SAFETY DATA SHEETS

This SDS packet was issued with item:

071885227

N/A

DENTSPLY/International DENTSPLY/Caulk Safety Data Sheet

577898

1. Identification

Product Name	SDS Code Number
ZIRCATE ^{® Prophy Paste}	577898
Substance Identity	Date of Last Revision
ZIRCATE ^{®□} Prophy Paste	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
Not Applicable	(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)

2. Hazard(s) Identification



Warning

Causes serious eye irritation
Wash hands thoroughly after handling
Wear protective gloves, face protection.

If in eyes: Rinse cautiously with water for several minutes. Remove contact lens, if present and easy to do. Continue rinsing.

Do not rub affected areas.

If eye irritation persists: Get medical advice attention.

3. Composition/Information on Ingredients

Hazardous Components	C.A.S. Number	Exposure Limits	%
Zirconium Silicate	10101-52-7	5 mg/M^3	< than 75
Tin Oxide	18282-10-5	2 mg/M^3	< than 10

Other Information: Parasepts are used as a preservative. Sweetener is Sodium Saccharin.

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

3. Hazard Identification

Emergenc	Emergency Overview: Material may be irritating to eyes due to the grittiness of the fillers.					
Routes of	G: 1G	Single, Repeated, or	Severity (Mild,	Acute and Chronic Health	T. (0 ()	
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	Not Applicable	
				the product.		
Skin	Generally the product does not	Repeated	Mild	Irritation or possible allergic	Not Applicable	
	irritate the skin.			response.		
Inhalation	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	
Ingestion	Material is probably not harmful	Not Applicable	Mild	Not Applicable	Not Applicable	
	if swallowed					
Other	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	
Medical Con	ditions Aggravated by Exposure Oper	n 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 v	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	Skin Generally the product does not irritate the skin. Rinse with warm water.		Not Applicable

	This may not be of concern when using clinically relevant quantities.			
Inhalation	Not Applicable	Not Applicable	Not Applicable	
Ingestion	Ingestion Rinse out mouth and then drink plenty of water.		Not Applicable	
This may not be of concern when using clinically relevant quantities.				
Other Not Applicable		Not Applicable	Not Applicable	
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:	Other: Not				
	LEL: Not Applicable UEL: Not Applicable	Not Applicable	Applicable				
Flame Propagation or Burning Rate (for Solids):	Properties Contributing to Fire Intensity: Not Applicable	Flammability Classification:					
Not Applicable		Not Applicable					
Extinguishing Media: Use fire extinguishing method	ods suitable to surrounding conditions.	Extinguishing Media to Avoid: N	ot Applicable				
Protection and Procedures for Firefighters: Firefighters should wear self-contained respiratory protective devices.							
Unusual Fire and Explosion Hazards: Not Applica	ble						

6. Accidental Release Measures

Containment Techniques: Material is a high viscosity paste, but will flow somewhat.				
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	Individual Protection Personal Protective Equipment for Normal Use	
Measures		Emergencies
Eye/Face	Safety Glasses	Not Applicable
Skin	Skin The glove material has to be impermeable and resistant to the product.	
Inhalation	Inhalation Not Required. This may not be of concern when using clinically relevant quantities.	
Body Protection Protective work clothing		Not Applicable
Occupational Exposure Lim	its: Not Applicable	Engineering Controls: Not Applicable

9. Physical and Chemical Characteristics

	<u> </u>	
Appearance: Grey colored paste.	Odor: Spearmint odor.	
Normal Physical State: Paste		Melting Point: Not Applicable
Specific Gravity: 2.5 g/cm ³	Solubility in Water: Partially soluble.	pH: Not Applicable
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): Not Applicable	
Hazardous Products Produced During Decomposition: Not Applic	cable
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,	Toxicity Data, Epidemiology Studies, Carcinogenicity, Neurological Effects, Genetic Effects, Reproductive Effects, or Structure Activity Data:					
For ingestion, t	For ingestion, the LD ₅₀ for glycerine in Rats is $17,000 - 27,000$ mg/Kg.					
Emergency Ove	erview: Material may be mildly irritat	ing to eyes.				
Routes of		Single, Repeated, or	Severity (Mild, Moderate,	Acute and Chronic Health		
Exposure	Signs and Symptoms	Lifetime Exposure	Severe)	Effect(s)	Target Organ(s)	
Eye	Material may cause slight	Single & Repeated	Moderate	Irritation and possible corneal	Not Applicable	
	transient (temporary) irritation.			damage due to the fillers used in		
				the product.		
Skin	This may not be of concern when	Repeated	Mild	Irritation or possible allergic	Not Applicable	
using clinically relevant response.						
	quantities.					
Inhalation	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	

Ingestion	Material is probably not harmful	Not Applicable	Mild	Not Applicable	Not Applicable	
	if swallowed. This may not be of					
	concern when using clinically					
	relevant quantities.					
Other	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	
Medical Condi	Medical Conditions Aggravated by Exposure Open sores and wounds of the skin.					
Carcinogenicity	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 Envir	Potential Environmental Effects: Potential Environmental Effects Do not allow to enter sewers/ surface or ground water.					
NFPA Hazard	NFPA Hazard Classification Ratings (Scale 0-4), Health = 1. Fire = 0. 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	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

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>U.S. State Regulations California Proposition 65:</u> 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 Chemicals 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.

DENTSPLY/International DENTSPLY/Caulk Safety Data Sheet

577898

1. Identification

Product Name	SDS Code Number
ZIRCATE ^{® Prophy Paste}	577898
Substance Identity	Date of Last Revision
ZIRCATE ^{®□} Prophy Paste	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
Not Applicable	(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)

2. Hazard(s) Identification



Warning

Causes serious eye irritation
Wash hands thoroughly after handling
Wear protective gloves, face protection.

If in eyes: Rinse cautiously with water for several minutes. Remove contact lens, if present and easy to do. Continue rinsing.

Do not rub affected areas.

If eye irritation persists: Get medical advice attention.

3. Composition/Information on Ingredients

Hazardous Components	C.A.S. Number	Exposure Limits	%
Zirconium Silicate	10101-52-7	5 mg/M^3	< than 75
Tin Oxide	18282-10-5	2 mg/M^3	< than 10

Other Information: Parasepts are used as a preservative. Sweetener is Sodium Saccharin.

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

3. Hazard Identification

Emergency Overview: Material may be irritating to eyes due to the grittiness of the fillers.						
Routes of	G: 1G	Single, Repeated, or	Severity (Mild,	Acute and Chronic Health	T. (0 ()	
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	Not Applicable	
				the product.		
Skin	Generally the product does not	Repeated	Mild	Irritation or possible allergic	Not Applicable	
	irritate the skin.			response.		
Inhalation	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	
Ingestion	Material is probably not harmful	Not Applicable	Mild	Not Applicable	Not Applicable	
	if swallowed					
Other	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	
Medical Con	ditions Aggravated by Exposure Oper	n 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 v	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	Generally the product does not irritate the skin. Rinse with warm water.	Not Applicable	Not Applicable

	This may not be of concern when using clinically relevant quantities.			
Inhalation	Not Applicable	Not Applicable	Not Applicable	
Ingestion	Rinse out mouth and then drink plenty of water.	Not Applicable	Not Applicable	
	This may not be of concern when using clinically relevant quantities.			
Other	Not Applicable	Not Applicable	Not Applicable	
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:	Other: Not			
	LEL: Not Applicable UEL: Not Applicable	Not Applicable	Applicable			
Flame Propagation or Burning Rate (for Solids):	Properties Contributing to Fire Intensity: Not Applicable	Flammability Classification:				
Not Applicable		Not Applicable				
Extinguishing Media: Use fire extinguishing method	Extinguishing Media to Avoid: N	ot Applicable				
Protection and Procedures for Firefighters: Firefighters should wear self-contained respiratory protective devices.						
Unusual Fire and Explosion Hazards: Not Applica	ble					

6. Accidental Release Measures

Containment Techniques: Material is a high viscosity paste, but will flow somewhat.			
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. This may not be of concern when using clinically relevant quantities.	Not Applicable
Body Protection Protective work clothing		Not Applicable
Occupational Exposure Lim	Engineering Controls: Not Applicable	

9. Physical and Chemical Characteristics

	<u> </u>	
Appearance: Grey colored paste.		Odor: Spearmint odor.
Normal Physical State: Paste		Melting Point: Not Applicable
Specific Gravity: 2.5 g/cm ³	Solubility in Water: Partially soluble.	pH: Not Applicable
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
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Other: Not Applicable		

10. Stability and Reactivity Data

Incompatibility (Materials to Avoid): Not Applicable	
Hazardous Products Produced During Decomposition: Not Applic	cable
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:							
For ingestion, t	For ingestion, the LD ₅₀ for glycerine in Rats is $17,000 - 27,000$ mg/Kg.						
Emergency Ove	erview: Material may be mildly irritat	ing to eyes.					
Routes of		Single, Repeated, or	Severity (Mild, Moderate,	Acute and Chronic Health			
Exposure	Signs and Symptoms	Lifetime Exposure	Severe)	Effect(s)	Target Organ(s)		
Eye	Material may cause slight	Single & Repeated	Moderate	Irritation and possible corneal	Not Applicable		
	transient (temporary) irritation.			damage due to the fillers used in			
				the product.			
Skin	This may not be of concern when	Repeated	Mild	Irritation or possible allergic	Not Applicable		
	using clinically relevant			response.			
quantities.							
Inhalation	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable		

Ingestion	Material is probably not harmful	Not Applicable	Mild	Not Applicable	Not Applicable		
	if swallowed. This may not be of						
	concern when using clinically						
	relevant quantities.						
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: 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 = 0							

12. Ecological Information

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Regulations: Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

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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.

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Requirements Under SARA Title III, Section 313 (40 CFR 372): None Section 302 Extremely Hazardous Substances (TPQ): None

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<u>U.S. State Regulations California Proposition 65:</u> 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 Chemicals Substances (EINECS):

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Other: Not Applicable

16.Other Information

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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.

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