Material Safety Data Sheet

Caulk

1. Product and Company Identification				
Product Name	MSDS Code Number			
REGISIL® Bite Registration Material	519899			
Trade Name & Synonyms	Date of Last Revision			
REGISIL® Vinyl Polysiloxane Bite	09/25/06			
Registration Material				
Chemical Name	Manufacturer			
Vinyl Polysiloxane	DENTSPLY/Caulk			
C.A.S. Number	Address			
N. A.	38 West Clarke Avenue			
	Milford DE 19963-1805			
	http://www.caulk.com			
Grades or Minor Variant Identities	Information Telephone Number			
Regisil, Regisil 2X, Regisil PB, Regisil Rigid	(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)			
Product Use (for Canada)	Emergency Telephone Number			
Dental Bite Registration Material	(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)			

2. Composition Of Ingredients				
Hazardous Components	C.A.S. Number	Exposure Limits	%	
Silicon Dioxide -Crystalline	14464-46-1	0.05 mg/m^3	< than 55	
Silicon Dioxide - Amorphous	7631-86-9	1.2 mg/m^3	< than 35	
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	

<u>Colorant Information</u> 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.

	3. Hazard Identification					
Emergency	Overview: Material n	nay be mildly irritati	ng 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	N. A.	
Skin	Material may be an irritant	Single & Repeated	Moderate	Irritation or possible allergic response.	N. A.	
Inhalation	N. A.	N. A.	N. A.	N. A.	N. A.	
Ingestion	Material is probably not harmful if swallowed	N. A.	Mild	Low order of toxicity is expected when large amounts of material are ingested. Acute toxicology study in rats LD ₅₀ >2,000mg/kg.	N. A.	
Other	N. A.	N. A.	N. A.	N. A.	N. A.	
Medical Condi	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						
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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	N. A.	N. A.		
Skin	Immediately wash with soap and water and rinse thoroughly	N. A.	N. A.		
Inhalation	Supply fresh air, consult physician if symptoms persist	N. A.			
Ingestion	If symptoms persist consult physician	N. A.	Low order of toxicity is expected when large amounts of material are ingested. Acute toxicology study in rats LD ₅₀ >2,000mg/kg.		
Other	N. A.	N. A.	N. A.		
Note to Physicians (Treating, Testing and Monitoring) N. A.					

5. Fire and Explosion Data			
Flashpoint Method: N. A.	Flammable (Explosive) Limits in Air LEL: N. A. UEL: N. A.	Autoignition Temperature: N. A. Product will not autoignite.	Other: N. A.
Flame Propagation or Burning Rate (for Solids) N. A.	Properties Contributing to Fire Intensity: N. A.	Flammability Classification: N. A.	
Extinguishing Media: CO ₂ , extinguishing powder, or water spray. Fight larger fires with water spray or alcohol resistant foam. Use fire-extinguishing methods suitable to surrounding areas.			r 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 knownProduct does not present an explosion hazard.			

6. Accidental Release Measures			
Containment Techniques: Material is available in several viscosities. It may be a high viscosity paste and as such will not flow. Or a runny paste.			
Spill/Leak Clean-up Procedures and Equipment: Wear protective clothing and scoop up bulk material and place in a labeled plastic or metal conta	ner.		
Avoid gross skin contact to minimize the possibility of contact dermatitis to susceptible persons. Ensure adequate ventilation.			
Evacuation Procedures: N. A.			
Special Instructions: N. A.			
Reporting Requirements: N. A.			

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				
Ventilation: None r	required during normal intended use of this product Other Engineering Controls: N. A.			
Routes of Entry	Personal Protective Equipment (PPE) for Normal Use	PPE for Emergencies		
Eye/Face	Safety Glasses	N. A.		
Skin	The glove material has to be impermeable and resistant to the product.	N. A.		
Inhalation	Not Required	N. A.		
Body Protection Protective work clothing		N. A.		
General Hygiene Considerations and Work Practices: Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing. Wash hands before breaks and at end of work. Avoid contact with the eyes and skin. Do not eat, drink or smoke when using.				
Protective Measures During Repair and Maintenance of Contaminated Equipment: N. A.				
Other Protective Measures and Equipment: N. A.				

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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 Melting Point: N. A.				
Viscosity Liquid (Paste) to a more runny material.				
Specific Gravity: 1.2 g/cm ³ (1.6 g/cm ³ for PB & Rigid)	pH: N. A.			
Vapor Pressure (mm Hg): N. A.	Evaporation Rate (Butyl Acetate =1) N. A.			
Other: N. A.				

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.

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: N. A.				
Do Changes in Quantities, packaging, or shipm	ent me	thod change	DOTE	Hazard Class N. A.	UN Number: N. A.
product classification? No					
DOT Labels Required (49CFR172.101): N/A		Other:	N. A.		
IATA Shipping Name: Not Regulated	IATA	A Hazard Class	: N/A	UN Number:	N/A
IATA Hazard Labels Required: N/A					
IMDG Shipping Name: Not Regulated	IMD	G Hazard Class	s: N/A	UN Number:	N/A
IMDG Hazard Labels Required: N/A					

15.Regulatory Information

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 contains crystalline silica, a substance that is known to the State of California to cause cancer.

The particles are contained in a paste and as such are not airborne particles of respirable size.

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: N. A.

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.