SAFETY DATA SHEETS

This SDS packet was issued with item:

071818509

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

071818517

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).

071813310 071813328 071813336 071813385 071813393 071813401 071813500 071813518 071818467 071818475 071818483

DENTSPLY/International DENTSPLY/Caulk Safety Data Sheet

1. Identification			
Product Name	SDS Code Number		
Reprosil [®] Impression Material	526385		
Substance Identity	Date of Last Revision		
Reprosil [®] Vinyl Polysiloxane Impression Material	02/02/11		
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		
Dental Impression Material	(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)		

2. Hazard(s) Identification



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	%
Silicon Dioxide - Crystalline	14464-46-1	0.05 mg/m^3	< than 30
Silicon Dioxide - Amorphous	68855-54-9	1.2 mg/m^3	< than 30
Calcium Sulfate	7778-18-9	10 mg/m^3	< than 15
Hydrophobic Amorphous Fumed Silica	68611-44-9	10 mg/m^3	< than 10
Titanium Dioxide	13463-67-7	10 mg/m^3	< than 5

Colorant Information The base pastes may contain fluorescent organic dyes and/or ultramarine pigments.

The Chemical structure of all Ultramarine pigments, regardless of color, is Sodium Aluminosulfosilicate.

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. If symptoms persist consult physician	Not Applicable	Not Applicable		
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	Not Applicable	Low order of toxicity is expected when large amounts of material are ingested. Acute toxicology study in rats LD ₅₀ >2,000mg/kg.		
Other	Not Applicable	Not Applicable	Not Applicable		
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: No dangerous decomposition products known 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



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 Lim	Engineering Controls: Not Applicable	

9. Physical and Chemical Characteristics

Appearance: Various colored pastes, may be high viscosity paste or runny. Catalyst is grey-colored. Odor: Characteristic sweet ester odor.				
Normal Physical State: Material is available in several visco	Melting Point: Not Applicable			
(Paste) to a more runny material.				
Specific Gravity: Varies from 1.2 g/cm ³ to 1.5 g/cm ³	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 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 may irritate the skin and mucous membranes. The unpolymerized product may cause irritation to the skin in susceptible persons. On the eye the product has an irritating effect. Sensitization: No sensitizing effects known. Emergency Overview: Material may be mildly irritating to eyes. Routes of Single, Repeated, or Severity (Mild, Acute and Chronic Health Effect(s) Exposure Signs and Symptoms Lifetime Exposure Moderate, Severe) Target Organ(s) Material can cause irritation. Moderate Irritation and possible corneal damage Not Applicable Eye Single Irritation or possible allergic response. Skin Material may be an irritant Single & Repeated Moderate Not Applicable Inhalation Not Applicable Not Applicable Not Applicable Not Applicable Not Applicable Ingestion Material is probably not Not Applicable Mild Low order of toxicity is expected when Not Applicable harmful if swallowed large amounts of material are ingested. Acute toxicology study in rats LD₅₀ >2,000mg/kg. Other Not Applicable Not Applicable Not Applicable Not Applicable Not Applicable Medical Conditions Aggravated by Exposure Open sores and wounds of the skin IARC monographs?: Not listed NTP?: Not listed OSHA regulated?: No All components of this product are in Carcinogenicity 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 = 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. 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

<u>EPA Toxic Substances Control Act (TSCA) Status:</u> 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
Reprosil [®] Impression Material	526385
Substance Identity	Date of Last Revision
Reprosil [®] Vinyl Polysiloxane Impression Material	11/04/16
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
Dental Impression Material	(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)

2. Hazard(s) Identification



CAUSES SKIN IRRITATION

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3. Composition/Information on Ingredients

Hazardous Components	C.A.S. Number	Exposure Limits	%	
Silicon Dioxide - Crystalline	14464-46-1	0.05 mg/m ³	< than 30	
Silicon Dioxide - Amorphous	68855-54-9	1.2 mg/m^3	< than 30	
Calcium Sulfate	7778-18-9	10 mg/m ³	< than 15	
Hydrophobic Amorphous Fumed Silica	68611-44-9	10 mg/m ³	< than 10	
Titanium Dioxide	13463-67-7	10 mg/m ³	< than 5	

Colorant Information The base pastes may contain fluorescent organic dyes and/or ultramarine pigments. The Chemical structure of all Ultramarine pigments, regardless of color, is Sodium Aluminosulfosilicate.

4. First Aid Measures

Routes of	First Aid Instructions	Immediate	Delayed Effects	
Exposure		Medical Attention		
Eye	Rinse opened eye for several minutes under running water. If	Not Applicable	Not Applicable	
	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	Not Applicable	Low order of toxicity is expected when large	
			amounts of material are ingested. Acute	
			toxicology study in rats LD ₅₀ >2,000mg/kg.	
Other	Not Applicable	Not Applicable	Not Applicable	
Note to Physicia	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: No dangerous decomposition products known 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



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	Not Required	Not Applicable
Body Protection	Protective work clothing	Not Applicable
Occupational Exposure Limi	Engineering Controls: Not Applicable	

9. Physical and Chemical Characteristics

Appearance: Various colored pastes, may be high viscosity p	Odor: Characteristic sweet ester odor.		
Normal Physical State: Material is available in several viscos	Melting Point: Not Applicable		
(Paste) to a more runny material.			
Specific Gravity: Varies from 1.2 g/cm ³ to 1.5 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): N A	
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,	Toxicity Data, Epidemiology Studies, Carcinogenicity, Neurological Effects, Genetic Effects, Reproductive Effects, or Structure Activity Data:						
Product may irritate the skin and mucous membranes. The unpolymerized product may cause irritation to the skin in susceptible persons. On the eye the							
product has an irritating effect. Sensitization: No sensitizing effects known.							
Emergency Ov	Emergency Overview: Material may be mildly irritating to eyes.						
Routes of		Single, Repeated, or	Severity (Mild,	Acute and Chronic Health Effect(s)			
Exposure	Signs and Symptoms	Lifetime Exposure	Moderate, Severe)		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.	Not Applicable		
Inhalation	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable		
Ingestion	Material is probably not	Not Applicable	Mild	Low order of toxicity is expected when	Not Applicable		
	harmful if swallowed			large amounts of material are ingested.			
				Acute toxicology study in rats LD ₅₀			
				>2,000mg/kg.			
Other	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable		
Medical Condit	Medical Conditions Aggravated by Exposure Open sores and wounds of the skin.						
Carcinogenicity	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 = 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.

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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

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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.

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