SAFETY DATA SHEETS

This SDS packet was issued with item:

071871060

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

071871029

DENTSPLY/International DENTSPLY/Caulk Safety Data Sheet

520898

1. Identification

Product Name	SDS Code Number
Tylok® Plus Anhydrous Polycarboxylate Cement	520898
Substance Identity	Date of Last Revision
Tylok® Plus Anhydrous Polycarboxylate Cement	02/21/14
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
Not Applicable	(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)
Product Use (for Canada)	Emergency Telephone Number
Dental Cement	(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

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Hazardous Components	C.A.S. Number	Exposure Limits	%		
Zinc oxide	1314-13-2	10 mg/M^3	> than 75		
Magnesium Oxide	1309-48-4	10 mg/M^3	< than 10		
Stannous Fluoride	7783-47-3	2.5 mg/M^3	< than 10		
Polyacrylic acid	9003-01-4	Not Applicable	< than 10		

Other Information: Red colorant is inorganic iron oxide.

3. Hazard Identification

		OT TIMEMI	a lacinification				
Emergenc	Emergency Overview: Material may be irritating to eyes. No significant hazards for emergency responses are known.						
Routes of		Single, Repeated, or	Severity (Mild,	Acute and Chronic Health			
Exposure	Signs and Symptoms	Lifetime Exposure	Moderate, Severe)	Effect(s)	Target Organ(s)		
Eye	Material may cause slight transient (temporary) irritation.	Single & Repeated	Moderate	Irritation and possible corneal damage due to the powders used in the product.	Not Applicable		
Skin	Material may be an irritant after repeated and prolonged exposure.	Repeated	Mild	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	Not Applicable	Not Applicable		
Other	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable		
Medical Cor	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 En	vironmental Effects Do not allow to en	nter sewers/ surface or gro	ound water.				

4. First Aid Measures

Routes of	First Aid Instructions	Immediate Medical	Delayed Effects
Exposure		Attention	
Eye	Rinse opened eye for several minutes under running water.	Not Applicable	Not Applicable

	If 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	Rinse mouth out and then drink plenty of water. If symptoms persist consult physician.	Not Applicable	Not Applicable		
Other	Not Applicable	Not Applicable	Not Applicable		
Note to Physici	Note to Physicians (Treating Testing and Monitoring): Treat symptomatically				

5. Fire and Explosion Data

Flashpoint Method: Not Applicable	Flammable (Explosive) Limits in Air		Autoignition Temperature: Not	Other: Not
	LEL: Not Applicable UEL:	Not Applicable	Applicable.	Applicable
Flame Propagation or Burning Rate (for	Properties Contributing to Fire Into	ensity: Not	Flammability Classification:	
Solids) Not Applicable	Applicable		Not Applicable	
Extinguishing Media: CO ₂ , powder, or water spray. 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: During a fi	re, formation of toxic and/or irritatin	g compounds may be p	present.	

6. Accidental Release Measures

Containment Techniques: Material is a solid and as such containment is limited to steps to reduce dust.					
Spill/Leak Clean-up Procedures and Equipment: Wear protective clothing and scoop up bulk material and place in a labeled plastic or metal container.					
Evacuation Procedures: 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. 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 Lim	Occupational Exposure Limits: Not Applicable		

9. Physical and Chemical Characteristics

Appearance: Light pink, free flowing powder with acidic odor.		Odor: Mild odor.
Normal Physical State: High Viscosity Liquid (Paste)		Melting Point: Not Applicable
Specific Gravity: 4.5 g/cm ³	Solubility in Water: Partially soluble.	pH: 3.2-4.5 (10% in water)
Vapor Pressure (mm Hg): Not Applicable	Vapor Density (AIR=1): Not Applicable	Evaporation Rate (Butyl Acetate =1): Not Applicable
Flashpoint Method: Not Applicable	Flammable (Explosive) Limits in Air	Autoignition Temperature: Not Applicable
	LEL: Not Applicable UEL: Not Applicable	
Other: Not Applicable		

10. Stability and Reactivity Data

Incompatibility (Materials to Avoid): Strong acids, strong oxidizing agents, water or moisture (relative humidity >50%) will cause the material to harden.				
Hazardous Products Produced During Decomposition: Oxides of Zinc.				
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, Not Applicable	Epidemiology Studies, Carcinogenicity	y, Neurological Effects, G	enetic Effects, Reproduc	tive Effects, or Structure Activity Dat	a:
Emergency Ov	erview: Material may be mildly irritat	ing 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 may cause slight transient (temporary) irritation.	Single & Repeated	Moderate	Irritation and possible corneal damage due to the fillers used in the product.	Not Applicable
Skin	Material may be an irritant after repeated and prolonged exposure.	Repeated	Mild	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	Not Applicable	Not Applicable

Other	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	
Medical Condit	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					act are in	
compliance with the inventory listing Requirements of the U. S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory.						
Potential Environmental Effects: Potential Environmental Effects Do not allow to enter sewers/ surface or ground water.						
NFPA Hazard (Classification Ratings (Scale 0-4), Hea	lth = 1. Fire = 0. Reactivit	y = 1			

12. Ecological Information

Toxicity Data, Environmental Fate, Physical/Chemical Data, or other Data Supporting Environmental Hazard Statements: Water Hazard Class 2 (Self-assessment): Very toxic to fish. Do not allow product to reach ground water, water streams or sewage system. Also poisonous for fish and plankton in water bodies. R50/53Very toxic to aquatic organisms may cause long-term adverse effects in the aquatic environment.



Danger Hazardous to aquatic life

13.Disposal Considerations

Regulations: Must not be disposed of together with household garbage. 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

		1	
Regulated for Shipping: No. Not Regulated	DO	T Shipping Name: Not Regulated	Packing Group: Not Applicable
Do Changes in Quantities, packaging, or shipment	DO	T 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.

Canada WHMIS, Workplace Hazardous Materials Information System: This product is not a controlled product.

<u>International Regulations: Canadian Environmental Protection Act:</u> This product is a medical device and not subject to chemical notification requirements.

European Community Labeling: Not a dangerous preparation.

European Community Labeling: R50/53Very toxic to aquatic organisms may cause long-term adverse effects in the aquatic environment. S22 Do not breathe dust. S25 Avoid contact with eyes. S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. S28 After contact with skin, wash immediately with plenty of water. S57 Use appropriate container to avoid environmental contamination. S60 This material and its container must be disposed of as hazardous waste.

<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

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 Milford Safety Data Sheet

1. Identification

Product Name	SDS Code Number
Tylok® Plus Anhydrous Polycarboxylate Cement	520898
Substance Identity	Date of Last Revision
Tylok® Plus Anhydrous Polycarboxylate Cement	12/14/16
Manufacturer:	Address
DENTSPLY Milford	38 West Clarke Avenue
	Milford DE 19963-1805
	http://www.dentsply.com
Grades or Minor Variant Identities	Information Telephone Number
Not Applicable	(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)
Product Use (for Canada)	Emergency Telephone Number
Dental Cement	(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	%
Zinc oxide	1314-13-2	10 mg/M ³	> than 75
Magnesium Oxide	1309-48-4	10 mg/M^3	< than 10
Stannous Fluoride	7783-47-3	2.5 mg/M^3	< than 10
Polyacrylic acid	9003-01-4	Not Applicable	< than 10

Other Information: Red colorant is inorganic iron oxide.

3. Hazard Identification

Emergenc	Emergency Overview: Material may be irritating to eyes. No significant hazards for emergency responses are known.					
Routes of		Single, Repeated, or	Severity (Mild,	Acute and Chronic Health		
Exposure	Signs and Symptoms	Lifetime Exposure	Moderate, Severe)	Effect(s)	Target Organ(s)	
Eye	Material may cause slight transient (temporary) irritation.	Single & Repeated	Moderate	Irritation and possible corneal damage due to the powders used	Not Applicable	
	transient (temporary) irritation.			in the product.		
Skin	Material may be an irritant after	Repeated	Mild	Irritation or possible allergic	Not Applicable	
	repeated and prolonged exposure.			response.		
Inhalation	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	
Ingestion	Material is probably not harmful if swallowed	Not Applicable	Mild	Not Applicable	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 En	Potential Environmental Effects Do not allow to enter sewers/ surface or ground water.					

4. First Aid Measures

Routes of	First Aid Instructions	Immediate Medical	Delayed Effects
Exposure		Attention	
Eye	Rinse opened eye for several minutes under running water.	Not Applicable	Not Applicable
	If 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	Rinse mouth out and then drink plenty of water. If symptoms persist consult physician.	Not Applicable	Not Applicable		
Other	Not Applicable	Not Applicable	Not Applicable		
Note to Physici	Note to Physicians (Treating Testing and Monitoring): Treat symptomatically				

5. Fire and Explosion Data

Flashpoint Method: Not Applicable	Flammable (Explosive) Limits in Air		Autoignition Temperature: Not	Other: Not
	LEL: Not Applicable UEL:	Not Applicable	Applicable.	Applicable
Flame Propagation or Burning Rate (for	Properties Contributing to Fire Inte	ensity: Not	Flammability Classification:	
Solids) Not Applicable	Applicable		Not Applicable	
Extinguishing Media: CO ₂ , powder, or water spray.			to Avoid: Water with full jet.	
Protection and Procedures for Firefighters: Firefighters should wear self-contained respiratory protective devices.				
Unusual Fire and Explosion Hazards: During a fi	re, formation of toxic and/or irritatin	g compounds may be p	present.	

6. Accidental Release Measures

Containment Techniques: Material is a solid and as such containment is limited to steps to reduce dust.				
Spill/Leak Clean-up Procedures and Equipment: Wear protective clothing and scoop up bulk material and place in a labeled plastic or metal container.				
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. 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 Lim	Engineering Controls: Not Applicable	

9. Physical and Chemical Characteristics

	7. I hybreat and Chemical Characteristics			
Appearance: Light pink, free flowing powder with acidic odor.		Odor: Mild odor.		
Normal Physical State: High Viscosity Liquid (Paste)		Melting Point: Not Applicable		
Specific Gravity: 4.5 g/cm ³	Solubility in Water: Partially soluble.	pH: 3.2-4.5 (10% in water)		
Vapor Pressure (mm Hg): Not Applicable	Vapor Density (AIR=1): Not Applicable	Evaporation Rate (Butyl Acetate =1): Not Applicable		
Flashpoint Method: Not Applicable	Flammable (Explosive) Limits in Air	Autoignition Temperature: Not Applicable		
	LEL: Not Applicable UEL: Not Applicable			
Other: Not Applicable				

10. Stability and Reactivity Data

Incompatibility (Materials to Avoid): Strong acids, strong oxidizing agents, water or moisture (relative humidity >50%) will cause the material to harden.				
Hazardous Products Produced During Decomposition: Oxides of Zinc.				
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	y, Neurological Effects, G	enetic Effects, Reproduc	tive Effects, or Structure Activity Dat	a:
Not Applicable					
Emergency Ov	erview: Material may be mildly irritat	ing to eyes.			
Routes of		Single, Repeated, or	Severity (Mild,	Acute and Chronic Health	
Exposure	Signs and Symptoms	Lifetime Exposure	Moderate, Severe)	Effect(s)	Target Organ(s)
Eye	Material may cause slight transient (temporary) irritation.	Single & Repeated	Moderate	Irritation and possible corneal damage due to the fillers used in the product.	Not Applicable
Skin	Material may be an irritant after repeated and prolonged exposure.	Repeated	Mild	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	Not Applicable	Not Applicable
Other	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable
Medical Condi	tions Aggravated by Exposure Open so	ores and wounds of the ski	n.		

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: Potential Environmental Effects Do not allow to enter sewers/ surface or ground water.

NFPA Hazard Classification Ratings (Scale 0-4), Health = 1, Fire = 0, Reactivity = 1

12. Ecological Information

Toxicity Data, Environmental Fate, Physical/Chemical Data, or other Data Supporting Environmental Hazard Statements: Water Hazard Class 2 (Self-assessment): Very toxic to fish. Do not allow product to reach ground water, water streams or sewage system. Also poisonous for fish and plankton in water bodies. R50/53Very toxic to aquatic organisms may cause long-term adverse effects in the aquatic environment.



Danger Hazardous to aquatic life

13.Disposal Considerations

Regulations: Must not be disposed of together with household garbage. 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.

<u>Canada WHMIS, Workplace Hazardous Materials Information System:</u> This product is not a controlled product.

<u>International Regulations: Canadian Environmental Protection Act:</u> This product is a medical device and not subject to chemical notification requirements.

European Community Labeling: Not a dangerous preparation.

<u>European Community Labeling:</u> R50/53Very toxic to aquatic organisms may cause long-term adverse effects in the aquatic environment. S22 Do not breathe dust. S25 Avoid contact with eyes. S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. S28 After contact with skin, wash immediately with plenty of water. S57 Use appropriate container to avoid environmental contamination. S60 This material and its container must be disposed of as hazardous waste.

<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

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.