SAFETY DATA SHEETS

This SDS packet was issued with item: 071738608

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).

071737402 071737444 071738020 071891258 078289800 078291200 078291900

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DENTSPLY/International DENTSPLY/Caulk Safety Data Sheet

510897

1. Identification

1. Identification			
Product Name	SDS Code Number		
IRM [®] LIQUID - Zinc Oxide Eugenol	510897		
Intermediate Restorative Material			
Substance Identity	Date of Last Revision		
IRM [®] LIQUID - Zinc Oxide Eugenol	04/15/11		
Intermediate Restorative Material			
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	99-53-0	10 mg/M^3	> than 98
Acetic Acid	64-19-7	10 PPM	< than 2

3. Hazard Identification

Emergency	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	Single & Repeated	Moderate	Irritation and possible corneal	Not Applicable		
	transient (temporary) irritation.			damage due to the powders used			
				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	Not Applicable	Mild	Not Applicable	Not Applicable		
	if swallowed						
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.						
Carcinogenic	Carcinogenicity NTP?: Not listed IARC monographs?: Not listed OSHA regulated?: No All components of this product are in						
compliance v	with the inventory listing Requirement	s of the U.S. Toxic Subs	tances Control Act (TSCA) Chemical Substance Inventory.			
Potential Env	vironmental Effects Do not allow to er	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.		

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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			
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 Physicia	Note to Physicians (Treating Testing and Monitoring): Treat symptomatically.					

5. Fire and Explosion Data

Flashpoint Method: 110°C (230°F)	Flammable (Explosive) Limits in 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 Intensity: Not		Flammability Classification:		
Solids) Not Applicable	Applicable		Not Applicable		
Extinguishing Media: CO2, 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	lividual Protection Personal Protective Equipment for Normal Use	
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	
Others Net Applicable		

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 Overview: Material may be mildly irritating to eyes.

 Routes of
 Single, Repeated, or

 Signe and Sumptoms
 Lifetime Exposure

 Moderate Seyers
 Effect(a)

Exposure	Signs and Symptoms	Lifetime Exposure	Moderate, 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	Material may be an irritant after	Repeated	Mild	Irritation or possible allergic	Not Applicable
	repeated and prolonged exposure.			response.	

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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 A					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	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 (Self-assessment): 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	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

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.S. State Regulations California Proposition 65: 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. S24/25 Avoid contact with skin and eyes. S36 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/International DENTSPLY/Caulk Safety Data Sheet

510897

1. Identification	
Product Name	SDS Code Number
IRM [®] LIQUID - Zinc Oxide Eugenol	510897
Intermediate Restorative Material	
Substance Identity	Date of Last Revision
IRM [®] LIQUID - Zinc Oxide Eugenol	04/15/11
Intermediate Restorative Material	
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	99-53-0	10 mg/M^3	> than 98
Acetic Acid	64-19-7	10 PPM	< than 2

3. Hazard Identification

Emergenc	y Overview: Material may be	irritating to eyes. No	significant hazards f	or emergency responses are ki	nown.
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	Single & Repeated	Moderate	Irritation and possible corneal	Not Applicable
	transient (temporary) irritation.			damage due to the powders used	
				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	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.	· · · · · · · · · · · · · · · · · · ·	
Carcinogenio	city NTP?: Not listed	IARC monographs?: 1	Not listed OSHA regul	lated?: No All components of this pro	duct are in
compliance v	with the inventory listing Requirement	s of the U.S. Toxic Subs	tances Control Act (TSCA) Chemical Substance Inventory.	
Potential Env	vironmental Effects Do not allow to er	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.		

~Verified on 2014-04 by Henry Schein to be the most current version of the SDS. To be verified again on 2017-04. ~ Created by Global Safety Management, Inc. -Tel: 1-813-435-5161 - www.gsmsds.com

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 Physicia	ns (Treating Testing and Monitoring): Treat symptomatically		

5. Fire and Explosion Data

Flashpoint Method: 110°C (230°F) Closed Cup	Flammable (Explosive) Limits in A LEL: Not Applicable UEL:		Autoignition Temperature: Not Applicable.	Other: Not 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 Med		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 fire, formation of toxic and/or irritating compounds may be 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 liquic	1.	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	
04 N (A 1' 11		

Other: Not Applicable

10. Stability and Reactivity Data

Incompatibility (Materials to Avoid): Strong oxidizing agents.	
Hazardous Products Produced During Decomposition: Forms cart	oon 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 Overview: Material may be mildly irritating to eyes. Single, Repeated, or Severity (Mild, Acute and Chronic Health Routes of Exposure Signs and Symptoms Lifetime Exposure Moderate, Severe) Effect(s) Target Organ(s) Material may cause slight Irritation and possible corneal Eye Single & Repeated Moderate Not Applicable transient (temporary) irritation. damage due to the fillers used 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	Not Applicable	Mild	Not Applicable	Not Applicable
	if swallowed				
Other	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable
Medical Condit	tions Aggravated by Exposure Open so	ores and wounds of the skin	1.		
Carcinogenicity	y NTP?: Not listed	IARC monographs?: Not	listed OSHA regular	ted?: No All components of this proc	luct are in
compliance wit	h the inventory listing Requirements of	f the U.S. Toxic Substanc	es Control Act (TSCA)	Chemical Substance Inventory.	
Potential Envir	onmental Effects: Potential Environme	ental Effects Do not allow	to enter sewers/ surface	or ground water.	
NFPA Hazard	Classification Ratings (Scale 0-4), Hea	lth = 1, Fire = 1, Reactivit	y = 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

<u>EPA Toxic Substances Control Act (TSCA) Status:</u> All of the components of this product are listed on the TSCA inventory. <u>U.S. State Regulations California Proposition 65:</u> This product does not contain any chemicals, which are on the California

Proposition 65 list. 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/International DENTSPLY/Caulk Safety Data Sheet

510896

1	Identification
	Identification

1. Identification			
Product Name	SDS Code Number		
IRM [®] Powder Zinc Oxide Eugenol	510896		
Intermediate Restorative Material			
Substance Identity	Date of Last Revision		
IRM [®] Powder Zinc Oxide Eugenol	04/15/11		
Intermediate Restorative Material			
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		
Temporary Restorative	(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	%
Zinc oxide	1314-13-2	10 mg/M^3	> than 75

3. Hazard Identification

Emergenc	Emergency Overview: Material may be irritating to eyes. No significant hazards for emergency responses are known.				
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 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	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 Physicians (Treating, Testing and Monitoring): Treat symptomatically.				

5. Fire and Explosion Data

Flammable (Explosive) Limits in Air		Autoignition Temperature: Not	Other: Not	
LEL: Not Applicable UEL:	Not Applicable	Applicable.	Applicable	
Properties Contributing to Fire Inte	ensity: Not	Flammability Classification:		
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 fire, formation of toxic and/or irritating compounds may be present.				
	LEL: Not Applicable UEL: Properties Contributing to Fire Inte Applicable ay. ghters should wear self-contained res	LEL: Not Applicable UEL: Not Applicable Properties Contributing to Fire Intensity: Not Applicable ay. Extinguishing Media ghters should wear self-contained respiratory protective device	LEL: Not Applicable UEL: Not Applicable Applicable. Properties Contributing to Fire Intensity: Not Applicable Flammability Classification: Not Applicable ay. Extinguishing Media to Avoid: Water with full jet. ghters should wear self-contained respiratory protective devices. Flammability Classification:	

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	its: 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	
Other: Not Applicable		

10. Stability and Reactivity Data

Incompatibility (Materials to Avoid): Strong acids, strong oxidizi	ng 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 Emergency Overview: Material may be mildly irritating to eyes. Routes of Single, Repeated, or Severity (Mild, Acute and Chronic Health Effect(s) Target Organ(s) Exposure Signs and Symptoms Lifetime Exposure Moderate, Severe) 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 Material may be an irritant after Repeated Mild Irritation or possible allergic Not Applicable repeated and prolonged exposure. response Not Applicable Inhalation 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 = 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 longterm adverse effects in the aquatic environment.



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

<u>EPA Toxic Substances Control Act (TSCA) Status:</u> All of the components of this product are listed on the TSCA inventory. <u>U.S. State Regulations California Proposition 65:</u> This product does not contain any chemicals, which are on the California Proposition 65 list.

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.

<u>European Community Labeling:</u> 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.