SAFETY DATA SHEETS

This SDS packet was issued with item: 071810290

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

071719376 071810308 078306250

DENTSPLY/International DENTSPLY/Caulk Safety Data Sheet

531898

1. Identification				
Product Name	SDS Code Number			
PRISMA [®] GLOSS [™] & PRISMA [®] GLOSS [™] ExtraFine	531898			
Substance Identity	Date of Last Revision			
PRISMA [®] GLOSS [™] & PRISMA [®] GLOSS [™] ExtraFine	04/15/11			
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			
Not Applicable	(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)			

2. Hazard(s) Identification



Warning Causes serious eye irritation Wash hands thoroughly after handling Wear protective gloves, face protection. If in eyes: Rinse cautiously with water for several minutes. Remove contact lens, if present and easy to do. Continue rinsing. Do not rub affected areas. If eye irritation persists: Get medical advice attention.

3. Composition/Information on Ingredients

Hazardous Components	C.A.S. Number	Exposure Limits	%	
Aluminum Oxide	1344-28-1	10 mg/M^3	< 65	
Glycerine	56-81-5	10 mg/M^3	< 50	
Hydrophobic Amorphous Fumed Silica	68611-44-9	3 mg/M^3	< 5	

3. Hazard Identification

			a facilitation		
Emergenc	y Overview: Material may be i	rritating to eyes. No	significant hazards f	for emergency responses are kn	nown.
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 may cause slight transient (temporary) irritation.	Single & Repeated	Moderate	Irritation and possible corneal damage due to the fillers used in the product.	Not Applicable
Skin	Material may be an irritant after repeated and prolonged exposure.	Repeated	Mild	Irritation or possible allergic response.	Not Applicable
Inhalation	Vapors are minimal due to physical properties.	Not Applicable	Not Applicable	Not Applicable	Not Applicable
Ingestion	Material is probably not harmful if swallowed	Not Applicable	Mild	Not Applicable	Not Applicable
Other	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable
Medical Con	ditions Aggravated by Exposure Oper	n sores and wounds of the	skin.		
Carcinogenic compliance	vity NTP?: Not listed with the inventory listing Requirement	IARC monographs?: 1 s of the U. S. Toxic Subs		lated?: No All components of this pro	duct are in
	vironmental Effects Do not allow to er			/	
NFPA Hazar	d Classification Ratings (Scale 0-4), H	Health = 1, Fire = 0, Reac	tivity = 0		

4. First Aid Measures

Routes of	First Aid Instructions	Immediate Medical	Delayed Effects
Exposure		Attention	
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	Supply fresh air, consult physician if symptoms persist.	Not Applicable	Not Applicable	
Ingestion	If symptoms persist consult physician. Do not induce vomiting unless	Not Applicable	Not Applicable	
instructed to do so by medical personnel.				
Other	Not Applicable	Not Applicable	Not Applicable	
Note to Physicians (Treating, Testing and Monitoring): Treat symptomatically.				

5. Fire and Explosion Data

Flashpoint Method: 390°F (199°C) for	Flammable (Explosive) Limits in Air	Autoignition Temperature:	Other: Not			
Glycerine. Pensky-Martin Closed Cup	LEL: Not Applicable UEL: Not Applicable	698°F (370°C)	Applicable			
Flame Propagation or Burning Rate (for	Properties Contributing to Fire Intensity: Not	Flammability Classification:				
Solids) Not Applicable	Applicable	Not Applicable				
Extinguishing Media: CO2, Water fog or fine spr	Extinguishing Media to Avoid: W	/ater with full				
Type).	jet.					
Protection and Procedures for Firefighters: Firefighters should wear self-contained respiratory protective devices.						
Unusual Fire and Explosion Hazards: During a fire, smoke may contain glycerine in addition to unidentified toxic and/or irritating compounds. Hazardous						
combustion products may include but not limited	combustion products may include but not limited to aldehydes, carbon monoxide and carbon dioxide.					

6. Accidental Release Measures

Conta	Containment Techniques: Material is a high viscosity paste, but will flow somewhat.				
Spill/I	Spill/Leak Clean-up Procedures and Equipment: Wear protective clothing and scoop up bulk material and place in a labeled plastic or metal container.				
Evacu	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. Store away from food and beverages. Glycerine freezes at 64°F (18°C). Product should be kept above 64°F (18°C) but less than 130°F (54°C).

8. Exposure Control / Personal Protection



Individual Protection	Personal Protective Equipment for Normal Use	Personal Protective Equipment for
Measures		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
Occupational Exposure Limi	ts: Not Applicable	Engineering Controls: Not Applicable

9. Physical and Chemical Characteristics

Appearance: Creamy viscous white paste.		Odor: Mild odor.
Normal Physical State: High Viscosity Liquid (Paste)		Melting Point: Not Applicable
Specific Gravity: 1.7 g/cm ³	Solubility in Water: Partially soluble.	pH: Not Applicable
Vapor Pressure (mm Hg): Not Applicable	Vapor Density (AIR=1): Not Applicable	Evaporation Rate (Butyl Acetate =1): N A
Flashpoint Method: Not Applicable	Flammable (Explosive) Limits in Air	Autoignition Temperature: Not Applicable
	LEL: Not Applicable UEL: Not Applicable	
Other: Not Applicable		

10. Stability and Reactivity Data

Incompatibility (Materials to Avoid): Strong Oxidizing materials such as Sodium Hypochlorite or Hypochlorous Acid			
Hazardous Products Produced During Decomposition: Acrolein.			
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,	Toxicity Data, Epidemiology Studies, Carcinogenicity, Neurological Effects, Genetic Effects, Reproductive Effects, or Structure Activity Data:					
For ingestion, t	he LD ₅₀ for glycerine in Rats is 17,000	0 – 27,000 mg/Kg.				
Emergency Ov	erview: Material may be mildly irritat	ting to eyes.				
Routes of	f Single, Repeated, or Severity (Mild, Moderate, Acute and Chronic Health					
Exposure	xposure Signs and Symptoms Lifetime Exposure Severe) Effect(s) Target Organ(s)					
Eye	Eye Material may cause slight Single & Repeated Moderate Irritation and possible corneal Not Applicable					
-	transient (temporary) irritation. damage due to the fillers used in					
				the product.		

Skin	Material may be an irritant after	Repeated	Mild	Irritation or possible allergic	Not Applicable	
	repeated and prolonged exposure.			response.		
Inhalation	Vapors are minimal due to physical properties.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	
Ingestion	Material is probably not harmful if swallowed	Not Applicable	Mild	Not Applicable	Not Applicable	
Other	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	
Medical Condit	tions Aggravated by Exposure Open so	ores and wounds of the s	skin.			
Carcinogenicity		IARC monographs?: N		ted?: No All components of this prod	uct are in	
	compliance with the inventory listing Requirements of the U.S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory.					
Potential Envir	Potential Environmental Effects: Potential Environmental Effects Do not allow to enter sewers/ surface or ground water.					
NFPA Hazard	Classification Ratings (Scale 0-4), Hea	lth = 0, Fire = 1, Reacti	vity = 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. 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

<u>Section 313 Toxic Chemicals:</u> 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>U.S. State Regulations California Proposition 65:</u> 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 Milford Safety Data Sheet

1. Identification

Product Name	SDS Code Number
PRISMA [®] GLOSS [™] & PRISMA [®] GLOSS [™] ExtraFine	531898
Substance Identity	Date of Last Revision
PRISMA [®] GLOSS [™] & PRISMA [®] GLOSS [™] ExtraFine	02/02/17
Manufacturer:	Address
DENTSPLY Milford	38 West Clarke Avenue
	Milford DE 19963-1805
	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
Not Applicable	(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)

2. Hazard(s) Identification



Warning Causes serious eye irritation Wash hands thoroughly after handling Wear protective gloves, face protection. If in eyes: Rinse cautiously with water for several minutes. Remove contact lens, if present and easy to do. Continue rinsing. Do not rub affected areas. If eye irritation persists: Get medical advice attention.

3. Composition/Information on Ingredients

Hazardous Components	C.A.S. Number	Exposure Limits	%
Aluminum Oxide	1344-28-1	10 mg/M ³	< 65
Glycerine	56-81-5	10 mg/M ³	< 50
Hydrophobic Amorphous Fumed Silica	68611-44-9	3 mg/M ³	< 5

3. Hazard Identification

Emergenc	Emergency Overview: Material may be irritating to eyes. No significant hazards for emergency responses are known.					
Routes of		Single, Repeated, or	Severity (Mild,	Acute and Chronic Health		
Exposure	Signs and Symptoms	Lifetime Exposure	Moderate, Severe)	Effect(s)	Target Organ(s)	
Eye	Material may cause slight transient (temporary) irritation.	Single & Repeated	Moderate	Irritation and possible corneal damage due to the fillers used in the product.	Not Applicable	
Skin	Material may be an irritant after repeated and prolonged exposure.	Repeated	Mild	Irritation or possible allergic response.	Not Applicable	
Inhalation	Vapors are minimal due to physical properties.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	
Ingestion	Material is probably not harmful if swallowed	Not Applicable	Mild	Not Applicable	Not Applicable	
Other	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	
Medical Con	Medical Conditions Aggravated by Exposure Open sores and wounds of the skin.					
Carcinogenic	Carcinogenicity NTP?: Not listed IARC monographs?: Not listed OSHA regulated?: No All components of this product are in					
compliance v	compliance with the inventory listing Requirements of the U. S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory.					
Potential Env	Potential Environmental Effects Do not allow to enter sewers/ surface or ground water.					
NFPA Hazar	NFPA Hazard Classification Ratings (Scale 0-4), Health = 1, Fire = 0, Reactivity = 0					

4. First Aid Measures

Routes of	First Aid Instructions	Immediate Medical	Delayed Effects
Exposure		Attention	
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	nhalation Supply fresh air, consult physician if symptoms persist.		Not Applicable	
Ingestion	If symptoms persist consult physician. Do not induce vomiting unless	Not Applicable	Not Applicable	
	instructed to do so by medical personnel.			
Other Not Applicable		Not Applicable	Not Applicable	
Note to Physicians (Treating, Testing and Monitoring): Treat symptomatically.				

5. Fire and Explosion Data

Flashpoint Method: 390°F (199°C) for	Flammable (Explosive) Limits in Air	Autoignition Temperature:	Other: Not		
Glycerine. Pensky-Martin Closed Cup	LEL: Not Applicable UEL: Not Applicable	698°F (370°C)	Applicable		
Flame Propagation or Burning Rate (for	Properties Contributing to Fire Intensity: Not	Flammability Classification:			
Solids) Not Applicable	Applicable	Not Applicable			
Extinguishing Media: CO ₂ , Water fog or fine spray, foam, carbon dioxide or alcohol resistant foams (ATC Extinguishing Media to Avoid: Water with full					
Type).	jet.				
Protection and Procedures for Firefighters: Firefighters should wear self-contained respiratory protective devices.					
Unusual Fire and Explosion Hazards: During a fire, smoke may contain glycerine in addition to unidentified toxic and/or irritating compounds. Hazardous					
combustion products may include but not limited to aldehydes, carbon monoxide and carbon dioxide.					

6. Accidental Release Measures

Containment Techniques: Material is a high viscosity paste, but will flow somewhat.				
Spill/Leak Clean-up Procedures and Equipment: Wear protective clothing and scoop up bulk material and place in a labeled plastic or metal container.				
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. Store away from food and beverages. Glycerine freezes at 64°F (18°C). Product should be kept above 64°F (18°C) but less than 130°F (54°C).

8. Exposure Control / Personal Protection



Individual Protection Personal Protective Equipment for Normal Use		Personal Protective Equipment for
Measures		Emergencies
Eye/Face	Eye/Face Safety Glasses	
Skin	The glove material has to be impermeable and resistant to the product.	Not Applicable
Inhalation	Inhalation Not Required	
Body Protection Protective work clothing		Not Applicable
Occupational Exposure Limits: Not Applicable		Engineering Controls: Not Applicable

9. Physical and Chemical Characteristics

Appearance: Creamy viscous white paste.	Odor: Mild odor.	
Normal Physical State: High Viscosity Liquid (Paste)	Melting Point: Not Applicable	
Specific Gravity: 1.7 g/cm ³	Solubility in Water: Partially soluble.	pH: Not Applicable
Vapor Pressure (mm Hg): Not Applicable	Vapor Density (AIR=1): Not Applicable	Evaporation Rate (Butyl Acetate =1): N A
Flashpoint Method: Not Applicable	Flammable (Explosive) Limits in Air	Autoignition Temperature: Not Applicable
	LEL: Not Applicable UEL: Not Applicable	
Other: Not Applicable		

10. Stability and Reactivity Data

	Incompatibility (Materials to Avoid): Strong Oxidizing materials such as Sodium Hypochlorite or Hypochlorous Acid		
Hazardous Products Produced During Decomposition: Acrolein.			
Hazardous Polymerization: May Occur May Not Occur Conditions to Avoid: None known		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:					
For ingestion, t	For ingestion, the LD ₅₀ for glycerine in Rats is $17,000 - 27,000$ mg/Kg.					
Emergency Ov	erview: Material may be mildly irritat	ting to eyes.				
Routes of	Routes of Single, Repeated, or Severity (Mild, Moderate, Acute and Chronic Health					
Exposure	Signs and Symptoms	Lifetime Exposure	Severe)	Effect(s)	Target Organ(s)	
Eye	Material may cause slight	Single & Repeated	Moderate	Irritation and possible corneal	Not Applicable	
-	transient (temporary) irritation.			damage due to the fillers used in		
	the product.					

Skin	Material may be an irritant after	Repeated	Mild	Irritation or possible allergic	Not Applicable
	repeated and prolonged exposure.			response.	
Inhalation	Vapors are minimal due to physical properties.	Not Applicable	Not Applicable	Not Applicable	Not Applicable
Ingestion	Material is probably not harmful if swallowed	Not Applicable	Mild	Not Applicable	Not Applicable
Other	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable
Medical Conditions Aggravated by Exposure Open sores and wounds of the skin.					
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: Potential Environmental Effects Do not allow to enter sewers/ surface or ground water.					
NFPA Hazard Classification Ratings (Scale $0-4$), Health = 0, 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. 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>U.S. State Regulations California Proposition 65:</u> 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.