SAFETY DATA SHEETS

This SDS packet was issued with item:

071707157

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

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1. Identification

Product Name	SDS Code Number
Comspan [®] and Comspan [®] Opaque	555899
Substance Identity	Date of Last Revision
Comspan [®] and Comspan [®] Opaque	06/04/10
Composite Luting Cement - Radiopaque	
Manufacturer:	Address
DENTSPLY Caulk	38 West Clarke Avenue
	Milford DE 19963-1805
	http://www.caulk.com http://www.dentsply.com
Grades or Minor Variant Identities	Information Telephone Number
Not Applicable	(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)
Product Use (for Canada)	Emergency Telephone Number
Self-Curing Dental Luting Cement	(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)

2. Hazard(s) Identification



WARNING
MAY CAUSE AN ALLERGIC SKIN REACTION

Wash hands thoroughly after handling. Wear protective gloves.

3. Composition/Information on Ingredients

	<u> </u>		
Hazardous Components	C.A.S. Number	Exposure Limits	%
Barium boron alumino silicate glass	65997-17-3	10 mg/m^3	< than 70
Bis-GMA	1565-94-2	Not Established	< than 35
Polymerizable dimethacrylate resins	24448-20-2/109-16-0	Not Established	< than 20
Hydrophobic Amorphous Silica	68611-44-9	3 mg/m^3	< than 5
Titanium Dioxide	13463-67-7	10 mg/m^3	< than 5

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

3. Composition/Information on Ingredients – Catalyst Paste

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Hazardous Components	C.A.S. Number	Exposure Limits	%
Barium boron alumino silicate glass	65997-17-3	10 mg/m ³	< than 70
Bis-GMA	1565-94-2	Not Established	< than 35
Polymerizable dimethacrylate resins	24448-20-2/109-16-0	Not Established	< than 20
Hydrophobic Amorphous Silica	68611-44-9	3 mg/m^3	< than 5
Benzoyl peroxide	94-36-0	5 mg/m ³	< than 5
Aluminum Oxide	1344-28-1	10 mg/m^3	< than 5

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.	Not Applicable	Not Applicable
	If symptoms persist consult physician		
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.	Not Applicable	Not Applicable
If symptoms persist consult physician			
Note to Physicians (Treating, Testing and Monitoring): Treat symptomatically.			

5. Fire Fighting Measures

Flame Propagation or Burning Rate	Properties Contributing to Fire Intensity	Flammability Classification: Not Applicable	Other: Not Applicable	
	1 0	Tianimaonity Classification. 140t Applicable	Other. Not ripplicable	
(for Solids) Not Applicable	Not Applicable			
Extinguishing Media: CO ₂ , extinguishing powder, foam carbon dioxide or water		Extinguishing Media to Avoid: Water with full je	et.	
spray. Fight larger fires with water sp	ray or alcohol resistant foam.			
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			
Engineering Controls: Not Applicable			
Individual Protection	Personal Protective Equipment for Normal Use	Personal Protective Equipment	
Measures	• •	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

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Appearance: Base is creamy viscous paste. Multiple shades. Catalyst is off white paste.		Odor: Characteristic sweet acrylic ester odor.
Normal Physical State: High Viscosity Liquid (Paste)		Melting Point: Not Applicable
Specific Gravity: 1.9 g/cm ³	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	Autoignition Temperature: Not Applicable,
	LEL: Not Applicable UEL: Not Applicable	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 danger	ous 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 Ov	erview Material is irritating to	eyes, respiratory system	and skin.		
Routes of		Single, Repeated, or	Severity (Mild,	Acute and Chronic Health Effect(s)	Target Organ(s)
Exposure	Signs and Symptoms	Lifetime Exposure	Moderate, Severe)		
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 probably not harmful if swallowed	Not Applicable	Mild	Not Applicable	Not Applicable
Mucosa	Not Applicable	Not Applicable	Not Applicable	Not Applicable	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	DOT Hazard Class: Not Applicable	UN Number: Not Applicable
method change product classification? No		

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: <u>CERCLA 103 Reportable Quantity</u>: 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.

DENTSPLY/International DENTSPLY/Caulk Safety Data Sheet

555899

1. Identification

Product Name	SDS Code Number
Comspan [®] and Comspan [®] Opaque	555899
Substance Identity	Date of Last Revision
Comspan [®] and Comspan [®] Opaque	05/16/13
Composite Luting Cement - Radiopaque	
Manufacturer:	Address
DENTSPLY Caulk	38 West Clarke Avenue
	Milford DE 19963-1805
	http://www.caulk.com http://www.dentsply.com
Grades or Minor Variant Identities	Information Telephone Number
Not Applicable	(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)
Product Use (for Canada)	Emergency Telephone Number
Self-Curing Dental Luting Cement	(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)

2. Hazard(s) Identification



CAUSES SKIN IRRITATION

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	%
Barium boron alumino silicate glass	65997-17-3	10 mg/m ³	< than 70
Bis-GMA	1565-94-2	Not Established	< than 35
Polymerizable dimethacrylate resins	24448-20-2/109-16-0	Not Established	< than 20
Hydrophobic Amorphous Silica	68611-44-9	3 mg/m^3	< than 5
Titanium Dioxide	13463-67-7	10 mg/m^3	< than 5

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

3. Composition/Information on Ingredients - Catalyst Paste

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C.A.S. Number	Exposure Limits	%			
65997-17-3	10 mg/m^3	< than 70			
1565-94-2	Not Established	< than 35			
24448-20-2/109-16-0	Not Established	< than 20			
68611-44-9	3 mg/m^3	< than 5			
94-36-0	5 mg/m ³	< than 5			
1344-28-1	10 mg/m^3	< than 5			
	C.A.S. Number 65997-17-3 1565-94-2 24448-20-2/109-16-0 68611-44-9 94-36-0	C.A.S. Number Exposure Limits 65997-17-3 10 mg/m³ 1565-94-2 Not Established 24448-20-2/109-16-0 Not Established 68611-44-9 3 mg/m³ 94-36-0 5 mg/m³			

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.	Not Applicable	Not Applicable
	If symptoms persist consult physician		
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.	Not Applicable	Not Applicable
	If symptoms persist consult physician		·

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

5. Fire Fighting Measures

Flame Propagation or Burning Rate	Properties Contributing to Fire Intensity	Flammability Classification: Not Applicable	Other: Not Applicable	
(for Solids) Not Applicable	Not Applicable			
Extinguishing Media: CO ₂ , extinguishing powder, foam carbon dioxide or water Extinguishing Media to Avoid: Water with full jet.				
spray. Fight larger fires with water spray or alcohol resistant foam.				
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						
Engineering Controls: N	Engineering Controls: Not Applicable					
Individual Protection	Personal Protective Equipment for Normal Use	Personal Protective Equipment				
Measures	1 1	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: Base is creamy viscous paste. Multiple shades. Catalyst is off white paste.		Odor: Characteristic sweet acrylic ester odor.
Normal Physical State: High Viscosity Liquid (Paste)		Melting Point: Not Applicable
Specific Gravity: 1.9 g/cm ³ 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	Autoignition Temperature: Not Applicable,
	LEL: Not Applicable UEL: Not Applicable	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: ☐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

Emergency Ove	Emergency Overview ivraterial is inflating to eyes, respiratory system and skin.				
Routes of		Single, Repeated, or	Severity (Mild,	Acute and Chronic Health Effect(s)	Target Organ(s)
Exposure	Signs and Symptoms	Lifetime Exposure	Moderate, Severe)		
Eye	Material can cause	Single	Moderate	Irritation and possible corneal damage	Not Applicable
	irritation.				
Skin	Material may be an	Single & Repeated	Moderate	Irritation or possible allergic response.	Not Applicable
	irritant			Severe allergic response may result in	
				breathing difficulties.	
Inhalation	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable

Ingestion	Material is probably not	Not Applicable	Mild	Not Applicable	Not Applicable
	harmful if swallowed				
Mucosa	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable
Medical Condi	tions Aggravated by Exposure	Open sores and wounds	of the skin. Individuals	with known sensitivity to methacrylates, acr	rylates, or urethane
dimethacrylate	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 (Selfassessment): 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	DOT Hazard Class: Not Applicable	UN Number: Not Applicable
method change product classification? No		

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.

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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.