

Document Detail

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Approvals

<u>Role</u>	<u>Sign-off By</u>	<u>Sign-off Date</u>	
Milford Document Control	Michelle Wilson	20-Jun-2019 12:21 pm	GMT
Milford Research & Development Approver	Xiaoming Jin	24-Jun-2019 12:49 pm	GMT
Milford EHS Approver	Colby Landiss	20-Jun-2019 12:40 pm	GMT
Milford Design & Development Engineering Approver	David West	21-Jun-2019 2:31 pm	GMT
Milford QA_RA Approver	Karen Trovalli	20-Jun-2019 2:55 pm	GMT
Milford External DPD Approver	Heather Shellenberger	24-Jun-2019 12:49 pm	GMT
Milford EHS Approver	Anthony Milbut	25-Jun-2019 11:56 am	GMT
Milford Website Approver	Sabine Dabisch	25-Jun-2019 6:51 am	GMT
Milford External DPD Approver	Lucy Brenneman	27-Jun-2019 11:35 am	GMT
Milford External DeTrey (Konstanz) Approver	Susanne Bachmeier	26-Jun-2019 2:11 pm	GMT
Milford Research & Development Approver	Barbara Colburn	25-Jun-2019 3:54 pm	GMT



1. Product and Company Identification

Product Name Aquasil®	SDS Code Number 578617
Substance Identity Aquasil, Aquasil Ultra, Aquasil Ultra Xtra, Smart Wetting® Impression Material, Aquasil Ultra Cordless Tissue Managing Impression Material, Aquasil Ultimate - Tissue Managing Impression Material, Aquasil Ultra + Smart Wetting Impression Material	Date of Last Revision 6/10/19
Manufacturer: DENTSPLY Caulk	Address 38 West Clarke Avenue Milford DE 19963-1805 http://www.dentsplysirona.com
Grades or Minor Variant Identities AQUASIL MONOPHASE, AQUASIL RIGID, AQUASIL LV, AQUASIL Easy 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, 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, Aquasil Ultra + Smart Wetting Impression Material Fast and Regular Setting - all viscosities.	Company Telephone Number (Product Inquiries) (302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)
Product Use (for Canada) Dental Impression Material	Emergency Telephone Number CHEMTREC: 1-800-424-9300 (24 hours) (Outside U.S. +1-703-527-3887) CCN6510

2. Hazard(s) Identification



WARNING
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	1.20 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

Colorant Information: 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 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 (for Solids): Not Applicable	Properties Contributing to Fire Intensity: Not Applicable	Flammability Classification: Not Applicable	Other: Not Applicable
Extinguishing Media: CO ₂ , extinguishing powder, foam carbon dioxide or water spray. Fight larger fires with water spray or alcohol resistant foam.		Extinguishing Media to Avoid: Water with full jet.	
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.			

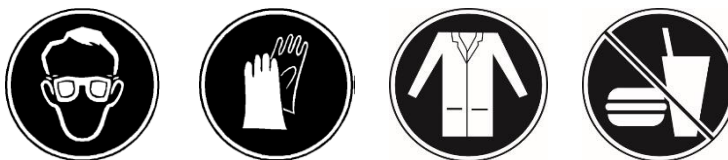
6. Accidental Release Measures

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 Measures	Personal Protective Equipment for Normal Use	Personal Protective Equipment 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
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 white to grey-colored.	Odor: Peppermint odor.
Normal Physical State: Material is available in several viscosities. It varies from a very high viscosity liquid (Paste) to a more runny material.	Melting Point: Not Applicable
Specific Gravity: Varies from 1.1 g/cm ³ to 1.5 g/cm ³	Solubility in Water: Not soluble
Vapor Pressure (mm Hg): Not Applicable	pH: Not Applicable
Flashpoint Method: Not Applicable	Vapor Density (AIR=1): Not Applicable
Other: Not Applicable	Evaporation Rate (Butyl Acetate =1): N A
	Flammable (Explosive) Limits in Air
	LEL: Not Applicable UEL: Not Applicable
	Autoignition Temperature: Not Applicable, Product will not autoignite.

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: <input type="checkbox"/> May Occur <input checked="" type="checkbox"/> May Not Occur	Conditions to Avoid: None known
Stability? <input checked="" type="checkbox"/> Stable <input type="checkbox"/> 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 Exposure	Signs and Symptoms	Single, Repeated, or Lifetime Exposure	Severity (Mild, Moderate, Severe)	Acute and Chronic Health Effect(s)	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 harmful if swallowed	Not Applicable	Mild	Low order of toxicity is expected when large amounts of material are ingested. Acute toxicology study in rats LD ₅₀ >2,000mg/kg.	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 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 method change product classification? No	DOT Hazard Class: Not Applicable	UN Number: Not Applicable

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 Chemical 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.