DENTSPLY/International DENTSPLY/Caulk Safety Data Sheet

1. Identification

1. Identification	
Product Name	SDS Code Number
FYNAL [®] LIQUID - Zinc Oxide Eugenol	509899
Permanent Cement	
Substance Identity	Date of Last Revision
FYNAL [®] LIQUID - Zinc Oxide Eugenol	12/11/15
Permanent Cement	
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 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	%
Eugenol	97-53-0	10 mg/M^3	> than 98
Acetic Acid	64-19-7	10 PPM	< than 2

3. Hazard Identification

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 Con	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 Env	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 a physician.		

Skin	Immediately wash with soap and water and rinse thoroughly.	Not Applicable	Not Applicable		
Inhalation	Supply fresh air, consult physician if complaint persist.	Not Applicable	Not Applicable		
Ingestion	Rinse mouth out and then drink plenty of water.	Not Applicable	Not Applicable		
_	Induce vomiting and call for medical help.				
Other	Not Applicable	Not Applicable	Not Applicable		
Note to Physician	Note to Physicians (Treating, Testing and Monitoring): Treat symptomatically				

5. Fire and Explosion Data

Flashpoint Method: 110°C (230°F)	Flammable (Explosive) Limits in A	Air	Autoignition Temperature: Not	Other: Not
Closed Cup	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 , foam, 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: Absorb spill with inert material (e.g. vermiculite, sand, and earth), then place material in suitable labeled plastic or metal container.

 Spill/Leak Clean-up Procedures and Equipment: Absorb spill with inert material (e.g. vermiculite, sand, and earth), then place material in suitable labeled plastic or metal container. Ensure adequate ventilation.

 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. Protect from heat and direct sunlight.

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	its: Not Applicable	Engineering Controls: Not Applicable

9. Physical and Chemical Characteristics

Appearance: Colorless or pale yellow liquid.		Odor: Oil of cloves.
Normal Physical State: Liquid.		Melting Point: -10°C (14°F)
Specific Gravity: 1.06 g/cm ³	Solubility in Water: Insoluble	pH: Not Applicable
Vapor Pressure (mm Hg): 0.009	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	
Othern Net Annlieshle		

Other: Not Applicable

10. Stability and Reactivity Data

Incompatibility (Materials to Avoid): Strong oxidizing agents.		
Hazardous Products Produced During Decomposition: Forms carbon monoxide and/or carbon dioxide.		
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: The Oral LD₅₀ for Eugenol, in rats, is 1930mg/Kg.

Emergency Ov	Emergency Overview: Material may be mildly irritating 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	Not Applicable
				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	Not Applicable	Mild	Not Applicable	Not Applicable
	if swallowed				
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 = 1, Reactivity = 0					

12.Ecological Information

Toxicity Data, Environmental Fate, Physical/Chemical Data, or other Data Supporting Environmental Hazard Statements: Water Hazard Class 1 (Selfassessment): slightly hazardous for water. Do not allow product to reach ground water, water streams or sewage system.

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

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.

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

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 Community Labeling: R22 Harmful if swallowed. \$24/25 Avoid contact with skin and eyes. \$36 Wear suitable protective clothing.

European Inventory of New and Existing Chemicals Substances (EINECS): This product is a medical device and not subject to chemical notification requirements. CAS# Eugenol 97-53-0 EINECS: 202-589-1 Eugenol.

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

1 Internation				
Product Name	SDS Code Number			
FYNAL [®] Powder - Zinc Oxide Eugenol Permanent Cement	509898			
Substance Identity	Date of Last Revision			
FYNAL [®] Powder - Zinc Oxide Eugenol Permanent Cement	06/24/16			
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)			
Dental Cement	(502) 422-4311 (8:00 Alvi – 4:30 PM Eastern 11me)			

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

	0		
Hazardous Components	C.A.S. Number	Exposure Limits	%
Zinc oxide	1314-13-2	10 mg/M ³	> than 75

Other Information: Yellow colorant is inorganic iron oxide.

3. Hazard Identification

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		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 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.					

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	Rinse mouth out and then drink plenty of water. If symptoms persist consult physician.	Not Applicable	Not Applicable		
Other	Other 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 Intensity: Not		Flammability Classification:	
Solids) Not Applicable	Applicable		Not Applicable	
Extinguishing Media: CO ₂ , powder, or water spray. Extinguish		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	Unusual Fire and Explosion Hazards: During a fire, formation of toxic and/or irritating compounds may be 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	reisonal riolective Equipment for Normal Ose	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	Body Protection Protective work clothing	
Occupational Exposure Limits: Not Applicable		Engineering Controls: Not Applicable

9. Physical and Chemical Characteristics

Appearance: Off white powder.		Odor: Mild odor.
Normal Physical State: Dry powder.		Melting Point: Not Applicable
Specific Gravity: 5.7 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	
O(1 N) (A 1' 11		

Other: Not Applicable

10. Stability and Reactivity Data

Incompatibility (Materials to Avoid): Strong acids, strong oxidizing agents.		
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, Neurological Effects, Genetic Effects, Reproductive Effects, or Structure Activity Data:						
Not Applicable	Not Applicable					
Emergency Ove	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 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 Envir	Potential Environmental Effects: Potential Environmental Effects Do not allow to enter sewers/ surface or ground water.					

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.

	DOT	ADR/RID	IMDG	ICAO / IATA
UN number	None	3077	3077	3077
UN proper	Not	Environmentally hazardous	Environmentally hazardous	Environmentally hazardous
shipping name	regulated	substance, solid, n.o.s.	substance, solid, n.o.s.	substance, solid, n.o.s.
		(contains zinc oxide)	(contains zinc oxide)	(contains zinc oxide)
Transport hazard	None	9	9	9
class				
Packing group	None	III	III	III
Environmental	Yes	Yes	Yes	Yes
Hazards				

14.Transport Information

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.

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

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 Community Labeling: R50/53Very toxic to aquatic organisms may cause long-term adverse effects in the aquatic environment. S57 Use appropriate container to avoid environmental contamination. S60 This material and its container must be disposed of as hazardous waste.

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.