SAFETY DATA SHEETS

This SDS packet was issued with item:

071709831

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 0717078221 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 071709187 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 071709708 071709708 071709716 071709724 071709732 071709740 071709757 071709765 071709773 071709781 071709799 071709807 071709815 071709823 071709849

Printing date 02.04.2015 Version number 3 Revision: 02.04.2015

SECTION 1: Identification of the substance/mixture and of the company/undertaking

· 1.1 Product identifier

· Trade name: Esthet.X HD

· Application: Light curing composite

- · 1.2 Relevant identified uses of the substance or mixture and uses advised against
- · Application of the substance / the mixture Dental filling material
- · Uses advised against No further relevant information available.
- · 1.3 Details of the supplier of the safety data sheet
- $\cdot \textit{Manufacturer/Supplier:}$

DENTSPLY DeTrey GmbH

De-Trey-Str. 1 D-78467 Konstanz

GERMANY

Tel.: +49-(0)7531-583-0 *Fax*: +49-(0)7531-583-104

email: KonstanzDEU.info-sdb@dentsply.com

- · Further information obtainable from:
- Departement Analytical Research / Research & Development for technical information
- Departement Marketing & Sales for distribution of the safety data sheets
- 1.4 Emergency telephone number: +49-(0)7531-583-0 8:00 17:00 (GMT + 1:00)

SECTION 2: Hazards identification

- · 2.1 Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

Skin Sens. 1 H317 May cause an allergic skin reaction.

- · 2.2 Label elements
- · Labelling according to Regulation (EC) No 1272/2008

As this product is a medical device in the meaning of Directive 93/42/EEC and intended for use by the end consumer and is applied in an invasive manner or body contact, it is exempt from the labelling requirements according to regulation 1272/2008.

The product is classified and labelled according to the CLP regulation.

· Hazard pictograms



- · Signal word Warning
- · Hazard-determining components of labelling:

Ethoxylated Bisphenol A Dimethacrylate 2,2'-Ethylendioxydiethyldimethacrylat

· Hazard statements

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

· Precautionary statements

Avoid breathing dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

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Trade name: Esthet.X HD

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P337+P313 If eye irritation persists: Get medical advice/attention.

P501 Dispose of contents/container in accordance with local/regional/national/international

regulations.

· 2.3 Other hazards

· Results of PBT and vPvB assessment

· **PBT**: Not applicable. · **vPvB**: Not applicable.

SECTION 3: Composition/information on ingredients

- · 3.2 Chemical characterisation: Mixtures
- · Description: Mixture of substances listed below with nonhazardous additions.

· Dangerous compone	ents:	
CAS: 126646-17-1	Urethane modified Bis-GMA dimethacrylate resin	3-<10%
	♦ Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	
CAS: 24448-20-2	Ethoxylated Bisphenol A Dimethacrylate	3-<10%
	♦ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	
CAS: 109-16-0	2,2'-Ethylendioxydiethyldimethacrylat	3-<10%
EINECS: 203-652-6	♦ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	

[·] Additional information For the wording of the listed risk phrases refer to section 16.

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- · After inhalation Supply fresh air; consult doctor in case of complaints.
- · After skin contact Immediately wash with water and soap and rinse thoroughly.
- · After eye contact

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

- · After swallowing If symptoms persist consult doctor.
- 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- · Information for doctor No further relevant information available.
- 4.3 Indication of any immediate medical attention and special treatment needed No further relevant information available.

SECTION 5: Firefighting measures

- · 5.1 Extinguishing media
- · Suitable extinguishing agents

CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

- · For safety reasons unsuitable extinguishing agents Water with full jet.
- 5.2 Special hazards arising from the substance or mixture No further relevant information available.
- · 5.3 Advice for firefighters
- · Protective equipment: No special measures required.

SECTION 6: Accidental release measures

- · 6.1 Personal precautions, protective equipment and emergency procedures Wear protective clothing.
- 6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- · 6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Ensure adequate ventilation.

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· 6.4 Reference to other sections

See Section 7 for information on safe handling

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

Observe normal care for working with chemicals.

- · Handling Product is intended for dental use only.
- · Information about fire and explosion protection: No special measures required.
- · 7.2 Conditions for safe storage, including any incompatibilities
- ·Storage
- Requirements to be met by storerooms and receptacles: Store only in the original receptacle.
- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions: Keep receptacle tightly sealed.
- · 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

- · Additional information about design of technical facilities: No further data; see item 7.
- · 8.1 Control parameters
- · Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

- · Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- · Personal protective equipment
- · General protective and hygienic measures

Keep away from foodstuffs, beverages and feed.

The usual precautionary measures are to be adhered to when handling chemicals.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

- · Respiratory protection: Not necessary if room is well-ventilated.
- · Protection of hands:



Protective gloves.

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· Material of gloves

Natural rubber, NR

Recommended thickness of the material: ≥ 0.12 mm

Permeation: Level ≥ 1

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

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· Penetration time of glove material

The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye protection:



Tightly sealed goggles.

· Body protection: Protective work clothing.

9.1 Information on basic physical of	and chemical properties
General Information Appearance:	
Form:	Pasty
Colour:	According to product specification
Odour:	Product specific
Odour threshold:	Not determined.
pH-value:	Not determined.
Change in condition	
Melting point/Melting range:	undetermined
Boiling point/Boiling range:	Undetermined.
Flash point:	Not applicable
Flammability (solid, gaseous)	Not applicable.
Ignition temperature:	Not applicable
Decomposition temperature:	Not determined.
Self-igniting:	Product is not selfigniting.
Danger of explosion:	Product does not present an explosion hazard.
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
Vapour pressure:	Not determined.
Density at 20 °C:	2.1 g/cm^3
Relative density	Not determined.
Vapour density	Not determined.
Evaporation rate	Not determined.
Solubility in / Miscibility with	
Water:	Not miscible or difficult to mix
Partition coefficient (n-octanol/wat	ter): Not determined.
Viscosity:	
dynamic:	Not determined.
kinematic:	Not determined.
Solvent content: Organic solvents:	

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· 9.2 Other information

No further relevant information available.

SECTION 10: Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- · 10.2 Chemical stability
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · 10.3 Possibility of hazardous reactions No dangerous reactions known
- · 10.4 Conditions to avoid No further relevant information available.
- · 10.5 Incompatible materials: No further relevant information available.
- · 10.6 Hazardous decomposition products: No dangerous decomposition products known

SECTION 11: Toxicological information

- · 11.1 Information on toxicological effects
- · Acute toxicity:
- · LD/LC50 values relevant for classification:

109-16-0 2,2'-Ethylendioxydiethyldimethacrylat

 Oral
 LD50
 >5000 mg/kg (rat)

 Dermal
 LD50
 >2000 mg/kg (mouse)

- · Primary irritant effect:
- · on the skin:

Irritant to skin and mucous membranes.

The unpolymerized product may be irritant to the skin for succeptible persons.

- on the eye: Strong irritant with the danger of severe eye injury.
- · Sensitisation:

Sensitisation possible through skin contact.

Repeated or prolonged contact with the not polymerized product may cause sensitization for acrylates / methacrylates.

· Additional toxicological information:

The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.

Irritant

SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity:

109-16-0 2,2'-Ethylendioxydiethyldimethacrylat

LC50/96h 16.4 mg/l (Fish acute toxicity study)

- · 12.2 Persistence and degradability No further relevant information available.
- · 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes:

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

- · 12.5 Results of PBT and vPvB assessment
- · **PBT**: Not applicable.
- · vPvB: Not applicable.

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· 12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation



Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· European waste catalogue

18 01 06* chemicals consisting of or containing dangerous substances

- · Uncleaned packaging:
- · Recommendation: Disposal must be made according to official regulations.

· 14.1 UN-Number		
· ADR, ADN, IMDG, IATA	Void	
· 14.2 UN proper shipping name · ADR, ADN, IMDG, IATA	Void	
· 14.3 Transport hazard class(es)		
· ADR, ADN, IMDG, IATA		
· Class	Void	
· 14.4 Packing group		
· ADR, IMDG, IATA	Void	
14.5 Environmental hazards:		
Marine pollutant:	No	
· 14.6 Special precautions for user	Not applicable.	
14.7 Transport in bulk according to Anne	ex II of	
MARPOL73/78 and the IBC Code	Not applicable.	

SECTION 15: Regulatory information

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture No further relevant information available.
- · 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product 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.

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Trade name: Esthet, X HD

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· Relevant phrases

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

$\cdot \textbf{\textit{Department issuing MSDS:}} \ Analytical \ Research$

· Contact: HotLine for urgent technical support: +49-7531-583-350

· Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

* * Data compared to the previous version altered.

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ACTIO MSDS ID: 956705

View Section: 12345678910111213141516

SECTION 1: CHEMICAL PRODUCT and COMPANY IDENTIFICATION 530699

Product Name: EsthetòX HD

Synonyms: EsthetòX« 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 û 4:30 PM Eastern Time)

Revision Date:06/03/08 Trade Names:EsthetòX« 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</pre>

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.

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/cm3
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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