SAFETY DATA SHEETS

This SDS packet was issued with item:

074082400

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).

074082392 078122492

DENTSPLY International

DENTSPLY PROFESSIONAL

Safety Data Sheet

Safety Data Sheet (in compliance with Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010)

Date Issued: 7 July 2008
Document Number: 537004
Date Revised: 25 September 2014
Revision Number: 6

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product Identifier:

Trade Name (as labeled):	**DELTON® Plus Light Cure Opaque Sealant**
Part/Item Number:	**2894, 2896, 28945, 28965**

1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against:

Recommended Use:	**DELTON® Plus Light Cure Opaque Pit & Fissure Sealants are indicated for the preventive sealing of pits and fissures in the primary and secondary dentition in combination with the acid-etch technique.**
Restrictions on Use:	**For Professional Use Only. Do not use on persons hypersensitive to methacrylates or other formula ingredients.**

1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name:	**DENTSPLY Professional**
Manufacturer/Supplier Address:	**1301 Smile Way** **York, PA 17404**
Manufacturer/Supplier Telephone Number:	**800-989-8826 or 717-767-8502 (Product Information)**
Email address:	**ProfessionalMSDS@dentsply.com**

1.4 Emergency Telephone Number:

Transportation Emergency Contact Number:	**800-424-9300 Chemtrec**

2. HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture:

GHS Classification:

Health	Environmental	Physical
Acute Toxicity Category 4 (H302) Eye Irritant Category 2 (H319) Skin Irritant Category 2 (H315) Skin Sensitizer Category 1 (H317) Specific Target Organ Toxicity Single Exposure Category 3 (H335)	Not Hazardous	Not Hazardous

EU Classification: Irritant (Xi) R36/37/38, R43

2.2 Label Elements:

Signal Word: Warning

Contains Resin Blend and Sodium Fluoride

Hazard Phrases	Precautionary Phrases
H302 Harmful if swallowed. H315 Causes skin irritation H319 Causes serious eye irritation H317 May cause an allergic skin reaction H335 May cause respiratory irritation.	P261 Avoid breathing dust, mist, or vapors. P264 Wash thoroughly after handling. P270 Do not eat, drink or smoke when using this product. P271 Use only outdoors or in a well-ventilated area. P272 Contaminated work clothing should not be allowed out of the work place. P280 Wear protective gloves, eye protection, and face protection. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present, and easy to do. Continue rinsing. P337 + P313 If eye irritation persists: Get medical attention. P302 + P352 IF ON SKIN: Wash with plenty of water. P333 + P313 If skin irritation or rash occurs: Get medical attention. P362 + P364 Take off contaminated clothing and wash it before reuse. P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing. P312 Call a POISON CENTER or doctor if you feel unwell. P301 + P312 IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell. P330 Rinse mouth. P403 + P233 Store in a well-ventilated place. Keep container tightly closed. P405 Store locked up. P501 Dispose of contents and container in accordance with local and national regulations.

2.3 Other Hazards: None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixture:

Hazardous Components	C.A.S. #	EINECS #	Classification	WT %
Resin Blend	Mixture	Mixture	Xi, R36/37/38, R43 Skin Irrit Cat. 2 (H315), Eye Irrit Cat 2 (H319), Skin Sens. Cat 1 (H317), STOT SE 3 (H335)	55-65

Silanated Milled Glass	65997-17-3	266-046-0	Not Classified	30-40
Sodium Fluoride	7681-49-4	231667-8	T, R25, R32, R36/38 Acute Tox. Cat 3 (H301), Skin Irrit Cat 2 (H315), Eye Irrit 2 (H319) EUH032	1-2
Titanium Dioxide	13463-67-7	236-675-5	Carc. Cat 2 (H351)	<1

Note: The Titanium Dioxide in this product is not unbound or respirable. Therefore, no warning is required.

The exact concentration is being withheld as a trade secret.

Refer to Section 16 for the full text of the GHS and EU Classifications.

4. FIRST AID MEASURES

4.1 Description of First Aid Measures:	
Eye	Flush victim's eyes with water for several minutes, while holding the eyelids apart. Remove contact lenses if present and easy to do and continue rinsing. Get medical attention if irritation persists.
Skin	Remove contaminated clothing. Wash skin thoroughly with soap and water for several minutes. Get medical attention if irritation or rash develops or persists. Launder clothing before re-use.
Inhalation	Remove victim to fresh air. Give artificial respiration if needed. If breathing is difficult, oxygen should be administered by qualified personnel. Get medical attention if irritation persists.
Ingestion	If conscious, wash mouth out with water. Do not induce vomiting. Never give anything by mouth to an unconscious or convulsing person. Get medical attention if you feel unwell.

4.2 Most Important Symptoms and Effects, Both Acute and Delayed:
May cause moderate eye, skin, and respiratory irritation. Prolonged or repeated contact with skin may cause an allergic skin reaction. If swallowed, may cause gastrointestinal irritation. Harmful if swallowed. Prolonged over exposure to sodium fluorides may cause fluorosis with symptoms of joint pain, limited mobility, brittle bones, calcification of ligaments, bone and teeth abnormalities and mottles tooth enamel.

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:
Immediate medical attention should not be required.
Note to Physicians (Treatment, Testing, and Monitoring): Treat symptomatically.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media:	Use carbon dioxide, foam, dry chemical, or water fog

5.2 Special Hazards Arising from the Substance or Mixture:
Hazardous polymerization may occur. Heat of fire may cause an exothermic autopolymerization reaction. Emits toxic fumes under fire conditions. Closed containers may explode due to pressure build up when exposed to extreme heat. Hazardous decomposition products include oxides of carbon, nitrogen, fluoride, irritating smoke and fumes.

5.3 Advice for Fire-Fighters:	
Fire Fighting Procedures:	Cool exposed intact containers with water spray.

Precautions for Fire Fighters:	Firefighters should wear full emergency equipment and approved positive pressure self-contained breathing apparatus. Do not enter fire area without proper protection.

Recommended Protective Equipment for Fire Fighters:			
EYES/FACE	**HANDS**	**RESPIRATORY**	**THERMAL**
			

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:			
Avoid contact with skin, eyes or clothing. Do not breathe dust, mist or vapors. Ventilate area. Wear appropriate protective clothing as described in Section 8.			
Recommended Personal Protective Equipment for Containment and Clean-up:			
EYES/FACE	**HANDS**	**RESPIRATORY**	**SKIN**
			

6.2 Environmental Precautions:
Prevent entry into sewers and waterways. Report releases as required by local and national authorities.

6.3 Methods and Material for Containment and Cleaning up:
Wipe up or collect using an inert absorbent material and place in appropriate containers for disposal. Rinse spill area with water. Report releases as required by local, state and federal authorities.

6.4 Reference to Other Sections:
Refer to Section 8 for Personal Protective Equipment and Section 13 for Disposal information.

7. HANDLING AND STORAGE

7.1 Precautions for Safe Handing:
Avoid contact with the eyes, skin and clothing. Do not breathe dust, mist or vapors. Wear protective clothing and equipment as described in Section 8. Use only with adequate ventilation. Wash thoroughly with soap and water after handling. Keep containers closed when not in use. Do not reuse containers. Empty containers retain product residues that can be hazardous. Follow all SDS precautions when handling empty containers.

7.2 Conditions for Safe Storage, Including Any Incompatibilities:
Store in a cool, dry, well-ventilated area. Keep away from heat, sparks, flames, and direct sunlight. Keep container tightly closed when not in use. Protect from physical damage. Keep away from oxidizers and other incompatible materials.
7.3 Specific End Use (s): For professional use only.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:

Occupational Exposure Limits:

Resin Blend	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
Silanated Milled Glass	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
Sodium Fluoride (as Fluoride)	United States	2.5 mg/m3 TWA ACGIH TLV 2.5 mg/m3 TWA OSHA PEL
	Germany	1 mg/m3 TWA, 4 mg/m3 STEL DFG MAK (Inhalable, skin)
	United Kingdom	2.5 mg/m3 TWA UK OEL
	European Union	2.5 mg/m3 TWA EU OEL
Titanium Dioxide	United States	10 mg/m3 TWA ACGIH TLV (Respirable) 15 mg/m3 TWA OSHA PEL (Total dust)
	Germany	None Established
	United Kingdom	10 mg/m3 (Inhalable), 4 mg/m3 (Respirable) TWA UK WEL
	European Union	Belgium: 10 mg/m3 TWA

Biological Exposure Limits: None Established

8.2 Exposure Controls:

Appropriate Engineering Controls: Use with adequate local exhaust ventilation to maintain exposures below the occupational exposure limits.

Individual Protection Measures (PPE):

Specific Eye/face Protection: Wear chemical safety goggles where contact is possible.

Specific Skin Protection: Wear rubber or other impervious gloves to avoid skin contact. Consult glove supplier for thickness and breakthrough times.

Specific Respiratory Protection: None should be needed for normal use. If the exposure limits are exceeded an approved dust/mist respirator or supplied air respirator appropriate for the form and concentration of the contaminants should be used. Selection and use of respiratory equipment must be in accordance with applicable regulations and good industrial hygiene practice.

Specific Thermal Hazards: None required.

Recommended Personal Protective Equipment			
EYES/FACE	**HANDS**	**RESPIRATORY**	**SKIN**
			

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

Appearance:	Creamy paste	**Explosive limits:**	**LEL:** Not determined **UEL:** Not determined
Odor:	Light acrylic odor.	**Vapor pressure (mmHg):**	Not available
Odor threshold:	Not available	**Vapor density:**	Not available
pH:	Not available	**Relative density:**	1.3
Melting/freezing point:	Not available	**Solubility(ies):**	Not available
Initial boiling point and boiling range:	Not available	**Partition coefficient: n-octanol/water:**	Not available
Flash point:	Not flammable	**Auto-ignition temperature:**	Not available
Evaporation rate:	Not available	**Decomposition temperature:**	Not available
Flammability (solid, gas):	Not applicable	**Viscosity:**	Not available
Explosive Properties:	Not explosive	**Oxidizing Properties:**	Not an oxidizer

9.2 Other Information: None available

10. STABILITY AND REACTIVITY

10.1 Reactivity: None known.
10.2 Chemical Stability: Stable under normal conditions.
10.3 Possibility of Hazardous Reactions: Polymerization can occur. Conditions leading to polymerization are excessive heat, oxygen-free atmosphere inhibitor depletion (due to excessive aging), direct sunlight, and contamination with polymerization catalysts.
10.4 Conditions to Avoid: Heat, sparks, open flame and other ignition sources, elevated temperatures, and direct sunlight.
10.5 Incompatible materials: Avoid contact with oxidizing agents, reducing agents, strong bases, acids and amines.
10.6 Hazardous Decomposition Products: Thermal decomposition may release Hazardous oxides of carbon, nitrogen, and fluoride and unknown materials.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:
Eyes: Direct contact may cause moderate irritation with excessive tearing, redness and blinking. Corneal damage may occur.
Skin: May cause moderate skin irritation with redness and pain. May cause an allergic skin reaction (skin sensitization)
Ingestion: Harmful if swallowed. May cause salivation, nausea, vomiting. Ingestion of large quantities may cause abdominal pain, weakness, tremor, spasm or convulsion. The following adverse reactions are possible in individuals hypersensitive to fluoride: eczema, atopic dermatitis, urticaria, gastric distress, headache, and weakness.
Inhalation: Inhalation of vapors, mists or dust from dried product may cause respiratory tract irritation with coughing, mucous production and shortness of breath.

Chronic Health Effects: Prolonged or repeated overexposure may cause sensitization in some individuals. Prolonged overexposure to sodium fluoride may cause cardiac disorders, damage to the kidney and brain, and fluorosis with symptoms of joint pain, limited mobility, brittle bones, calcification of ligaments, bone and teeth abnormalities and mottled tooth enamel.

Irritation: Sodium Fluoride: Highly irritating to not irritating in rabbit skin. Highly irritating to moderately irritating to rabbit eyes.

Corrosivity: This product is not a corrosive material.

Sensitisation: May cause an allergic skin reaction in sensitive individuals.

Carcinogenicity: This product contains Titanium dioxide, which is a classified as a Category 2B by IARC. However, the Titanium dioxide in this product is not unbound or respirable and is therefore not classified. Sodium Fluoride: A 2-year study in rats found a weak, equivocal fluoride-related increase in the occurrence of osteosarcomas in male rats, and no evidence of carcinogenicity in female rats or male or female mice. The weight of the evidence indicates that fluoridation of water does not increase the risk of developing cancer. IARC has determined that the carcinogenicity of fluoride to humans is not classifiable. None of the other components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU CLP.

Mutagenicity: Sodium fluoride was negative in the AMES test but was positive a mouse lymphoma cells assay. Sodium fluoride did not induce DNA strand breaks in testicular cells of rats treated in-vivo and did not cause chromosomal aberrations in bone marrow or testicular cells or sister chromatid exchanges in bone marrow cells of mice treated in-vivo.

Medical Conditions Aggravated by Exposure:
Individuals with pre-existing eye and skin conditions may be at increased risk from exposure.

Acute Toxicity Data:

Silinated Milled Glass: No data available

Resin blend: Oral rat LD50-10837 mg/kg

Titanium Dioxide: Oral rat LD50- 9,000 mg/kg

Sodium Fluoride Oral Rat LD50 - 32 mg/kg

Product ATE: Oral: 1600 mg/kg

Reproductive Toxicity Data: Sodium Fluoride: In a 75 day reproductive study with rats, doses of 4.5 ppm and 9.0 ppm showed a significant decrease in sperm count, sperm motility, sperm viability and sperm function. However, other animal studies, including two-generation studies, have not found alterations in serum hormone levels in male rats, testicular histopathology, sperm morphology, or fertility. None of the available laboratory animal studies examined reproductive toxicity at low fluoride doses. The inadequate human studies and conflicting animal studies do not allow for an assessment of the potential of fluoride to induce reproductive effects in humans. Animal studies have not found increases in the incidences of birth defects in the absence of maternal toxicity; at doses that caused maternal toxicity (decreases in body weight gain and food consumption), increases in abnormalities were found.

Specific Target Organ Toxicity (STOT):
Single Exposure: Sodium Fluoride: In a human exposure study, adults were given 250 mg. Effects included nausea, vomiting, epigastric distress, salvation and itching of the hands and feet. In an acute study, dogs were infused with an acute

dose of 36 mg/kg. Death occurred in less than 65 minutes. Principal effects included a decline in blood pressure, heart rate, central nervous system activity, vomiting and defecation.

Repeated Exposure: Sodium Fluoride: Brain, liver, kidneys and muscles demonstrate significant changes in essential trace element levels in adult female mice given 30, 60 and 120 ppm sodium fluoride in drinking water. Rats exposed to sodium fluoride in drinking water for 2 months developed thyroid effects; LOAEL 0.5 mg/kg/day. Mice exposed to sodium fluoride in drinking water for 4 weeks showed increased bone formation. LOAEL 0.8 mg/kg/day.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:
Sodium Fluoride: 96 hr LC50 Oncorhynchus mykiss (Rainbow trout) - 83.7 mg/L, 48 hr EC50 Daphnia magna - 98 mg/L
This product is not expected to present an environmental hazard.

12.2 Persistence and Degradability: Biodegradability does not apply to inorganic compounds.

12.3 Bio-accumulative Potential: No data is currently available

12.4 Mobility in Soil: No data is currently available

12.5 Results of PBT and vPvB Assessment: Not applicable.

12.6 Other Adverse Effects: None

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:

Regulations: Dispose in accordance with all national and local regulations.

Properties (Physical/Chemical) Affecting Disposal: This product will polymerize when exposed to sunlight. Empty containers retaining product residues can be hazardous. Follow all SDS precautions when handling empty containers.

Waste Treatment Recommendations: Dispose in accordance with national and local regulations.

14. TRANSPORT INFORMATION

	14.1 UN Number	14.2 UN Proper Shipping Name	14.3 Hazard Class(s)	14.4 Packing Group	14.5 Environmental Hazards
DOT	None	Not Regulated	None	None	Not applicable
ADR/RID	None	Not Regulated	None	None	Not applicable
IMDG	None	Not Regulated	None	None	Not applicable
IATA/ICAO	None	Not Regulated	None	None	Not applicable

14.6 Special Precautions for User: Not applicable.

14.7 Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code: Not applicable.

15. REGULATORY INFORMATION

15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture:

U.S. Federal Regulations

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): This product has a Reportable Quantity (RQ) of 50,000 lbs (based on the RQ of 1,000 lbs for Sodium Fluoride present at 1-2%). Report spills required under federal, state and local regulations.

Toxic Substances Control Act (TSCA): This product is a medical device and not subject to chemical notification requirements.

Clean Water Act (CWA): This material is not regulated under the Clean Water Act.

Clean Air Act (CAA): This material is not regulated under the Clean Air Act.

Superfund Amendments and Reauthorization Act (SARA) Title III Information:

SARA Section 311/312 (40 CFR 370) Hazard Categories:

Immediate Hazard:	Yes	**Pressure Hazard:**	No
Delayed Hazard:	No	**Reactivity Hazard:**	No
Fire Hazard:	No		

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):

Components	C.A.S. #	WT %
None		

State Regulations

California: This product contains the following substances known to the state of California to cause cancer and/or reproductive toxicity:

Components	C.A.S. #	WT %
Titanium Dioxide	13463-67-7	<1%

Note: The Titanium Dioxide in this product is not unbound or respirable. Therefore, no warning is required.

International Regulations

Canadian Workplace Hazardous Materials Information System (WHMIS): Medical devices are not subject to WHMIS.

Canadian Environmental Protection Act: This product is a medical device and not subject to chemical notification requirements.

This SDS has been prepared according to the criteria of the Controlled Products Regulation (CPR) and the SDS contains all of the information required by the CPR.

European Inventory of Existing Chemicals (EINECS): This product is a medical device and not subject to chemical notification requirements.

EU REACH: This product is a medical device and not subject to chemical notification requirements.

Australian Inventory of Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

China Inventory of Existing Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Japanese Existing and New Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Korean Existing Chemicals List: This product is a medical device and not subject to chemical notification requirements.

Philippine Inventory of Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

15.2 Chemical Safety Assessment: None required.

16. OTHER INFORMATION

HMIS Hazard Rating:
Health – 2 Flammability – 0 Physical Hazard– 0

Full text of Classification abbreviations used in Section 2 and 3:
T Toxic
Xi Irritant
R25 Toxic if swallowed
R32 Contact with acids liberates toxic gas
R36/37/38 irritating to eyes, respiratory system, and skin.
R36/38 Irritating to eyes and skin.
R43 May cause sensitization by skin contact.

Acute Tox Cat 3 Acute Toxicity Category 3
Acute Tox. Cat 4 Acute Toxicity Category 4
Carc Cat 2 Carcinogen Category 2
Eye Irrit Cat 2 Eye Irritant Category 2
Skin Irrit Cat 2 Skin Irritant Category 2
Skin Sens Cat 1 Skin Sensitizer Category 1
STOT SE 3 Specific Target Organ Toxicity Single Exposure Category 3
H301 Toxic if swallowed.
H302 Harmful if swallowed.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H351 Suspected of causing cancer.
EUH032 Contact with acids liberates very toxic gas

Supersedes: 24 June 2011
Date Revised: 25 September 2014
Revision Summary: Converted MSDS to Reach SDS. Updated all sections. Updated part numbers.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, IUCLID Dataset EU Chemical Bureau, ESIS, Country websites for occupational exposure limits.

DENTSPLY International

DENTSPLY PROFESSIONAL

Safety Data Sheet

Safety Data Sheet (in compliance with Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010)

Date Issued: 7 July 2008
Document Number: 537004
Date Revised: 25 September 2014
Revision Number: 6

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product Identifier:

Trade Name (as labeled):	**DELTON® Plus Light Cure Opaque Sealant**
Part/Item Number:	**2894, 2896, 28945, 28965**

1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against:

Recommended Use:	**DELTON® Plus Light Cure Opaque Pit & Fissure Sealants are indicated for the preventive sealing of pits and fissures in the primary and secondary dentition in combination with the acid-etch technique.**
Restrictions on Use:	**For Professional Use Only. Do not use on persons hypersensitive to methacrylates or other formula ingredients.**

1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name:	**DENTSPLY Professional**
Manufacturer/Supplier Address:	**1301 Smile Way** **York, PA 17404**
Manufacturer/Supplier Telephone Number:	**800-989-8826 or 717-767-8502 (Product Information)**
Email address:	**ProfessionalMSDS@dentsply.com**

1.4 Emergency Telephone Number:

Transportation Emergency Contact Number:	**800-424-9300 Chemtrec**

2. HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture:

GHS Classification:

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EU Classification: Irritant (Xi) R36/37/38, R43

2.2 Label Elements:

Signal Word: Warning

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Hazard Phrases	Precautionary Phrases
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2.3 Other Hazards: None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixture:

Hazardous Components	C.A.S. #	EINECS #	Classification	WT %
Resin Blend	Mixture	Mixture	Xi, R36/37/38, R43 Skin Irrit Cat. 2 (H315), Eye Irrit Cat 2 (H319), Skin Sens. Cat 1 (H317), STOT SE 3 (H335)	55-65

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Titanium Dioxide	13463-67-7	236-675-5	Carc. Cat 2 (H351)	<1

Note: The Titanium Dioxide in this product is not unbound or respirable. Therefore, no warning is required.

The exact concentration is being withheld as a trade secret.

Refer to Section 16 for the full text of the GHS and EU Classifications.

4. FIRST AID MEASURES

4.1 Description of First Aid Measures:	
Eye	Flush victim's eyes with water for several minutes, while holding the eyelids apart. Remove contact lenses if present and easy to do and continue rinsing. Get medical attention if irritation persists.
Skin	Remove contaminated clothing. Wash skin thoroughly with soap and water for several minutes. Get medical attention if irritation or rash develops or persists. Launder clothing before re-use.
Inhalation	Remove victim to fresh air. Give artificial respiration if needed. If breathing is difficult, oxygen should be administered by qualified personnel. Get medical attention if irritation persists.
Ingestion	If conscious, wash mouth out with water. Do not induce vomiting. Never give anything by mouth to an unconscious or convulsing person. Get medical attention if you feel unwell.

4.2 Most Important Symptoms and Effects, Both Acute and Delayed:
May cause moderate eye, skin, and respiratory irritation. Prolonged or repeated contact with skin may cause an allergic skin reaction. If swallowed, may cause gastrointestinal irritation. Harmful if swallowed. Prolonged over exposure to sodium fluorides may cause fluorosis with symptoms of joint pain, limited mobility, brittle bones, calcification of ligaments, bone and teeth abnormalities and mottles tooth enamel.

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:
Immediate medical attention should not be required.
Note to Physicians (Treatment, Testing, and Monitoring): Treat symptomatically.

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5.1 Extinguishing Media:	Use carbon dioxide, foam, dry chemical, or water fog

5.2 Special Hazards Arising from the Substance or Mixture:
Hazardous polymerization may occur. Heat of fire may cause an exothermic autopolymerization reaction. Emits toxic fumes under fire conditions. Closed containers may explode due to pressure build up when exposed to extreme heat. Hazardous decomposition products include oxides of carbon, nitrogen, fluoride, irritating smoke and fumes.

5.3 Advice for Fire-Fighters:	
Fire Fighting Procedures:	Cool exposed intact containers with water spray.

Precautions for Fire Fighters:	Firefighters should wear full emergency equipment and approved positive pressure self-contained breathing apparatus. Do not enter fire area without proper protection.

Recommended Protective Equipment for Fire Fighters:			
EYES/FACE	**HANDS**	**RESPIRATORY**	**THERMAL**
			

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:			
Avoid contact with skin, eyes or clothing. Do not breathe dust, mist or vapors. Ventilate area. Wear appropriate protective clothing as described in Section 8.			
Recommended Personal Protective Equipment for Containment and Clean-up:			
EYES/FACE	**HANDS**	**RESPIRATORY**	**SKIN**
			

6.2 Environmental Precautions:
Prevent entry into sewers and waterways. Report releases as required by local and national authorities.

6.3 Methods and Material for Containment and Cleaning up:
Wipe up or collect using an inert absorbent material and place in appropriate containers for disposal. Rinse spill area with water. Report releases as required by local, state and federal authorities.

6.4 Reference to Other Sections:
Refer to Section 8 for Personal Protective Equipment and Section 13 for Disposal information.

7. HANDLING AND STORAGE

7.1 Precautions for Safe Handing:
Avoid contact with the eyes, skin and clothing. Do not breathe dust, mist or vapors. Wear protective clothing and equipment as described in Section 8. Use only with adequate ventilation. Wash thoroughly with soap and water after handling. Keep containers closed when not in use. Do not reuse containers. Empty containers retain product residues that can be hazardous. Follow all SDS precautions when handling empty containers.

7.2 Conditions for Safe Storage, Including Any Incompatibilities:
Store in a cool, dry, well-ventilated area. Keep away from heat, sparks, flames, and direct sunlight. Keep container tightly closed when not in use. Protect from physical damage. Keep away from oxidizers and other incompatible materials.
7.3 Specific End Use (s): For professional use only.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:

Occupational Exposure Limits:

Resin Blend	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
Silanated Milled Glass	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
Sodium Fluoride (as Fluoride)	United States	2.5 mg/m3 TWA ACGIH TLV 2.5 mg/m3 TWA OSHA PEL
	Germany	1 mg/m3 TWA, 4 mg/m3 STEL DFG MAK (Inhalable, skin)
	United Kingdom	2.5 mg/m3 TWA UK OEL
	European Union	2.5 mg/m3 TWA EU OEL
Titanium Dioxide	United States	10 mg/m3 TWA ACGIH TLV (Respirable) 15 mg/m3 TWA OSHA PEL (Total dust)
	Germany	None Established
	United Kingdom	10 mg/m3 (Inhalable), 4 mg/m3 (Respirable) TWA UK WEL
	European Union	Belgium: 10 mg/m3 TWA

Biological Exposure Limits: None Established

8.2 Exposure Controls:

Appropriate Engineering Controls: Use with adequate local exhaust ventilation to maintain exposures below the occupational exposure limits.

Individual Protection Measures (PPE):

Specific Eye/face Protection: Wear chemical safety goggles where contact is possible.

Specific Skin Protection: Wear rubber or other impervious gloves to avoid skin contact. Consult glove supplier for thickness and breakthrough times.

Specific Respiratory Protection: None should be needed for normal use. If the exposure limits are exceeded an approved dust/mist respirator or supplied air respirator appropriate for the form and concentration of the contaminants should be used. Selection and use of respiratory equipment must be in accordance with applicable regulations and good industrial hygiene practice.

Specific Thermal Hazards: None required.

Recommended Personal Protective Equipment			
EYES/FACE	**HANDS**	**RESPIRATORY**	**SKIN**
			

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

Appearance:	Creamy paste	**Explosive limits:**	**LEL:** Not determined **UEL:** Not determined
Odor:	Light acrylic odor.	**Vapor pressure (mmHg):**	Not available
Odor threshold:	Not available	**Vapor density:**	Not available
pH:	Not available	**Relative density:**	1.3
Melting/freezing point:	Not available	**Solubility(ies):**	Not available
Initial boiling point and boiling range:	Not available	**Partition coefficient: n-octanol/water:**	Not available
Flash point:	Not flammable	**Auto-ignition temperature:**	Not available
Evaporation rate:	Not available	**Decomposition temperature:**	Not available
Flammability (solid, gas):	Not applicable	**Viscosity:**	Not available
Explosive Properties:	Not explosive	**Oxidizing Properties:**	Not an oxidizer

9.2 Other Information: None available

10. STABILITY AND REACTIVITY

10.1 Reactivity: None known.
10.2 Chemical Stability: Stable under normal conditions.
10.3 Possibility of Hazardous Reactions: Polymerization can occur. Conditions leading to polymerization are excessive heat, oxygen-free atmosphere inhibitor depletion (due to excessive aging), direct sunlight, and contamination with polymerization catalysts.
10.4 Conditions to Avoid: Heat, sparks, open flame and other ignition sources, elevated temperatures, and direct sunlight.
10.5 Incompatible materials: Avoid contact with oxidizing agents, reducing agents, strong bases, acids and amines.
10.6 Hazardous Decomposition Products: Thermal decomposition may release Hazardous oxides of carbon, nitrogen, and fluoride and unknown materials.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:
Eyes: Direct contact may cause moderate irritation with excessive tearing, redness and blinking. Corneal damage may occur.
Skin: May cause moderate skin irritation with redness and pain. May cause an allergic skin reaction (skin sensitization)
Ingestion: Harmful if swallowed. May cause salivation, nausea, vomiting. Ingestion of large quantities may cause abdominal pain, weakness, tremor, spasm or convulsion. The following adverse reactions are possible in individuals hypersensitive to fluoride: eczema, atopic dermatitis, urticaria, gastric distress, headache, and weakness.
Inhalation: Inhalation of vapors, mists or dust from dried product may cause respiratory tract irritation with coughing, mucous production and shortness of breath.

Chronic Health Effects: Prolonged or repeated overexposure may cause sensitization in some individuals. Prolonged overexposure to sodium fluoride may cause cardiac disorders, damage to the kidney and brain, and fluorosis with symptoms of joint pain, limited mobility, brittle bones, calcification of ligaments, bone and teeth abnormalities and mottled tooth enamel.

Irritation: Sodium Fluoride: Highly irritating to not irritating in rabbit skin. Highly irritating to moderately irritating to rabbit eyes.

Corrosivity: This product is not a corrosive material.

Sensitisation: May cause an allergic skin reaction in sensitive individuals.

Carcinogenicity: This product contains Titanium dioxide, which is a classified as a Category 2B by IARC. However, the Titanium dioxide in this product is not unbound or respirable and is therefore not classified. Sodium Fluoride: A 2-year study in rats found a weak, equivocal fluoride-related increase in the occurrence of osteosarcomas in male rats, and no evidence of carcinogenicity in female rats or male or female mice. The weight of the evidence indicates that fluoridation of water does not increase the risk of developing cancer. IARC has determined that the carcinogenicity of fluoride to humans is not classifiable. None of the other components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU CLP.

Mutagenicity: Sodium fluoride was negative in the AMES test but was positive a mouse lymphoma cells assay. Sodium fluoride did not induce DNA strand breaks in testicular cells of rats treated in-vivo and did not cause chromosomal aberrations in bone marrow or testicular cells or sister chromatid exchanges in bone marrow cells of mice treated in-vivo.

Medical Conditions Aggravated by Exposure:
Individuals with pre-existing eye and skin conditions may be at increased risk from exposure.

Acute Toxicity Data:

Silinated Milled Glass: No data available

Resin blend: Oral rat LD50-10837 mg/kg

Titanium Dioxide: Oral rat LD50- 9,000 mg/kg

Sodium Fluoride Oral Rat LD50 - 32 mg/kg

Product ATE: Oral: 1600 mg/kg

Reproductive Toxicity Data: Sodium Fluoride: In a 75 day reproductive study with rats, doses of 4.5 ppm and 9.0 ppm showed a significant decrease in sperm count, sperm motility, sperm viability and sperm function. However, other animal studies, including two-generation studies, have not found alterations in serum hormone levels in male rats, testicular histopathology, sperm morphology, or fertility. None of the available laboratory animal studies examined reproductive toxicity at low fluoride doses. The inadequate human studies and conflicting animal studies do not allow for an assessment of the potential of fluoride to induce reproductive effects in humans. Animal studies have not found increases in the incidences of birth defects in the absence of maternal toxicity; at doses that caused maternal toxicity (decreases in body weight gain and food consumption), increases in abnormalities were found.

Specific Target Organ Toxicity (STOT):
Single Exposure: Sodium Fluoride: In a human exposure study, adults were given 250 mg. Effects included nausea, vomiting, epigastric distress, salvation and itching of the hands and feet. In an acute study, dogs were infused with an acute

dose of 36 mg/kg. Death occurred in less than 65 minutes. Principal effects included a decline in blood pressure, heart rate, central nervous system activity, vomiting and defecation.

Repeated Exposure: Sodium Fluoride: Brain, liver, kidneys and muscles demonstrate significant changes in essential trace element levels in adult female mice given 30, 60 and 120 ppm sodium fluoride in drinking water. Rats exposed to sodium fluoride in drinking water for 2 months developed thyroid effects; LOAEL 0.5 mg/kg/day. Mice exposed to sodium fluoride in drinking water for 4 weeks showed increased bone formation. LOAEL 0.8 mg/kg/day.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:
Sodium Fluoride: 96 hr LC50 Oncorhynchus mykiss (Rainbow trout) - 83.7 mg/L, 48 hr EC50 Daphnia magna - 98 mg/L
This product is not expected to present an environmental hazard.

12.2 Persistence and Degradability: Biodegradability does not apply to inorganic compounds.

12.3 Bio-accumulative Potential: No data is currently available

12.4 Mobility in Soil: No data is currently available

12.5 Results of PBT and vPvB Assessment: Not applicable.

12.6 Other Adverse Effects: None

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:

Regulations: Dispose in accordance with all national and local regulations.

Properties (Physical/Chemical) Affecting Disposal: This product will polymerize when exposed to sunlight. Empty containers retaining product residues can be hazardous. Follow all SDS precautions when handling empty containers.

Waste Treatment Recommendations: Dispose in accordance with national and local regulations.

14. TRANSPORT INFORMATION

	14.1 UN Number	14.2 UN Proper Shipping Name	14.3 Hazard Class(s)	14.4 Packing Group	14.5 Environmental Hazards
DOT	None	Not Regulated	None	None	Not applicable
ADR/RID	None	Not Regulated	None	None	Not applicable
IMDG	None	Not Regulated	None	None	Not applicable
IATA/ICAO	None	Not Regulated	None	None	Not applicable

14.6 Special Precautions for User: Not applicable.

14.7 Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code: Not applicable.

15. REGULATORY INFORMATION

15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture:

U.S. Federal Regulations

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): This product has a Reportable Quantity (RQ) of 50,000 lbs (based on the RQ of 1,000 lbs for Sodium Fluoride present at 1-2%). Report spills required under federal, state and local regulations.

Toxic Substances Control Act (TSCA): This product is a medical device and not subject to chemical notification requirements.

Clean Water Act (CWA): This material is not regulated under the Clean Water Act.

Clean Air Act (CAA): This material is not regulated under the Clean Air Act.

Superfund Amendments and Reauthorization Act (SARA) Title III Information:

SARA Section 311/312 (40 CFR 370) Hazard Categories:

Immediate Hazard:	Yes	**Pressure Hazard:**	No
Delayed Hazard:	No	**Reactivity Hazard:**	No
Fire Hazard:	No		

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):

Components	C.A.S. #	WT %
None		

State Regulations

California: This product contains the following substances known to the state of California to cause cancer and/or reproductive toxicity:

Components	C.A.S. #	WT %
Titanium Dioxide	13463-67-7	<1%

Note: The Titanium Dioxide in this product is not unbound or respirable. Therefore, no warning is required.

International Regulations

Canadian Workplace Hazardous Materials Information System (WHMIS): Medical devices are not subject to WHMIS.

Canadian Environmental Protection Act: This product is a medical device and not subject to chemical notification requirements.

This SDS has been prepared according to the criteria of the Controlled Products Regulation (CPR) and the SDS contains all of the information required by the CPR.

European Inventory of Existing Chemicals (EINECS): This product is a medical device and not subject to chemical notification requirements.

EU REACH: This product is a medical device and not subject to chemical notification requirements.

Australian Inventory of Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

China Inventory of Existing Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Japanese Existing and New Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Korean Existing Chemicals List: This product is a medical device and not subject to chemical notification requirements.

Philippine Inventory of Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

15.2 Chemical Safety Assessment: None required.

16. OTHER INFORMATION

HMIS Hazard Rating:
Health – 2 Flammability – 0 Physical Hazard– 0

Full text of Classification abbreviations used in Section 2 and 3:
T Toxic
Xi Irritant
R25 Toxic if swallowed
R32 Contact with acids liberates toxic gas
R36/37/38 irritating to eyes, respiratory system, and skin.
R36/38 Irritating to eyes and skin.
R43 May cause sensitization by skin contact.

Acute Tox Cat 3 Acute Toxicity Category 3
Acute Tox. Cat 4 Acute Toxicity Category 4
Carc Cat 2 Carcinogen Category 2
Eye Irrit Cat 2 Eye Irritant Category 2
Skin Irrit Cat 2 Skin Irritant Category 2
Skin Sens Cat 1 Skin Sensitizer Category 1
STOT SE 3 Specific Target Organ Toxicity Single Exposure Category 3
H301 Toxic if swallowed.
H302 Harmful if swallowed.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H351 Suspected of causing cancer.
EUH032 Contact with acids liberates very toxic gas

Supersedes: 24 June 2011
Date Revised: 25 September 2014
Revision Summary: Converted MSDS to Reach SDS. Updated all sections. Updated part numbers.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, IUCLID Dataset EU Chemical Bureau, ESIS, Country websites for occupational exposure limits.