Not Applicable  
Vapor Density:(AIR = 1): Not Applicable  
Melting Point:Not Applicable  
Solubility:In Water: Not soluble  
Specific Gravity:2.1 g/cm<sup>3</sup>  
Evaporation Point:(Butyl Acetate = 1): Not Applicable  
Other:Not Applicable

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SECTION 10 : STABILITY and REACTIVITY530699

Chemical Stability:Stable.  
Conditions to Avoid:None known.  
Incompatibilities with Other Materials:(Materials to Avoid) Strong Oxidizing materials.  
Hazardous Polymerization:May Not Occur  
Conditions to Avoid: None known

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

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SECTION 11 : TOXICOLOGICAL INFORMATION530699

Toxicological Paragraph: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.

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SECTION 12 : ECOLOGICAL INFORMATION530699

Ecological Paragraph:Toxicity Data, Environmental Fate, Physical/Chemical Data, or other Data Supporting Environmental Hazard Statements: Water Hazard class1 (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.

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SECTION 13 : DISPOSAL CONSIDERATIONS530699

Waste Disposal: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.

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SECTION 14 : TRANSPORT INFORMATION530699

DOT Shipping Information:Regulated for Shipping: No. Not Regulated

Do Changes in Quantities, packaging, or shipment method change product classification: No

Other: Not Applicable

DOT Shipping Name:Regul d for Shipping: No. Not Regulated

DOT UN Number:Not Applicable

DOT Hazard Class:Not Applicable

DOT Packing Group:Not Applicable

DOT Subpart E Labeling Requirement:(49CFR172.101): Not Applicable

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## SECTION 15 : REGULATORY INFORMATION530699

Applies to all ingredients:

TSCA 8(b): Inventory Status:EPA Toxic Substances Control Act (TSCA) Status: All of the components of this product are listed on the TSCA inventory.

CERCLA Section 103: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 302 Extremely Hazardous Substances (TPQ):None

Section 313 Toxic Release Form: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

State:U.S. State Regulations California Proposition 65: This product does not contain any chemicals, which are on the California Proposition 65 list.

Canada WHMIS:International Regulations: Canadian Environmental Protection Act:

This product is a medical device and not subject to chemical notification requirements.

European Community Chemical Inventory Status: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

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## SECTION 16 : ADDITIONAL INFORMATION530699

NFPA:

Health:1

Fire Hazard:1

Reactivity:0

MSDS Revision Date:06/03/08

Disclaimer:

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.

NFPA Hazard Classification Ratings (Scale 0-4)

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