

**DENTSPLY/International
DENTSPLY/Caulk
Safety Data Sheet**

519899

1. Identification

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| Product Name Regisil[®] Bite Registration Material | SDS Code Number 519899 |
| Substance Identity Regisil[®] Vinyl Polysiloxane Bite Registration Material | Date of Last Revision 11/12/13 |
| Manufacturer: DENTSPLY Caulk | Address 38 West Clarke Avenue Milford DE 19963-1805 http://www.caulk.com, http://www.dentsply.com |
| Grades or Minor Variant Identities Regisil, Regisil 2X, Regisil PB, Regisil Rigid | Information Telephone Number (302) 422-4511 (8:00 AM – 4:30 PM Eastern Time) |
| Product Use (for Canada) Dental Bite Registration Material | Emergency Telephone Number (302) 422-4511 (8:00 AM – 4:30 PM Eastern Time) |

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 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 |

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

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| 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. | | | |

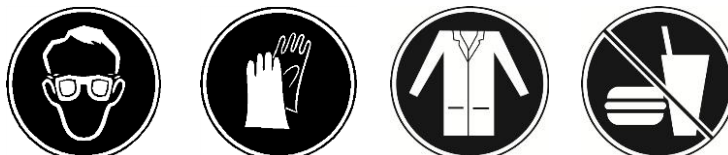
6. Accidental Release Measures

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| 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

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| 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

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| 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 (Paste) to a more runny material. | | Melting Point: Not Applicable |
| Specific Gravity: 1.2 g/cm ³ (1.6 g/cm ³ for PB & Rigid) | 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 LEL: Not Applicable UEL: Not Applicable | Autoignition Temperature: Not Applicable, Product will not autoignite. |
| Other: Not Applicable | | |

10. Stability and Reactivity Data

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| 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

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| 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. |
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13. Disposal Considerations

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| 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

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| 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

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| 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 |
| <u>Section 302 Extremely Hazardous Substances (TPQ)</u> : 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. |
| <u>International Regulations: Canadian Environmental Protection Act</u> : This product is a medical device and not subject to chemical notification requirements. |
| <u>European Community Labeling</u> : Not a dangerous preparation. |
| <u>European Inventory of New and Existing Chemicals Substances (EINECS)</u> : This product is a medical device and not subject to chemical notification requirements. |
| Other: Not Applicable |

16. Other Information

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| 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. |
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