



# DentsplySirona Safety Data Sheet

510897

## 1. Identification

Product Name <b>IRM<sup>®</sup> LIQUID - Zinc Oxide Eugenol Intermediate Restorative Material</b>	SDS Code Number <b>510897</b>
Substance Identity <b>IRM<sup>®</sup> LIQUID - Zinc Oxide Eugenol Intermediate Restorative Material</b>	Date of Last Revision <b>7/8/2019</b>
Manufacturer: <b>DENTSPLY Caulk</b>	Address <b>38 West Clarke Avenue Milford DE 19963-1805 http://www.dentsplysirona.com</b>
Grades or Minor Variant Identities <b>Not Applicable</b>	Company Telephone Number (Product Inquiries) <b>(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)</b>
Product Use (for Canada) <b>Not Applicable</b>	Emergency Telephone Number <b>CHEMTREC: 1-800-424-9300 (24 hours) (Outside U.S. +1-703-527-3887) CCN6510</b>

## 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 <sup>3</sup>	> than 98
Acetic Acid	64-19-7	10 PPM	< than 2

## 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 a 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 complaint persist.	Not Applicable	Not Applicable
Ingestion	Rinse mouth out and then drink plenty of water. Induce vomiting and call for medical help.	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

Flashpoint Method: 110°C (230°F) Closed Cup	Flammable (Explosive) Limits in Air LEL: Not Applicable UEL: Not Applicable	Autoignition Temperature: Not Applicable.	Other: Not Applicable
Flame Propagation or Burning Rate (for Solids) Not Applicable	Properties Contributing to Fire Intensity: Not Applicable	Flammability Classification: Not Applicable	
Extinguishing Media: CO <sub>2</sub> , 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 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 Measures	Personal Protective Equipment for Normal Use	Personal Protective Equipment for 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 Limits: 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 <sup>3</sup>	pH: Not Applicable
Solubility in Water: Insoluble	Evaporation Rate (Butyl Acetate =1): Not Applicable
Vapor Pressure (mm Hg): 0.009	Vapor Density (AIR=1): Not Applicable
Flashpoint Method: Not Applicable	Flammable (Explosive) Limits in Air LEL: Not Applicable UEL: Not Applicable
Autoignition Temperature: Not 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: <input type="checkbox"/> May Occur <input checked="" type="checkbox"/> May Not Occur	Conditions to Avoid: None known
Stability? <input checked="" type="checkbox"/> Stable <input type="checkbox"/> 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 LD <sub>50</sub> for Eugenol, in rats, is 1930mg/Kg.					
Emergency Overview: Material may be mildly irritating 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 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 (Self-assessment): slightly hazardous for water. Do not allow product to reach ground water, water streams or sewage system.
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## 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
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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 method change product classification? No	DOT Hazard Class: Not Applicable	UN Number: Not Applicable

#### 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
<u>Section 302 Extremely Hazardous Substances (TPQ)</u> : 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.
<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.
<u>European Community Labeling</u> : Not a dangerous preparation.
<u>European Community Labeling</u> : R22 Harmful if swallowed. S24/25 Avoid contact with skin and eyes. S36 Wear suitable protective clothing.
<u>European Inventory of New and Existing Chemicals Substances (EINECS)</u> : 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.

## *Document Detail*

**Type:** 0070-SDS  
**Document No.:** 0070-GR510896[4]  
**Title:** IRM Powder SDS  
**Comment**  
**Status:** INWORKS  
**Effective Date:** 03-Jul-2019

## *Approvals*

<u>Role</u>	<u>Sign-off By</u>	<u>Sign-off Date</u>
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GMT



**DentsplySirona  
Safety Data Sheet**

**510896**

**1. Identification**

Product Name IRM® Powder Zinc Oxide Eugenol Intermediate Restorative Material	SDS Code Number 510896
Substance Identity IRM® Powder Zinc Oxide Eugenol Intermediate Restorative Material	Date of Last Revision 06/21/19
Manufacturer: DENTSPLY Caulk	Address 38 West Clarke Avenue Milford DE 19963-1805 <a href="http://www.dentsplysirona.com">http://www.dentsplysirona.com</a>
Grades or Minor Variant Identities Not Applicable	Company Telephone Number (Product Inquiries) (302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)
Product Use (for Canada) Temporary Restorative	Emergency Telephone Number CHEMTREC: 1-800-424-9300 (24 hours) (Outside U.S. +1-703-527-3887) CCN6510

**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 <sup>3</sup>	> than 75

**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	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 LEL: Not Applicable UEL: Not Applicable	Autoignition Temperature: Not Applicable.	Other: Not Applicable
Flame Propagation or Burning Rate (for Solids) Not Applicable	Properties Contributing to Fire Intensity: Not Applicable	Flammability Classification: Not Applicable	
Extinguishing Media: CO <sub>2</sub> , 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.			

**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.

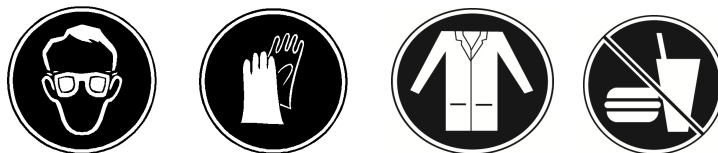
Evacuation Procedures: Not Applicable	Special Instructions: Not Applicable	Reporting Requirements: Not Applicable
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## 7. Handling and Storage

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 Measures	Personal Protective Equipment for Normal Use	Personal Protective Equipment for 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 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 <sup>3</sup>	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 LEL: Not Applicable UEL: Not Applicable	Autoignition Temperature: Not Applicable
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: <input type="checkbox"/> May Occur <input checked="" type="checkbox"/> May Not Occur	Conditions to Avoid: None known	
Stability? <input checked="" type="checkbox"/> Stable <input type="checkbox"/> 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 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 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. R50/53 Very 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

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

### 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
<u>Section 302 Extremely Hazardous Substances (TPQ)</u> : 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.
<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.
<u>European Community Labeling</u> : Not a dangerous preparation.
<u>European Community Labeling</u> : R50/53 Very 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.
<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,
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information necessary for safe use and storage of the product is given in the DFU.