SAFETY DATA SHEETS

This SDS packet was issued with item:

071806165

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

071806199 071806405 071806538

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).

071806082 071806090 071806413 071806421 071806439 071806447 071806546 071806553 071806561 071806579 071806744 071807403 071807494

DENTSPLY/International DENTSPLY/Caulk Safety Data Sheet

578617

1. Identification

Product Name	SDS Code Number
Aquasil	578617
Substance Identity	Date of Last Revision
Aquasil, Aquasil Ultra, Aquasil Ultra Xtra	02/02/11
Smart Wetting [®] Impression Material	
Vinyl Polysiloxane Impression Material	
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
AQUASIL MONOPHASE, AQUASIL RIGID, AQUASIL LV, AQUASIL Easy	(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)
Mix PUTTY, Smart Wetting® Impression Material, AQUASIL ULTRA	
MONOPHASE, AQUASIL ULTRA RIGID, AQUASIL ULTRA XLV, AQUASIL	
ULTRA LV, AQUASIL ULTRA HEAVY – Smart Wetting [®] Impression Material Fast Setting and Regular Setting – Including AQUASIL ULTRA DECA™ Smart	
Wetting® Impression Material for Dynamic Mixing Machines and digit® Targeted	
Delivery Systems. AQUASIL ULTRA Xtra – Wash, Tray and DECA Tray.	
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



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	1.20 mg/m^3	< than 30
Hydrophobic Amorphous Fumed Silica	68909-20-6	10 mg/m^3	< than 10
Titanium Dioxide	13463-67-7	10 mg/m^3	< than 5

<u>Colorant Information</u>: The base pastes may contain fluorescent organic dyes and/or ultramarine pigments and/or inorganic iron oxides. The base pastes may also contain a red pigment known as a Red 2B Toner or a Calcium salt of a beta oxynaphthoate. The Chemical structure of all Ultramarine pigments, regardless of color, is Sodium Aluminosulfosilicate.

<u>Odorant Information:</u> This product contains Peppermint oil which may cause irritation to skin or mucosa or other allergic responses in susceptible persons.

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

	icians (Treating		

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.			et.	
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.		
1	Avoid gross skin contact to minimize the possibility	of contact dermatitis to susceptible persons. E	nsure 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 Limits: Not Applicable		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 viscosities. It varies from a very high viscosity liquid		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 dangered	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,	Toxicity Data, Epidemiology Studies, Carcinogenicity, Neurological Effects, Genetic Effects, Reproductive Effects, or Structure Activity Data:				
Product may irr	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	o sensitizing effects know	vn.		
Emergency Ove	erview: 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 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	e inventory listing Requiren	nents of the U. S. Toxic Substances Cont	rol Act (TSCA) Chemical Substance Inventory.
Potential Environme	ental Effects Do not allow t	o enter sewers/ surface or ground water.	
NFPA Hazard Class	sification Ratings (Scale 0-4	1). 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 (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.

LLS Federal Regulations: CERCLA 103 Reportable Quantity: This product is not subject to CERCLA reporting requirements.

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/International DENTSPLY/Caulk Safety Data Sheet

578617

1. Product and Company Identification

Product Name	SDS Code Number
Aquasil	578617
Substance Identity	Date of Last Revision
Aquasil, Aquasil Ultra, Aquasil Ultra Xtra, Smart Wetting® Impression	01/15/15
Material, Aquasil Ultra Cordless Tissue Managing Impression Material,	
Aquasil Ultimate - Tissue Managing Impression Material	
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
AQUASIL MONOPHASE, AQUASIL RIGID, AQUASIL LV, AQUASIL Easy Mix PUTTY, Smart	(302) 422-4511
Wetting® Impression Material, AQUASIL ULTRA MONOPHASE, AQUASIL ULTRA RIGID,	(8:00 AM – 4:30 PM Eastern Time)
AQUASIL ULTRA XLV, AQUASIL ULTRA LV, AQUASIL ULTRA HEAVY – Smart Wetting®	(8.00 AM – 4.50 FM Eastern Time)
Impression Material Super Fast Set, Fast Setting and Regular Setting – Including AQUASIL ULTRA	
DECA™ Smart Wetting® Impression Material for Dynamic Mixing Machines and digit® Targeted	
Delivery Systems. AQUASIL ULTRA Xtra – Wash, Tray and DECA Tray. Aquasil Ultra Cordless	
Tissue Managing Wash Impression Material and Aquasil Ultra Cordless Tissue Managing Tray	
Impression Material, Aquasil Ultimate Cordless Tissue Managing Wash Impression Material, Aquasil	
Ultra Cordless Tissue Managing Tray Impression Material	
Product Use (for Canada)	Emergency Telephone Number
Dental Impression Material	(302) 422-4511
1	(8:00 AM – 4:30 PM Eastern Time)

2. Hazard(s) Identification



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	1.20 mg/m^3	< than 30
Hydrophobic Amorphous Fumed Silica	68909-20-6	10 mg/m^3	< than 10
Titanium Dioxide	13463-67-7	10 mg/m^3	< than 10

<u>Colorant Information</u>: The base pastes may contain fluorescent organic dyes and/or ultramarine pigments and/or inorganic iron oxides. The base pastes may also contain a red pigment known as a Red 2B Toner or a Calcium salt of a beta oxynaphthoate. The Chemical structure of all Ultramarine pigments, regardless of color, is Sodium Aluminosulfosilicate.

Odorant Information: This product contains Peppermint oil which may cause irritation to skin or mucosa or other allergic responses in susceptible persons.

4. First Aid Measures

Routes of	tes of First Aid Instructions		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 Physici	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	Timminuomey Cimbornouncin Tvot Eppiroucio	o there i tot i ippirettore	
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.					
ĺ	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.					
ſ	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 Limits: Not Applicable		Engineering Controls: Not Applicable

9. Physical and Chemical Characteristics

Appearance: Various colored pastes, may be high viscosity	Odor: Peppermint odor.	
Normal Physical State: Material is available in several visco	Melting Point: Not Applicable	
(Paste) to a more runny material.		
Specific Gravity: Varies from 1.1 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,
	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

Lineigency Ov	Emergency Overview. Material may be initially intracing 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 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					duct 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 (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

<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.